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Docket No. 25-4249

In the United States Court of Appeals For the Ninth Circuit

NEETA THAKUR, et al.,

Plaintiffs-Appellees,

v.

DONALD J. TRUMP, et al.,

Defendants-Appellants.

Appeal from a Decision of the United States District Court for the Northern District of California, No. 3:25-cv-04737-RFL · Honorable Rita F. Lin

APPELLEES' OPPOSITION TO APPELLANTS' MOTION FOR PARTIAL STAY

ANTHONY P. SCHOENBERG
LINDA S. GILLERAN
KYLE A. MCLORG
KATHERINE T. BALKOSKI
FARELLA BRAUN + MARTEL LLP
One Bush Street, Suite 900
San Francisco, California 94104
(415) 954-4400 Telephone
tschoenberg@fbm.com
lgilleran@fbm.com
kmclorg@fbm.com
kbalkoski@fbm.com

ELIZABETH J. CABRASER
RICHARD M. HEIMANN
KEVIN R. BUDNER
ANNIE M. WANLESS
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, California 94111
(415) 956-1000 Telephone
ecabraser@lchb.com
rheimann@lchb.com
kbudner@lchb.com
awanless@lchb.com

ERWIN CHEMERINSKY
CLAUDIA POLSKY
U.C. BERKELEY SCHOOL OF LAW
215 Boalt Hall
Berkeley, California 94720-7200
(510) 642-6483 Telephone
(619) 238-1126 Facsimile
echemerinsky@law.berkeley.edu
cpolsky@law.berkeley.edu





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INTRODUCTION

The University of California is the world's leading public research institution. Its ten campuses, three affiliate national laboratories, and dozens of institutes, centers, and facilities produce research that has changed the world, increased human knowledge, and contributed to the prominence and security of the United States and the health and welfare of all Americans.

Beginning January 20, 2025, President Trump issued Executive Orders directing agencies to terminate grants, including those related to disfavored topics, such as diversity, equity, and inclusion ("DEI"). The Environmental Protection Agency ("EPA"), National Science Foundation ("NSF"), and National Endowment for the Humanities ("NEH") (collectively, "Agency Defendants") implemented the President's orders by abruptly and unlawfully terminating grants *en masse*. They selected grants for termination using keyword searches for now-forbidden terms and concepts and terminated them via form letters without any reasoned explanation. Additionally, grants with no apparent connection to DEI concepts were also terminated via form letter without any reasoned explanation.

The terminations dealt a devastating blow to industry-leading researchers at the University of California, who relied on such federal grants. Add. 1, Order at 1-2 (June 23, 2025), Dkt. No. 54 ("Order"). From January 20th to early June 2025, the federal government had terminated over \$324 million in grants to the

University of California system. Compl. ¶ 112 (June 4, 2025), Dkt. No. 1; *see also* Order at 15 (citing same).

On June 4, 2025, Plaintiffs, who are University of California researchers with terminated federal grants, filed their Class Action Complaint for Declaratory and Injunctive Relief. Dkt. No. 1. A day later, Plaintiffs filed their Motion for Temporary Restraining Order (Dkt. No. 7), which the District Court later converted to a Motion for a Preliminary Injunction, and a Motion for Class Certification (Dkt. No. 18). The District Court granted limited expedited discovery and heard the motions on an emergency basis. Dkt. No. 32.

The Court granted Plaintiffs' motion for preliminary injunction, finding that Plaintiffs were likely to succeed on their Administrative Procedure Act ("APA") and First Amendment claims and that "the balance of equities and the public interest strongly favor the entry of a preliminary injunction." Order at 2-3; 47-48; see also Dkt. No. 55 (Preliminary Injunction as to Agency Defendants, attached as Exhibit 1). The District Court also certified two classes: (a) those whose grants were terminated by the Agency Defendants because the research ostensibly touched on blacklisted DEI topics (the "Equity Termination Class"), and (b) those whose grants were terminated by Agency Defendants via form letter without any

¹ The District Court did not reach Plaintiffs' other arguments. Order at 35.

grant-specific explanation (the "Form Termination Class"). Id.

The District Court denied Defendants' request for a stay pending appeal: "A stay is not appropriate because Plaintiffs are likely to succeed on the merits of their APA and First Amendment claims." Order at 62.2 "Moreover, Defendants have not carried their burden of showing that they are likely to face 'irreparable injury . . . during the period before the appeal is decided." *Id*.

Pursuant to the Order, Agency Defendants began reinstating grants, allowing Plaintiffs to access research funds and resume research. Dkt. Nos. 66, 72. Then, after waiting weeks, Defendants filed a notice of appeal and the instant motion to stay the preliminary injunction ("Motion"), which instills uncertainty for Plaintiffs whose newly reinstated NEH and EPA grants may be re-terminated if Defendants' Motion is granted. Defendants' Motion seeks a stay only as to two Agency Defendants (not NSF) and requests relief by August 4, 2025. Defendants do not explain why NEH and EPA will anomalously be harmed, but not NSF, and do not justify the arbitrary August 4 date.

Moreover, Defendants' Motion offers no new, relevant facts and rehashes arguments that failed below. In considering a stay, courts look to four factors:

(1) likelihood of success on the merits, (2) irreparable injury, (3) substantial injury

² Here and throughout, emphasis added and citations omitted unless otherwise indicated.

to other interested parties, and (4) the public interest. *Nken v. Holder*, 556 U.S. 418, 434 (2009). Defendants' request fails this test for at least five reasons.

First, as this Court recently concluded in a similar context, Article III courts, not the Federal Court of Claims, have jurisdiction over constitutional and statutory claims for injunctive relief, like Plaintiffs', even if the relief would result in the reinstatement of government funding.

Second, Defendants are unlikely to overcome the District Court's factual findings that Plaintiffs, whose work was suspended, whose livelihoods are threatened, and whose professional reputations and careers have been damaged by grant terminations, have *not* been sufficiently injured to have standing.

Third, Defendants are unlikely to show that the challenged agency actions satisfied the APA or were committed to agency discretion. Plaintiffs are not challenging discretionary funding decisions—they are challenging the administrative agencies' blatant failure to provide "reasonable and reasonably explained" rationale for their *en masse* terminations. *Ohio v. EPA*, 603 U.S. 279, 292 (2024); Order at 2. This is especially true given that the Court's ultimate review of the injunction will be governed by the permissive abuse of discretion standard. *Saravia for A.H. v. Sessions*, 905 F.3d 1137, 1141 (9th Cir. 2018).

Fourth, Defendants are unlikely to prevail on their contention that the President may direct agencies to terminate already-awarded research grants by

conducting keyword searches for forbidden words. Doing so violates the First Amendment.

Fifth, equities do not support a stay. Defendants have not shown that they will be irreparably harmed absent a stay. In contrast, the record shows that reterminating the now-reinstated grants during the pendency of this appeal will cripple critical research programs. This Court should maintain the status quo and deny the stay.

STANDARD OF REVIEW

In considering a stay, courts assess: (1) the likelihood of success on the merits, (2) irreparable injury, (3) substantial injury to other interested parties, and (4) the public interest. *See Nken v. Holder*, 556 U.S. 418, 434 (2009). Irreparable injury and likelihood of success "are the most critical" factors. *Id.* Injury to other parties and the public interest are considered only if the first two factors are satisfied. *Doe #1 v. Trump*, 957 F.3d 1050, 1058 (9th Cir. 2020).

ARGUMENT

- I. Plaintiffs Are Likely to Succeed on the Merits.
 - A. The District Court Has Article III Jurisdiction to Decide Plaintiffs' Claims.
 - 1. The Tucker Act Does Not Apply to Plaintiffs' Claims for Injunctive and Declaratory Relief.

The Tucker Act does not deprive Article III courts of jurisdiction over APA and constitutional challenges to grant terminations.

(a) California Does Not Change Controlling Ninth Circuit Law.

Defendants' Tucker Act arguments are squarely precluded by this Circuit's precedent. In *United Aeronautical Corp. v. U.S. Air Force*, this Court held that the Tucker Act divests jurisdiction over an action only if it "is a 'disguised' breach-of-contract claim," as determined by looking to "the source of the rights upon which the plaintiff bases its claims" and "the type of relief sought." 80 F.4th 1017, 1026 (9th Cir. 2023). "If rights and remedies are *statutorily or constitutionally* based, then district courts have jurisdiction" *Id.* (emphasis in original). Simply put, because the claims in this case are constitutional and statutory, not "*contractually* based," the Tucker Act does not apply. *Id*.

Rather than addressing *United Aeronautical*, Defendants rely on the Supreme Court's three-page order in *Department of Education v. California* ("*California*"). 145 S. Ct. 966 (2025). This Court rejected this same argument just two months ago. *See Cmty. Legal Servs. in East Palo Alto v. DHHS*, 137 F.4th 932, 939 (9th Cir. 2025) ("*CLSIPA*"). In *CLSIPA*, the district court issued a preliminary injunction, finding the plaintiffs likely to succeed on their APA claims related to the withdrawal of congressionally appropriated funds to provide legal representation to unaccompanied children in immigration proceedings. *Id.* at 936. As here, the government sought a stay pending appeal, relying on *California* to

argue that "the Tucker Act 'impliedly forbids' plaintiffs' suit because plaintiffs' claims sound in contract and accordingly can only be brought in the Court of Federal Claims (if at all)." *Id.* at 937, 939.

This Court disagreed, holding that the *CLSIPA* plaintiffs' claims sought "to enforce compliance with statutes and regulations, not any government contract" and were therefore "beyond the scope of the Tucker Act's exclusive jurisdiction." *Id.* at 938. *California* did "not change this conclusion," because that case "[i]nvolved a claim to enforce grant agreements that the plaintiffs had entered into directly with the government and thus 'to enforce a contractual obligation to pay money." *Id.* at 939. *California* "has no application where, as here, the claims sound in statute, rather than contract." *Id.*

As in *CLSIPA*, Plaintiffs' APA claims "sound in statute, rather than contract." *Id.* at 939. Plaintiffs do not seek "to enforce grant agreements [] entered into directly with the government" (*id.*) because they are not parties to these agreements. Their claims are based on the APA and other federal statutes, not an alleged breach of the grants themselves. Further, they have sought no money judgment, and the District Court need not review any grant to decide their claims. *Contra California*, 145 S. Ct. at 968. The District Court's preliminary injunction is also based on the First Amendment, and the Tucker Act does not apply to constitutional claims. *United Aeronautical*, 80 F.4th at 1026.

The First Circuit just reached the same conclusion. In American Public Health Association v. National Institutes of Health ("APHA"), the First Circuit held that the district court decision voiding grant-terminating directives and vacating prior terminations was not precluded under California because "the district court's orders here did not award 'past due sums,' but rather provided declaratory relief that is unavailable in the Court of Federal Claims" and "neither the plaintiffs' claims nor the court's orders depend on the terms or conditions of any contract." No. 25-1611, 2025 WL 2017106, at *6 (1st Cir. July 18, 2025). The First Circuit ultimately concluded that the district court "likely had jurisdiction to enter the orders here – which provided declaratory relief under the APA independent of any contractual language – to 'set[] aside an agency's action[s]' as arbitrary and capricious; the fact that the orders 'may result in the disbursement of funds' did not divest the court of its jurisdiction." *Id.* at *8 (citing *California*). The same conclusion should follow from the nearly identical facts of this case.

(b) Defendants' Argument Would Leave Plaintiffs with No Remedy

Defendants argue that (1) only the Court of Federal Claims should hear Plaintiffs' claims because they "seek[] specific performance of' a contract, but (2) Plaintiffs have no standing to enforce the contracts because they "are not the grant recipients." *See* Mot. at 14, 16 (July 11, 2025), Dkt. No. 7.1. Accepting Defendants' positions would mean Plaintiffs cannot be heard in either court, and

have no remedy for their harms. The District Court correctly found this contradiction fatal to Defendants' argument. Order at 35-36; *see also* Tr. at 25:15-27:8 (June 20, 2025), Dkt. No. 52 (attached as Exhibit 2).

In response, Defendants argue the District Court's Order renders "APA" review [] precluded for the parties with actual rights under the contract but not for third parties." Mot. at 15. To the contrary, as this Court recognized in both *United* Aeronautical and CLSIPA, APA review is available for grantees where the rights and remedies arise out of statute or the Constitution. Moreover, as a threshold matter, grants are not contracts. By statute, grants "carry out a public purpose" (31 U.S.C. § 6304), whereas contracts permit the government to "acquire ... property or services for [its] direct benefit or use" (31 U.S.C. § 6303). The FDA Grant Director's declaration confirms this, explaining that grants and contracts "are distinct funding mechanisms." Dkt. No. 48 at Ex. D ¶ 6 (attached as Exhibit 3). Further, for the Tucker Act to apply, contracts must give the contracting parties a "substantive right to recover" damages in the event of a breach (Rick's Mushroom Serv., Inc. v. United States, 521 F.3d 1338, 1343 (Fed. Cir. 2008)) and provide a 'direct' and 'tangible' benefit on the United States (St. Bernard Parish Gov't v. United States, 134 Fed. Cl. 730, 735-736 (2017)). Plaintiffs' grants do neither. Defendants hope the Court will simply accept that grants and contracts are synonymous, but as a matter of law, they are not.

Unsurprisingly, then, numerous courts (including the Supreme Court) have now rejected the government's efforts to punt funding claims to the Court of Federal Claims, including many cases brought directly by grantees.³

2. Plaintiffs, Who Have a "Personal Stake" in This Litigation, Have Standing.

Defendants contend that Plaintiffs lack standing because they (1) "are not the grant recipients" and (2) "have not made the necessary showing" that their institutions will be unable to provide alternate funds. Mot. at 16-17. They say these failures render class-wide relief inappropriate. But the first argument is a red herring, and the second is false.

First, for Article III standing, a plaintiff must have a "personal stake" in the litigation. Order at 47 (quoting *Diamond Alternative Energy, LLC, v. EPA*, No. 24-7, 2025 WL 1716141, at *11 (D. Colo. June 20, 2025)). This personal stake is established where, as here, all Plaintiffs and class members suffered injuries (grant termination) that were caused by Defendants and can be fully redressed only

³ See, e.g., Dep't of State v. AIDS Vaccine Advocacy Coal., 145 S. Ct. 753, 753 (2025); see also 770 F.Supp.3d 121, 129 (D.D.C. 2025); CLSIPA, 137 F.4th at 939; APHA, 2025 WL 2017106, at *6; Green & Healthy Home Initiatives, Inc. v. EPA, No. 25-cv-1096-ABA, 2025 WL 1697463, at *1, *14-15 (D. Md. June 17, 2025); S.F. AIDS Found. v. Trump, No. 25-cv-018244-JST, 2025 WL 1621636, at *3, *12 (N.D. Cal. June 9, 2025); Martin Luther King, Jr. Cnty. v. Turner, No. 2:25-cv-814, 2025 WL 1582368, at *6, *12 (W.D. Wash. June 3, 2025); S. Educ. Found. v. DOE, No. cv-25-1079-PLF, 2025 WL 1453047, at *1, *9 (D.D.C. May 21, 2025); Colorado v. HHS, No. 1:25-cv-00121-MSM-LDA, 2025 WL 1426226, at *3-4, *9 (D.R.I. May 16, 2025).

through a permanent injunction. *See Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016); Order at 47.

Second, Defendants argue that some Plaintiffs and class members lack standing because they may have found replacement funding, rendering class-wide relief improper. Mot. at 16-17. To make this point, Defendants focus on Plaintiff Thakur's and Plaintiff Foreman's efforts to obtain replacement funding, cherrypicking instances where they have found alternative sources. But Defendants have not shown that those plaintiffs (or any others) replaced 100% of the terminated funds (they did not), and Defendants wholly ignore the significant opportunity cost of seeking alternative funding and the reputational harm of the terminations. Order at 47-48 (discussing irreparable harm); e.g., Dkt. No. 10 at ¶ 25(a) ("Instead [of completing health analyses], I have had to spend significant time seeking alternate funding sources.") (attached as Exhibit 4). The fact that some Plaintiffs and class members may have found some limited alternative funding does not erase the opportunity costs and other injuries from termination.

That class members may have experienced different levels of harm is of no moment: The point of a Rule 23(b)(2) class is its focus on *defendants*' conduct, not whether all class members were injured in the same way. *See* Fed. R. Civ. P. 23(b)(2); 2 Newberg & Rubenstein on Class Actions § 4:28 (6th ed. 2022); *see* also Prantil v. Arkema France S.A., No. 4:17-cv-02960, 2022 WL 1570022, at *41

(S.D. Tex. May 18, 2022) ("The critical predicate of an injunctive class is common behavior by the defendant toward the class, not common effect on the class.").

Rule 23(b)(2) was expressly designed to afford and enforce injunctive relief in constitutional cases such as this. 2 Newberg § 4:26. All Plaintiffs have standing, and class-wide resolution is appropriate.

- B. Plaintiffs Are Likely to Succeed on Their APA Claims.
 - 1. Agency Defendants' Unreasonable and Unexplained Actions Are Arbitrary and Capricious.

"An agency action qualifies as 'arbitrary' or 'capricious' if it is not 'reasonable and reasonably explained." *Ohio*, 603 U.S. at 292. Here, rather than conduct an individualized review of each grant, Defendants in some cases identified certain topics (such as DEI) that they deemed newly inconsistent with agency policy, irrespective of the substance of individual grants. They then identified grants through keyword searches and terminated them through form letters. In other instances, grants with no apparent connection to DEI were inexplicably terminated. Illustrating the rushed nature of the terminations, the terminations are conflicting, contradictory, and rife with errors. "For example, the NEH form termination letters state that termination is pursuant to Executive Order No. 14217, which NEH now states that was a 'mistake[]." Order at 28.

Agencies may change their positions only if "they provide a *reasoned* explanation for the change, display awareness that [they are] changing position,

and consider serious reliance interests." *FDA v. Wages & White Lion Invs.*, *L.L.C.*, 145 S. Ct. 898, 917 (2025) (citation modified). It is not enough for agencies to simply reference changed agency priorities without explanation. Mot. at 22. And, contrary to Defendants' argument, merely grouping grants into categories—*e.g.*, "High, Medium, Low, or No Connection" to forbidden topics (Mot. at 21)—does not constitute a reasoned explanation for why that grant was so categorized and why it "no longer effectuates the program goals or agency priorities." 2 C.F.R. § 200.340(a)(4).

EPA's form termination letters exemplify the arbitrariness, vagueness, and ambiguity that have left class members in the dark as to the basis for their grants' cancellation. Dkt. No. 10 at ¶ 24. The cookie-cutter letters note that the terminations *may* be based on *any or all* of a research project's: failure to exhibit merit, fairness, and excellence; duplication; waste, fraud, or abuse; or failure to fulfill the "best interests of the United States." Order at 13. Terminating an agency-vetted, peer-reviewed project because it lacks "merit" or is not "excellent" is facially illogical; terminating it because it is "duplicative" requires explaining the research it purportedly duplicates; terminating a project because a researcher is alleged to have acted unfairly, abusively, or fraudulently is an extraordinary charge that cannot be rationally leveled without detailed evidence; and terminating a project because it is inconsistent with "the best interests of the United States" is

standardless where those interests are nowhere defined. The APA's requirement of reasoned explanation—particularly, where an agency reverses its prior position—demands far more.

Furthermore, agencies must consider the fact that "chang[ing] course" on "longstanding policies may have 'engendered serious reliance interests." *DHS v.*Regents of the Univ. of Cal., 591 U.S. 1, 30 (2020). That is certainly the case here. Plaintiffs and their institutions organize their affairs around multi-year grant awards—hiring staff, admitting students, purchasing equipment, recruiting study participants, contracting with vendors, and more. Shuttering these projects midstream destroys such studies and deprives researchers of opportunities.

Defendants' failure to consider these issues is itself fatal. Order at 30 ("Defendants have had the opportunity to introduce evidence showing that they considered Plaintiffs' reliance interests prior to terminating their grants, but have not done so.").

Indeed, in a substantially similar case regarding termination of National Institute of Health ("NIH") research grants, the First Circuit denied NIH a stay, in part because of the extensive reliance interests of grant-dependent researchers. Where an agency's "'prior policy has engendered serious reliance interest," it must offer a "a more detailed justification' than usual" of a change in course. *APHA*, 2025 WL 2017106, at *9 (*citing FCC v. Fox Television Stations, Inc.*, 556

U.S. 502, 515 (2009)).

The District Court properly found that the Agency Defendants' mass grant terminations carried out by standardized form letters were arbitrary and capricious.

2. NEH's Actions Were Contrary to Law Under the APA.⁴

The APA provides that courts must set aside agency action "not in accordance with law" or "in excess of statutory . . . authority." 5 U.S.C. § 706(2)(A)&(C). Through NEH's enabling statute, Congress directed NEH to authorize grants specifically to "initiate and support programs and research . . . that reach, or reflect the *diversity* and richness of our American cultural heritage, including the culture of, a minority, inner city, rural, or tribal community." 20 U.S.C. § 956(c). Congress also directed NEH's Chair to "give particular regard to scholars, and educational and cultural institutions, that have *traditionally been underrepresented.*" *Id.*

Defendants urge that the NEH's enabling statute does not require "the government to fund any particular grant." Mot. at 10. However, Plaintiffs do not

⁴ In the District Court, Plaintiffs raised several other reasons why Defendants' actions were "contrary to law": they violated (1) separation of powers because the President lacks the authority to refuse to spend funds appropriated by Congress; (2) the Impoundment Control Act of 1974; and (3) due process because the terminations were without notice and a hearing. Although the District Court did not decide these issues, the Court of Appeals may affirm on "any ground supported by the record." *Security Life Ins. Co. of Am. v. Meyling*, 146 F.3d 1184, 1190 (9th Cir. 1998).

challenge NEH's initial award decisions. As the District Court found, "though the NEH's statute might not have required it fund any specific project, the NEH was not free to terminate grants *because* they advance 'diversity' or 'give particular regard to [those] that have traditionally been underrepresented,' as mandated by Congress." Order at 23-24 (emphasis in original).

Defendants also contend that whether Plaintiffs' grants implicate the enabling statute's mandates is a fact-intensive question not suitable for class-wide resolution. Mot. at 11. They are wrong. A Rule 23(b)(2) class focuses on *defendants*' actions. The question is whether the Agency Defendants took mass actions that were contrary to Congress's instructions. For both Classes, Defendants took uniform action in terminating grants, making class-wide resolution appropriate. Plaintiffs' requested remedy merely undoes the harm Defendants caused when they implemented a Presidential directive to terminate all grants referencing equity or diversity.

3. Plaintiffs' Statutory and Constitutional Claims Are Reviewable Under the APA.

Relying on 2 C.F.R. Section 200.340(a)(4), Defendants contend that the terminations are "unreviewable" because the reallocation of funds is committed to agency discretion. Mot. at 18. Not so. While it is true that the APA bars judicial review for "agency action [that] is committed to agency discretion by law" (5 U.S.C. § 701(a)(2)), "[t]his exception has been construed 'narrowly' to apply only

in 'those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Cmty. Legal Servs.*, 137 F.4th at 939-40. This case does not present such a "certain circumstance[]" because there are APA and First Amendment standards. Order at 34 ("Defendants have not met their burden to show such unbounded discretion.").

Citing *Lincoln v. Vigil*, 508 U.S. 182 (1993), Defendants suggest that all decisions to discontinue a program funded by a lump sum appropriation are committed to agency discretion. Mot. at 18. But nothing in *Lincoln* absolves agencies of their obligations under Section 706(2)(A) when allocating resources to provide a reasoned explanation and comply with statutory requirements. *See AMA* v. *Reno*, 57 F.3d 1129, 1134-35 (D.C. Cir. 1995); *see also* Order at 29, n.25.

Moreover, Plaintiffs are not challenging Agency Defendants' discretionary funding decisions, making this case unlike *Milk Train, Inc. v. Veneman*, 310 F.3d 747, 741 (D.C. Cir. 2002); *see also* Mot. at 19-20 (describing NEH's discretionary funding process). Rather, Plaintiffs are bringing statutory and constitutional claims, alleging that Agency Defendants arbitrarily and capriciously, and unlawfully, terminated funding for previously awarded grants midstream. Defendants cite the "absence" of law on this issue as dispositive—"the absence of statutory provisions . . . *is* the government's point" (Mot. at 20, emphasis in original)—but they

misapprehend the standard. "[O]nly upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review." *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 141 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99, 105 (1977). Defendants have not done so here. In other words, it is the government's burden to rebut the presumption that the agency action is reviewable. The government has not rebutted such presumption, nor can it.

- C. Plaintiffs Are Likely to Succeed on Their First Amendment Claims.
 - 1. The Question Here Is Whether the Government May Terminate Already-Awarded Grants Based on Viewpoint (It May Not), Not Whether the Government Is Required to Fund Particular Programs.

Defendants effectively concede that they "selectively terminat[ed] grants that promote a message that the government does not favor." Mot. at 8. Plaintiffs do not deny that the government has latitude in deciding what speech to fund. The inquiry here is, instead, whether the government can terminate already-awarded grants—grants funded through congressional appropriations and selected for their scientific or cultural merit, in accordance with governing statutes and regulations—based on those grants' viewpoints. Thus, Defendants' cases concerning Congress's authority to choose what to fund do not support their claim that the President can

terminate grants based on viewpoint.⁵ Defendants do not cite a single case to support that proposition because there is none.

2. The Supreme Court Stresses Viewpoint Neutrality Even in the Context of Government Funding.

Moreover, even in government funding cases, the Supreme Court stresses viewpoint neutrality. In *Regan*, the Supreme Court confirmed that, notwithstanding the "especially broad latitude" for creating tax classifications, Congress could not "discriminate invidiously in its subsidies in such a way as to 'aim[] at the suppression of dangerous ideas." Regan v. Tax'n With Representation of Wash., 461 U.S. 540, 547-48 (1983) (quoting Cammarano v. United States, 358 U.S. 498, 513 (1959)); see also Rosenberger v. Rector & Visitors of Univ. of Va., 515 U.S. 819, 829 (1995) ("The government must abstain from regulating speech when the specific motivating ideology or the opinion or perspective of the speaker is the rationale for the restriction."). Moreover, in *Board of Regents of University of* Wisconsin v. Southworth, 529 U.S. 217, 233 (2000), the Supreme Court repeated in the context of government funding of student organizations: "The proper measure, and the principal standard of protection for objecting students, we conclude, is the

⁵ The Supreme Court has repeatedly held that the government cannot discriminate based on viewpoint unless it meets strict scrutiny. For example, *Matal v. Tam* says: "it is a fundamental principle of the First Amendment that the government may not punish or suppress speech based on disapproval of the ideas or perspectives the speech conveys." 582 U.S. 218, 248 (2017) (Kennedy, A., Ginsburg, R., Sotomayor, S., and Kagan, E. concurring in part).

requirement of viewpoint neutrality in the allocation of funding support."

Defendants rely heavily on *National Endowment for the Arts v. Finley*, 524 U.S. 569, 583 (1998). But in that case, the Supreme Court stressed that the challenged federal law "d[id] not engender the kind of directed viewpoint discrimination that would prompt this Court to invalidate a statute on its face." *Id.* Further, the Supreme Court emphasized that the case involved a facial challenge to a statute and the Supreme Court was "reluctant . . . to invalidate legislation 'on the basis of its hypothetical application to situations not before the Court." *Id.* at 572, 584. Conversely, here, Plaintiffs bring an as-applied challenge. Thus, it is not "hypothetical" whether Defendants would apply the President's directives in a manner which "preclude[s] or punish[es] the expression of particular views." *See id.* at 583.

Furthermore, in *Agency for International Development v. Alliance for Open Society International, Inc.*, the Supreme Court struck down a statute which "compell[ed] a grant recipient to adopt a particular belief as a condition of funding." 570 U.S. 205, 218 (2013). Defendants' actions here chill equity-related speech beyond the scope of federally funded grants.

Defendants argue that, because the government is not required to fund any particular program, it is authorized to terminate any grant that does not support the President's views, even though Congress had appropriated that funding. Such

viewpoint discrimination strikes at the core of the First Amendment. Their argument that the President can terminate grants based on viewpoint has no stopping point. It would empower the President to terminate any grant if the grantee criticized the President or took any position the President disagreed with. Such presidential power to engage in viewpoint discrimination is obviously inimical to the First Amendment.

II. <u>Defendants Have Not Shown that They Face Irreparable Injury.</u>

Defendants claim that the preliminary injunction risks irreparable harm to the government and to the public interest by: (1) requiring the payment of money that the government may never recover,⁶ and (2) interfering with the President's ability to execute core Executive Branch policies. Mot. at 22-23. Both assertions are unpersuasive.

The most glaring gap is Defendants' failure to explain what legal or factual circumstances would justify a stay as to EPA and NEH, but not as to NSF.

Defendants understate, via a footnote, that "NSF does not plan to re-terminate the grants while the appeal is pending[.]" Mot. at 6, n.1. If NSF will not be irreparably harmed during the pendency of the appeal, it is perplexing that EPA and NEH will

⁶ Defendants ignore existing mechanisms to recoup funds. *E.g.*, 2 C.F.R. § 200.345 (discussing post-closeout adjustments and refunds); *id.* § 200.346 (explaining that excess payments to grantees "constitute a debt; to the Federal Government"); *id.* § 200.410 (providing for collection of "unallowable" costs).

be.

Notwithstanding that logic gap, Defendants assert they are harmed by disbursing congressionally appropriated funds.⁷ Mot. at 22. That statement refutes itself: "agencies are not harmed" by disbursing congressionally appropriated funds "that agencies have already awarded." Order at 49; *see also Cmty. Legal Servs.*, 137 F.4th at 942-43; *United States v. McIntosh*, 833 F.3d 1163, 1175 (9th Cir. 2016).

Second, Defendants assert the injunction harms the "separation of powers" because it "interfer[es] with the President's ability to control his subordinates." Mot. at 23. To state the obvious, Congress—not the President—controls the purse. Further, Defendants are not harmed by an order prohibiting them from violating the law. *Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013) (government "cannot suffer harm from an injunction that merely ends an unlawful practice."); *Doe #1*, 957 F.3d at 1059.

Nevertheless, Defendants cite *Trump v. CASA, Inc.*, No. 24A884, 2025 WL 1773631, at *14 (U.S. June 27, 2025) to argue that the injunction "improperly intrud[es] on a coordinate branch of the Government." Mot. at 23. In *CASA*, the

⁷ Defendants also argue in passing that the nominal bond is inadequate, but district courts have wide discretion in determining bond amounts. *See Save Our Sonoran, Inc. v. Flowers*, 408 F.3d 1113, 1126 (9th Cir. 2005).

Supreme Court said that the nationwide injunction was overly broad. *Id.* at *15. Here, as discovery showed and as subsequent status reports revealed, Defendants had no issue identifying the class members' grants. Whereas the Supreme Court in *CASA* disapproved a nationwide injunction, this case, by contrast, is exactly what the Supreme Court approved: an injunction to provide necessary relief to specific Plaintiffs.

Finally, as in *APHA*, "[a]lthough the [government] may suffer some financial loss in the interim, it has neither quantified that potential loss nor provided any evidence that it will occur imminently." 2025 WL 2017106, at *12. Defendants have not met their burden to show irreparable harm absent a stay pending appeal.

III. Granting a Stay Will Harm Plaintiffs and the Public.

The Court should also deny Defendants' Motion because Plaintiffs will suffer significant and irreparable harm if a stay allows Defendants to terminate the newly re-instated grants. Nevertheless, Defendants argue that Plaintiffs' injury is monetary and, thus, a classic example of reparable harm.⁸ Their claim ignores what this case is about, in that far more than money is at stake. If grant funds are not

⁸ Defendants also rely upon *CASA* to claim that Plaintiffs cannot "morph" their reparable, monetary injury into an irreparable injury warranting an injunction. Mot. at 23-24. This mischaracterizes the case as Plaintiffs' claims are statutory and constitutional in nature.

restored now, and Plaintiffs must wait through months or even years of further litigation to receive funds they are due, it will be too late: labs will have closed, project partners will have pursued other opportunities, and researchers, post-doctorates, graduate students, and staff will have gone elsewhere. Order at 2-3, 48.

As an example, Plaintiff Thakur received years of funding from EPA for her research into air quality impacts on public health. (Dkt. No. 10 at ¶¶ 4-25). Staying the District Court's preliminary injunction would threaten her ability to continue research on the health impacts of wildfire smoke and thereby deprive the public of the results of such research, including relevant thresholds for public health guidance during wildfire events. Dkt. No. 10 at ¶ 25. As in *APHA*, at no point have Agency Defendants "refute[d] the plaintiffs' contentions that a stay would result in the setback of 'life-saving research by years if not decades' and would eliminate funding for 'urgent public health issues.'" 2025 WL 2017106, at *12.

In addition, "there is a substantial public interest 'in having governmental agencies abide by the federal laws that govern their existence and operations."
State v. Azar, 385 F. Supp. 3d 960, 985 (N.D. Cal. 2019), vacated on other grounds and remanded sub nom. Cal. ex rel. Becerra v. Azar, 950 F.3d 1067 (9th Cir. 2020); League of Women Voters of the U.S. v. Newby, 838 F.3d 1, 12 (D.C. Cir. 2016). This also includes not wasting taxpayer money by cutting off research midstream.

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Here, the balance of equities weighs against a stay.

CONCLUSION

Defendants cannot meet the factors for a stay pending appeal. The Court should deny Defendants' Motion.

Dated July 22, 2025

FARELLA BRAUN + MARTEL LLP

By: /s/ Anthony P. Schoenberg

Anthony P. Schoenberg (CA Bar No. 203714)

tschoenberg@fbm.com

Linda S. Gilleran (CA Bar No. 307107)

lgilleran@fbm.com

Kyle A. McLorg (CA Bar No. 332136)

kmclorg@fbm.com

Katherine T. Balkoski (CA Bar No. 353366)

kbalkoski@fbm.com

FARELLA BRAUN + MARTEL LLP

One Bush Street, Suite 900

San Francisco, CA 94104

Telephone: 415. 954.4400

Erwin Chemerinsky (admitted pro hac vice)

echemerinsky@law.berkeley.edu

Claudia Polsky (CA Bar No. 185505)

cpolsky@law.berkeley.edu

U.C. BERKELEY SCHOOL OF LAW

Law Building

Berkeley, CA 94720-7200

Telephone: 510.642.6483

Elizabeth J. Cabraser (CA Bar No. 83151)

ecabraser@lchb.com

Richard M. Heimann (CA Bar No. 63607)

rheimann@lchb.com

Kevin R. Budner (CA Bar No. 287271)

kbudner@lchb.com

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Annie M. Wanless (CA Bar No. 339635) awanless@lchb.com LIEFF CABRASER HEIMANN & BERNSTEIN, LLP 275 Battery Street, 29th Floor San Francisco, CA 94111 Telephone: 415.956.1000

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STATEMENT OF RELATED CASES (CIRCUIT RULE 28-2.6)

There are no other cases which are related to the instant matter.

Dated: July 22, 2025 FARELLA BRAUN + MARTEL LLP

By: /s/ Anthony P. Schoenberg
Anthony P. Schoenberg

Case: 25-4249, 07/22/2025, DktEntry: 11.1, Page 35 of 475

CERTIFICATE OF COMPLIANCE

This Opposition complies with the type-volume limit of Ninth Circuit Rules 32-3 and 27-1(1)(d) because it contains 5,597 words. This Opposition also complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 27(d)(1)(E) and 32(a)(5)-(6) because it was prepared using Microsoft Word in Time New Roman font, a proportionally spaced typeface.

Dated: July 22, 2025 FARELLA BRAUN + MARTEL LLP

By: /s/ Anthony P. Schoenberg
Anthony P. Schoenberg

Case: 25-4249, 07/22/2025, DktEntry: 11.1, Page 36 of 475

EXHIBIT - 1

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA

NEETA THAKUR, et al.,
Plaintiffs.

Case No. 25-cv-04737-RFL

v.

PRELIMINARY INJUNCTION

DONALD J. TRUMP, et al.,

Defendants.

For the reasons set forth in the Court's accompanying opinion (Dkt. No. 54), it is hereby **ORDERED** that a preliminary injunction is entered as follows:

1. The Form Termination Class consists of:

All University of California researchers, including faculty, staff, academic appointees, and employees across the University of California system who are named as principal researchers, investigators, or project leaders on the grant applications for previously awarded research grants by the EPA, NSF, or NEH (or their sub-agencies) that are terminated by means of a form termination notice that does not provide a grant-specific explanation for the termination that states the reason for the change to the original award decision and considers the reliance interests at stake, from and after January 20, 2025.

Excluded from the class are Defendants, the judicial officer(s) assigned to this case, and their respective employees, staffs, and family members.

2. As to the Form Termination Class:

a. All grant terminations by the National Endowment for the Humanities, the National Science Foundation, and the Environmental Protection Agency (collectively, "Agency Defendants") communicated by means of a form termination notice that does not provide a grant-specific explanation for the termination that states the reason for the change to the original award decision and considers the reliance interests at stake, which result in the termination of

- funding as to a member of the Form Termination Class, are VACATED.
- b. Agency Defendants are **ENJOINED** from giving effect to any grant termination that results in the termination of funding as to a member of the Form Termination Class, where the termination was communicated by means of a form termination notice that does not provide a grant-specific explanation for the termination that states the reason for the change to the original award decision and considers the reliance interests at stake.
- c. Agency Defendants shall **RESTORE** the affected members of the Form
 Termination Class to the status quo and **REINSTATE** the terminated grants.
- 3. The Equity Termination Class consists of:

All University of California researchers, including faculty, staff, academic appointees, and employees across the University of California system who are named as principal researchers, investigators, or project leaders on the grant applications for previously awarded research grants by the EPA, NSF, or NEH (or their sub-agencies) that are terminated pursuant to Executive Orders 14151 or 14173, from and after January 20, 2025.

Excluded from the class are Defendants, the judicial officer(s) assigned to this case, and their respective employees, staffs, and family members.

- 4. As to the Equity Termination Class:
 - a. All grants terminated by Agency Defendants pursuant to Executive Orders
 14151 or 14173, which result in the termination of funding as to a member of
 the Equity Termination Class, are VACATED.
 - b. Agency Defendants are **ENJOINED** from giving effect to any grant termination that results in the termination of funding as to a member of the Equity Termination Class, where the termination was pursuant to Executive Orders 14151 or 14173.
 - c. Agency Defendants shall **RESTORE** the affected members of the Equity

 Termination Class to the status quo and **REINSTATE** the terminated grants.
- 5. This relief applies on a prospective basis. While this matter remains pending, any

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future grant terminations by Agency Defendants meeting the above criteria are

vacated upon issuance, and the Agency Defendants are enjoined as to those

terminations in the manner stated above.

6. By June 30, 2025, Plaintiffs SHALL post a nominal bond of \$100 with the Clerk of

the Court.

7. This order **SHALL** remain in effect until further order of the Court.

This injunction shall apply to all Agency Defendants as well as any subagencies of Agency

Defendants and any officers, agents, servants, employees, or attorneys of Agency Defendants or

any of their subagencies. This injunction shall further apply to persons who are in active concert

or participation with Agency Defendants' officers, agents, servants, employees, and attorneys,

including but not limited to Defendant Department of Government Efficiency ("DOGE"). Fed.

R. Civ. P. 65(d)(2).

IT IS SO ORDERED.

Dated: June 23, 2025

RITA F. LIN

United States District Judge

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EXHIBIT - 2

Pages 1 - 71

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Before The Honorable Rita F. Lin, Judge

NEETA THAKUR, on behalf of themselves and all others similarly situated,

Plaintiffs,

VS.) NO. 3:25-cv-04737-RFL

DONALD J. TRUMP, in his) official capacity as President) of the United States, et al.,)

Defendants.

San Francisco, California Friday, June 20, 2025

TRANSCRIPT OF REMOTE PROCEEDINGS

APPEARANCES:

For Plaintiffs:

LIEFF, CABRASER, HEIMANN

& BERNSTEIN LLP

275 Battery Street - 29th Floor San Francisco, California 94111

BY: ELIZABETH J. CABRASER, ATTORNEY AT LAW RICHARD M. HEIMANN, ATTORNEY AT LAW KEVIN R. BUDNER, ATTORNEY AT LAW ANNIE M. WANLESS, ATTORNEY AT LAW

FARELLA, BRAUN & MARTEL LLP One Bush Street - Suite 900

San Francisco, California 94104

BY: ANTHONY P. SCHOENBERG, ATTORNEY AT LAW KYLE ANDREW MCLORG, ATTORNEY AT LAW

(APPEARANCES CONTINUED ON FOLLOWING PAGE)

Reported By: Ruth Levine Ekhaus, RMR, RDR, FCRR, CCG

Official Reporter, CSR No. 12219

1	APPEARANCES: (CONTINUE	ED)
2	For Plaintiffs:	
3		UC BERKELEY SCHOOL OF LAW 215 Boalt Hall
4	BY	Berkeley, California 94720 ERWIN CHEMERINSKY, ATTORNEY AT LAW
5	For Defendants:	
6	For Derendants:	DEPARTMENT OF JUSTICE Civil Division
7		950 Pennsylvania Avenue NW Washington, D.C. 20530
8	BY	
9		
10		
11		
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Friday - June 20, 2025 1 10:01 a.m. 2 PROCEEDINGS ---000---3 THE CLERK: All rise. This Court is now in session. 4 5 The Honorable Rita F. Lin presiding. (Pause in proceedings.) 6 THE CLERK: Please be seated. 7 Calling Civil Case 25-4737, Thakur, et al., v. Trump, 8 et al. 9 10 Counsel, please state your appearances for the record beginning with the plaintiffs. 11 MR. CHEMERINSKY: Erwin Chemerinsky for the 12 plaintiffs. 13 MS. CABRASER: Good morning, Your Honor. Elizabeth 14 15 Cabraser of Lieff Cabraser Heimann & Bernstein for the plaintiffs, with Richard Heimann of Lieff Cabraser for the 16 plaintiffs as well. 17 MR. McLORG: Good morning, Your Honor. Kyle McLorg 18 for the plaintiffs. 19 20 MR. SCHOENBERG: Good morning, Your Honor. Tony 21 Schoenberg from Farella Braun & Martel for the plaintiffs. 22 MR. BUDNER: Good morning, Your Honor. Kevin Budner 23 from Lieff Cabraser for the plaintiffs. 24 MS. WANLESS: Annie Wanless from Lieff Cabraser for 25 the plaintiffs.

MR. ALTABET: Jason Altabet on behalf of the Department of Justice representing the United States.

THE COURT: Good morning to all of you.

Let me start out by just giving you a sense of my thoughts on the case initially so far. I'm, obviously, open to hearing more; that's the whole reason we're here. But I thought it'd be useful for your argument to hear how I see the case.

Then I'd like to go through the questions that I put out for the parties to be prepared on yesterday. And then at the end, I promise you, you will have time to tell me more about whatever else you think I should know about the case.

So just at the outset, in terms of how I see the case so far, I have to say that I am quite troubled by the information I see in the record.

Researchers across the University of California system rely heavily, of course, on federal funds. The record is that the University of California system had over \$4 billion in federal grants in 2024. In the last few months, \$324 million in grants have already been terminated.

These are multiyear projects, funded after a highly competitive process with peer review, expert selection panels. It looks to me, from the record, like the administration has terminated grants on a massive scale without reasoned consideration.

The record shows grants being flagged for review based on keywords in their title, like having "diversity" or "equity" in the title. There are form letters being issued with no explanation at all other than "there's been a change to the agency priorities."

There's no explanation as to why the particular grant doesn't serve agency priorities anymore. And there's no explanation as to why it falls within a forbidden topic, like DEI, diversity, equity, or inclusion, or any of the other prohibited areas.

Dr. Thakur's grant is really a grant example of this, it seems to me. The record describes her as doing research at UCSF on genetic differences in lung disease among racially and ethnically diverse groups, and she was funded for a federal grant about how wildfire smoke affects those particular populations.

It is hard to understand why that would be DEI or diversity, equity, or inclusion-related work, but there was no explanation in the letter as to why it falls within that category. It -- I have to say, just looking at the record at this initial stage, it seems totally arbitrary.

The Administrative Procedure Act, as you all know, requires a reasoned explanation when the agency changes its priorities and changes its mind about a particular grant. It requires reasoned consideration of reliance interests. These

terminations are upending years of investment of resources. It just looks like a blatant violation of the APA's requirements.

It also seems likely to me that the practice of terminating grants because they are on -- or they involved research that touches on a blacklisted topic, like diversity or equity, is likely in violation of the First Amendment.

Obviously, the Government can build programs with certain goals and favor certain speech in order to achieve that, but that does not appear to be what these executive orders are doing. They appear to be targeted at penalizing forbidden ideas across the board to drive them out of the marketplace of ideas, which is not allowed.

A number of courts have reached that conclusion in other cases. It seems right to me.

Also, it seems to me that both of these claims, the arbitrary and capricious claim and the First Amendment, are appropriately treated as classwide claims. These are classic, class action type claims.

I do have some questions about class scope and definition. But the arbitrary and capricious claim is a classic form letter claim. We litigate these types of form letter class actions all the time in the federal courts.

And the First Amendment claim involves two executive orders that NEH, NSF, and EPA all said they were implementing by searching for and terminating grants on forbidden topics.

It appears to me that the defendants' main argument is that I shouldn't consider the merits of these claims because the researchers don't have Article III standing, that they aren't injured by the termination of the grants.

I have to say I'm having a hard time understanding that point. I absolutely understand that they could not bring a breach of contract claim, most likely, because they're not parties to the grant agreement. The grant agreement is with the University of California, not with the individual researchers.

But what I don't understand is why that means they were not harmed. Justice Scalia famously described the standing inquiry as, "What's it to you?"

These are folks who have been doing research for years and then have the rug pulled out from under them. They can't hire grad students. The research has to be delayed, maybe even thrown out.

Obviously, it has a profound effect on their careers.

It's hard to imagine who would be more affected by the grant terminations than the researchers who applied for the grants and are conducting the research.

So that's the fundamental disconnect that I'm seeing with the Government's argument. I hope that's helpful, the initial sense of where I am in the case.

Let me ask both parties to send whoever is going to

```
argue to the podium for both sides, and then we'll just go
 1
     through the questions one by one, and each side can respond.
 2
     I'll tell you who should address each question first when I
 3
     finish it.
 4
 5
              MR. CHEMERINSKY:
                                Your Honor, I'm going to be arguing
     in favor of the motion for preliminary injunction, so I'll be
 6
     addressing Questions 1, 2, and 6. And my co-counsel,
 7
     Ms. Cabraser, is going to have a class certification. So when
 8
     we get to Questions 3, 4, and 5, she'll address those for you.
 9
10
              THE COURT: Great.
                                  Thank you.
11
              MR. ALTABET: And I'll be addressing all the
     questions.
12
13
              THE COURT:
                          Thank you.
              So let's just start with Question 1. I'll read it so
14
15
     we're all on the same page. (as read):
              "The defendants argue that plaintiffs lack
16
17
          Article III standing because they are not parties to
          the grant agreements between the agencies and the
18
          University of California. Is it the defendants'
19
20
          position that a non-party to a contract could never
21
          suffer cognizable injury from its termination unless
22
          the non-party is an intended third-party beneficiary
23
          to the contract?"
24
              And then relatedly (as read):
25
              "Why would traditional Article III standing rules
```

be any different merely because the injury occurs in the context a contract termination?"

Obviously, that's a question for the Government to take the first crack at.

MR. ALTABET: Yeah. And I apologize, because I think this is a product of inartful briefing because we were trying to set out possible ways that plaintiffs could have an interest of their own that they're asserting.

So sort of starting with *Lujan*, the standing test requires a violation of a legally protected interest. And I think cases like *DOL v. Triplett*, T-R-I-P-L-E-T-T, and *Kowalski*, K-O-W-A-L-S-K-I, are setting out this idea that even if you suffer a factual concrete injury -- so in *Triplett*, it's the loss the money to an attorney because claimants there had their fee structure basically regulated by the Government in a way that no one doubted caused a monetary injury to their attorney.

And similar in *Kowalski*, no one argued that they didn't have a pocketbook, concrete injury, the type of thing we think about as an injury, in fact, that's well established in American English law. Everyone agreed that that happened, but because the rights those two attorneys were asserting were others -- in *Triplett*, it was the due process rights of their clients; in *Kowalski*, it was at Sixth Amendment rights of the potential clients -- the Court required both the concrete

actual factual injury and a determination as to the right of the third party and whether the person could assert that right.

And our understanding of this case is -- as sort of in the motion in the complaint, the grants are described as "plaintiffs' grants." And even in their reply, they say on page 7, lines 1 to 2 (as read):

"Plaintiffs demonstrated concrete and actual harm resulting from the invasion of their interest in the grants."

So I think it's just a matter of law, and I think everyone agrees, they have to have some sort of interest in the grant for them to assert the rights, at least as they've asserted the right. So I think the First Amendment claim is a great example.

So they are arguing that the Government has canceled funding under grant agreements in violation of the First Amendment because of some viewpoint discriminatory reason because of the subject matter of the grants. That -- for example, that's the language they used in the proposed order for the findings that the Court would issue if the First Amendment claim was successful on their part.

And the subject matter of grants belongs to the University of California institutions. They submitted the grants. For example, some of these plaintiffs are co-principal investigators or otherwise not even the people who helped to

draft the original grant or, like, sort of if they have 1 ownership even if they're arguing --2 (Reporter interrupts for clarification of the record.) 3 MR. ALTABET: Sorry. It's too fast. 4 THE COURT: The court reporter has to write every 5 word. 6 MR. ALTABET: Okay. Even in situations where a 7 plaintiff -- we'll say a project manager versus a co-principal 8 investigator. It's the institution that is submitting the 9 10 grant application, the grant agreement; and therefore, the subject matter of the grant belongs to the University of 11 California. 12 So I think what plaintiffs have to show, for example, 13 in the First Amendment context is that they have some sort of 14 15 positive law interest in the funding that would then allow them to be asserting their own rights. Because, otherwise, I think 16 they are, like in Kowalski or in Triplett, asserting the rights 17 of the University of California to funding. 18 THE COURT: Let me ask you about Kowalski and 19 20 Triplett. 21 It seems to me that the legal lens through which 22 the Court should look at those cases is really causation and 23 redressability. The Court is saying that there's too much of a 24 gap in the chain for that to count as an injury; but, here, 25 although the injury occurs through a contract termination to

another party, there is a lot of evidence about a close causal link and evidence of redressability.

Do you agree that *Triplett* and *Kowalski* are really cases that are about causation and redressability? And if that's the case, why shouldn't the Court just apply the traditional causation/redressability test?

MR. ALTABET: So I don't think they're about that.

And I think the language of the cases and even, frankly, where they are in the casebook on federal courts in the federal system, is about whether someone is asserting their own rights or the rights of another. And I don't think that's a causation and a redressability question. It's whether the positive law has provided a legal interest that someone is themselves asserting, because I don't think there is a causation or redressability problem, say, in Triplett.

Everyone agrees that these claimants will either be sending more or less money to the attorney depending on how the statute operates. If the statute is in violation of due process, then the attorney gets more money. If the violation -- if it's not in violation of due process, the attorney gets less money.

I don't think that's a causation or redressability problem. But still, the attorney couldn't assert -- like the attorney had no due process right in the fee structure, as understood by the Court. It had to be the clients and the

claimants, and therefore, there was a third-party standing analysis.

THE COURT: Let me ask you about -- a hypothetical.

Let's just imagine that we have another administration -- not

this administration, a future administration -- that engages in

just blatantly illegal racial discrimination. So let's say,

EPA goes out, looks at every grant and says: Does the lead

researcher have an Asian last name? And if the answer is yes,

we're terminating those grants.

Obviously, this has a profound effect on all the lead researchers across the country who have Asian last names.

Is it the Department of Justice's view that none of those researchers would have standing to sue because they are not parties to the contract that was terminated?

MR. ALTABET: No. Because, I think, in that scenario, it's the individual rights of the researchers or the principal investigators that are the legally invaded interest.

And I brought an example to Your Honor's question about: Is there any scenario where we think that the contract termination would lead to a cognizable injury?

I could think of a lot of examples, but it just depends on what the claim is. So again, here is the claim as to funding, and so they have to have an interest in the funding.

But let's say the Sixth Amendment context --

(Reporter interrupts for clarification of the record.)

MR. ALTABET: Yes. I will.

THE COURT: Just help out the court reporter. She has to write every word as you say it. We have time to hear your argument. If we go too long, we'll take a break.

MR. ALTABET: Yes, Your Honor.

Think, for example, about the Sixth Amendment. Let's say I am arrested for a felony and I'm sitting in jail awaiting an attorney, and the State of Aims [sic] has a contract with the legal aid group that represents indigent criminal defendants, and they terminate that contract. They say it's too much money; no one is going to be representing indigent criminal defendants.

In that case, the termination of the contract leads to a cognizable injury, as a felony defendant, because I am no longer receiving an attorney. That's a personal right to myself.

But that contrasts with the First Amendment context where it's about funding, and so they need to have an interest in the funding that is recognized under law. And here we try to spell out a possible way that they could have the -- sort of the only possible way we could think of where they would have a positive law, cognizable legal interest in the funding because of third-party beneficiary status.

THE COURT: So going back to the hypothetical that I

posed to you about termination of all grants of researchers who have an Asian last name, your view would be, in that scenario, the researchers have an independent injury because the -- the harm inflicted was on them directly? And the right at issue was their right to be free of racial discrimination?

MR. ALTABET: Yes. It's targeting them directly through the equal protection right that they have.

And here, at least as pled, as set up as a First Amendment claim, it's about the right to continued funding. So they must have a legal interest in that funding.

And I think that has to come from the positive law or some way that's been recognized. I don't think First Amendment law recognizes, in any of these funding cases, people -- like employees, say, at the institutions in the USAID case, the Open Society Foundation.

The employees there were no longer receiving funding for their projects because of Open Society's inability to take a pledge about sex trafficking and prostitution. But we would, I think, say that it's the First Amendment right of Open Society -- not the First Amendment right of the employees who also face a lack of funding -- that's being asserted in that case. And I don't think the employees of Open Society would have a legally cognizable interest to bring their own lawsuit in that case.

THE COURT: Is there case law saying that the

employees who are required to, say, take -- or to participate in this -- or who are prohibited from advocating for particular causes that they want to -- or, in this case, doing the research that they want to -- that they want to conduct, the Government is now saying these are forbidden topics, you can't research these topics?

I'm having a hard time understanding why the person who is doing the research hasn't suffered an independent First Amendment injury.

MR. ALTABET: And I think the reason I -- I think these cases like *Kowalski* and *Triplett* -- and if Your Honor sees them differently, then that is a substantial part of our argument. But cases like *Kowalski* and *Triplett* stand for the proposition that even a cognizable pocketbook injury, if the right being asserted is not my own, but rather, an action happens, a third party suffers harm that flows to me, the right I'm asserting matters.

And if it's the due process right, say, of the third party where, ultimately, the consequences flow to me, I need to show the third-party standing test of close relationship and hinderance.

THE COURT: Is that because the target of the Government's regulation is the third party, rather than the plaintiff in those cases?

MR. ALTABET: I think, yes. And in particular, it's

about -- I think in this context especially -- what the content of the claim is.

And here the content of the claim is funding, and unless you have an interest independently known in the positive law in that funding, then I don't think you have this legally cognizable injury. And I think *Triplett* is the same, you don't have a due process right in the funding scheme for the fees.

THE COURT: But why isn't the target here the researcher and the research that's being done?

MR. ALTABET: Because, at least in this context, the researchers, I do not think, are asserting their own

First Amendment rights as described. Because in, for example, a case where the United States says that every principal investigator must take a pledge of X, Y, Z -- in the Open Society way. I think that's an example where their rights are being targeted and affected.

But here, at least as pled, it's about a funding stream to a third party. The funding does eventually reach these researchers, but it's still through that third party, and so it's the right of the third partying to funding.

I don't think you can just go down the line.

Employee -- well, maybe the researcher hires a nonprofit to help them with their project. So now does the nonprofit have standing?

Then the nonprofit has employees. Does the nonprofit

employees have standing?

I think it would be disruptive to this whole area of law to think that anyone who has been affected by, for example, the Government's choice on funding, can now bring a suit independent of the actual recipient of the funding.

THE COURT: Let me just give plaintiffs an opportunity to respond.

MR. CHEMERINSKY: Thank you, Your Honor.

Kowalski and Triplett are third-party standing cases.

Kowalski, for example, is about whether a criminal defense lawyer could raise the rights of criminal defendants by repeal in Michigan.

We could talk about whether or not the plaintiffs here can represent the University of California, but this isn't a third-party standing case. This is an instance where the plaintiffs are suing over the injuries they've suffered with regard to their research being stopped.

It's a loss of income to many of them to the extent they're paid out of that. The Supreme Court has always said that an economic injury is sufficient for standing. It's harm to their professional work. The Supreme Court has recognized that harm to one's professional work is an injury sufficient for standing. It's a harm to reputation. The Supreme Court has said that's sufficient for standing.

I also think that the Government's premise

misunderstands how grants work. The grants functionally are to the researchers. They're through the Regents of the University of California. Generally, the researchers can take them with them if they move to another institution.

Also, the First Amendment harm is to the individuals

Also, the First Amendment harm is to the individuals that are being denied grants because of the viewpoints that they're expressing in their research, as perceived by the Government. First Amendment is always a personal harm.

Now, we could go on and talk about could there be third-party standing. And I think this is different than <code>Kowalski</code> and <code>Triplett</code> if you needed to get to third-party standing because this situation where there's sufficient identity of interest between the plaintiff and the third party, so it's more like <code>Singleton vs. Wulff</code> or <code>Craig vs. Boren</code>.

But, Your Honor, you don't need to get to third-party standing. As you said in your remarks, this is about the injuries that these plaintiffs have suffered.

THE COURT: Let's just move to Question 2.

MR. ALTABET: Can I just address one thing, Your Honor, that was said?

It's just -- they actually -- in order to take those grants with them, they need to -- the institution would need to agree. It's not the researchers' grants.

As a matter of fact, the institution would have to say -- let's say, our principal investigator moves to a new

place. The institution would have to say, "I relinquish this 1 grant to, say, the new institution." 2 Isn't it true that if the -- I thought I THE COURT: 3 4 saw somewhere in the grant agreements that if the 5 institution -- if the University of California, we have a grant that goes to Researcher A, and now the University of California 6 wants to reassign it to Researcher B, that they have to let the 7 Government know, and the Government has to approve that change? 8 9 MR. ALTABET: Yes, Your Honor. But I think in -similar to any contract, if someone is doing work for me and a 10 new person is going to start doing the work, I might have the 11 ability to say: Person 1, that's fine. Person 2 is a good 12 13 enough substitute. I agree. THE COURT: In terms of Question 2, my question was 14 15 (as read): "Assuming plaintiffs have Article III standing to 16 bring their claims, do defendants contend that 17 plaintiffs' claims could actually be heard in 18 the Court of Federal Claims under the Tucker Act?" 19 20 Let's just start with that. 21 MR. ALTABET: Yes, Your Honor, we do. 22 And I think it's most helpful to start with B and C, 23 the consideration and the right to monetary recovery, and then 24 move to A.

So starting with that, we cited Boaz Housing Authority

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as our main case on this -- B-O-A-Z, Housing Authority -- a 2021 federal circuit case. And there, the topic matter was a contract for public housing authority subsidies to states and localities. It was through a statutory discretionary program, and the Housing and Urban Development Agency created contracts to send this subsidy money to states and localities to help fund public housing. So it was for the benefit of the public.

The Court didn't even question the consideration portion. It just moved to whether there was a right to monetary recovery.

And there, I think you can see what has happened with the Rick's Mushroom case.

The United States for decades has tried to argue that these grant agreements in the Court of Federal Claims in the Federal Circuit are not cognizable there, and we've lost that war. And I think Boaz Housing Authority is a good example of that.

The Court says there's only three categories of contracts where there would not be a right to monetary recovery. That would be express disavowals, contracts involving criminal cases, and specific special cost-sharing agreements like that in *Rick's Mushroom*.

And what you'll see over the course of the decades after *Rick's Mushroom* is that case is essentially limited to its facts where the government and the person receiving the

funds worked very closely together, with the United States doing substantial work and the other person doing substantial work. So it's not that kind of case.

I have one case that's not in the briefing but that's responsive to Your Honor's question. It's *Columbus Regional Hospital v. United States*, 990 F.3d 1330, which I think answers Your Honor's A and B category questions.

First, that case was about an agreement between FEMA and Indiana for disaster relief funds. And there, the Court said: (as read):

"Consideration in this context is satisfied if
the Government has imposed a variety of duties on the
counterparty, even if it's in a standard form
agreement."

So I think this is to the contrast of *St. Bernard*, which is just a Court of Federal Claims case. It's not precedential under the Court of Federal Claims' rules, and it was affirmed on different grounds.

Meanwhile, this is a Federal Circuit Case, post-dating St. Bernard, and it makes it clear that consideration is allowed in this context, and particularly so here, where the Government has chosen topics in notice of funding opportunities to -- that it wants research done on and then has imposed terms on the counterparty.

I'll also note that in the Boaz Housing Authority

case, that case makes clear that in the event of a breach of contract, the counterparty to the United States can recover as if the contract had gone its entire term.

So there's no question that here, if plaintiffs were to succeed in the Court of Federal Claims -- or the University of California were to succeed, they could recover the entire term of the contract. It doesn't matter that it was purportedly terminated halfway through.

And now, I guess I'll turn to Your Honor's first, A, which is, "Could plaintiffs bring the suit there?"

Yes. The Court of Federal Claims would have subject matter jurisdiction over the suit. The question would be on the merits. "Do plaintiffs have an express contract, an implied-in-fact contract, or third-party beneficiary status?"

That's in *Columbus Regional Hospital*. That cleared up several different cases on that at the Court of Federal Claims, whether it's a 12(b)(1) or a 12(b)(6) dismissal when someone doesn't have a contract.

And so long as it's not a frivolous claim, the Court of Federal Claims has jurisdiction but then, on the merits, may say that they lose. And *Columbus Regional Hospital* is a great example. There, the Columbus Regional Hospital was not a direct party to United States' contract with Indiana.

But they argued that in the negotiations over the contract, worksheets involving Columbus Regional Hospital were

approved by the United States -- maybe similar to this situation where the research is approved as part of the agreement with the United States and University of California institutions.

And the Court held that it was non-frivolous, and the Court had jurisdiction over whether that was an express contract, an implied-in-fact contract, or the Court even held that it might be a third-party beneficiary situation.

Now, we think that this is not -- we still think that they cannot succeed on third-party beneficiary status. But it's not a frivolous claim that the Court of the Federal Claims would not have jurisdiction over.

THE COURT: If plaintiffs haven't asserted third-party beneficiary status as the basis for their claims, is it still your view that there would be jurisdiction over their claims in this action?

They don't assert breach of contract. They don't assert third-party beneficiary either, so it is hard for me to see how the Federal Circuit can conclude that this is breach of contract within the Tucker Act.

MR. ALTABET: And that's -- the reason that we can assert that is the *MegaPulse* test and its progeny, which requires looking at the substance of whether an action is, in essence, a contract action regardless of how it's pled.

And I think one important note there, the Tuscon

Airport Authority case from the Ninth Circuit that we cited, I think, is the most on point in explaining this, specifically, because, there, the Court rejected the idea that there needs to be even an adequate remedy in the Court of Federal Claims. It just needs to have jurisdiction over the essence of the action, and that included constitutional claims.

And the Court still held that the implied preclusion test under *MegaPulse* applies. You look at the essence of the action, and if it is, in essence, a contract action on a claim-by-claim analysis -- some claims could be, some claims could not be. But if a claim is, in essence, a contract action, then it needs to be brought in the Court of Federal Claims, and there's implied preclusion, even if you're going to lose.

THE COURT: Just to stay for a minute on the MegaPulse test.

So let's just assume that I find that the plaintiffs would be irreparably harmed by termination of the grants because their research would be interrupted, they'd have to lay off their researchers, it would hurt their career opportunities.

If I -- if I reach that conclusion and I send plaintiffs to the Court of Federal Claims, am I -- are you in agreement that that means they would not be able to get preliminary injunctive relief there to -- to arrest that harm?

MR. ALTABET: I think it would depend on which claims, Your Honor has concluded fit -- under the *MegaPulse* test belong in the Court of Federal Claims.

If, for example, Your Honor found three of their claims, but one claim doesn't, so one claim the Court maintains jurisdiction over, and that one claim was the basis for the preliminary injunction, then, no, because the Court would have jurisdiction over that claim.

But I think it's true that if the Court lacks jurisdiction over all of plaintiffs' claims that would provide preliminary injunctive relief, then the preliminary injunction could not continue upon a conclusion that there's a lack of jurisdiction in this court.

THE COURT: So, essentially, if I -- if I agree with the Government's position which is that the whole case should go to the Court of Federal Claims, even if I think that plaintiffs have been irreparably harmed, and injunctive relief would otherwise issue to protect them, it's your view I should send them to this court where they can't get any of that relief and nothing can be done to prevent that irreparable harm.

Am I understanding the Government's position correctly?

MR. ALTABET: Yes. I mean, our position -- I will embrace this -- is that if there's a lack of subject matter jurisdiction in this court, then the Court cannot issue a

preliminary injunction on the basis of a case that lacks subject matter jurisdiction.

And in the Court of Federal Claims, the plaintiffs could ask for expedited relief. They could ask for, you know, a quick turnaround on whether there's been a breach of contract to retrieve the money. But, ultimately, if there is no jurisdiction, there can be no preliminary injunction regardless of irreparable harm.

THE COURT: And isn't that part of the MegaPulse test, though, to look at the rights and remedies that are at issue, and if the remedy -- the principal remedy that is sought is to arrest immediately these irreparable harms, why does it make sense to send it to a court where they can't do that?

MR. ALTABET: I don't think it's part of the MegaPulse test in the same way that if we were asserting that there is as explicit preclusion -- let's say Congress passed a statute "This Court shall not have jurisdiction over this action," or, you know, the subject matter of this action, then the Court couldn't issue a preliminary injunction just because the remedies -- there is irreparable harm if Congress has precluded the action.

And similarly, the *MegaPulse* test is a way of thinking about: Does this court have subject matter jurisdiction?

I don't think it's amenable to, then, bringing in, say, the equities or irreparable harm. I think it is a

formalistic test as to whether under 702 there is implied preclusion or whether under, say, *Armstrong*, there's been preclusion because there's a separate statutory scheme designed to deal. And that's for the ultra vires claims.

THE COURT: Let me give plaintiffs an opportunity to respond.

MR. CHEMERINSKY: Thank you.

Your Honor, the flaw in the Government's argument -- and this also goes to your first question -- is in thinking of this as a contract. That's wrong both factually and legally under binding Ninth Circuit precedent.

Factually, I would point you to a declaration the Government filed, the Pendleton declaration, paragraph 6. It specifically says there's an important distinction between a grant and a contract, and these are grants not contracts.

In terms of the law, there's a binding Ninth Circuit precedent, United States Aeronautical Corporation vs. United States Air Force. And specifically, if you look at 80 F.4th at page 1026, it says you have to look where the cause of action arises.

And it says explicitly, if the cause of action arises from the constitution or statute, then the Tucker Act doesn't apply. Only if the cause of action is for breach of contract does the Tucker Act apply.

All of the causes of action of the complaint are for

constitutional and statutory violations.

Indeed, a number of federal district courts in two other cases from the Northern District have held that the Tucker Act doesn't apply.

Now, to go to the three factors that you pointed to -and I think there's no need to go to those factors because the
Tucker Act doesn't apply -- as to the first, it's notable the
Government wants to have it both ways because the first factor
says it has to be a contract between the Government and the
plaintiff.

And arguing for no standing, they want to say, "Oh, this isn't a contract with these individuals." But, here, they want to say, "Yes. Treat it as if it is a contract with these individuals."

I'd also go to the third of the factors that you identify in the question yesterday, and that's whether money damages would be available.

This isn't a case for money damages. This is a case for an injunction; and as you pointed out, no injunction is available in Federal Court of Claims. This would leave the plaintiffs with no remedy.

Your Honor, long ago *Marbury v. Madison* said: With a right, there has to be a remedy.

THE COURT: And what is your view of the issues that were flagged in Question 2? Is it your view that Federal

Circuit precedent would preclude the claims from being -- from 1 going forward in the Court of Federal Claims? If I sent it 2 there, would they just be sending it right back, or are you in 3 agreement with the Government that if -- if I looked at the 4 5 more modern Federal Circuit precedents that they would allow those cases to continue in the Court of Federal Claims? 6 I don't think the Federal Court of 7 MR. CHEMERINSKY: Claims would take jurisdiction here because, just what I said, 8 these are constitutional and statutory claims. They're not 9 10 breach of contract claims. In terms of the first factor, I think that -- very 11 well the Court of Claims could say what the Government says in 12 its standing argument: This isn't a contract with these 13 individuals. 14 15 I think with regard to the third, the Court of Claims would say: We're focused on money damages. This is a case for 16 an injunction. Not money damages. That should be in the 17 District Court. 18 THE COURT: And let me just confirm. 19 It seems 20 implicit in some of the briefing, but I want to confirm with 21 you. 22 Is it plaintiffs' position that your claims don't rely 23 in any way on the terms of the grant agreements? 24 MR. CHEMERINSKY: Well, Your Honor, we're saying that

the Government didn't follow the constitution and statutory

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requirements, that -- also the agency didn't follow its own procedures. So we're not focusing on the terms of the grant agreements in that sense.

THE COURT: Well, let's say -- let's do another hypothetical.

MR. CHEMERINSKY: Okay.

THE COURT: Let's say, in a future administration we have a day all the lawyers go on vacation that day, and the Government just decides to extend grants without having an actual grant agreement; they just decide that they're going to start paying the money, and they tell the researchers: The plan is to fund your research for the next few years.

And then the Government abruptly terminates the funding after two years without any explanation and -- because it involves a forbidden topic of research.

Would you have the same claim, even though there's no actual grant agreement in that situation?

MR. CHEMERINSKY: Well, I would start by wanting to know, is there a statute that appropriates the money, in which case that means that the money is there, and that administration can't cut it off.

But in terms of your specific question, yes, it would be the same. Think of it with regard to the Administrative Procedures Act. The agency still can't act in a manner that's arbitrary, capricious, or abuse of discretion. It still has

to, under $\mathit{Ohio}\ v.\ \mathit{EPA}$, be reasonable and reasonably explained when they would take that action.

Also, in terms of the First Amendment, you still can't punish people because of their viewpoint, even if they didn't have a right to the money.

And in terms of due process, it may be different, but so long as they have a reasonable expectation to continued receipt of a benefit, under *Roth v. Board of Regents*, they still have a property interest requiring due process.

THE COURT: Thank you.

Last opportunity for the Government to respond.

MR. ALTABET: I'll just -- just a couple of things.

So Boaz Housing Authority addresses Your Honor's question about what happens when an agency uses a contract versus doesn't use a contract in this sort of program involving grants. And there, the Court says when the government chooses to use a contract, it is then subject to the Court of Federal Claims so long as the general requirements are met.

In regards to grant versus contract, the Federal Circuit -- we've made this argument for decades, again, that the grants are not subject to Court of Federal Claims, and we've lost.

And so grants and contracts are both, as we've described them under the Pendleton declaration, in the Federal Circuit -- or in the Federal Circuit and the Court of Federal

Claims.

And just a couple of last points. We argue that they are bringing claims that involve the Constitution and statute but that require the terms of the contract because it's the terms of the contract that set out the obligation for funding, that certain parties receive funding.

And the cases we cite, from *Tucson Airport Authority* onward, address those points and say constitutional and statutory claims, as pled in the District Court, may still belong in the Court of Federal Claims if it's about the termination of a contract.

And lastly, as to implied preclusion, just because these plaintiffs would lose on the merits in the Court of Federal Claims under *Tucson Airport Authority*, that is, that they don't have an adequate remedy, doesn't matter under implied preclusion because implied preclusion is about whether the actual subject matter has been moved to a different court.

And Congress, for example, in the Civil Service Reform

Act context says that employees have the ability to bring

certain suits in the Merit Systems Protection Board, but the

union might not be able to bring suit there, but would still be

precluded from bringing a suit in district court on the same

subject matter.

I think that kind of understanding applies here as well.

THE COURT: Let me give plaintiff an opportunity to respond about the Civil Service Reform Act point.

MR. CHEMERINSKY: I'm not sure I understand the question you're asking.

THE COURT: So as I understand the Government's argument, it's that just because there is no opportunity for plaintiffs to bring their case in the Court of Federal Claims, that doesn't mean that this Court has jurisdiction over it as long as someone could enforce these rights, for example, the University of California could sue in the Court of Federal Claims. That's good enough.

MR. CHEMERINSKY: Your Honor, that's not the law, and it's not what due process would say.

The United States Supreme Court, in a long line of cases has always said statutes should be interpreted to make sure that somebody is not precluded from any jurisdiction in a court.

Johnson v. Robison, Osterreicher, and cases like that.

What this would say, then, is these plaintiffs have no forum that they can go to to vindicate their rights. The Government is saying they can't come to Federal District Court to vindicate their rights, and they can't go to the Federal Court of Claims.

The Supreme Court has never said, "Well, because somebody else might be able to sue, your due process rights are

vindicated."

Their due process rights mean they have to have a forum, and what the Supreme Court has said is statutes should be interpreted to preserve the ability of people to be able to have their day in court. The Government leaves them with no day in court.

THE COURT: Let's move to Question 3.

I'll start with plaintiffs on this question. So Question 3 is (as read):

"In the event that the Court finds the Winter's factor satisfied with respect to the arbitrary and capricious claim and the First Amendment claim as to the DEI executive orders without reaching the other claims asserted, should the Court consider certifying separate classes for each claim? And if so, should the class definition for the arbitrary and capricious claim be tailored to those researchers whose grants are terminated via a form letter that lacks a grant-specific explanation stating why the agency changed its position from the original word and considering the reliance interest in the funding regardless of which executive order, if any, served as the basis for the grant termination?"

Let's start with plaintiffs on that.

MS. CABRASER: Good morning, Your Honor, Elizabeth

Cabraser.

We -- we interpreted this question as one of class scope and class structure. And having thought about it and having had several different answers since yesterday, I think where we land is this: First of all, Rule 23(c)(1)(b) does require the Court in certifying a class to specify the claims or issues as to which the class is being certified. And, of course, a class can be certified as to some claims or issues and not others, hence the rule.

We had considered, in proposing our revised class definition, that it would serve equally for any and all claims that the Court would certify, and that we did not need different class definitions or different class scopes for that.

That said, the Court's suggestion with respect to tailoring the APA claim, the arbitrary and capricious claim to the use of form letters, has a certain precedent and a certain appeal. First of all, it is an objective class definition, and courts always strive for that, even in 23(b)(2) classes where it's less important than in 23(b)(3). And it would be certainly possible to look at all of the letters and see that they are form letters that lack these qualities. Indeed, that is what the record shows to date.

We do have a concern on the margins about that class definition. And that is that it would be easy or at least possible as the case goes on toward the final judgment for the

agencies to amend termination letters or to issue new termination letters that include more boilerplate that says: We reviewed your grant specifically, and we considered your reliance issues.

For -- and that is one reason why we would submit, all of this is discretionary with the Court, that the same class definition can serve with respect to both of those claims.

Our claim under the APA, arbitrary and capricious, is really that none of these form letters, however amended, however they might be varied, can remedy the basic problem here which is that the way grant terminations were done from the outset violates, categorically, the APA. It was not a reasonable process.

And if you don't have a reasonable process, you can't have a reasoned explanation for it. And I think the most recent example of that was the *Green & Healthy v. EPA* case that we submitted yesterday, issued on June 17th, involving a group of block grants that had been approved by Congress, appropriated by Congress, given out to do environmental justice.

And once the EO's were issued earlier this year that condemned environmental justice as a grant project, of course, the grants were terminated. And the problem was Congress said it wanted environmental justice. That statute had never been amended. The money was appropriated. The money was paid out,

and suddenly, no environmental justice. It couldn't a starker contrast. And it's the same type of contrast that is illustrated throughout this case.

Judge Ableson, in that case, doing the individual APA work of looking at the complete administrative record and all the e-mails and the minutia of the grant termination process, found there was no way to square what the EPA had done with any semblance of a reasonable process or that it was even possible to give a reasoned explanation. And that's our position here, and we think those are common questions capable of classwide adjudication.

That said, we don't object to this additional specificity if the Court feels that that is going to result in a more managed -- manageable and more focused inquiry going forward.

THE COURT: The question I have is whether there's a situation in which the administration could administer a grant termination program pursuant to the executive orders that require reduction in federal spending, generally, in a way that is reasoned and that does provide a reasoned explanation in the form letters.

In order to provide a reasoned explanation, one would, of course, have to conduct reasoned inquiry. So I don't think that a boilerplate letter that just says: "We've done the reasoned inquiry," without explaining what it is, is really the

same thing as what we currently have.

But the worry that I have is if the claim that I am finding likelihood of success on and issuing preliminary injunctive relief on is an arbitrary and capricious claim, it does seem to me that to the extent I'm issuing prospective injunctive relief, it needs to be tailored to the form in which the notice is provided.

So I'm curious, though, what plaintiffs' reaction is to that tentative view.

MS. CABRASER: Your Honor, other than our -- other than our position that it is not necessary because of the nature of our claim that, at least with respect to previously terminated grants, there is no possibility of papering over what happened.

But the point about prospective relief is an interesting one, and of course, that is what an injunction is for. It is also to protect the class against future violations.

And with that in mind, in terms of enforceability of the injunction and notice to the agencies and the defendants of what is enjoined, then I think that is a matter that is at the discretion of the Court. I don't think it would be erroneous, and I think, our skepticism aside about what agencies might do to try to get around it, that is a matter for another day with respect to enforceability of the injunction. And we have no

objection to that.

And I would say that as -- as -- as our briefing shows, we are not requesting grant termination immunity for anyone. We are simply requesting that the process that -- processes that were in place before the executive orders are restored, and that the agencies get back to what they were doing and how they were doing it, and the careful evaluations they were giving to both grant approvals and the rare, very rare grant terminations prior to these executive orders.

The concerns that we have, again, on the margins about a reason coming up, you know, funding, and that being a potentially valid reason, the EOs -- the executive orders listed, the class definition, aren't only the DOGE orders, the DEI, the DEI environmental justice, and gender ideology, they're also the EOs that say: We are going to cut the government.

So, in fact, there is a sword hanging over these agencies' heads if they don't continue to do what we are asking them to be enjoined to do because they could be eliminated.

It's an unprecedented situation, Your Honor, but it's one that is going to require, I think, vigilance in the enforcement of the injunction.

But as I say, that said, we don't have an objection to that class definition being tailored in that manner to the APA claim.

THE COURT: Let me give defendants an opportunity to comment on it as well.

MR. ALTABET: So just a couple of points, Your Honor.

First, my understanding is that for a (b)(2) class action, even if there are subclasses, that the broader class still needs to meet all of the 23(a) and the (b)(2) requirements. So we sort of think the same objections that we have to the broader class would apply even if there were additional subclasses.

Also, under Ninth Circuit precedent, subclasses need to meet the 23(a) and the (b)(2) requirements separately. And we think there are a couple of problems there, and the main one is just for the arbitrary and capricious claim.

Since we have raised a committed-to-agency-discretion-by-law basis, which would eliminate all APA review if correct, and that committed-to-agency-discretion-by-law analysis requires looking at, agency by agency, what does the statutory scheme permit in terms of discretion, we think there's still the kind of individualized inquiry for an arbitrary and capricious subclass that bars a (b)(2) class action or class subclass because the Court would have to find for each agency whether or not it's committed to agency discretion by law to determine funding priorities.

So, for example, plaintiffs note that in the EPA they would raise that the environmental justice funding from

Congress creates a mandatory directive that would forbid the committed-to-agency-discretion-by-law success for the Government.

But by contrast, the NEH statutory scheme gives full discretion to the NEH chairperson to decide what grants to fund, if to fund them, and how to fund them. So I think that there has to be an individualized inquiry would defeat the commonality and typicality for that subclass under arbitrary and capricious.

Lastly, for the First Amendment DEIA subclass, I still think there's differences across agencies that would defeat commonality and typicality, but it is certainly of a different kind than the arbitrary and capricious example, where I do think it's a real substantial individual inquiry for each agency. And --

THE COURT: When you say it's an individual inquiry, you're suggesting that the Court really needs to have a subclass for each -- on the arbitrary and capricious class. It would need to have a subclass for each individual agency; is that really what you're saying?

But you're not saying that within the EPA or within those grants that were terminated by NEH or NSF that each of those involve an individualized inquiry, are you?

MR. ALTABET: So I mean, we stand by our objection that -- in our briefing that arbitrary and capricious requires

that individual review generally. But putting that aside, assuming Your Honor does not agree, we think -- we just want to point out that the committed-to-agency-discretion-by-law portion certainly requires agency-by-agency individualized inquiry.

Not grant by grant, but agency by agency. And then there would be a real problem if there were agency-by-agency subclasses because they have to meet 23(a) numerosity and other requirements. And so for many of these grants -- for many of these agencies, as we've seen, there would not be enough terminations for there to be numerosity.

THE COURT: Let me give plaintiffs an opportunity to respond.

MS. CABRASER: Thank you, Your Honor.

None of those arguments prevent this Court from certifying either separate classes on 1A and the APA, that those are not subclasses. There are representatives for each of them that are currently named. There's numerosity -- which the Government did not contend -- and certainly, commonality.

If the Court determined it were appropriate to certify agency-specific subclasses, we also have named proposed class representatives that dealt with -- dealt directly with -- were the names that were searched out by those specific agencies, with the exception of NIH, and we have an additional plaintiff from UCSF who has confirmed she would be willing to serve as a

representative for an agency-specific subclass.

She had a \$5 million NIH grant that was terminated based on gender ideology. So with respect to gender ideology-specific EO plaintiff and an NIH-specific plaintiff, if the Court were inclined to parse the class that way with respect to separate classes and even subclasses, we can meet those requirements and we can do so expeditiously.

With respect to the numerosity issue for a subclass, that's a -- numerosity is a relaxed standard for subclasses because the Courts recognize that there are many, many reasons -- including Rule 42 reasons, you know, partial issue adjudications -- why the Court might want to focus on a smaller group. And I believe the case law in the Ninth Circuit has certified subclasses with as many as ten or a dozen class members in them.

So, again, we don't think it's necessary to subdivide the class in that way because the big questions are common questions, and all of the researchers, regardless of their agency, regardless of the EO, whose language was borrowed to terminate their grant, have claims against the directors from the top, against the Trump and the DOGE defendants.

So everyone has those claims. Any of the plaintiffs can represent all of the class with respect to those claims.

And it's simply a matter of how -- how granular the Court wants to get in terms of class structuring. And our complaint

recognizes that subclasses can be designated. It's something that we have had in mind from the beginning.

And as you see, researchers continue to come forward and contact us and offer to provide their information, as you saw the declarants did -- by the way, many of those declarants are also willing to serve as class representatives in the case. So that is not a situation where the case will fail or some portion of the class will go unrepresented, depending on how you structure the class order.

THE COURT: Let me move to Question 4, which is about the juridical link theory.

Plaintiffs challenge the termination of grants by NEH, NSF, and EPA. That's the named plaintiffs. But the lawsuit generally also sues other agency defendants on a juridical link theory on behalf of the proposed class.

The Ninth Circuit has confined that doctrine to situations where the defendants followed a mandatory rule requiring them to carry out the challenged conduct in the same common way, not just in encouragement for them all to do it from the same playbook. That's the Martinez case that I've cited in the notice of questions.

What mandatory rule required the grant terminations to be carried out in the same arbitrary and capricious way, allegedly, across the agencies or in the -- this way that violated the First Amendment without the required

considerations?

MS. CABRASER: Your Honor, those mandatory -- well, those rules are the executive orders: the DOGE creation order; the DOGE implementation order; and the DEI and environmental justice, gender ideology, and the antidiscrimination merit EO.

They all have mandatory language. They are not guidelines. They are not suggestions.

Unlike the Federal Rules, they use "must," "shall,"
"shall not." It's not "might." It's not "may." And they are
marching orders to the agencies, and they set deadlines.

I mean, there is nothing suggestive about them. There is nothing in the record that indicates any of the agencies felt that they didn't have to follow these EOs, that they could ignore them, or even that they could combine them with their own pre-existing processes.

Everything changed. In fact, the DOGE creation EO says: This order commences a transformation in the way the Federal Government spends money on contracts, grants, et cetera.

So it was a transformative, transformatory order, set of orders, from the top. That was completely absent from the Martinez case. Those were guidelines and suggestions for what to do for special needs children during COVID.

And, of course, the school districts did all sorts of

things. The school districts were able to do all sorts of things. That is not what happened here.

That said, the juridical link is not the sole basis for our contention that we have a classwide claim against all of the named defendants because, in fact, the relationship among these defendants -- which is unprecedented; it doesn't have a name -- it's much closer than a juridical link. We called it a convergent -- convergence in our briefing.

The closest thing that I could think of from existing law would be the association-in-fact enterprise that -- that is used in enterprise liability or civil RICO claims. But it's even closer than that. And we know it's closer than that because the President said so.

When Elon Musk left DOGE, the President said: All of my cabinet members are now in charge of DOGE, and they're all going to implement DOGE.

And the executive orders I just mentioned are all still in place. So now we have a situation where the President, all the agency heads that we name in our complaint, are running DOGE, and DOGE is running all of the agencies that we name as defendants in our complaint. There couldn't be a closer relationship. It is something that is far cozier, for lack of a better word, than the juridical link.

So that's something that does not depend on the application of the juridical link as the courts have utilized

it. It's not necessary here.

There's another basis on which courts rejecting juridical link have included defendants with whom plaintiffs had not -- had no direct dealings in a class and in a case, and that is Federal Rule of Civil Procedure 20(a).

The Eleventh Circuit in case called Moore v. Comfed surveyed all the juridical link cases, rejected them under the factual circumstances of the case but said because there is -- because plaintiffs' claims all arose out of a series of transactions or occurrences that have a question of law or fact common to all defendants -- that is the case here -- they could be joined under Rule 20(a) in the case.

And the named plaintiffs who had direct dealings with only a few of those defendants could represent the entire class. That's *Moore v. Comfed Savings Bank*, 908 F.2d 834, from 1990.

So that is a third basis upon which our currently named plaintiffs have standing to and can adequately represent the class against all of the defendants, even if the Court did not exercise its discretion to create separate classes or subclasses that are agency-specific or claim-specific or executive order-specific, for that matter.

THE COURT: Let me give defendants an opportunity to respond.

MR. ALTABET: Your Honor, I think that pointing out

the mandatory rule and juridical link doctrine here is, I think, well taken by the Government. We think there is no mandatory rule that's been identified in the way that matters for the legal claims.

So as Your Honor pointed out specifically, how grant terminations were carried out, including consideration of required factors or reasoned explanation, they have pointed to no mandatory rule requiring the way that it was carried out, which I think is ultimately what Your Honor is very focused on here.

And so given that, I think what they've described does not support named plaintiffs bringing suit for these other agencies.

THE COURT: Do you have a response to the Rule 20 point?

MR. ALTABET: Your Honor, I'm not familiar, particularly, with Rule 20(a), nor the case that plaintiffs have cited except to say we don't think that a transaction or occurrence or association-in-fact sort of analysis makes sense here. We're in a pretty standard discussion of administrative law and administrative law class actions.

And I think there's well-taken 23 law on this subject including, as Your Honor pointed out, this question of whether there's a mandatory rule and an understanding of whether other defendants can be brought into the case.

So I don't know that 20(a) is particularly relevant.

THE COURT: One question I have for plaintiffs about this Rule 20(a) analysis, which is new to me, is why do the courts even have this juridical link doctrine? If you could get around the juridical link requirements by joining parties through 20(a), it would seem to -- it would seem totally superfluous to have juridical link doctrine.

Help me just understand the interaction between these two.

MS. CABRASER: Sometimes the most obvious solutions are hiding in plain sight, Your Honor. There are many attorneys that have not read through the Federal Rules of Civil Procedure recently, or perhaps at all; and I often find something new, and I think that I'm fairly familiar with the rules.

And I think the answer to that question is a legal history question -- or a legal history answer, which is that the juridical link sprang out of a particular case in the Ninth Circuit. It looked like a good solution to a recurring problem in class actions, and so other courts adopted it; and all of a sudden you've got a juridical link doctrine.

And, frankly, I think that it had its first heyday when the courts were unclear about how standing in class actions worked. And we have more clarity on that here, so it may be a doctrine that, while it was -- it is a helpful analogy

to us because our relationship among the defendants as we allege it and as the publicly facing statements of the administration describe it is far closer, both among the defendants themselves and in their dealings with the plaintiffs.

Then the instances in which the juridical link was used to come up with something that didn't look like a conspiracy or a concert of action or an enterprise; right? So I -- it's not -- it's not a doctrine on which our -- the scope of our class stands or falls.

THE COURT: Let's move to Question 5 which is: Why are the named plaintiffs typical and adequate to represent class members whose grants were terminated under the gender -- quote/unquote, gender ideology executive order and the, quote/unquote, environmental justice executive order?

I didn't put that in the question, but I think it's a similar scenario.

MS. CABRASER: We do have environmental justice plaintiffs, the DEI/environmental justice.

There's two DEI executive orders, so it's a little confusing. There's one that is about restoring merits-based competition, and so you can't say anything about race or gender or groups.

And then the DEI/environmental justice calls out these two areas of now forbidden ideas or speech.

THE COURT: I really should have -- I said that wrong.

I didn't mean the environmental justice, but there's an

executive order that's about improving American energy --

MS. CABRASER: Yes.

THE COURT: -- that is in a related environmental area, but I didn't see clear indication of which plaintiff is associated.

MS. CABRASER: I don't think presently that we have a named plaintiff for that category. We could supply one, if necessary. We do have named plaintiffs for all of the other executive orders with respect to gender ideology. As I mentioned before, we have an additional class representative whose termination letter is a form letter which borrows from the gender ideology executive order to supply the reason for the grant termination.

Her grant is a five-year study, and it included -- but it wasn't -- the focus of the study was not transgender women, but it included transgender women in the participant group because the point of the study was to look at diseases across all groups.

So the problem there is both it included a group which now is now to be addressed or included, and it included in it language that was tagged and flagged and used to terminate the grant, although it's not the point of the study.

So if the Court decides to structure the class along

either agency-specific or executive order lines, gender ideology is covered.

That said, we believe that present class representatives are adequate to represent all of the class regardless of executive orders that were paraphrased or expressly referenced in a particular termination letter by any of the agencies, A, because of the close relationship -- now the merger -- of all the agencies and DOGE; and the administration completely bypassing Congress -- by the way, congress is the only one not included in that group.

But also because for many of these grants, they cross executive order lines; right? They involve both gender ideology and other DEI terms. They might include environmental justice, DEI, and gender ideology aspects. That's what science is and does, and that is why all of these terminations violate the APA.

But, again, it's a matter of the degree of specificity and granularity that the Court decides is appropriate here, and we can meet it.

THE COURT: Anything further from defendants on that topic?

MR. ALTABET: Yes, briefly.

I think that the last statement from plaintiffs helps to clarify why there's not adequacy and typicality, and more broadly, some of the problems with the class action structure

here, which is depending on a grant-by-grand review, you may find that one or more executive orders and the content of those executive orders are involved. But the fact that that requires such an individualized inquiry, is why adequacy, typicality, commonality are so problematic on that First Amendment claim.

THE COURT: You're saying because it's -- the issue is identifying which grants have been terminated because of the DEI orders?

It seemed to me from the materials that the parties submitted that it was quite clear the agencies went -- did rounds of grant termination that were driven by the DEI orders. So it doesn't seem like it would be hard to figure out who got their grant terminated for a DEI reason.

But let me know if there's something else in the record you think I should be looking at.

MR. ALTABET: I meant in terms of the legal analysis in determining whether there's a First Amendment violation from each executive order, I think, requires a separate analysis.

So is the gender identity EO something that is violative of the First Amendment in how it's implemented versus the DEIA?

And we agree with Your Honor that there is, for example, in one agency a spreadsheet where there's ways of identifying which executive order may be in play. And so we don't think it's from a sort of finding as sort of acquiring

which particular grant was terminated for reasons, but in terms 1 of how the analysis is done across executive orders. We think 2 this is demonstrative of the commonality and typicality 3 4 problems. 5 THE COURT: So you're saying that the analysis as to whether the DEI orders violate First Amendment by 6 discriminating on viewpoint would involve a separate analysis 7 than looking at whether the gender ideology or, for example --8 violated the First Amendment by discriminating on viewpoint? 9 10 MR. ALTABET: And the energy order and these other executive orders that have been cited, yes. 11 THE COURT: But so executive order by executive order 12 13 but not necessarily grant by grant? MR. ALTABET: That's right. But determining if, say, 14 a confluence, as plaintiffs just posited, for example, a grant 15 that includes multiple topics would require -- would require 16 determining the First Amendment analysis as to each executive 17 order, or that the confluence of executive orders causes a 18 First Amendment problem. 19 20 It partly depends on Your Honor's understanding and

analysis of what the First Amendment problem is.

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THE COURT: Let's move to Question 6, which is the final agency action question. This is really question for plaintiffs in the initial phase, and then I can hear from defendants. (as read):

"If the Court finds that the final agency action 1 here is the individual grant terminations and finds 2 the grant terminations to be arbitrary and 3 capricious, what prospective relief is appropriate 4 5 for individuals who have not yet had their grants Could the Court, for example, enjoin 6 terminated? defendants from giving effect to future form 7 termination notices that are issued to UC 8 researchers?" 9 10 The answer to your latter question, MR. CHEMERINSKY: 11 Your Honor, is yes. What we're asking is that the Government be required 12 to comply with the law with regard to grant terminations, in 13 essence, to go back to the procedures that were followed before 14 15 January 20th. We proposed language for this. You would find it in 16 the document titled "Temporary Restraining Order and Order to 17 Show Cause. " It was filed on June 5th. And I'm specifically 18 19 focusing on page 4, paragraph 3. 20 It's short so I can read it because I think it 21 directly answers Your Honor's question. 22 It says (as read): 23 "TRO defendants are further enjoined to return to 24 the lawful and orderly grant procedures they employed

prior to January 20th, 2025, including but not

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limited to, A, providing plaintiffs and proposed class members reasonable notice and opportunity to be heard prior to terminating already awarded grants; and B, providing plaintiffs and proposed class members a meaningful, individualized explanation of the reasons for any imposed grant termination rather than a barely customized form letter."

THE COURT: Let me give defendants an opportunity to respond.

MR. ALTABET: I think if Your Honor determines that the final agency action is the grant terminations itself, then there can be no prospective relief as to agency actions that are not -- that haven't occurred. There's no agency action, and they're not final for non-terminated grants.

So, I think, taking the premise of Your Honor's question, Your Honor has identified, I think, a serious issue with prospective relief, and plaintiffs cannot rely, for example, on just the executive order because under *Dalton* and *Franklin*, the APA doesn't apply to the President. It's only when it's reduced to final agency action at the agency level. And if Your Honor has determined it's the grant terminations, then there's no prospective relief.

THE COURT: Why couldn't the Court, for example, say that upon issuance of a purported grant termination that is enacted through a form letter that doesn't have any

explanation, that as soon as the agency issues that letter, there's now a final agency action and that letter is essentially dead on arrival; in other words, it's vacated upon its issuance because it lacks the required elements under the Administrative Procedure Act, and then the agency's enjoined from effectuating that termination letter?

Tell me what's wrong, in the Government's view, with an approach like that.

MR. ALTABET: So the APA's final agency action bar is institute inaction, and it's what gives this Court the ability to act on the administrative agencies. And I think what the Court has described is prospectively saying that future final agency actions not currently within the bounds of Section 702 will be set aside in the future.

And I just don't know of -- I don't think that's possible. I don't think that there's a legal basis for saying that actions that have not occurred are, as of here and now, forbidden under the APA. I don't think there's a set-aside or an injunctive order that can issue as to future expected final agency actions.

THE COURT: Why is that? Because it seems -- it seems like if the final agency action is exactly the same agency action that has already occurred, courts routinely enjoin, for example, agencies from taking an action, and then they say, "If you're going to reenact the same thing under a different name,

you can't do it. That's enjoined, too."

So why is this different from that scenario?

MR. ALTABET: So that's because it depends on -- I think it still depends on what the final agency action is. So if the final agency action is a policy, then the Court could say that actions flowing from that policy at the agency level are forbidden because I vacated or enjoined the policy you've described.

But if the Court determines it's the actual terminations itself, I think those -- it's just different cases. There are other cases where policies or rules are barred. But here we're discussing final agency actions being the terminations. And therefore, there's not the same sort of flow-down that we see in an APA case where it's a policy or a rule or a guidance document.

MR. CHEMERINSKY: Your Honor, that can't be right because, otherwise, what you could do is say, "All of the grants that have been cut off should be restored."

And then tomorrow the Government could do exactly the same thing and then the same thing again and then the same thing again.

I think the flaw in the Government's argument is it's drawing an arbitrary distinction between the Government's policy to cut off grants in this way and the actual termination of individual grants.

What you're saying is, from the policy perspective, the Government has to comply with the APA and that its actions have to be reasonable and reasonably explained. And all your order would be saying is to the Government, "You have to comply with the law in the future, and you can't continue to violate it."

THE COURT: Thank you.

I promised you all that you'd have an opportunity at the end to tell me anything else you wanted me to know. It's plaintiffs' motion, so it's your turn first. Then I can hear from defendants, and then plaintiff will have the last word.

MR. CHEMERINSKY: Thank you.

Your Honor, what I was going to address was how the requirements for preliminary injunction have been fulfilled. I will just be very brief as to those requirements and, of course, answer any questions that you have.

I would go in the order of there's irreparable injury; likelihood regarding the merits; and on balance, it would serve the public interest to have the injunction in terms of the equities.

In terms of irreparable injury, we've already addressed this. The reality is, these researchers have had their research stopped. If, someday in the future, a year or two from now, they're able to resume, they'll already have lost their graduate students. They'll have already lost their labs.

They'll have already lost their post-docs.

As I said to you earlier, with regard to the injury requirement, there's a financial loss. There's a loss with regard to the professional work. There's a loss with regard to the reputation.

With regard to likelihood of prevailing on the merits, I think, here, Section 706(2) of the Administrative Procedures Act very much outlines how this Court can go about it. And I think A, B, C, and D are all separately met, though, of course only one would need to be met for an injunction.

A, is that it's arbitrary, capricious, and abuse of discretion. We've already talked about that. So the only thing I want to say here is, the Government makes the argument that this doesn't apply because it's committed to agency discretion.

And here, I want to point this Court to what I think is controlling Ninth Circuit law. The Ninth Circuit case that I would point you to here is *Community Legal Services*v. Health & Human Services, specifically at 137 F.4th 939 to 940.

Speaking of this, this exception has been construed narrowly to apply only in those rare circumstances where the relevant statute is drawn so that the Court would have no meaningful standard against which to judge the agency's exercise of discretion.

That's not true here. The Supreme Court in $Ohio\ v.$ EPA said, as I mentioned, an agency action is to be reasonable and reasonably explained.

That's not true for these termination of grants.

With regard to 706(2)(B), you're allowed to grant an injunction if the agency action violates the Constitution. And we raise three constitutional arguments.

One is separation of powers. Congress has the spending power, not the President. If Congress passes a spending billing, the President can choose to veto it. But if it's adopted, including over the President's veto, the President doesn't get another veto by choosing to spend money and refusing to spend the money that's been appropriated by statute.

We, second, in terms of a constitutional claim, raise the First Amendment, which you've addressed and which have talked about as this being viewpoint discrimination.

And the third constitutional claim is due process. We believe that the researchers do have a reasonable expectation to continue to receive a benefit, and no procedural due process has been provided.

706(2)(C) allows you to set aside an agency action when it violates a statute. And the one thing we haven't mentioned this morning, here, is the Impoundment Control Act, which is very specific that says that when Congress has

appropriated money, the President has no authority to impound it. He can propose a recision to Congress and has 45 days to act.

But that hasn't occurred to any of these funds. And the Impoundment Control Act can be enforced, Your Honor, through the Administrative Procedures Act.

True, that only the comptroller general could bring an action under the Impoundment Control Act, but 706(2)(C) says you can enjoin it because of the violation of statute.

And finally, 706(2)(D) says that you can set aside an agency action for not following proper procedures. Proper procedures weren't followed here. Each agency has within its rules procedures for terminating grants. None of them have been followed here.

The final part, of course, for an injunction concerns the balance of the equities and the public interest. And we think here, when you look at the irreparable harm that's done to these researchers and their constitutional rights, it way outweighs what the Government's interests are.

And I'm glad to answer any questions, but I would simply conclude by saying that, Your Honor, this is a case of such profound importance -- because it really raises the issue:

Does the President have the power to refuse to spend money appropriated by Congress without any legal basis for doing so, not following any procedures specified in the Constitution or

statutes?

THE COURT: Let me give defendants an opportunity to respond.

MR. ALTABET: I'll just make a couple -- or few points, Your Honor, and I'll try to focus on what Your Honor has indicated you're interested in based on the questions. So I want to start with just a broad stepping-back for a moment.

Federal agencies receive tens of thousands of grant applications every year and can only fund a small fraction of them. That's in plaintiffs' complaint. That's in the record.

And so, when they decide what to fund, it's not just about whether a research topic is meritorious scientifically or artistically. But it also is about whether it's a topic the agency is interested in based on the agency's priorities.

And that, obviously, has to be true; Programmatic factors are required. And even looking that every research opportunity begins with a notice of funding opportunity, which is the agency saying what topics they're interested in.

And those necessarily include executive priorities.

For example, we cited that 2021 EPA research notice of funding opportunity, which focused on executive orders related to racial equity and environmental justice because at the time those were administration priorities; and, obviously, those priorities by executive order have shifted.

So I think that's an important framing for thinking

about this case more broadly.

This isn't about that, by statute, agencies are required to fund certain topics, but that they are required within a certain bound to be thinking about and filing notice of funding opportunities and to fund research that includes topical choices within a larger subject matter, for example, at EPA.

So briefly, just walking through a couple of other points.

On the First Amendment inquiry, I think we all agree that it's the subject matter of the grant that's at issue here. That's, for example, in plaintiffs' own proposed order. They asked this Court to conclude that based on the subject matter of the grant, there has been a violation of the First Amendment.

So the question we're asking is how the executive branch can choose its funding priorities within a program in compliance with the First Amendment or not in compliance with the First Amendment.

And to the extent there's any question whether the executive branch is setting the priorities, not the legislative branch, that has been addressed by the case law. For example, we cited *Rust*. That was a situation where the executive branch, by regulation, was setting out priorities.

So it doesn't matter, necessarily, that Congress is

not setting the priorities. *Finley* also stands for that because *Finley*, using terms like "decency" and "respect," gave the executive branch discretion to determine which types of research or what types of projects to fund.

And that brings me to committed-to-agency-discretion by-law. And just to be clear, that -- the APA includes, say, a reasonable explanation requirement, doesn't give law to apply for committed-to-agency-discretion-by-law, because that's a bar in 702 that, if something is committed to agency discretion by law, arbitrary and capricious does not apply.

And here we just would turn the Court to the *Milk*Train case in the DC Circuit because we think that's a helpful framing device for thinking of which statutes are committed to agency discretion by law, or which topics are and which aren't because there the statute said to provide assistance directly to dairy producers in a manner determined appropriate by the secretary, and stated that it was for economic losses incurred during 1999. So there's sort of two statutory hooks there at the discretion of the secretary and for certain types of losses.

The DC Circuit surveying the law explained: Well, that first part, the providing assistance in an appropriate manner determined by the secretary, that's committed to agency discretion by law because courts can't determine how, within a broad mandate, funding decisions should be made.

But whether the economic losses incurred during 1999 or what the secretary looked at could be reviewed, because that's a direct statement, and there the secretary was looking at losses from other years, and that was illegitimate.

But the funding decisions themselves were within the bounds of committed to agency discretion by law, and I think when the Court looks at the statutory schemes here, the Court will see that several of the statutory schemes are of such a discretionary basis, like the NEH statute, that it is committed to agency discretion by law to determine what to fund and how to fund it.

Just -- I'm going to skip due process, Your Honor, because I don't think Your Honor is particularly interested in the procedural due process point.

On MegaPulse and Tucson Airport Authority, I would just urge Your Honor to think claim by claim about whether plaintiffs, in their constitutional and statutory claims, are relying on the contracts.

And here, I think that they are because, for example, for the First Amendment claim, plaintiffs are saying the contracts were terminated on an illegitimate basis. There is money owed to the University of California. But the fact of the money being owed to University of California is based on a contract, and the reason that the money should continue to flow into the University of California is from the First Amendment.

And so *Tucson Airport Authority* addresses that kind of case and says in that instance, even though the right is constitutional, it's the contract that forms the basis for the relief and forms the basis within the claim as to why there's a problem, and therefore, it is within the Tucker Act jurisdiction.

And I think California and Sustainability Institute go to that. And in fact, paragraph 3 of plaintiffs' complaint is clear that they're seeking to have the lost funding restored, in their language; and I think that is clearly within the bounds of the MegaPulse and Tucson Airport Authority test.

And finally, on irreparable injury, I would just point Your Honor to the SDNY case that we cited. We think it's helpful for standing. We think it's helpful on a few bases.

But one thing the Court noted was, there, Columbia
University chose to continue funding projects where the Federal
Government had chose to no longer fund them.

So we think, on that basis, that there is, in fact, a choice at the University of California of -- and Iowa State and the other educational institutions, of whether to continue funding the projects that makes this far more attenuated monetary harm of the type that is not amenable to irreparable harm -- that's also part of our causation and redressability -- rather than the sort of irreparable harm that plaintiffs cite, like a bankruptcy, that's direct coming from their claims.

Last word for the plaintiff. 1 THE COURT: Thank you. Just a few quick points. 2 MR. CHEMERINSKY: First, with regard to the initial point that the 3 Government makes, that the Court gets -- the Government gets to 4 decide what it wants to fund. Of course, it's the power of 5 Congress to decide, and an agency can change its priorities, 6 but it has to do so in a manner that it explains. It has to be 7 reasonable and reasonably explained. 8 9 And here I'd refer you to a case that we filed 10 yesterday that came down the day before yesterday. And this is the Green & Healthy Homes v. EPA case from the District of 11 Maryland. And it makes exactly the point that we're advancing 12 to this Court now as to why the agency can't say: Well, we've 13 just changed our mind. 14 15 That is inconsistent with the requirements of the Administrative Procedures Act. 16 Second, as to the First Amendment, the Government just 17 pointed you to two cases, Rust v. Sullivan and Finley v. NEA. 18 19 What's so striking about those -- and in both instances 20

Congress passed a statute that said that: We want money to be used in a particular way.

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That's not what this has involved at all. And in both those cases, the Supreme Court made clear it wasn't viewpoint discrimination.

In NEA v. Finley, the Court went out of its way to

say: There wasn't viewpoint discrimination going on here.

This is all about viewpoint discrimination saying that the Government didn't want to fund certain views.

Third, with regard to committed to agency discretion, the Ninth Circuit has made clear that this is limited to a situation where there aren't legal standards for the Court to apply. Here, there clearly are legal standards in each of the four areas that I talked about under 706(2).

Fourth, with regard to going back to the Tucker Act, again, I believe that this is resolved for this Court by the decision that I cited in the *United States Aeronautics*Corporation v. United States Air Force. And it's interesting, never does the Government talk about that.

Your Honor, there, the Ninth Circuit -- and I think it's 80 F.4th 1026 -- specifically says that when a cause of action arises under the Constitution or under a statute, the Tucker Act doesn't apply.

Every cause of action that is presented by plaintiffs is under the Constitution and with regard to a statute.

I would simply conclude, Your Honor, by saying that what the Government is trying to say to this Court is that the President and the executive agencies have unlimited authority to refuse to spend money appropriated by Congress, and that no court can grant injunctive relief.

No court in the country has ever taken that position,

and many courts, in just the last few weeks, have come to the 1 opposite conclusion. 2 3 Thank you. Thank you all for the argument. I'll take 4 THE COURT: 5 the matter under submission and issue a written order. I am conscious, obviously, that this is a preliminary 6 injunction matter, and so I will endeavor to get the opinion 7 out shortly. I do think that it will probably be early next 8 week at the earliest. 9 10 Thank you all. 11 MR. CHEMERINSKY: Thank you so much. THE CLERK: Court is in recess. 12 (Proceedings adjourned at 11:35 a.m.) 13 ---000---14 15 CERTIFICATE OF REPORTER I certify that the foregoing is a correct transcript 16 from the record of proceedings in the above-entitled matter. 17 18 Saturday, June 21, 2025 19 DATE: 20 Tuth home to 21 22 23 Ruth Levine Ekhaus, RMR, RDR, FCRR, CCG, CSR No. 12219 Official Reporter, U.S. District Court 24 25

Case: 25-4249, 07/22/2025, DktEntry: 11.1, Page 112 of 475

EXHIBIT - 3

Case: 25-4249, 07/22/2025, DktEntry: 11.1, Page 113 of 475 Case 3:25-cv-04737-RFL Document 48 Filed 06/19/25 Page 1 of 5

1	Erwin Chemerinsky (pro hac vice) echemerinsky@law.berkeley.edu	
2 3	Claudia Polsky (CA Bar No. 185505) cpolsky@law.berkeley.edu U.C. BERKELEY SCHOOL OF LAW	
4	Law Building Berkeley, CA 94720-7200	
5	Telephone: 510.642.6483	
6	Elizabeth J. Cabraser (CA Bar No. 83151) ecabraser@lchb.com	
7	Richard M. Heimann (CA Bar No. 63607) rheimann@lchb.com	
8	LIEFF CABRASER HEIMANN & BERNSTEIN, LLP	
9	275 Battery Street, 29th Floor San Francisco, CA 94111	
10	Telephone: 415.956.1000	
11	Anthony P. Schoenberg (CA Bar No. 203714) tschoenberg@fbm.com	
12	Linda S. Gilleran (CA Bar No. 307107) lgilleran@fbm.com FARELLA BRAUN + MARTEL LLP	
13	One Bush Street, Suite 900 San Francisco, CA 94104	
14	Telephone: 415. 954.4400	
15	Attorneys for Plaintijfs and the Proposed Class	
16	INITED STATES DI	STRICT COURT
17	UNITED STATES DISTRICT COURT	
18	NORTHERN DISTRICT	
19	NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST,	Case No. 3:25-cv-4737
20	CHRISTINE PHILLIOU, and JEDDA FOREMAN, on behalf of themselves and all	DECLADATION OF ELIZADETH L
21	others similarly situated,	DECLARATION OF ELIZABETH J. CABRASER IN SUPPORT OF
22	Plaintiffs,	SUPPLEMENTAL BRIEF
23	V.	
24	DONALD J. TRUMP, in his official capacity as President of the United States;	
25	DEPARTMENT OF GOVERNMENT EFFICIENCY ("DOGE"); AMY CLEASON in hor official consists of	
26	AMY GLEASON, in her official capacity as Acting Administrator of the Department of	
27	Government Efficiency; NATIONAL SCIENCE FOUNDATION; PRIAN STONE in his official consoity as	
28	BRIAN STONE, in his official capacity as Acting Director of the National Science	

1	Foundation; NATIONAL ENDOWMENT FOR THE
2	HUMANITIES; MICHAEL MCDONALD, in his official
3	capacity as Acting Chairman of the National
4	Endowment for the Humanities; UNITED STATES ENVIRONMENTAL PROTECTION AGENCY;
5	LEE ZELDIN, in his official capacity as Administrator of the U.S. Environmental
6	Protection Agency; UNITED STATES DEPARTMENT OF
7	AGRICULTURE; BROOKE ROLLINS, in her official capacity as
8	Secretary of the U.S. Department of Agriculture; AMERICORPS (a.k.a. the CORPORATION
9	FOR NATIONAL AND COMMUNITY SERVICE);
10	JENNIFER BASTRESS TAHMASEBI, in her official capacity as Interim Agency Head of
11	AmeriCorps; UNITED STATES DEPARTMENT OF
12	DEFENSE; PETE HEGSETH, in his official capacity as
13	Secretary of the U.S. Department of Defense; UNITED STATES DEPARTMENT OF
14	EDUCATION; LINDA MCMAHON, in her official capacity as
15	Secretary of the U.S. Department of Education; UNITED STATES DEPARTMENT OF
16	ENERGY; CHRIS WRIGHT, in his official capacity as
17	Secretary of Energy; UNITED STATES DEPARTMENT OF
18	HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official
19	capacity as Secretary of the U.S. Department of Health and Human Services;
20	UNITED STATES CENTERS FOR DISEASE CONTROL;
21	MATTHEW BUZZELLI, in his official capacity as Acting Director of the Centers for Disease
22	Control; UNITED STATES FOOD AND DRUG
23	ADMINISTRATION; MARTIN A. MAKARY, in his official capacity
24	as Commissioner of the Food and Drug Administration;
25	UNITED STATES NATIONAL INSTITUTES OF HEALTH;
26	JAYANTA BHATTACHARYA, in his official capacity as Director of the National Institutes of
27	Health; INSTITUTE OF MUSEUM AND LIBRARY
28	SERVICES;

1 2 3 4 5 6 7 8 9	KEITH SONDERLING, in his official capacity as Acting Director of the Institute of Museum and Library Services; UNITED STATES DEPARTMENT OF THE INTERIOR; DOUG BURGUM, in his official capacity as Secretary of the Interior; UNITED STATES DEPARTMENT OF STATE; MARCO RUBIO, in his official capacity as Secretary of the U.S. Department of State; DEPARTMENT OF TRANSPORTATION; SEAN DUFFY, in his official capacity as Secretary for the U.S. Department of Transportation, Defendants.		
10			
11	I, Elizabeth J. Cabraser, declare as follows:		
12	1. I am an attorney admitted to practice in the state of California. I am a partner of		
13	Lieff Cabraser Heimann & Bernstein LLP ("LCHB"). I respectfully submit this declaration in		
14	support of Plaintiffs' Supplemental Motion. I have personal knowledge of the facts set forth in		
15	this declaration, and could testify competently to them if called upon to do so.		
16	2. On June 17, 2025, Defendants produced information to Plaintiffs in response to the		
17	Court's Discovery Order, ECF 32.		
18	3. In response to Category 1 of the Court's order (the "Agency Process" category),		
19	Defendants produced:		
20	a. For the Environmental Protection Agency, a two-page declaration.		
21	b. For the National Science Foundation, a two-page declaration, two emails,		
22	and three documents with information publicly available on NSF's website.		
23	c. For the National Endowment for the Humanities, a four-page declaration		
24	and three emails.		
25	d. For the Food and Drug Administration, a two-page declaration, which		
26	attached the "HHS Grants Policy Statement," a 105-page document.		
27	4. In response to Category 3 of the Court's order (the "Exemplar Termination		
28	Letters" category), Defendants produced exemplar termination letters for AmeriCorps,		

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a number of Attorneys General in Commonwealth of Massachusetts, et al. v. Robert F. Kennedy, Jr. et al., No: 1:25-cv-10814, Dkt. 127 (June 9, 2025) (proposed order attaching the certified administrative record in that case). That evidence confirms that NIH terminated grants using the same general procedures as the other Federal Agency Defendants and in violation of the Constitution and Administrative Procedure Act. I declare under penalty of perjury under the laws of the State of California and the United States that the foregoing is true and correct. Executed this 19th day of June, 2025, in San Francisco. /s/Elizabeth Cabraser Elizabeth Cabraser

EXHIBIT A

DECLARATION OF DANIEL COOGAN

I, Daniel Coogan, declare and state as follows:

- 1. I am the Deputy Assistant Administrator for Infrastructure and Extramural Resources in the Office of Mission Support, for the United States Environmental Protection Agency ("EPA") located at 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460. I have been in my current position since December 2023, and I have been at the agency since November 2004. I make the following factual statements based on my personal knowledge and belief. If called as a witness, I could and would competently testify thereto.
- 2. The use of the term "grant" in context of the terminations includes both grant awards and cooperative agreements.
- 3. I was unable to identify readily available non-privileged documents so I submit this declaration to answer the Court's order.
- 4. This is response to the Court's order requesting readily available, non-privileged documents or declarations to show:
 - a. The policy for selecting grants for termination;
 - b. The overarching Executive Order(s) or directive(s) animating the termination policy;
 - c. The way in which the policy or overarching priority was communicated to each agency and by whom; and
 - d. The way in which the termination policy was implemented at each agency (e.g., keyword searches, AI tools, etc.).
- 5. In response to the Court's request for the policy selecting grants for termination, distinct from any Executive Order or OMB memorandum, EPA leadership conducted an individualized, grant-by-grant review to determine which grants should continue, which should be modified, and which should be terminated

1 based on Administration prioritizing merit, fairness, and excellence, or the purposes 2 for which the Federal award was made. 3 6. In response to the Court's request for overarching Executive Order(s) or directive(s) animating the termination policy, EPA's grant review process 4 5 occurred independent from any Executive Order or OMB memorandum. 7. In response to the Court's request for the way in which the policy or 6 7 overarching priority was communicated to EPA and by whom, Travis Voyles, 8 Assistant Deputy Administrator, orally communicated decisions to me and I sent an 9 email back to Travis and others documenting the decisions. I then communicated the 10 decision to career leadership in EPA's Office of Grants and Debarment to initiate 11 the terminations. I did not receive communications from outside the Agency. 12 8. In response to the Court's request for the way in which the termination policy was implemented at each agency, terminations were made on an 13 individualized, grant-by-grant basis, which began by looking at grant titles and 14 project descriptions, including reviews of grant workplans. 15 16 17 18 I declare under penalty of perjury that the foregoing is true and correct. 19 20 DANIEL 21 COOGAN Date: 2025.06.16 17:34:01 -04'00' 22 Daniel Coogan 23 Deputy Assistant Administrator for Infrastructure and Extramural 24 Resources Office of Mission Support 25 U.S. Environmental Protection 26 Agency 27 28

Digitally signed by

DANIEL COOGAN

EXHIBIT B

CUI

FAQs

- 1. Why is NSF terminating awards? All Federal agencies that support research and development (R&D), including NSF, must ensure that taxpayer dollars are spent in the most efficient way possible consistent with each Agency's mission. This requires that NSF regularly evaluate its research priorities within the policy framework established by Congress, the Administration and the Director of NSF. Awards and funding opportunities that do not align with these priorities cannot be funded.
- 2. Why is NSF changing its priorities? NSF is continuing to prioritize cutting-edge discovery science and engineering (S&E) research, advancing technology and innovation, and creating opportunities for all Americans in every region of the Nation. NSF has always established priorities within the policy context set forth by Congress, the Administration and the Director of NSF, and it continues to do so.
- 3. What types of awards are being terminated? Awards that are not aligned with NSF's priorities have been terminated, including but not limited to those on diversity, equity, and inclusion (DEI) and misinformation/disinformation.
- 4. Can I still propose broadening participation activities (e.g., outreach) in fulfillment of the Broader Impacts criterion? Investigators should prioritize the first six broader impacts goals as defined by the America COMPETES Reauthorization Act of 2010. Investigators wishing to address goal seven—expanding participation in STEM for women and underrepresented groups—must ensure that all outreach, recruitment, or participatory activities in NSF projects are open and available to all Americans. Investigators may conduct these types of engagement activities to individuals, institutions, groups, or communities based on protected characteristics only as part of broad engagement activities. Investigators may also expand participation in STEM based on non-protected characteristics, including but not limited to institutional type, geography, socioeconomic status, and career stage. However, engagement activities aimed at these characteristics cannot indirectly preference or exclude individuals or groups based on protected characteristics.

CUI

5. Will NSF consider proposals directed to a legally mandated NSF program/funding opportunity? NSF will continue to operate programs that contain elements of broadening participation for individuals based on protected characteristics that are explicitly established in law and prioritized in NSF appropriations language. The research and broader impacts activities proposed in response to these programs should align with the relevant statutory language and aim to generate knowledge broadly impactful to Americans from all backgrounds and regions in the country.

Projects submitted to legally mandated broadening participation programs must not directly or indirectly preference or exclude any Americans on the basis of protected characteristics. Projects that have limited impact or rely on DEI frameworks or advocacy do not effectuate NSF priorities.

- 6. What about the court order that says you cannot withhold funding due to the EOs? Isn't NSF in violation of that? No. NSF has continued to fund new awards and support existing awards that are in alignment with NSF priorities.
- 7. What are the protected and non-protected characteristics? Protected characteristics are those contained in relevant laws, such as but not limited to, the Equal Protection Clause of the Constitution and Title VII of the Civil Rights Act of 1964.
- 8. There are still gaps in the achievements of certain groups of people. Can we still research those? NSF will continue to fund projects that rate highly using our Intellectual Merit and Broader Impacts review criteria in high priority S&E areas. Projects that aim to create more opportunities for more people in every region of the country to participate in science and technology remain an important part of NSF's mission.

NSF will continue to operate legally mandated programs that aim to expand participation in STEM for individuals of protected characteristics so long as the projects submitted to these programs do not preference or limit participation based on these protected characteristics.

CUI

- 9. Can I research individuals or groups based on protected characteristics in other areas of S&E? Yes. Researchers may recruit or study individuals based on protected characteristics when doing so is (1) intrinsic to the research question (e.g., research on human physiology), (2) not focused on broadening participation in STEM on the basis of protected characteristics, and (3) aimed to fill an important gap in S&E knowledge. For example, research on technology to assist individuals with disabilities may be supported even when the research subject recruitment is limited to those with disabilities.
- 10. **Is there a list of words I should be avoiding?** There is not a list of words. Investigators should focus on Intellectual Merit and Broader Impacts for proposals in a way that is consistent with NSF priorities.
- 11. Can I still work with Minority Serving Institutions (MSIs)? Yes. Collaboration and partnerships between and among various types of institutions of higher education (IHEs) as well as cross-sector partnerships involving government, academia, and the private sector remain a top priority.
- 12. Are centers impacted? What about facilities that have DEI plans, will those be impacted? The NSF guidance on broadening participation applies to all current and future NSF awards.
- 13. Are you still funding research on misinformation/disinformation? Per the Presidential Action announced January 20, 2025, NSF will not prioritize research proposals that engage in or facilitate any conduct that would unconstitutionally abridge the free speech of any American citizen. NSF will not support research with the goal of combating "misinformation," "disinformation," and "malinformation" that could be used to infringe on the constitutionally protected speech rights of American citizens across the United States in a manner that advances a preferred narrative about significant matters of public debate.



MEMORANDUM

April 18, 2025

SUBJECT: Statement of U.S. National Science Foundation Priorities

The U.S. National Science Foundation (NSF) was established in 1950 to promote the progress of science, advance the national health, prosperity and welfare, and secure the national defense. It does this by investing in the most promising ideas and people across all fields of science and engineering (S&E). NSF priorities are grounded in the mission of the agency and modulated by statutory directives and administration priorities.

NSF uses two statutory criteria to ensure that every award has the potential to advance new knowledge (Intellectual Merit) with maximum impact on the Nation and its people (Broader Impacts). NSF investments unleash groundbreaking discoveries, translational solutions and expand participation in STEM. These efforts strengthen our domestic workforce to fuel economic prosperity, national security, and global S&E competitiveness.

The principles of merit, competition, equal opportunity, and excellence are the bedrock of the NSF mission. NSF continues to review all projects using Intellectual Merit and Broader Impacts criteria.

NSF's broadening participation activities, including activities undertaken in fulfillment of the Broader Impacts criterion, and research on broadening participation, must aim to create opportunities for all Americans everywhere.

These efforts should not preference some groups at the expense of others, or directly/indirectly exclude individuals or groups. Research projects with more narrow impact limited to subgroups of people based on protected class or characteristics do not effectuate NSF priorities.

NSF will continue to support research with the goal of understanding or addressing participation in STEM, in accordance with all applicable statutes and mandates, with the core goal of creating opportunities for all Americans.

NSF will continue to support basic and use-inspired research in S&E fields that focus on protected characteristics when doing so is intrinsic to the research question and is aligned with Agency priorities.

Sethuraman Panchanathan Director

U.S. NATIONAL SCIENCE FOUNDATION OFFICE OF THE DIRECTOR ALEXANDRIA, VA 22314 STAFF MEMORANDUM

OD 25-27 April 18, 2025

COMMUNICATION

SUBJECT: U.S. National Science Foundation Priorities

I want to share an update with you on the agency's priorities. As you know, the U.S. National Science Foundation (NSF) was established in 1950 to promote the progress of science, advance the national health, prosperity and welfare, and secure the national defense. We do this by investing in the most promising ideas and people across all fields of science and engineering (S&E). NSF uses two statutory criteria to ensure that every award has the potential to advance new knowledge (Intellectual Merit) with maximum impact on the Nation and its people (Broader Impacts). NSF priorities are grounded in the mission of the agency and modulated by statutory directives and administration priorities.

Let me be clear, NSF will continue to use the gold standard merit review criteria and consider all projects using Intellectual Merit and Broader Impacts criteria. NSF's efforts to expand participation in science, technology, engineering, and mathematics (STEM) must strengthen our domestic workforce to fuel economic prosperity, national security, and global S&E competitiveness. To do this, all of NSF's broadening participation activities, including research on broadening participation, must aim to create opportunities for all Americans everywhere. These efforts should not preference some groups at the expense of others, or directly/indirectly exclude individuals or groups.

I know many of you were involved in the review of our current awards and I know that was not an easy task. I want to express my sincerest gratitude to all of you for the time and care you have taken to go through the numerous reviews. Using this new guidance, a number of current awards have been identified that are not aligned with NSF priorities. Terminations of those awards will begin today. These reviews will continue, including for new proposals that are submitted and pending proposals that are still in the review process.

We have developed a list of <u>FAQs</u> reflecting NSF priorities that will be made public on our website this afternoon. They are attached for your reference. We will continue to add to this list as questions come in, so please submit those <u>here</u>. We know there will be a lot of questions from our community and various stakeholders. Please point them to the <u>website</u> with the attached memo and FAQs.

Sethuraman Panchanathan Director

Distribution: All Staff

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA

NEETA THAKUR, et al.,	Case No. 25-cv-04737-RFL
Plaintiffs,	
v.	
DONALD J. TRUMP, et al.,	
Defendants.	

DECLARATION OF BRIAN STONE

Pursuant to 28 U.S.C. § 1746, I, Brian Stone, declare as follows:

- 1. I am employed as the Chief of Staff, Office of the Director (OD), National Science Foundation (NSF). I am currently the Senior Official Performing the Duties of the NSF Director.
- 2. I have held the Chief of Staff position since April 2016, and I have been performing the Duties of the NSF Director since April 25, 2025, when Dr. Sethuraman Panchanathan resigned his position as NSF Director.
- 3. In my current position, I am responsible for performing the Duties of the NSF Director, which includes serving as the head of NSF, coordinating with the Executive Office of the President as well as other federal agencies, and overseeing operations of the agency. My function as Chief of Staff is to serve as the primary advisor and confidente to the NSF Director and to provide policy and strategic advice as needed.

- 4. On April 18, 2025, NSF issued a "Statement of U.S. National Science Foundation Priorities" (hereinafter "Statement"). The Statement elucidated that "NSF priorities are grounded in the mission of the agency and modulated by statutory directives and administration priorities."
- 5. The Statement, along with Frequently Asked Questions (FAQs), was published on NSF's public-facing website (NSF.gov). NSF also issued a Foundation-wide Staff Memorandum (OD 25-17) to communicate the Statement to the entire workforce.
- 6. NSF formed an internal panel to review grant awards and determine if they aligned with NSF priorities. Based on the review, NSF began terminating awards beginning April 18th and conducted several rounds of terminations on a rolling basis. Awards were identified through keyword searches and analytics and were terminated, generally on Fridays for approximately four weeks. Some awards were identified by NSF employees; some awards were identified by employees of the United States DOGE Service ("USDS") who were detailed to NSF; and some awards were identified by USDS employees who were not detailed to NSF.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this $\underline{17}^{th}$ day of June, 2025.

Brian Stone

Senior Official Performing the Duties of the

NSF Director

National Science Foundation

Case: 25-4249 07/22/2025, DktEntry: 11.1, Page 130 of 475 Document 48-2 Filed 06/19/25 Page 10 of 11

From: Greenwell, Amanda H
To: Williams, Angel R.

Subject: FW: Documents- EMBARGOED until 3:05pm or when it goes live [Contains CUI]

Date: Thursday, June 5, 2025 11:56:15 AM

Attachments: <u>image001.png</u>

Memo Statement of US National Science Foundation Priorities.pdf

OD Memo NSF Priorities FINAL doc.docx

FAQs FINAL.pdf

From: Greenwell, Amanda H

Sent: Friday, April 18, 2025 2:01 PM

To: NSF Executive Leadership Team <nsf-exec-leadership-team@nsf.gov>; Heit, Evan K.

<EKHEIT@nsf.gov>

Subject: Documents- EMBARGOED until 3:05pm or when it goes live [Contains CUI]

CUI

I'm attaching three things:

- 1. The note to staff that will go at 3pm
- 2. The Director's memo on priorities
- 3. FAQs on the priorities and terminations

Things to note- the Director's note will contain the Directors memo and FAQs. As soon as the note is sent both the memo and the FAQs will go live on a new website that you can access from any NSF page.

Social posts on X and LinkedIn will go as soon as the website is live along with a proactive media statement and will point back to the website.

-Amanda

Amanda Hallberg Greenwell

Head, Office of Legislative and Public Affairs

Office of the Director

Office: 703-292-8070

Email: agreenwe@nsf.gov

U.S. NATIONAL SCIENCE FOUNDATION

2415 Eisenhower Ave, Alexandria, VA 22314, USA



Case: 25-4249 07/22/2025, DktEntry: 11.1, Page 131 of 475 Document 48-2 Filed 06/19/25 Page 11 of 11

From: Williams, Angel R.

To: Panchanathan, Sethuraman; Stone, Brian; Marrongelle, Karen A.; Cheatham, Micah; Greenwell, Amanda H

Subject: RE: Statement of NSF Priorities [Contains CUI]

Date: Friday, April 18, 2025 11:57:01 AM

CUI

Received.

Thank you.

From: Panchanathan, Sethuraman <spanchan@nsf.gov>

Sent: Friday, April 18, 2025 11:17 AM

To: Stone, Brian <bstone@nsf.gov>; Marrongelle, Karen A. <kmarrong@nsf.gov>; Cheatham, Micah

<miccheat@nsf.gov>; Williams, Angel R. <angwilli@nsf.gov>; Greenwell, Amanda H

<AGREENWE@nsf.gov>

Subject: Statement of NSF Priorities [Contains CUI]

CUI

CUI/PRIVILEGED

This email is to inform you that I am operating within my authority as Director of the U.S. National Science Foundation (NSF) and the attached memo memorializes a shift in NSF priorities.

Furthermore, the President has directed agencies to ensure that no Federal Government officer, employee, or agent engages in or facilitates any conduct that would unconstitutionally abridge the free speech of any American citizen and that no taxpayer resources are used to engage in or facilitate any conduct that would unconstitutionally abridge the free speech of any American citizen. Therefore, NSF will not support research with the goal of combating "misinformation," "disinformation," and "malinformation" that could be used to infringe on the constitutionally protected speech rights of American citizens across the United States in a manner that advances a preferred narrative about significant matters of public debate.

Sethuraman Panchanathan Director

EXHIBIT C

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

NEETA THAKUR, et al.,

Plaintiffs,

v.

No. 3:25-cv-4737

DONALD J. TRUMP, et al.,

Defendants.

DECLARATION OF MICHAEL MCDONALD

- I, Michael McDonald, hereby declare under penalty of perjury:
 - 1. I am the Acting Chairman of the National Endowment for the Humanities ("NEH").
 - 2. President Trump appointed me to the Acting Chairman position on March 10, 2025.
- 3. I have worked at NEH since May 2003 in a variety of positions including Deputy General Counsel, General Counsel, Assistant Chairman for Programs, and Acting Deputy Chairman.
- 4. Congress created NEH in 1965 within the executive branch of the federal government to support research, education, preservation, and public programs in the humanities.
- 5. In the statute creating NEH, Congress authorized the NEH Chairperson and only the NEH Chairperson to enter contracts, grants, loans and other forms of assistance to carry out the agency's humanities functions.
- 6. President Trump issued Executive Order 14151, Ending Radical And Wasteful Government DEI Programs and Preferencing on January 20, 2025; Executive Order 14173,

Ending Illegal Discrimination and Restoring Merit-Based Cpportunity issued on January 21, 2025; and Executive Order 14168, Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government on January 20, 2025, when Shelly C. Lowe was still Chair of NEH.

- 7. Between January 20 and February 7, 2025, Chair Lowe directed NEH program staff to review open grants in light of the new Executive Orders.
- 8. At the direction of then-Chair Lowe, on February 7, 2025, NEH's Chief Information Officer ("CIO") Brett Bobley emailed NEH program directors asking them to identify projects funded under the Biden Administration that might be implicated by President Trump's Executive Orders.
- 9. Between February 7 and March 16, 2025, CIO Bobley created a system for staff to mark Biden-era projects on spreadsheets as either "High, Medium, Low, or No Connection" in terms of the Executive Orders and communicated this to NEH program directors.
- 10. During this same time frame, NEH program directors worked on filling in the spreadsheets with their individualized assessment of each grant's connection to the President's Executive Orders.
- 11. On March 10, 2025, President Trump terminated NEH Chair Lowe and appointed me to be Acting Chairman of NEH.
- 12. On or about March 12, 2025, representatives from the Department of Government Efficiency ("DOGE"), Justin Fox and Nate Cavanaugh, contacted NEH to discuss and advise me on implementing the President's priorities as stated in the Executive Orders, including terminating grants that a reasonable person could deem to violate the Executive Orders.

- 13. On March 17 18, 2025, I worked with NEH Assistant Chairman for Programs Adam Wolfson to conduct a further individualized review of the spreadsheets of open grants created by program staff.
- 14. On March 19, 2025, NEH CIO Bobley sent NEH Assistant Chair for Planning and Operations Pranita Raghavan a final spreadsheet containing only those projects that I and Mr. Wolfson deemed to conflict with President Trump's Executive Orders.
- 15. On March 20, 2025, Ms. Raghavan transmitted this list to the Office of Management and Budget ("OMB") as directed by the Presidential Executive Orders.
- 16. On March 26, 2025, Mr. Wolfson and I reviewed additional spreadsheets of grants that included those the program directors had initially listed as having no connection to the President's Executive Orders.
- 17. On March 31, 2025, I sent NEH's DOGE contacts, Mr. Fox and Mr. Cavanaugh, the final results of NEH's review in which we identified grants that did not appear to us to be in conflict with the Trump Administration's priorities.
- 18. On or about April 1 2, 2025, I terminated a number of, but not all, open NEH grants in compliance with Presidential Executive Order 14222 and in consultation with DOGE.
- 19. The April termination emails were carried out pursuant to Executive Order 14222, Implementing the President's "Department of Government Ejficiency" Cost Ejficiency Initiative issued on February 26, 2025. The grant termination emails mistakenly referenced Executive Order 14217, Commencing the Reduction of the Federal Bureaucracy, issued on March 14, 2025, and should have referenced Executive Order 14222.
- 20. As noted above, the policy for selecting grants for termination at NEH focused first on first on identifying open grants that focused on or promoted (in whole or in part)

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"environmental justice," "diversity, equity, and inclusion" or "diversity, equity, inclusion and

accessibility," and "gender ideology."

21. Subsequently, and in consultation with DOGE, I more broadly chose grants for

termination that did not contribute to the public's confidence in how NEH expended its

taxpayer funds as required by NEH's authorizing statute. See 20 U.S.C. § 951(5).

22. NEH's authorizing statute does not set forth any prohibition or limitation on the

sole discretion of the NEH Chairperson to terminate or rescind grant awards. I am not aware

of any such limitation in any law or regulation.

23. NEH's authorizing statute does not set forth any requirement that NEH maintain or

award a particular number of grants, make grants to particular recipients, or expend a particular

amount of grant funds in a given time frame. I am not aware of any such requirement in any

law or regulation.

June 17, 2025

Michael P. McDonald

Digitally signed by Michael P. McDonald Date: 2025.06.17 12:00:39 -04'00'

MICHAEL MCDONALD

Acting Chairman

National Endowment for the Humanities

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From: McDonald, Michael

To: McDonald, Michael

Date: Monday, June 16, 2025 1:32:39 PM

Attachments: image001.png

From: Bobley, Brett < bbobley@neh.gov>
Sent: Friday, February 7, 2025 5:39 PM

To: !Division Directors < !DivisionDirectors@neh.gov>

Cc: !SeniorManagement < SeniorManagement@neh.gov>; Brundage, Richard

<<u>RBrundage@neh.gov</u>>

Subject: NEH EO Award Review Spreadsheet

Dear Program Directors,

Here are the review criteria for reviewing all the awards from 2021 to the present:

As per OMB's January 27, 2025 memo (M-25-13), please identify any funded projects that "advance Marxist equity, transgenderism, or green new deal social engineering policies." More specifically, following the descriptions provided in the Administration's recent Executive Orders, you should identify grants that focus on or promote (in whole or in part): (i) "environmental justice"; (ii) "diversity, equity, and inclusion " or "diversity, equity, inclusion, and accessibility" (even if these exact terms are not used); and (iii) "gender ideology," which, according to the Executive Order, replaces sex with "an internal, fluid, and subjective sense of self unmoored from biological facts" or with "an ever-shifting concept of self-assessed gender identity."

Here is the shared spreadsheet that contains all the awards to review:

NEH-Awards-2025 Data Call.xlsx

Important notes about the spreadsheet and the review process:

- We are working to make the spreadsheet a little prettier looking formatting-wise. But you
 are welcome to start using it now. Please forward this email to your deputy/assistant
 director if they will be working with you.
- Each division has their awards on their own tab. Feel free to re-sort or change the layout/wrapping to whatever works best for you.
- It includes all recommended and above application statuses (e.g. recommended, approved, offered, awarded, closed out, etc).

5

Order of work:

- Please start by tackling the open awards coming from the November 2024 council.
- Then work on the ones for March council.
- Then all the remaining ones.
- You can sort on the council date column to do them in this order.
- The Agency-Wide tab contains all the ARP awards, so don't forget about doing those too. You'll want to sort on the application number to see all of yours as a group. As a reminder:
 - o ZDH = ODH
 - ZED = Education
 - O ZPA = P&A
 - o ZPP = Public
 - o ZRE = Research
 - ZIN and ZOR = Challenge
- The last four columns are the key thing you will be filling in:
 - Column Q "Proposal Needs Further Discussion" you can only enter Yes or No.
 That way, we can sort it later to find the ones that need discussion. When
 completed there should be a Yes or No for every award.
 - Columns R, S, T directly map to the three criteria at the beginning of this email. You can put any notes in these columns to inform future discussions.

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From: <u>Voyatzis, Lisette</u>
To: <u>Hylan, Kimberly</u>

Subject: FW: historical review of grants
Date: Monday, June 16, 2025 1:39:46 PM

Attachments: image001.png

From: McDonald, Michael <mmcdonald@neh.gov>

Sent: Thursday, March 13, 2025 3:20 PM **To:** Voyatzis, Lisette <evoyatzis@neh.gov> **Subject:** FW: historical review of grants

From: Wolfson, Adam <a wolfson@neh.gov> Sent: Thursday, March 13, 2025 3:17 PM

To: nate.cavanaugh@gsa.gov; justin.fox@gsa.gov Cc: McDonald, Michael <mmcdonald@neh.gov>

Subject: historical review of grants

Hi Nate, hi Justin,

Great meeting you yesterday and catching up today. As discussed, I've copied below the link for the award spreadsheet created by Brett that the program directors used for their historical review of NEH's grants since January 2021.

It's broken down by program office, each one having its own tab. The directors reviewed the grants made through their office and entered comments for the three relevant categories (i.e., DEI/DEIA; gender ideology; and environmental justice) and rated them based on level of involvement with any of the categories (high, medium, low, N/A).

There's also a tab for agency-wide grants (which applies mainly to ARP awards and Chair's awards). A few of the directors still need to review awards made through their office for this tab and enter their comments.

Mike and I will appreciate having your thoughts and suggestions. We've set aside a block of time Monday morning to finalize the list for OMB.

Thanks.

Adam

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From: <u>Voyatzis, Lisette</u>
To: <u>Hylan, Kimberly</u>

Subject: FW: NEH Active Awards / Grants

Date: Monday, June 16, 2025 1:41:40 PM

From: McDonald, Michael <mmcdonald@neh.gov>

Sent: Tuesday, April 1, 2025 12:52 PM **To:** Voyatzis, Lisette <evoyatzis@neh.gov> **Subject:** FW: NEH Active Awards / Grants

From: Justin Fox - A < <u>justin.fox@gsa.gov</u>> Sent: Monday, March 31, 2025 11:53 PM

To: bstewert@nea.gov; Bobley, Brett bstewert@nea.gov; Bobley, Brett bstewert@nea.gov; Bobley, Brett bbobley@neh.gov>

Cc: McDonald, Michael < mmcdonald@neh.gov >; Nate Cavanaugh - Q2 < nate.cavanaugh@gsa.gov >

Subject: NEH Active Awards / Grants

Brett, Beth,

Hope you've been doing well! Could you please send us an eGMS pull containing the below columns tomorrow on active grants? Appreciate the help, let us know where you have any questions:

- Award #
- award id fain (matches with USA Spending, if available)
- Status
- Division (i.e. State / Federal Partnership, etc.)
- Program
- Award Start Date
- Award End Date
- Award \$
- \$ Outlayed to date
- \$ Remaining
- Award Description
- Awardee Name
- Awardee email address (Primary POC)

My understanding is this would be somewhere around 1,440 active grants and 62 sub-awards per USA spending but would like to have a source of truth from you all as we're reviewing.

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Thank you, Justin

Justin Fox
General Services Administration
justin.fox@gsa.gov

M: (771) 210-9025

EXHIBIT D

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA

NEETA THAKUR, et al.,

Plaintiffs,

v.

DONALD J. TRUMP, et al.,

Defendants.

Case No: 3:25-cv-4737

DECLARATION OF KIMBERLY PENDLETON

I, Kimberly Pendleton, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, as follows:

- 1. I am the Director of the Division of Grants, Agreements, and Acquisition Support (DGAAS-Grants) within the Food and Drug Administration (FDA), a component of the U.S. Department of Health and Human Services (HHS).
- 2. In this role, I am responsible for, among other things, monitoring administrative and fiscal aspects of FDA's grant and cooperative agreements; assuring compliance with Federal laws and HHS administrative policies and procedures; and maintaining official grant files for grant awards. In this role, I have oversight of the entirety of FDA's grants management branch and process, am kept abreast of all of FDA's grantees, and review all agency correspondence pertaining to grant awards, including those to the University of California.
- 3. This declaration is based upon my personal knowledge, information acquired by me in the course of performing my official duties, information contained in the records and systems of FDA to which I have access in the course of my duties, and information conveyed to me by other knowledgeable FDA employees with whom I work on a regular basis.
- 4. I submit this declaration in response to the Court's June 12, 2025 order in the above-captioned matter requiring expedited discovery concerning: (1.a) "the policy for selecting grants for termination at [FDA]"; (1.b) "The overarching Executive Order(s) or directive(s) animating the termination policy at [FDA]"; (1.c) "The way in which the policy or overarching priority was communicated to each agency and by whom"; (1.d) "The way in which the termination policy was implemented at [FDA] (e.g., keyword searches, AI tools, etc.)"; and (2) "an estimate of the number of

grants issued to the University of California Regents or specific UC campuses that were terminated between January 20, 2025 and the present."

- 5. My responses are presented out of sequence in an attempt to correct any misunderstandings and to better explain FDA's termination of grants to UC entities and its polices concerning the termination of grants, or rather lack thereof.
- 6. At the outset, it is important to understand the difference between a grant and a contract, which are distinct funding mechanisms. A grant is used when the principal purpose of the transaction is the transfer of money, property, services, or anything of value to accomplish a public purpose of support or stimulation authorized by Federal statute. The primary beneficiary under a grant is the recipient, as a proxy for the public, as opposed to the Federal government. A contract is used when the principal purpose of a transaction is acquisition, by purchase, lease, or barter, of property or services for the direct benefit or use of the Federal government. The primary beneficiary under a contract is the Federal government. In other words, grants are used when the benefit is for the public, and contracts are used when the benefit is for the Federal government.
- 7. Grants and contracts are administered separately within FDA using separate teams and systems.
- 8. Between January 20, 2025 to the present, FDA has not terminated any of its grants with UC entities (i.e., grant awards where a UC entity is listed as the primary grantee). FDA currently has a total of approximately 21 grants with UC entities. I am not aware of any plans to terminate any grants to any UC entity.
- 9. To the best of my knowledge, FDA does not have specific policies concerning the selection of grants (to UC or any other entity) for termination. General procedures concerning the termination of grants are set out in HHS's Grants Policy Statement, attached hereto as "Exhibit 1."
- 10. To the best of my knowledge, FDA does not have distinct policies implementing this Administration's executive orders concerning grants and contracts. Instead, based on my experience, these executive orders are implemented individually, meaning that when an executive order is issued that may impact FDA grants or contracts, it is communicated via an emailed directive from the relevant component of the Office of the Secretary to the appropriate team. For executive orders involving FDA grants, the DGAAS-Grants team would handle implementation by querying the relevant databases using keywords to identify the relevant grants and entities and initiating the appropriate next-steps.

¹ The FDA "grant" referenced in Plaintiffs' Pimentel Declaration is in fact a contract between FDA and Columbia University; the University of California Berkeley is designated as a subcontractor to that agreement. *See* Dkt. 15.

HHS Grants Policy Statement

Effective date: April 16, 2025

This HHS Grants Policy Statement (GPS) replaces all prior versions

Contact grantpolicyreq@hhs.gov with GPS feedback

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Introduction and General Information

The Grants Policy Statement (GPS) is incorporated by reference in the official Notice of Award (NoA) as a standard term and condition.

The GPS provides information on HHS agencies that make awards, the award process, and where to find and apply for awards. The GPS also provides information about the legal and regulatory rules that apply to your award and will be used for enforcement purposes. The GPS will be updated to reflect changes in law and policy.

The latest version of the GPS is at www.hhs.gov/grants/grants/grants-policies-regulations/index.html and it includes:

- Introduction and General Information
- Pre-Award
- Post-Award
- Single Audit
- Appendices
 - A. Awarding Agency Overview
 - B. Abbreviations and Glossary
 - C. Post-Award Considerations by Type of Program, Activity, or Recipient
 - D. HHS Administrative and National Policy Requirements
 - E. Financial Assistance General Certifications and Representations

Supersession

This GPS replaces the HHS Grants Policy Statement dated January 1, 2007.

This GPS reflects the current 45 CFR part 75 regulation and eight flexibilities from 2 CFR part 200 (effective October 1, 2024). It will be updated in 2025 to reflect the HHS adoption of 2 CFR part 200 in its entirety and the retention of certain HHS specific provisions in 2 CFR part 300. From this date on, HHS plans to update the GPS annually to make sure it reflects changes in statutes, regulations, and policies.

Applicability

The 2024 HHS GPS applies to awards and award modifications that add funding made on or after April 16, 2025. This includes supplements to award, competing and non-competing continuations. The GPS applies to all HHS recipients and the requirements flow down to subrecipients.

The HHS GPS does not apply to awards made by the National Institutes for Health (NIH). For NIH awards, please see the <u>National Institutes of Health Grants Policy Statement (NIHGPS)</u>, which is the policy document describing the requirements that serve as the terms and conditions of NIH awards.

The HHS GPS does not apply to non-discretionary awards or to awards made to individuals. HHS agencies have the discretion to apply certain parts of the GPS to non-discretionary awards and other policies to your non-discretionary or individual award.

Agencies that administer HHS awards include:

- Administration for Children and Families (ACF)
- Administration for Community Living (ACL)
- Agency for Healthcare Research and Quality (AHRQ)
- Assistant Secretary for Planning and Evaluation (ASPE)
- Assistant Secretary for Preparedness and Response (ASPR)
- Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Office of the Assistant Secretary for Health (OASH)
- Office of the Inspector General (OIG)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

See Appendix A for more information.

Requirements

The following impose requirements on your award and are addressed in the GPS:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (45 CFR § 75)
- Eight provisions of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200):
 - 2 CFR § 200.1 Modified Total Direct Cost Definition, Equipment Definition, Supplies Definition
 - 2. 2 CFR § 200.313(e) Equipment Disposition
 - 3. 2 CFR § 200.314(a) Supply Disposition
 - 4. 2 CFR § 200.320 Micro-purchase Threshold
 - 5. 2 CFR § 200.333 Fixed Amount Subawards Amount
 - 6. 2 CFR § 200.344 Closeout Provisions
 - 7. 2 CFR § 200.414(f) Indirect Cost Rate Provisions
 - 8. 2 CFR § 200.501 Audit Provisions
- The Notice of Award (NoA)
- The Notice of Funding Opportunity (NOFO), if stated in the NOA

Other regulations or statutes with more requirements might apply to your award. These include:

- Grants for Research Projects 42 CFR part 52
- Procedures of the Departmental Grant Appeals Board <u>45 CFR part 16</u>
- Claims Collection 45 CFR part 30
- Equal Treatment for Faith-Based Organizations 45 CFR part 87
- Restrictions on Lobbying 45 CFR part 93
- Metric Conversion Policy for Federal Agencies <u>15 CFR part 273</u>
- Public Health Service Policies on Research Misconduct 42 CFR part 93
- Protection of Human Subjects, <u>45 CFR part 46</u>

See Appendix D for more information.

Terms and Conditions

HHS states the requirements of an award in the award terms and conditions:

- The GPS is incorporated by reference as a standard term and condition of awards.
- The NoA includes all terms and conditions of a specific award.
- Notice of Funding Opportunities (NOFOs) describe program requirements, which may be included as terms and conditions.

Types of HHS Awards

Awards fall into two main types:

- Discretionary: HHS chooses who gets the award and how much. Selection of these awards are generally competitive. The amount of an award can be competitive or by a set formula. Types of discretionary awards include research, training, services, construction, and conference support.
- Non-discretionary: A statute determines the recipients and amounts, either directly or by a formula (i.e., each State gets an award of a certain amount). This includes block grants and entitlement programs.

Award Instruments

Award instruments are legal agreements between an awarding agency and a recipient. The two kinds generally addressed in the GPS are:

- Grants: The awarding agency is not substantially involved in the project (<u>31 USC</u> 6302, 6304).
- Cooperative agreements: The awarding agency is substantially involved in the project (31 USC 6302, 6305).

Roles and Responsibilities

This section highlights roles and responsibilities. The GPS supplies more details throughout.

Recipient Roles and Responsibilities

Recipients manage performance and funds. Required roles are:

- Authorized Organizational Representative (AOR): The AOR has authority to act for the organization and is responsible for meeting award requirements, properly managing the award, and providing oversight. The AOR's signature on a grant application guarantees that the information in the application is correct and the organization is responsible for following all requirements.
- Principal Investigator or Project Director (PI/PD): The PI/PD is the individual(s)
 designated by the recipient to direct the project or program being supported by the
 award. The PI/PD is responsible and accountable to officials of the recipient
 organization for the proper conduct of the project, program, or activity.

Awarding Agency Roles and Responsibilities

HHS is responsible to Congress and U.S taxpayers for carrying out its mission in a cost-effective and compliant way. The HHS agencies that administer awards have grants offices and staff designated to conduct this work. The roles and responsibilities of HHS staff (at each awarding agency) include:

- Grants Management Officer (GMO): The GMO is the official who handles the non-program parts of an award for the HHS agency. The GMO is the focal point for receiving and acting on requests for prior approval or for changes in the terms and conditions of award. The GMO is the only official authorized to obligate the HHS awarding agency to the expenditure of federal funds or to change the funding, duration, or other terms and conditions of an award.
- Grants Management Specialist (GMS): Acts as the main grants administration contact for recipients. Handles administrative activities on behalf of the GMO. The GMS contact information can be found on the NoA.
- Project Officer or Program Official (PO): Responsible for the programmatic, scientific, and technical sides of award programs, including oversight and monitoring. The PO contact information can be found on the NoA.
- Review Administrator (RA): Provides oversight of the application review process, although not all agencies have this role.

Pre-Award

This section helps you find funding opportunities, prepare, and apply.

Locating Funding Opportunities

Agencies announce competitive funding opportunities. All discretionary Notice of Funding Opportunities are listed on <u>Grants.gov</u>. There are three other ways to find more information about HHS financial assistance.

Grants.gov, Forecasts, and the Notice of Funding Opportunity (NOFO)

HHS policy requires maximum competition for discretionary grants to the greatest extent possible. As such, HHS agencies promote the widest and earliest possible spread of information through forecasts of upcoming grant opportunities and NOFOs. Awarding agencies post discretionary or competitive NOFOs at <u>Grants.gov</u>.

<u>Grants.gov</u> forecasting is the direct way to find NOFOs. NOFOs are usually open for at least 60 days. Only rarely are they open for fewer than 30 days.

Because HHS aims for the widest and earliest possible spread of information, HHS agencies post future opportunities on Grants.gov through forecasts. Forecasts may be posted weeks or months before NOFOs. Forecasted NOFOs can be found in the <u>Grants.gov</u> search page by clicking the "forecasted" button. Forecasts include helpful information such as:

- expected number of awards
- estimated award amounts
- description of the program
- estimated NOFO posting date
- estimated application due date
- estimated project start date and period of performance

How to Subscribe to HHS Grants Forecast

When you create a Grants.gov account, you can customize the type of email notifications you receive. Log in and then go to <u>the subscription page</u> to sign up for news updates about system enhancements, notifications about saved searches, new funding opportunities, and more.

Awarding Agency Websites

Most awarding agencies have award web pages. See Appendix A.

SAM.gov and Assistance Listings

Assistance listings are public descriptions of federal assistance programs. All assistance listings are included on the System for Award Management (SAM.gov), a site run by the U.S. General Services Administration. Search assistance listings at SAM.gov.

Preparing to Apply

The first step is to read the entire NOFO and the links in it. Each part of the NOFO sets out basic information for that award.

To apply, you must:

- be an eligible entity
- address the NOFO requirements
- submit a complete and compliant application by the deadline(s)

General Eligibility Considerations

In general, HHS awards may be made to domestic public or private, non-profit or for-profit organizations. Foreign or international organizations are eligible for research awards, or if expressly authorized by law.

The NOFO includes specific eligibility criteria and any requirements to prove eligibility. Applicant eligibility criteria for all HHS NOFOs are almost always based on statute or program regulation.

HHS policy requires open competition to the greatest extent possible. Restricting eligibility, as compared to statute or program regulations, is only done with appropriate justification in rare cases.

Agencies review applications for eligibility when they receive them. The AOR signature generally serves as assurance of eligibility, unless additional proof of eligibility is required in the NOFO. If the applicant is not eligible, the application will not be reviewed.

Additional Eligibility Restrictions

Concurrent Applications

You cannot apply for funding for the same project or activities from multiple HHS Public Health Service (PHS) agencies at the same time. If you do, your applications will be returned. See <u>Appendix A</u> for a list of PHS agencies.

Suspension, Debarment, and Exclusion

Agencies are required to check <u>SAM.gov</u> for individuals and organizations that are debarred, suspended, declared ineligible, or voluntarily excluded from receiving HHS award funds. HHS will not give awards to or pay these individuals and entities, including recipients and subrecipients. If such an individual is involved in an award, costs like their salary are not allowed.

Applicants must disclose if any of the following conditions apply to their organization, planned staff or principals (as defined in <u>2 CFR § 180.995</u>), including Principal Investigators (PIs), and other key personnel:

- Are currently excluded or disqualified;
- Were convicted within the previous three years of any offenses listed in <u>2 CFR §</u> 180.800(a) or had a civil judgment for one of those offenses during that time;
- Are currently indicted for or otherwise facing criminal or civil charges by a
 governmental entity (federal, state, or local) for any of the offenses listed in <u>2 CFR §</u>
 180.800(a); or,
- Have had any public transactions (federal, state, or local) terminated within the previous three years for cause or default.

Recipients of HHS awards must also make subrecipient organizations and subrecipient participants follow federal Debarment and Suspension regulations ($\underline{2 \text{ CFR part } 376}$ and $\underline{2 \text{ CFR part } 180}$). These participants can include:

- Consortiums
- Subcontracts
- Consultants
- Collaborators
- Contractors that require the provision of goods or services that will equal or exceed \$25,000

These subrecipients must also make sure that anyone they hire with award funds follow the same rules. Before entering into an agreement, these participants should tell the award recipient if he, she, or any principals are excluded or disqualified at that time.

Ultimately, it is the job of the applicant or recipient to make sure none of the subrecipient and principals involved are excluded or disqualified. Award recipients cannot make a transaction with someone who is disqualified unless they get an exception under the disqualifying statute, Executive Order, or regulation from HHS.

For more information, see Suspension and Debarment at <u>45 CFR § 75.213</u>, <u>2 CFR part 180</u> and <u>2 CFR part 376</u>.

Delinquency on Federal Debt

If an entity or individual owes money to the U.S. with a lien, they cannot get an award. Applicants must state in their applications whether they are delinquent on any federal debts. Agencies may delay awards until federal debts are settled.

Do not include a person in the application if they have unpaid federal debts with a lien. Agencies will disallow costs for these individuals.

See 28 U.S.C. 3201(e).

Lobbying Prohibition

Applicants must certify they will not use federal funds to pay any person to influence agency staff, Congress members, and officers or employees of Congress about federal awards.

Applicants with total proposed costs of more than \$100,000 must certify that they:

- have not made unallowable lobbying payments,
- will be responsible for reporting on non-federal funds used for lobbying,
- will include these requirements in consortium agreements, subawards, and contracts of more than \$100,000 under their award.

See 2 CFR part 93, 2 CFR § 200.450, and the SF-424 for more about lobbying requirements.

HHS Application Process

Types of Applications

HHS uses these application types:

- New application: A request for funds for new activities. It can be competitive or not.
- Non-competing continuation application: A request for funds for the next budget period(s) within a period of performance. Agencies provide an NoA with new budget details.
- Competing continuation or renewal application: A request to continue a project that is ending with a new period of performance. This is competitive.
- Supplemental application: A request for more funds in the current budget period.
 This can be for changes in the project scope, expansion of already approved activities, or for unexpected costs.
- Revised application: A previously not funded application updated and submitted again for review.

Pre-applications and Letters of Intent

Before a full application, an agency might ask for:

- Pre-applications: Used to filter out applicants that will be unlikely to receive funding through an objective review. This saves time before writing a full application.
- Letters of Intent: Agencies might want notice that you plan to apply. This is usually optional and doesn't mean you have to apply. It's mostly to gauge interest and help the HHS agency estimate how many applications to expect.

Application Forms

Forms and instructions are on <u>Grants.gov</u>. You can find a NOFO's required forms in the application package in Grants.gov. The NOFO is your best source when completing forms. The NOFO agency contact, located on the NOFO, can answer any questions you may have.

Application Budgets

You will need to include a budget as part of your application. Some applications require a detailed budget. The NOFO will describe the budget requirements. For HHS budgets, applicants and recipients need to understand:

- The costs allowable under the program
- The relevant cost principles
- The difference between direct and indirect costs
- When you need an indirect cost rate or research patient care cost rate, and
- Any matching or cost sharing requirements

Project costs include allowable direct costs plus allocable indirect costs, minus applicable credits. See below Cost Principles, Direct Costs and Indirect Costs sections of the GPS.

Cost allowability is subject to the governing statute, program regulations, and award terms and conditions. There are situations when HHS will not reimburse indirect costs.

Cost Principles

Developing an application budget depends on understanding what costs are allowable under HHS financial assistance programs.

For more information about how cost principles apply to your organization, see 45 CFR § 75.401.

This section on cost principles interprets the regulations at 45 CFR part 75 and is not all-inclusive.

Cost principles:

- Establish general standards for the allowability of costs.
- Provide guidance on treating costs as direct or indirect.
- Provide principles for selected items of cost.

The cost principles apply to all recipients.

You can use your own accounting system to implement the cost principles if you meet the standards for financial management systems at 45 CFR § 75.302.

The federal-wide cost principles are in 45 CFR part 75, subpart E.

The cost principles for:

- Hospitals are at 45 CFR part 75 Appendix IX
- For-profit organizations are at 48 CFR § 31.2

If specifically identified, use the applicable cost principles for your type of organization. Cases where the cost principles do not apply are listed in $45 \text{ CFR } \S 75.401(a)$.

Is It Allowed?

As the HHS agency official for the non-program parts of awards, the Grants Management Officer (GMO) makes the final determination on allowability.

For all allowability requirements see 45 CFR § 75.403. Following is a summary.

A cost is allowable if all the following apply:

- It is necessary and reasonable for award performance.
- It complies with any limitations or exclusions in the cost principles or the federal award about types or amounts of cost items.
- It is consistent with policies and procedures across all recipient activities, regardless of source of funding.
- It is consistent across all activities in identifying direct and indirect costs.

- It follows generally accepted accounting principles (GAAP). See 45 CFR § 75.403(e) for exceptions.
- It is not used for cost-sharing requirements of another federally financed program, unless specifically allowed by law.
- You maintain required documentation.

Is It Reasonable?

For all reasonableness requirements see 45 CFR §75.404. Following is a summary.

Considerations for reasonableness include:

- If the cost is generally recognized as ordinary and necessary.
- The requirements of:
 - Sound business practices
 - Arm's-length bargaining
 - o Federal, state, local, tribal, and other laws and regulations
 - Terms and conditions of the federal award
- If the cost aligns with market prices for comparable goods or services in the geographic area.
- The cost does not significantly deviate from your established practices and policies regarding such costs, regardless of source of funding.

Allocability

Allocability in grants means costs that can be applied to your award. For all allocability requirements see <u>45 CFR § 75.405</u>. Following is a summary.

A cost is allocable if any of the following apply:

- It is spent only for the work under a federal award.
- It benefits both the federal award and other recipient work and can be distributed using reasonable methods.
- It is necessary to your overall operations and can be assigned to the federal award.

Direct and Indirect Costs

Costs can be direct or indirect:

- Direct costs: Directly related to the cost of the project or project activities. These
 costs are based on actual expenses or easily estimated accurately. Examples of
 direct costs are generally salaries, travel, equipment, and supplies directly for grant
 activities.
- Indirect costs: Not readily tied directly to the project or project activities. If a cost is indirect, it cannot also be listed as a direct cost for any federal award. Examples may be facilities operation and maintenance costs, depreciation, and administrative

expenses. You must have or negotiate an indirect cost rate to reimburse indirect costs.

See 45 CFR §§ 75.413-414, and 45 CFR § 200.414.

Indirect Cost Rates

As stated above, indirect costs are for common activities that cannot be specifically tied to a particular project. Examples include facilities operation and maintenance costs, depreciation, and administrative expenses. You must treat costs as direct or indirect consistently.

Indirect costs are allowable under most HHS awards and are charged as a rate. There are three ways indirect costs may work:

- Specified rate. The rate may be specified in statute, regulations, or policy. If this is so, the difference between the specified rate and the negotiated rate can satisfy match or cost sharing requirements. There are three HHS-specific specified rates to consider:
- Training grants, including career awards, are limited to 8%.
- Indirect costs to foreign organizations and foreign public entities when the awarded work is performed fully outside of the territorial limits of the U.S. are limited to 8%.
- Negotiated Indirect Cost Rate Agreement (NICRA). You can negotiate a rate with your cognizant federal agency. If the cognizant agency is HHS, a rate is negotiated by <u>Program Support Center Cost Allocation Services (CAS)</u> or the <u>Division of Financial Advisory Services (DFAS)</u> in the NIH Office of Acquisition Management and Policy (responsible for negotiating indirect cost rates for for-profit recipients). Indirect cost proposals must use the applicable cost principles and cognizant agency guidance.
 - O See 45 CFR part 75, Appendix III for institutions of higher education.
 - See 45 CFR part 75, Appendix IV for non-profits.
 - See <u>45 CFR part 75, Appendix V</u> for state and local government cost allocation plans.
 - See 45 CFR part 75, Appendix VI for public assistance.
 - See <u>45 CFR part 75, Appendix VII</u> for state and local governments and Indian Tribe indirect cost plans.
- De minimis rate. If you do not have a NICRA, you can use the de minimis rate indefinitely. We are applying the newly revised rate, in <u>2 CFR § 200.414(f)</u>, of 15% of modified direct costs. Modified direct costs are salaries and wages, fringe benefits, materials and supplies, services, travel, and no more than \$50,000 of each subaward, minus some exclusions. See <u>2 CFR § 200.2</u> for the full definition. See <u>2 CFR § 200.414</u> for more on the de minimis rate.

The de minimis rate is not applicable for some recipients. These recipients include governmental agencies that receive more than \$35 million in direct funding and Indian tribal governments. See $\underline{\text{2 CFR}}$ Appendix VII to § 200 D.1.b.

Exclusions

Some HHS awards and recipients are not eligible for indirect cost reimbursement. This will be described in the NOFO.

Indirect costs are not paid for:

- Grants to federal institutions, 45 CFR § 75.217(b)(3)
- Grants to individuals, including fellowships, scholarships, traineeships, or fixed amounts like educational allowances or tuition and fees, <u>45 CFR § 75.2</u> (Definition of Micro-Purchase Threshold).

Pass-through Entities

Pass-through entities must use their subrecipient's federal NICRA. A 15% de minimis rate may be used if there is no federally negotiated agreement. See <u>2 CFR § 200.414</u>.

Salary Rate Limit (SRL)

Generally, the HHS Appropriations Act includes an SRL. This statutory requirement limits the amount of funds under a grant or other extramural mechanism that can be used to pay individual salaries (including executive salaries) at a rate above the Executive Level II. Recipients may pay salaries at a rate higher than the Executive Level II if the amount beyond the HHS SRL is paid with non-HHS funds. Since the Executive Level II rate and HHS Appropriations Act citation changes each year, HHS refers to the Office of Personnel Management (OPM) posting the most recent information at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/24Tables/exec/html/EX.aspx.

The HHS SRL applies to:

- The majority of HHS awards.
- Both direct and indirect costs under applicable HHS awards.

Effective October 1, 2024, when HHS is the cognizant agency for indirect costs or when HHS is acting as the shared-service provider for another cognizant agency for indirect costs, the HHS component that reviews and negotiates indirect cost rate proposals and cost allocation plans will issue NICRAs that incorporate the HHS SRL, to comply with the HHS Appropriations Act requirement.

Beginning with HHS awards, including continuation and supplemental awards, made on or after October 1, 2024, HHS recipients that do not have an approved indirect cost rate that complies with the HHS SRL requirement must take and document the following actions.:

- Identify any HHS award where HHS funds are used to pay any salary that exceeds the SRL using the HHS award. This includes both direct and indirect costs, both in whole and any portion of a salary that at a full-time equivalent exceeds the SRL.
- Have written policies and procedures that ensure the recipient does not draw down HHS award funds, whether as direct or indirect costs, to pay for salaries above the HHS SRL.

This may occur because the NICRA was issued before October 1, 2024, and it is not yet up for renewal, OR because the NICRA was issued by another cognizant agency for indirect costs that does not have an identical SRL.

A recipient may request a companion rate on the NICRA from HHS that does not incorporate the HHS SRL if:

- HHS is their cognizant agency for indirect costs or HHS is the shared-service provider for their cognizant agency for indirect costs; and
- The recipient is applying for an award from another Federal agency or from a program not subject to the HHS SRL.

Cost Sharing

Cost sharing refers to project costs that are not funded by the HHS agency. It is also sometimes called "match."

Cost sharing can be voluntary or can be required by statute or regulation.

NOFOs include information about:

- Whether there is required or voluntary cost sharing
- The agency's approach to looking at cost sharing during the application review
- Any caps on the agency's portion of total award costs
- Any restrictions on the types of funding that are acceptable as cost-sharing (e.g., inkind contributions)
- Required documents, like commitment letters

See more on cost-sharing requirements at 45 CFR § 75.306.

Program Income and Third-Party Reimbursement

Program income is money a recipient earns that is both:

- Earned during the period of performance
- Earned directly from an activity funded by the award or due to the award

This can include money earned from things like:

- Services performed under the award,
- Renting property bought with award funds,
- Selling items made with award funds,
- Third-party reimbursement, such as payments for health services, and fees based on ability to pay,
- Principal and interest on loans made with award funds, and
- Royalties from patents and copyrights.

It does not include:

 Interest earned on advances of Federal funds or things like rebates, credits, discounts, and interest earned on any of them unless stated otherwise in the NOFO or NoA.

The full definition for program income is found at 45 CFR § 75.2 "Program income"

NOFOs might ask for estimated program income in the budget. NOFOs explain how to use expected program income.

There are no requirements for what to do with income earned after the end of the award period of performance, unless the NOFO or NoA says otherwise.

See more on the treatment of program income at 45 CFR § 75.307.

Unique Entity Identifier (UEI) and Registering in SAM.gov

Every applicant needs a Unique Entity ID (UEI) from SAM.gov.

- For a new UEI, register on SAM.gov. You'll get an email when it's active. This can take time.
- If you already have a UEI, renew on SAM.gov yearly.
- Keep your SAM registration details current.
- Make sure that your SAM registration is accurate for both contracts and grants.

For more information, see <u>Get Ready for Grants Management</u> at HHS.gov.

State and Local Review Requirements

Federal rules allow state and local governments and health agencies to review and comment on applications. You will find the requirements in the NOFO. There are two types of reviews:

- Intergovernmental review. <u>Executive Order 12372</u> and <u>45 CFR part 100</u> allow for intergovernmental review by state and local governments through the State Single Point of Contact (SPOC).
- Public health system reporting. This reporting provides state and local health
 agencies with information on applications by health care delivery programs. If a
 state or local health official wants to review a full application, the official contacts
 the SPOC.

Contact your SPOC to learn more. Find SPOCs at the <u>Office of Management and Budget website</u>. Not all states have this process.

Applying

In almost all cases, you will need to submit applications online. All HHS agencies are required to post their competitive NOFOs on Grants.gov and will also post there how to apply online.

Agencies will not review applications that are from ineligible applicants, incomplete, are not compliant, or are not responsive to program requirements.

Send your application by the NOFO's deadline. If you are late, it will almost always be deemed non-compliant and will not be reviewed.

The AOR's signature on an application certifies that:

- The information in it is truthful, complete, and accurate,
- The applicant will comply with all required certifications and assurances,
- The applicant will comply with terms and conditions when accepting an award, and
- The non-federal entity is aware that any false, fictitious, or fraudulent statements or claims may subject the applicant to criminal, civil, or administrative penalties.

Some agencies might allow paper or email submissions. The NOFO will explain exemption requests. These are rare.

PLEASE NOTE: Applicants must register with Grants.gov. For how to register with Grants.gov, see <u>Registering an Organization</u> or contact the Grants.gov contact center at 1-800-518-4726 or <u>support@grants.gov</u>. Registering can take up to one month.

Application Receipt and Review

Initial Eligibility Review

The awarding agency screens applications for eligibility. Unless the NOFO requires specific proof of eligibility, the AOR's application certification is enough.

Use of Application Information

Agencies protect your application information during merit review and in accordance with laws like the <u>Freedom of Information Act</u> and <u>Privacy Act of 1974</u>. Once awarded, the government can only use or share data as federal law allows. To help safeguard your information:

- Avoid sharing personally identifiable information.
- Only add confidential information if necessary.

See the Access to Research Data section of the GPS.

Merit Review

Merit review is a review by those with expertise in the programmatic subject matter area for the submitted applications.

Applications for discretionary programs, whether received in response to a NOFO, requested from a single source (very rare), or received as an unsolicited request for grant funding, will go through a merit review.

The merit review provides recommendations to the individuals responsible for making award decisions. Merit review is necessary to make sure HHS choses applications that best meet the needs of

the program. These needs must be based on what the NOFO says about what makes a successful application.

Peer review is a form of merit review. Reviewers are peers with expert knowledge about how the program topic. Sometimes, the program statute may tell us which type of reviewers to pick or how a review should happen.

Award Risk and Business Review

Before award, agencies do pre-award risk and business reviews of applications. These can include:

- Cost analysis of the budget
- Assessment of management systems
- Final review of applicant eligibility
- Compliance with public policy requirements

During this review, the agency might request more details or actions from you.

Following review, officials make decisions about making the award, adding special conditions, and funding level.

Cost Analysis

HHS agencies careful review of the applicant budget includes:

- a review of the cost breakdowns
- a check to make sure the cost data in the application is correct
- an overall review of the costs for need for and the reasonableness and allowability of proposed costs

The review depth depends on project complexity, applicant prior experience, and other factors.

Management System Analysis

Applicants must have systems, policies, and procedures in place to manage award funds and activities. HHS agency staff take a close look at your financial and business management systems. This review includes property management and procurement systems and helps ensure:

- Applicant organizations apply policies and procedures consistently, regardless of funding source, and
- Systems meet the standards and requirements in 45 CFR § 75.302, Financial Management.

Civil Rights Assurance

Domestic recipients, subrecipients, and contractors must file Form HHS 690, Assurance of Compliance once with the HHS Office for Civil Rights (OCR). It is not needed for each application.

The recipient must ensure that subrecipients and contractors have filed the form.

Additionally, recipients must comply with all applicable Federal anti-discrimination laws material to the

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government's payment decisions for purposes of 31 U.S.C. § 372(b)(4).

- (1) Definitions. As used in this clause -
- (a) DEI means "diversity, equity, and inclusion."
- (b) DEIA means "diversity, equity, inclusion, and accessibility."
- (c) Discriminatory equity ideology has the meaning set forth in Section 2(b) of Executive Order 14190 of January 29, 2025.
- (d) Discriminatory prohibited boycott means refusing to deal, cutting commercial relations, or otherwise limiting commercial relations specifically with Israeli companies or with companies doing business in or with Israel or authorized by, licensed by, or organized under the laws of Israel to do business.
- (e) Federal anti-discrimination laws means Federal civil rights law that protect individual Americans from discrimination on the basis of race, color, sex, religion, and national origin.
- (2) Grant award certification.
- (a) By accepting the grant award, recipients are certifying that:
- (i) They do not, and will not during the term of this financial assistance award, operate any programs that advance or promote DEI, DEIA, or discriminatory equity ideology in violation of Federal anti-discrimination laws; and
- (ii) They do not engage in, and will not during the term of this award engage in, a discriminatory prohibited boycott.
- (3) HHS reserves the right to terminate financial assistance awards and claw back all funds if the recipients, during the term of this award, operate any program in violation of Federal anti-discriminatory laws or engages in prohibited boycott.

Human Subjects and Animal Welfare Assurance

If IRB review and approval is required but still pending at the time of award, agencies will restrict human subjects research until they get and approve the needed proof. Additional information is available on the Office of Human Research Protections website. This includes a series of decision charts to help assess whether an activity is human subjects research covered by the regulation and when an exemption may apply.

Before getting an award, if applicants plan to use vertebrate animals, they must send an <u>Animal Welfare Assurance</u> to HHS' Office of Laboratory Animal Welfare. This confirms that a committee has reviewed the parts of the application related to animals.

Communicating Decisions

Agencies inform applicants about their decisions in various ways:

- Award: If you are getting an award, you will receive a Notice of Award (NoA).
- Denial: If the agency decides not to fund your application, the AOR gets a letter.
- Approved unfunded: Sometimes, despite a good review, there's not enough funds.

- The awarding agency could keep your application for future funding. The awarding agency will notify the AOR that your application is approved but unfunded.
- Revised application eligibility: If not successful, the NOFO might allow you to adjust and reapply later. However, some agencies cap the number of revisions and retries.

You cannot appeal a denial or the amount of funds awarded.

The Notice of Award

The Notice of Award is a legal instrument. See 45 CFR § 75.210 for the contents of an NoA.

Accepting the Award

Once accepted, the contents of NoAs are binding.

Applicants become recipients when the NoA is signed by the awarding agency's Chief Grants Management Officer (CGMO) or his/her delegate. The recipient accepts an award by drawing down funds. HHS expects recipients to draw down funds in the first 30 days of the period of performance.

Declining or Negotiating Awards

During the time between the NoA being signed and the drawing down of funds, if you can no longer accept an award or you need to negotiate any award parts, tell the awarding agency. If no agreement is reached, the agency will cancel the award. You cannot challenge the agency's decisions on the terms and conditions.

Periods of Performance

HHS uses the period of performance system for funding awards. Funding is provided in approved yearly increments called budget periods. The total period of performance includes the initial competitive

segment, any additional segments authorized by approved continuation applications, and any no-cost extensions.

A competitive segment usually will be no longer than five years, not including no-cost extensions. A single federal award for the entire period of support may be used if the project is only construction or modernization or if the total planned project will be less than 18 months.

The awarding agency will determine the length of the period of performance based on:

- Any statutory, regulatory, or administrative requirements,
- The length of time requested by the applicant,
- Any time limits on the period of performance recommended by merit review,
- The frequency of merit review, and
- The funding principles as specified in the NOFO.

The NoA generally approves a period of performance that goes beyond the current budget period, showing the HHS awarding agency's intention to continue providing support. Funding for future budget periods is not guaranteed at the level shown on the current NoA. There is no legal obligation for HHS awarding agencies to provide funding beyond the end date of the current budget period in the NoA.

Recipients must submit a continuation application or annual report to get approval and funding for each new budget period within the approved period of performance. The HHS agency will make its decision to fund the next budget period by issuing a NoA which shows the new budget period and amount of new funding. Funding is based on adequate performance, availability of funding, and the best interests of the federal government.

Budget periods usually last 12 months. However, they may be shorter or longer based on programmatic or administrative needs. The NoA will show the total approved budget for the applicable budget period. This includes direct costs, applicable indirect costs, and any required matching or cost sharing.

Costs in the NoA

The initial NoA and each subsequent NoA provide details of the award and the amount awarded. After the initial budget period, NoAs may reflect any authorized carryover and amounts previously awarded for the full period of performance. The amount awarded is shown either as total direct and indirect costs and as a categorical (line item) budget breakdown. This is based on the requirements in the NOFO.

Recipients have certain rebudgeting flexibility within the overall amount awarded. However, the total amount awarded is the maximum amount the awarding agency is obligated to pay under that award. Once an award is made, the HHS awarding agency is not required to provide any supplemental or additional funding.

Post-Award

As a recipient, you will manage HHS awards and activities including:

Project performance, <u>45 CFR § 75.301</u> and <u>2 CFR § 200.202</u>

- Use of award funds
- Compliance with award terms and conditions
- Issuing and monitoring subawards per 45 CFR § 75.352

Recipient internal controls and policies must meet 45 CFR § 75.303.

Awarding agency staff monitor recipients for compliance, performance, and need for technical assistance. Reviews include:

- Recipient reports
- Financial and progress reports
- Audit reports
- Correspondence,
- Onsite and remote site visits, and
- Other information.

The Notice of Award supplies HHS contact information and instructions for reporting.

Changes to Awards

Prior Approvals

At times, you may need to make changes to the program budget or activities. Some changes require prior written approval. To find out if a change needs prior approval:

- Carefully review your NoA.
- Review 45 CFR § 75.407 for actions needing prior approval.
- Review Appendix E of the GPS for prior approval requirements for certain types of awards.
- Ask your GMS if you are not sure.
- Ask your cognizant agency for indirect costs if you have questions about changes to indirect costs. The cognizant agency is the federal agency that approved your indirect cost proposal.

Seeking Prior Approval

Once you know that you need prior approval, you can request it from your GMS. Prior approval requests must include:

- Recipient name
- Principal investigator (PI) or project director (PD) and authorized organizational representative (AOR) name
- PI or PD and AOR telephone numbers and e-mail addresses

You must send your prior approval requests in writing, by mail, prior approval system, or email. It must:

- Be signed by the AOR (if sent in an email, attach the signed letter/memo)
- Include any necessary supporting documentation
- Get to the awarding agency in enough time for approval before making the change

Once received, the awarding agency GMO or his or her designee will review and approve or deny the request:

- If the GMO or GMS decides the change does not actually require prior approval, the awarding agency must promptly inform you.
- If prior approval is required, the GMS will send a decision to the AOR with a copy to the PI or PD within 30 calendar days of receipt.

Only the GMO or GMS, as the GMO's delegate, can issue written approval. Informal answers are not valid.

There is no appeal for denial of a prior approval request.

Subrecipient Prior Approvals

The recipient has the authority to give prior approval for changes to sub-award or contract activities or budget. This does not include any action inconsistent with the award purpose or terms and conditions. The awarding agency must approve any actions that will result in a change to project scope. Ask the GMS if you have questions about a proposed change.

Budget and Scope Changes

Minor Budget Changes

Within a budget period, you can adjust your budget without prior approval if:

- The change is within or between approved direct cost categories.
- Your award's federal share is below the simplified acquisition threshold, and your NoA doesn't include a prior approval need. Check the current threshold in the Federal Acquisition Regulation (FAR) at 2.101, Definitions.

Significant Budget Changes

Significant budget changes require prior approval when they constitute a change of scope or exceed 25 percent of total direct costs of the last approved budget period. When you are not clear if your budget change is beyond the scope, call your GMS.

Expanded Authority

If expanded authority is not granted in your NoA, you do not have it. To know if you have any expanded authorities:

- Review your NoA. Expanded authorities may be adopted by reference.
- Review your specific award conditions. These may include expanded authorities or limits on them.

When using expanded authorities as granted in the NoA, make sure you follow award requirements and the cost principles. All changes are subject to monitoring, audit, and related remedies for noncompliance. See the section below.

For a full understanding, see 45 CFR § 75.308(d)(1). Expanded authorities may include:

- Waiving the prior approval requirements in <u>45 CFR part 75</u>, except for those listed in 45 CFR § 75.308(c)(1); and
- Three specific waivers in 45 CFR § 75.308(d), including:
 - o Incurring project costs up to 90 calendar days before award. Doing so is at the recipient's risk.
 - Carrying forward unobligated balances to the next budget period unless the funds are currently restricted. You need prior approval to carry forward any unobligated balance to any budget period other than the next budget period.
 - Initiating a one-time extension of the period of performance by up to 12 months unless any of the following are true:
 - The extension requires additional federal funds
 - The extension involves any change in the approved project objectives or scope

Recipients may not use a one-time extension only to use unobligated balances.

Please Note: For awards that support research, unless your awarding agency provides other instructions in the NoA in general or because it is part of a regulation, the three specific waivers above (in 45 CFR § 75.308(d)) are automatic and noted in your NoA.

Several expanded authorities have specific deadlines for reports or notification. If a recipient consistently fails to meet them, the awarding agency may stop their ability to use them. Be sure to read your NoA carefully or ask your GMS if you have questions about expanded authorities under your award.

Extensions to Awards

The awarding agency may provide more time and funds after an award is made. The two types of extensions are:

- No-cost extensions: A time extension without more funds.
- Funding extension with funds: A time extension with added funds.

No-Cost Extensions

HHS agency prior approval is required for no-cost extensions, unless provided as an expanded authority.

When prior approval is required, the recipient must request the no-cost extension no less than 10 days prior to the end of the budget period.

In cases where there is expanded authority, the recipient must notify the HHS agency in writing with the supporting reasons and a recommendation for revised period of performance at least 30 calendar days before the end of the period of performance in the original NoA.

Regardless of whether approval is required, no-cost extensions are not meant to just spend unobligated funds. The purpose of a no cost extension is to:

- complete the project,
- provide for an orderly shutdown, or
- in some cases, provide a bridge to the next award.

If using expanded authority, and you do not need permission, you must tell the awarding agency.

Reminders for All Extensions

- You can't extend a period already lengthened by the awarding agency.
- Award terms and conditions still apply during the extended time.
- No matter the extension length, you must keep sending required reports as set out in your award.
- You must update all necessary certifications and assurances, including those about human subjects and animal welfare, following relevant rules and policies.
- A second extension longer than 12 months should be rare and will need special justification.
- If the agency denies an extension, you cannot appeal it.

Supplemental Funding Extension Without Change in Scope

A recipient may request supplemental funding with an extension of time without a change in scope that is under 25% of the total approved budget or \$250,000, whichever is less, for the period of performance. These extensions are not competitive. Approving a request is at the discretion of the agency and depends on availability of funds.

Supplemental Funding Extension with Change in Scope

For supplemental funding and an extension of time with a change in scope, you must submit the request at least 30 days before the period of performance ends. The request must include the proposed revised ending date and justify both the extension and any additional funds. These extensions are not competitive. However, the HHS agency will conduct a merit review and will have to internally justify the award.

Transferring Major Work to A Subrecipient

Non-Pass-Through Programs

For these awards, you have a substantial project role and cannot just be a conduit for another party.

Before transferring major or substantive work to a subrecipient not in the approved application, you must get prior approval. This does not apply to buying or obtaining regular goods or services.

When asking for prior approval, include:

- What activities or tasks you want to transfer.
- Why a third party should do them.
- A detailed cost estimate and reasons, including any indirect costs and their reimbursement method.
- How you'll choose the subrecipient.
- The type of subaward planned.
- The types of organizations you'll solicit. If you've already chosen one, name it and explain why.

Pass-Through Recipient

A pass-through recipient means a non-Federal recipient that provides a subaward to a subrecipient to carry out part of a Federal program. In a pass-through program, the recipient:

- Chooses subrecipients to deliver services.
- Coordinates and oversees their activities
- Gives needed administrative support to meet awarding agency requirements.

For these programs, you don't need prior approval to give a subaward.

Change in Recipient or Recipient Status

The following section addresses policies for changes in recipient organization, scope, status of key personnel, and organizational status.

Change of Recipient Organization

To transfer the legal and management responsibility of an award to another organization, you must get prior approval.

The awarding agency must ensure the award's purpose and scope remain the same and the transfer aligns with federal appropriations laws and the statute or authority for the underlying award.

HHS allows transfer to a new recipient organization if:

- The award to be transferred has been terminated per 45 CFR § 75.372.
- There is a successor in interest or name change. Please contact your GMS for more information about the difference between these two.
- The awarding agency holds back a non-competing continuation award for reasons other than the project's performance. This can relate to the recipient's award management or not meeting terms and conditions.
- The original recipient agrees to give up the award before the period of performance ends. This can happen if a PI moves to a different organization. The project, with the same PI, can continue up to the current period of performance but not beyond.
 Costs cannot exceed the approved direct and applicable indirect costs.

Send your request as soon as possible before the end of the approved budget period within the period of performance.

If you want a change in organization, you must get prior approval from the GMS and sometimes, the Office of General Counsel. Contact the GMS if you believe the award needs to go to a new organization, ideally a few months ahead. Early requests enable important discussions, smooth review of the request, and avoid delays.

Supporting Documentation Needed for Requests

From the original organization:

- The PHS 3734, "Official Statement Relinquishing Interests and Rights in a Public Health Service Research Grant," or an equivalent form from the awarding agency.
- For research awards, include a "Final Invention Statement and Certification."
- A final Federal Financial Report within 120 days after the end of HHS support.

From the proposed new organization, the awarding agency will request an application and will provide instructions for completing the application.

Requirements for Review and Possible Approval

Transfer requests are only considered when:

- All benefits of the original award, including equipment purchased fully or partly with award funds, are transferrable;
- The awarding agency decides there is a continued need;
- There is no change in the project's scope. If there is, it may need a merit review and possibly a different procedure;
- The facilities and resources at the new organization will allow for successful performance; and,
- For transfers to or between foreign or international organizations, any special approval requirements are met. This might include approval by an advisory council or board.

Even if the requirements above are met, the HHS agency may reject the request or terminate the award.

To implement a recipient change, the HHS agency:

- Sends a revised NoA to the original recipient, updating the budget and end dates;
- Removes any support for future years;
- Deobligates any remaining funds, based on the expenses from the relinquishing statement; and,
- Issues an NoA to the new recipient, reflecting the balance from the relinquishing statement.

Change in Scope

The PI/PD may want to make changes in the methodology, approach, or other aspects of the project that do not change the scope. The GMS must give prior approval for a proposed change in scope.

A change in scope occurs when the recipient proposes to change the objectives, aims, or purposes identified in the approved application. This might include:

- Shifting the research emphasis from one disease area to another;
- Changing the service area;
- Eliminating a primary care delivery site; or,
- Making budget changes that cause a project to change substantially.

The HHS agency makes the determination of whether a proposed change is a change in scope.

Change in Status of Key Personnel

Key personnel include the PI or PD and any other key personnel named in the NoA.

Provide written request to the GMS if any key personnel:

- Withdraw from the project entirely;
- Are absent from the project for a period of three months or more; or,
- Reduce time devoted to the project by 25 percent or more from the approved level.

The awarding agency must approve replacement of key personnel, or any alternate arrangement proposed.

A request for approval to substitute key personnel includes:

- A justification for the change
- The proposed person's biography
- Other sources of support, if applicable
- Any budget changes resulting from the proposed change

If your proposed arrangements are not acceptable to the awarding agency, they may suspend or terminate the award. If unable to make suitable arrangements, you may relinquish the award. To do so, notify the GMS in writing. The GMS will forward closeout instructions.

Change in Organizational Status

You must inform the awarding agency ahead of time about specific changes in your organizational status to ensure a smooth transition and maintain compliance with administrative requirements. The following are the situations that require prior notification:

- Successor-in-interest: This happens when the obligations and rights of an award are acquired as a part of the transfer of assets. Common causes include legislation or legal actions such as mergers or shifts in corporate structure.
- Name change: This occurs when an organization changes its name, but it doesn't affect the rights or obligations of the award recipient.

- Merger: This is when two or more entities legally unite. Handling of this scenario depends on its nature:
 - If the merger results in the transfer of awards, use the policies for a successor-in-interest.
 - o If the merger doesn't involve award transfers, it's treated as a name change.

If the change would be considered a change of recipient organization as discussed above, then you must obtain prior approval.

For any change in organizational status, ask your GMS. This agency is usually the one that has granted you the most awards. The GMS can clarify whether the change will be treated as a name change or a successor-in-interest and guide you on the necessary steps to follow.

Financial Management

You must meet the standards and requirements for financial management systems in <u>45 CFR § 75.302</u>. You must have adequate internal controls and a way to manage your award consistent with Department of the Treasury requirements. See the Payment section of GPS.

Financial management systems must:

- Provide accurate, current, and complete financial information about federal awards.
- Provide reasonable procedures to ensure that subaward recipients submit timely financial reports.
- Maintain records that:
 - o Identify the sources of funds for award-assisted activities
 - Identify the award's purposes and uses, including authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and any program income
 - Include accounting records supported by source documentation, such as canceled checks, paid bills, payrolls, and time and attendance records
 - Maintain effective control and accountability for all cash, property, and other assets under the award; adequately safeguard them; and ensure that they are used only for authorized purposes.
 - Compare actual expenditures with the approved budget amounts for the award.
 - Include written procedures to implement the requirements of 45 CFR § 75.305.
 - Include written procedures for determining the allowability of costs in accordance with <u>45 CFR part 75</u>, <u>subpart E</u>.

Deficiencies in your financial management system may result in specific award conditions or increased monitoring.

States must expend and account for funds according to state laws and procedures for the state's own funds and ensure compliance with all the requirements above.

Payment

You accept an award and its terms and conditions by drawing down or requesting award funds from the designated HHS payment system or office.

HHS generally makes award payments through the Payment Management System (PMS). HHS grant payments are generally advance payments. You should draw down funds as often as needed.

In accordance with Department of Treasury regulations, you must draw federal cash only for your immediate needs. At time of draw down, you will certify you will not hold cash beyond three working days. You are responsible for knowing when funds are deposited into your bank account so that you can disburse them on time. You may end up with excess Federal cash on hand if you do not disburse or return funds on time. Do not request cash to cover unliquidated encumbrances, obligations, or accrued expenditures until payment is pending.

Refer to the <u>Payment Management System (PMS) website</u> and <u>PMS User Guide | HHS PSC FMP Payment Management System</u> for further guidance.

Types of Payment

As noted, HHS grant payments are generally advance payments. There are multiple ways to receive payments, including SMARTLINK II/ACH, CASHLINE/ACH, and cash request.

- SMARTLINK II/ACH: directly deposits funds to your bank account after you request them from PMS. You must have Internet access to submit a request for funds to PMS. This method makes funds available the day after the request using the Federal Reserve Bank's Automated Clearinghouse process.
- CASHLINE/ACH: directly deposits funds to your bank account using a telephone to call a "voice-response" computer at PMS. Makes funds available the day after the request with direct deposit using the Federal Reserve Bank's Automated Clearinghouse process.
- Cash request: provides payment if you are not eligible for unrestricted advance of funds. It will say in the NoA if you must use cash requests for payment. Cash requests may be an advance or reimbursement.

You may request funds monthly for advance payments. This request should be based on expected disbursements for following month and the amount of Federal funds already on hand.

A request for reimbursement may be submitted more often than monthly. You should submit requests to the awarding agency at least 2 weeks before the cash is needed. PMS makes payment electronically through the ACH process upon receipt of the approved payment request from the agency.

Refer to the <u>Payment Management System (PMS) website</u> and <u>PMS User Guide | HHS PSC FMP</u> Payment Management System for further guidance.

Interest Earned on Advances of Award Funds

You must keep advance payments in interest-bearing accounts, except as provided in $\underline{45 \text{ CFR } \S}$ $\underline{75.305(b)(8)}$. You can keep interest earned up to \$500 per year for administrative expenses. Each year, you must remit any interest earned over \$500 per year to the Payment Management System.

Indirect Costs

Indirect Cost Rate Negotiation and Salary Rate Limit (SRL) Policy

Please see Indirect Cost Rate Negotiation and SRL Policy in the Application Section.

New or Amended Indirect Costs

The GMO may permit new or increased indirect costs on an award when:

- A timely cost proposal was not received.
 - O This can happen only if funds are available.
 - The amount is limited to the period after the effective date of the rate agreement.
- Rebudgeting changes a direct cost, which impacts an indirect cost.
 - The recipient may adjust the budget within the award ceiling and generally does need prior approval. See the Prior Approvals section of GPS.
- The indirect cost rate changes.
 - Generally, award amounts will not be adjusted based on a negotiated indirect cost rate different from that used at award.
 - However, if funds are available, a GMO may provide additional funds for indirect costs, only if:
 - An error was made in computing the award. This includes when a higher rate is negotiated after award and the date of the new rate agreement is within a month prior to the budget period start.
 - The awarding agency restores funds previously recaptured as part of an unobligated balance.
 - The recipient is eligible for additional indirect costs associated with additional direct costs awarded, such as a supplemental award.
 - A provisional rate was approved, and an approved indirect cost rate is now in effect.
 - The permanent rate will be used to determine indirect cost reimbursement, however:

- If the permanent rate is lower than the provisional rate, the award will not be adjusted downward, unless the indirect cost proposal included unallowable costs.
- The awarding agency is not required to provide new funds to accommodate a higher rate.

Applicable Credits

Applicable credits are funds saved or received that can reduce costs. Common examples include:

- Discounts
- Rebates
- Refunds for losses
- Corrections for overcharges

If you have any of these credits, you need to update the Federal Financial Report (FFR) to ensure that the proper amounts are charged to the award. If there are any extra steps, the awarding agency will let you know.

See 45 CFR § 75.406.

Allowable Costs and Activities

Allowable costs are either a direct cost or an indirect cost, and:

- Meet the applicable cost principles, including all the following:
 - Meet the factors affecting allowability. See 45 CFR § 75.403.
 - Are reasonable. See 45 CFR § 75.404.
 - Are allocable. See 45 CFR § 75.405.
 - Are allowable under the NOFO, program requirements, and NoA, including specific conditions and overall terms and conditions.
- Are specifically approved in the award, which means either:
 - The cost was included in the original award.
 - The cost is later approved by the awarding agency. See the Prior Approvals section of GPS.

Contact the GMS before incurring a cost if you have questions about allowability.

Subrecipients and contractors under the award must follow the requirements of their applicable cost principles.

Costs that Require Prior Approval

If you specifically describe a cost or activity that requires prior approval in your application budget, that cost is approved by the agency when you receive your award unless otherwise stated in the NoA. You do not need to get additional prior approval for that cost or activity.

You must get prior approval from the agency if you do not describe the cost or activity that requires prior approval in your application.

Profits and Fees

HHS will not provide profits or fees, except for the Small Innovation in Research (SBIR) and the Small Business Technology Transfer (STTR) Programs.

You can't pay fees to subrecipients or consortium members, even if they are for-profit.

Contractors can make a profit for common goods or services in accordance with normal commercial practice. See 45 CFR § 75.351.

Expenditure Adjustments

Expenditure adjustments are used to correct accounting or bookkeeping errors. These adjustments move costs between two budget categories, with at least one related to the HHS award. Once the error is found, it must be corrected within 90 days. If after 90 days, you must ask the GMO for approval.

Don't use expenditure adjustments to cover cost overruns or for unallowable costs.

Documentation

The adjustment must be supported by documentation that fully explains how the error occurred. Documentation must:

- Explain how the error happened and have an official from your organization certify the correction.
- Show how the adjustment meets the cost principles of allowability, allocability, and reasonableness.
- Support why the adjustment is needed, considering the type of cost, the original charge, and when it was first recorded.

Unless the expenditure adjustment needs GMO approval, you don't need to send the documentation to the GMS. Keep records for monitoring or audits. See <u>45 CFR § 75.364</u>.

Send a revised Federal Financial Report (FFR) if the adjustment changes your previous FFR.

Your financial system should catch errors quickly. Regular mistakes suggest you need to improve your accounting or internal controls. Agencies might ask for corrective actions or add terms and conditions to your award.

Rate of Expenditure and Drawdowns

Expenditure and drawdown rates give information about progress, financial management, and internal controls.

Expenditures

The GMS monitors spending rates within each budget period and throughout the period of performance.

The funds for each budget period are based on:

- the work planned for that time
- your budget, including any unobligated funds

HHS expects spending rates and types to match the approved plan and budget.

Drawdowns

The GMS checks drawdown patterns to see if money is taken out too early or too slowly. This can show:

- problems with your financial management system or internal controls
- risk of not finishing the project on time and within budget

If issues are found, the GMS will ask for more details and help you make corrections, which may include coordinating with the agency PO and GMS.

Cost Allocation

If a cost benefits more than one project or activity, divide the cost based on the benefit to each project.

If it is hard to determine the split because the projects are closely linked, distribute the costs on a reasonable basis with clear and documented explanations.

Treatment of Unobligated Balances

Unobligated balances are funds under an HHS award that you have not obligated. You calculate this by subtracting the cumulative amount of funds obligated from the cumulative amount of funds authorized.

Unliquidated obligations are commitments you have made, but not yet paid. Unliquidated obligations should not be reported as part of an unobligated balance.

If you have unobligated balances in your annual FFR, the awarding agency can:

- Carry Over: Revise the NoA to carry over to a following budget period.
- Offset: Move them to the next budget period but deduct the total from the award amount.
- A Mix: Use a mix of carry over and offset.

During an active budget period, if you have unobligated balances from a previous budget period, you can ask the awarding agency in writing to use them. If approved, the awarding agency will amend the NoA. If approved, funds carried over can be used for costs within scope of the project.

Program Income

Program income is gross income earned by an award recipient, subrecipient, or contractor and directly generated by an award-supported activity or earned as a result of the award.

Program income includes:

- fees for services
- charges for the use or rental of real property, equipment, or supplies bought with the award
- the sale of products made under an award
- charges for research resources
- license fees and royalties on patents and copyrights

The NoA governs the use of royalties and other income earned from a copyrighted work, patents, patent applications, trademarks, or inventions.

Accountability

Accountability refers to whether the awarding agency specifies how the program income is to be used, if the income needs to be reported to the awarding agency, and for what length of time. The following general policies apply:

- Unless otherwise specified in the award terms and conditions, you are not accountable for program income earned after the period of performance ends.
- Program income may be used only for allowable costs using the applicable cost principles and award terms and conditions.
- Subawards and contracts are subject to the same terms regarding generated income as the recipient. The following policies apply related to when the program income is earned:
 - Received and expended during the period of performance. Recipient is required to use program income as provided in the NoA.
 - Received and expended after the period of performance. Required to adjust the final FFR to reflect receipt and use of the income as directed by the GMO.
 - Received during the project period but expended after the period of performance. This may happen if you earn the income during the final budget period of the period of performance, please get GMO approval to use income post final budget period and adjust the final FFR accordingly.

Alternatives for Use

The NoA will tell you how to use program income. Here are the alternatives:

- Additive: Add it to the project's funds to further allowable objectives. Program
 income must be used for the purposes and under the conditions of the award.
- Deductive: Deduct it from the project's total costs and reduce federal funds and recipient cost-sharing contributions.
- Combination: Uses the additive alternative for program income up to \$25,000 and the deductive alternative for any amount over \$25,000.

Matching: Use it as all or part of the non-federal (matching) part of an award.

See 45 CFR 75.307(e) for more information.

Generally:

- For non-research projects: If not specified in the NoA, use the deductive method.
- For research projects (except for awards to for-profit organizations other than the SBIR and STTR programs): If it is not specified, use the additive method.

Reporting of Program Income

Recipients must report the amount of net program income earned and expended on the FFR. This is the gross program income earned minus the costs associated with generating the income.

- Report program income using the additive alternative on line 10n, which will populate line 10o.
- Report program income using the deductive alternative on line 10m, which will populate line 10o.
- Report program income used to satisfy match on line 10j. Do not include it on line 10l.

Reporting requirements for accountable income earned after award support ends are in the NoA.

Cost Sharing

Cost sharing — or matching — is the portion of project costs not paid by federal funds, unless otherwise authorized by federal statute. This may include:

- The value of allowable third-party in-kind contributions.
- Non-award funded expenditures made by the recipient.

See 45 CFR § 75.306 for rules on cost sharing or matching.

The following policies apply:

- Cost sharing may be voluntary or required by the NoA.
- Required cost sharing is part of the total approved budget in the NoA. It is part of the award requirements and enforceable.
- Cost sharing must follow the same requirements as the federal portion of the budget. This includes applicable cost principles, prior approval requirements, and other rules for allowability.
- Recipients may apply program income toward cash match only when expressly permitted by the NoA with prior approval.
- All cost sharing contributions must be from allowable sources. See 45 CFR § 75.403,
 45 CFR § 75.404 and 45 CFR § 75.405

• For research awards:

- Voluntary cost sharing is not expected under research proposals.
- Voluntary cost sharing cannot be used as a factor during merit review of research applications unless explicitly described in the NOFO review criteria.
- Only mandatory cost sharing or cost sharing committed in the budget must be included in your research base for computing your indirect cost rate or reflected in allocating indirect costs.

The awarding agency will accept shared costs or matching funds, including cash and third-party in-kind contributions, when they meet all the following:

- follow 45 CFR § 75.306(e) for volunteer services
- are verified from the recipient records
- are necessary and reasonable to accomplish project objectives
- are provided for in the approved budget when required
- are not paid by the federal government under another federal award, unless specifically allowed by law. See 45 CFR § 75.306(b)(5)

The following policies apply:

- Sources of cost sharing or matching contributions must follow the applicable cost principles. See 45 CFR part 75, subpart E.
- If an awarding agency authorizes the recipient to donate buildings or land for construction or facility acquisition or long-term use, the value of the donated property for cost sharing or matching is generally the lesser of:
 - the value of the remaining life of the property recorded in the recipient's accounting records at the time of donation
 - the current fair market value

See 45 CFR § 75.306(d).

- You must document in your records all costs and contributions used to satisfy a matching or cost-sharing requirement. These are subject to audit.
- You may use unrecovered indirect costs to satisfy cost sharing requirements with prior approval. These are the difference between the amount charged to the award and the amount that could have been charged to the award under the recipient's approved negotiated indirect cost rate.
- A third-party in-kind contribution to a fixed-price contract may count towards satisfying a cost sharing or matching requirement only if either:
 - it is an increase in the services or property provided under the contract without added cost to the recipient or subrecipient, or
 - o it is a cost savings to the recipient or subrecipient.

If the NOFO specifies that matching or cost sharing is required, it will also say:

- Whether including matching or cost sharing in the application is an eligibility requirement or an evaluation criterion.
- The nature of the requirement. For example, whether it is a fixed percentage.
- Required documentation, like letters of commitment.

Valuation of Volunteer Services

Anyone offering skilled or manual work can volunteer for award-related activities. See 45 CFR § 75.306(e)-(f).

To value the services:

- For individuals:
 - Use the usual rates your organization pays or area market rates for similar work.
 - o If you do not have a set rate, use the typical local rate for that work.
 - You can also add a fair amount for fringe benefits.
- For employees lent by other companies:
 - Use their regular rate if they are doing their typical job.
 - Use the method for individuals if they are doing something different.

Valuation of Donated Buildings and Land

If an awarding agency authorizes you to donate buildings or land for construction or facilities acquisition projects or long-term use, the value of the donated property for cost sharing must be the lesser of the following:

- the value of the remaining life of the property
- the current fair market value

See 45 CFR § 75.306(d), (h), and (i).

Enforcement

If you do not meet the specified level of cost sharing in the NoA, an awarding agency may do any or all of the following:

- reduce the award amount
- adjust down award funds during the budget period
- disallow costs post award

Procurement Management

You may acquire goods or services in support of award activities. The following policies apply when procuring property and services under an award:

- States must follow the same policies and procedures it uses for non-federal funds. Follow the requirements at 45 CFR § 75.326.
- All other recipients and subrecipients of a state must follow the procurement standards in 45 CFR §§ 75.327 through 75.335.

In order to procure goods and services, you must:

- Have written procurement procedures and standards of conduct that reflect applicable state, local, and tribal laws and regulations,
- Use a procurement method
- Do a cost or price analysis for all procurements above the simplified acquisition threshold
- Choose responsible contractors
- Follow all requirements in this section of the GPS

The HHS awarding agency has no direct relationship with your contractor.

Recipients other than federal institutions cannot use General Service Administration (GSA) supply sources except states who may acquire hardware and software from the GSA supply sources consistent with the terms and conditions of the GSA schedule.

Fixed Amount Subawards

With prior written approval from the GMO, you may provide subawards based on fixed amounts up to \$500,000 (2 CFR § 200.333). Fixed amount subawards must meet the requirements for fixed amount awards in 45 CFR § 75.201.

Requirements for States

States may follow the same policies and procedures for procurements using non-federal funds. States will comply with $\underline{45 \text{ CFR} \S 75.331}$ and ensure that every purchase order or other contract includes any clauses required by $45 \text{ CFR} \S 75.335$.

States may acquire hardware and software from Federal Supply Schedules consistent with the terms and conditions of the schedules.

State agencies or agencies that are political subdivisions of states must comply with <u>section 6002 of the Solid Waste Disposal Act as amended by the Resource and Conservation Act</u>. The requirements include:

- Procuring only items noted in guidelines of the Environmental Protection Agency (EPA) at 40 CFR § 247 that contain the highest practical percentage of recovered materials.
- Keeping an acceptable level of competition, where the purchase price of the item is more than \$10,000 or the value of the amount acquired during the previous fiscal year was more than \$10,000.
- Procuring solid waste management services to maximize energy and resource recovery.
- Establishing an affirmative procurement program for procurement of recovered materials identified in the EPA guidelines.

Requirements for Foreign Entities

The HHS awarding agency may require a review of all proposed procurements exceeding a certain dollar amount or for certain types of services. The HHS awarding agency may also add specific terms and conditions to its awards that address the procurement of such goods and services.

Selecting Responsible Contractors

You must avoid acquiring duplicate or unnecessary services or goods. You should use the most efficient strategy for acquisition. You should use federal excess and surplus property whenever possible to reduce project costs. You must award contracts based on factors like:

- Integrity
- Compliance with public policy
- Past performance
- Financial and technical resources

System for Award Management (SAM) Eligibility

You must check the System for Award Management (<u>SAM.gov</u>) to make sure that you do not make a subaward or contract to a debarred, suspended, or ineligible organization. SAM needs to be checked:

- By the recipient organization:
 - o for all first tier subawards, regardless of the amount
 - o for all first-tier procurement contracts of \$25,000 or more
 - o for all lower tiers of contracts under covered non-procurement transactions. See <u>2 CFR § 376.220</u>.
- By the subaward recipient for all lower tier subaward recipients.

Written Agreements

You must execute a written agreement between your organization and the subrecipient, if applicable. The agreement must include all the following:

the activities to be performed

- time schedule
- the provisions required by 45 CFR § 75.335 and found in 45 CFR part 75, Appendix II.
- policies and requirements that apply to the contractor, including 45 CFR § 75.327 and other relevant award terms and conditions
- maximum amount of funds to be awarded
- cost principles to be used in determining allowable costs for cost-type contracts

The following policy applies:

• The agreement must not affect your overall responsibility for the project or accountability to the federal government.

Subrecipient Periods of Performance - Contracts

If the term of the contract and the award budget period are not the same, you may charge the contract costs to the budget period in which the contract is executed even though some of the services will be performed in a later period. These conditions apply:

- You must notify the awarding agency.
- The expected contract performance period goes beyond the current budget period.
- You have a legal commitment to settle all contractual and administrative issues. See 45 CFR § 75.327(k).
- Only costs for services provided during the period of performance are allowable.
- For rental costs for facilities and equipment charge the applicable amount in each budget period as applicable. Contact the GMS before entering into leases that will result in direct charges to the award.

To limit liability, recipients should insert a clause in contracts less than \$100,000 that states that payment after the end of the current budget period is contingent on continued federal funding.

Time and Materials Contracts

Time and materials contracts may only be used if:

- there is no other appropriate contract type
- the contract includes a ceiling price that the contractor exceeds at its own risk
- the direct hours are fixed and include wages, general and administrative expenses, and profit

Procurement Methods

You must use one of the following methods of procurement:

- Micro-purchases
- Small purchase procedures
- Sealed bids
- Competitive proposal

Noncompetitive proposal

Micro-purchase procurements are the acquisition of supplies or services when the total dollar amount is less than the micro-purchase threshold (\$50,000). To the extent possible, you must distribute micro-purchases equitably among qualified suppliers. Micro-purchases do not require soliciting competitive quotations if cost is reasonable.

Small purchase procurements involve simple procurement methods for securing services, supplies, or other property less than the Simplified Acquisition Threshold (\$250,000). Non-federal entities must obtain price or rate quotes from sufficient qualified sources.

Sealed bid procurements require public solicitation for bids, leading to a firm fixed price contract (lump sum or unit price) given to the bidder whose bid is the lowest in price and complies with all material terms and conditions.

Competitive proposals usually involve more than one source sending an offer. A fixed price or cost-reimbursement type contract is awarded. It is generally used when sealed bids are not appropriate. You must adhere to the following requirements when using this procurement method:

- Requests for proposals must be publicized and identify all evaluation factors and their relative importance. Any response to publicized requests for proposals must be considered to the maximum extent practical.
- Proposals must be solicited from an adequate number of qualified sources.
- You must have a written method for technical evaluations of the proposals and for selecting bids.
- Contracts must be awarded to the responsible firm whose proposal is best for the program.

You can also use the competitive proposal procedures for qualifications-based procurement of architectural/engineering (A/E) professional services. Applicant qualifications are evaluated and the most qualified competitor is selected, subject to negotiation of fair and reasonable compensation.

Non-competitive proposals solicit a proposal from a single source. You may only use this method when the item is only available from a single source or in the event of a public emergency to expedite the acquisition, or when there is inadequate competition for a product, material, or service. You can get approval for non-competitive proposals from the GMO or his/her delegate.

Upon request, you are required to undergo a pre-procurement review and submit procurement documents to the HHS awarding agency or pass-through entity when:

- Your procurement procedures or operations do not comply with the procurement standards required by those regulations.
- The procurement is expected to exceed the Simplified Acquisition Threshold and is to be awarded without competition, or only one bid or proposal is received in response to a solicitation.
- A procurement that will exceed the Simplified Acquisition Threshold specifies a "brand name" product.

- A proposed award over the Simplified Acquisition Threshold is to be awarded to other than the apparent low bidder under a sealed-bid procurement.
- A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount considered to be a simplified acquisition.
- When prior written approval is required, the non-federal entity must make available sufficient information to enable review. This may include, at discretion, presolicitation technical specifications or documents, such as requests for proposals or invitations for bids, or independent cost estimates. Approval may be deferred pending submission of additional information by the non-federal entity or may be conditioned on the receipt of additional information. Any resulting approval does not constitute a legal endorsement of the business arrangement by the federal government nor does such approval establish the HHS awarding agency as a party to the contract or any of its provisions.

Written Standards of Conduct and Conflict of Interest

Recipients must maintain written standards of conduct covering conflicts of interest. Individuals affiliated with a recipient organization cannot participate in the selection, award, or administration of a contract supported by a federal award if they have a real or apparent conflict of interest with:

- Employees
- Officers
- Agents
- Immediate family members, spouses, or partners
- Potential employer

These individuals are prohibited from soliciting gratuities, favors, or anything of monetary value from subrecipients. However, recipients may set standards for situations where financial interest is not

agency for utilization using the SF-428-B (final) or SF-428-C (disposition). The recipient will receive disposal instructions from the HHS awarding agency.

Revocable License

In some cases, federally owned property may be made available to a recipient under what is called a "revocable license agreement." This agreement means the HHS awarding agency allows the recipient to use the property for the period of the award under the following conditions:

- The title to the property remains belongs to the federal government;
- The HHS awarding agency reserves the right to require the property to be returned to the should it be determined to be in the best interests of the federal government to do so:
- The use to which the non-federal entity puts the property does not permanently damage it for federal government use; and,
- The property is controlled and maintained in accordance with the requirements of the NoA.

Equipment

Equipment is tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit purchase cost which equals or exceeds the lesser of the capitalization level established by the recipient for financial statement purposes, or \$10,000.

Please see the general requirements under <u>45 CFR § 75.320</u> and <u>45 CFR § 75.439</u> for how to manage and track equipment. Unless a statute specifically says the recipient should own the title for equipment without further obligation to the HHS awarding agency, the title must be a conditional title. Under this conditional title, the recipient must:

- Use the equipment for the authorized purposes of the project during the period of performance, or until the property is no longer needed for the purposes of the project; and,
- Not restrict the use of the equipment without approval of the HHS awarding agency.
- Subject to disposition instructions provided by the HHS awarding agency, use the equipment in the project it was acquired in as long as needed, whether or not the project continues to be supported by the federal award.

Important Property Reminders

- You must classify equipment that will be permanently attached or fixed to the land as real property.
- States must use, manage, and dispose of equipment acquired under a federal award by the state in accordance with state laws and procedures.
- Real property constructed or renovated with award support may not be conveyed, transferred, assigned, mortgaged, leased, or in any other manner encumbered by the recipient, except as expressly authorized in writing by the awarding agency.

- If you default on a mortgage, you must immediately notify the GMS by telephone and in writing. If the mortgage holder intends to foreclose, you must notify the GMS in writing at least 30 days before the foreclosure action is initiated.
- The mortgage agreement must specifically allow, in the case of default, that HHS or its designee may assume the role of mortgagor (borrower) and continue to make payments.

Insurance

You must insure property and equipment acquired or improved under an award. The following policies apply:

- You must provide the same insurance coverage for property under an award as you
 do for other such property.
- You don't need to insure federally owned property unless required by the award terms and conditions.
- If your organization is a government agency, you may follow your own insurance requirements.
- If title to real property bought with award funds vests with your organization, you must provide the following minimum insurance coverage:
 - O Title insurance policy covering the fee interest in the real property for an amount not less than the full appraised value of the property, even if federal support is partial.
 - Physical destruction insurance policy covering the full appraised value of the facility from risk of partial and total physical destruction, even if federal support is partial.
 - You must maintain the insurance policy for the duration of the federal interest in the property.

Within five days of completion or beneficial occupancy, you must submit a written statement signed by the AOR to the GMS. This statement must assure that you have purchased the required insurance policies and will maintain the insurance coverage as required above.

Self-Insurance

The awarding agency may waive one or both of the requirements above if you are effectively self-insured. If you claim self-insurance, you must provide the awarding agency an assurance that includes:

- A statement that you meet the definition of effectively self-insured. This means that
 you have sufficient funds to pay for any damage to the facility, including total
 replacement, or to satisfy any liens placed against the facility.
- The source of the funds, such as the organization's endowment or other special funds set aside for this purpose.

See 45 CFR § 75.447.

Notice of Federal Interest for Construction, Acquisition, and Modernization

A Notice of Federal Interest (NFI) is required for construction, acquisition, and modernization, except for Minor A&R. The non-federal entity (or owner, if other than the non-federal entity) must file an NFI prior to initiating construction or modernization, or when an existing facility or land is acquired with federal funds. The non-federal entity must:

- Record the NFI by the owner in the appropriate public records of the jurisdiction where the property is located. Associated fees are allowable costs.
- Provide a copy of the NFI to the HHS awarding agency.
- Accurately indicate that the property was constructed, acquired, or modernized with HHS awarding agency funds and, that during its useful life of the facility, as defined in the NFI, the HHS awarding agency's use and disposition requirements apply.
- Seek review by the HHS awarding agency to make sure it is acceptable.

The federal interest may not be conveyed, transferred, assigned, mortgaged, leased, or otherwise be encumbered or subordinated by a non-federal entity unless approved by the HHS awarding agency.

Property and Equipment Disposition

According to 45 CFR § 75.318(c), you must request disposition instructions from the awarding agency when:

- Property under the award is no longer needed for the intended purpose or you will
 not be using the property for other activities currently or previously supported by an
 awarding agency.
- Federal statutes, regulations, or awarding agency disposition instructions in the NoA do not say otherwise.

Equipment

Unless the NoA or HHS awarding agency instructions say otherwise, you must dispose of the property as follows, in accordance with awarding agency disposition instructions:

- Retain, sell, or dispose of equipment items with a current fair market value of \$10,000 or less, with no further responsibility to the government. See <u>2 CFR §</u> <u>200.313(e)(1)</u>. The provision also clarifies that Indian Tribes may use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.
- Retain or sell equipment items with a current fair market value over \$10,000. The following apply:
 - You pay the awarding agency the current fair market value according to the percentage of the federal share in its original cost.

- If sold, the awarding agency may allow you to deduct the lesser of \$500 or ten percent of the proceeds from the federal share.
- If you organization is a non-profit institution of higher education or nonprofit organization with a principal purpose of scientific research, you are exempt from any requirement to account for proceeds from a sale.
- Transfer property title to the federal government or an eligible third party. You are entitled to compensation for its share of the current fair market value.

Supplies

Your organization is assigned the title to supplies when you acquire them. If you have more than \$10,000 in supplies after the award is terminated or project is completed, you must retain the supplies for use on other activities, or sell them, and then compensate the federal government for its share. See 2 CFR §200.314.

Modernization of Real Property

Modernization includes both major and minor alterations and renovations (A&R) unless otherwise stated. Modernization is not an allowable cost under the following:

- Federal awards to individuals
- Conference awards

You may not perform major A&R using federal funds or required matching or cost sharing unless

- There is specific statutory authority, and
- The NoA explicitly allows it.

Minor A&R is an allowable cost under all types of awards with prior approval under the following criteria, unless restricted in the NOFO or NoA:

- The governing statute or program regulations do not exclude it.
- The work is required to use the space more effectively to meet the program needs.
- The building has a useful life consistent with the project and is architecturally and structurally suitable for conversion.
 - If you own the property, it has a useful life consistent with the project.
 - o If you lease the property, the terms and length of your lease are consistent with the project.
- Work and costs to get an initial occupancy permit is not an allowable cost. Costs must be for purposes other than human occupancy (e.g., storage).
- If the building is under construction or the A&R will take place in an incomplete structure, the costs are only allowable if:
 - It is cost-effective to perform the A&R while the building is under construction or being completed, and

- Minor A&R costs are limited to the difference between the cost of completing the interior space for general use and the cost of adapting it for the federal award supported purpose.
- The space involved will be occupied by the project.
- National Environmental Policy Act (NEPA) and the National Historic Preservation Act (NHPA) requirements are followed, as applicable.

The following are not considered minor A&R:

- Costs associated with routine maintenance, painting, and repair of facilities or equipment that are normal business costs and generally charged as indirect.
- Certain costs of installing equipment, such as the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization, unless the non-federal entity's accounting system considers these modernization costs rather than equipment costs.
- Costs of furnishings and movable equipment.

Federal Interest Involving Construction and Modernization of Leased Property

You must make sure any leased property that you propose construction or modernization costs for has a long enough lease for the full value of the federal award supported improvements to benefit the award activity and support the expected useful life of the facility. You must submit additional documentation to the HHS awarding agency in these cases:

- You must submit lease language to the HHS awarding agency prior to drawing down funds or being reimbursed.
- The property owner must consent to the proposed work, acknowledge federal interest in the property, and file a Notice of Federal Interest (NFI), if required. The lease must include, or be amended to include:
 - Your full use of and access to the leased property during the term of the lease.
 - Your agreement not to sublease, assign, or otherwise transfer the leased property, or use the property for a non-federal award-related purpose(s) without the written approval of the HHS awarding agency (at any time during the term of the lease, whether or not federal award support has ended).
 - That the lessor will inform the HHS awarding agency of any default by the non-federal entity under the lease.
 - The HHS awarding agency has 60 days from the date of receipt of the lessor's notice of default in which to attempt to eliminate the default, and that the lessor will delay exercising remedies until the end of the 60-day period.

- The HHS awarding agency intervening to ensure that the default is eliminated by the non-federal entity or another non-federal entity named by the HHS awarding agency.
- The lessor accepting payment of money or performance of any other obligation by the HHS awarding agency's designee, for the non-federal entity, as if such payment of money or performance had been made by the non-federal entity.
- If the non-federal entity defaults, the federal award is terminated, or the non-federal entity vacates the leasehold before the end of the lease term, the HHS awarding agency has the right to designate a replacement for the non-federal entity for the balance of the lease term, subject to approval by the lessor in a separate agreement with HHS, which will not be withheld except for good reason.
- Documentation of a NFI for the leased property (if required).

Intangible Property

Intangible property is property having no physical existence. These may include:

- trademarks, copyrights, patents, and patent applications
- property, such as loans, notes, and other debt instruments; lease agreements; stock; and other instruments of property ownership

Intellectual Property

HHS expects you and your PIs and PDs to make your award results and accomplishments available to the research community and the public. If the research results in inventions, the Bayh-Dole Act of 1980 and 37 CFR part 401 apply. If you follow these requirements, you have the right to retain title to any invention conceived or first actually reduced to practice.

The law and regulation promote:

- commercialization of federally funded inventions.
- free competition and enterprise without restricting future research and discovery.

The law and regulation require recipients to:

- Make efforts to develop and commercialize the technology to advance to industry for development.
- Make unpatented research products or resources available through licensing to vendors or other investigators.
- Share copyright-protected research outcomes in journal articles or other publications.

Irrevocable and Royalty-Free License

Except as otherwise provided in the NoA, you may assert copyright in any publications, data, or other copyright-protected work developed under an award. Doing so does not require awarding agency approval.

Rights in data also extend to students, fellows, or trainees under awards with an educational purpose. In this case, authors are free to assert copyright in works.

The federal government has a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use material resulting from a supported project or program. This applies whether HHS funded all or part of the project. You are responsible for ensuring that any necessary copyrights obtained from your subrecipients also allow the material to be used by the federal government.

HHS may also extend this license to others for federal purposes. For example, to make it available in government-sponsored databases for use by other researchers. The NoA addresses the specific scope of awarding agency rights. See 45 CFR § 75.322(d), 45 CFR § 75.365.

Access to Research Data

A federal agency may use award-related research data in developing an agency action that has the force and effect of law. If so, 45 CFR 75.322(e)(1) requires recipients to release the research data to the awarding agency to support a FOIA request. See 45 CFR 75.322(e). See also:

- the definition of research data at 45 CFR § 75.322(e)(3).
- the definition of records, which includes research data at 45 CFR § 5.3.

Excluded are:

- drafts of scientific papers
- plans for future research
- peer reviews
- communications with colleagues
- physical objects (e.g., laboratory samples, audio or video tapes)
- trade secrets
- commercial information
- materials necessary to be held confidential by a researcher until publications in a peer-reviewed journal
- information that is protected under the law such as intellectual property
- personnel, medical files, and similar files, if disclosure would constitute an unwarranted invasion of personal privacy
- information that could be used to identify a particular person in a research study

If the data are publicly available, HHS directs the requester to the public source. Otherwise, the awarding agency FOIA coordinator handles the request, consulting with the recipient and the PI. The recipient may charge a reasonable fee to cover their costs to respond. HHS may do the same.

This requirement to release research data does not apply to for-profit organizations or to research data produced by state or local governments. However, if a state or local government recipient contracts with an educational institution, hospital, or non-profit organization, and the contract results in covered research data, those data are subject to disclosure.

Patents and Inventions

Inventions conceived or first actually reduced to practice under awards are governed by the Bayh-Dole Act, 35 USC 200-212, and implementing regulations at 37 CFR part 401.

The regulations at 37 CFR § 401 apply if both the following are true:

- Inventions result from federally funded research.
- Your organization or your subrecipient or contractor is a university, non-profit entity, governmental entity, or small or large business.

See iEdison for more information.

Royalties and Licensing Fees from Copyrights, Inventions, and Patents

You may commercially apply intellectual property and require payments for its use.

Unless the NoA says otherwise, you do not have to report program income earned from license fees and royalties. This includes copyright-protected material, patents, patent applications, trademarks, and inventions made under an award.

You may pay royalties to others as an allowable direct cost.

See 45 CFR § 75.448.

Invention Reporting

For information, see <u>Invention Reports at iEdison</u>. See also <u>37 CFR part 401</u>.

Seek the advice of the GMS about:

- Whether an invention made under a career development award is a subject invention
- The extramural technology transfer policy
- Reporting of inventions

Publications and Acknowledgement of Support

Publications

HHS encourages you to publish the results and accomplishments of awards. You can publish your results without prior approval. These policies apply, unless otherwise specifically addressed in your NoA:

• You may assert copyright in scientific and technical articles based on data produced under the award.

- You may transfer copyright to the publisher or others for journal publication or other professional activities.
- All copyrights, including transfers, are subject to a royalty-free, non-exclusive and irrevocable license to the federal government, and any agreement must include that the assignment is subject to the government license.
- You must account for royalties and income earned from a copyrighted work as specified by the awarding agency.
- You must submit one copy of each publication resulting from work under an award with the annual or final progress report.
- If you plan to issue a press release about award-supported activities, you must notify the awarding agency in advance to allow for coordination.

Stevens Amendment

HHS will include the following information in your NoA and NOFO. When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents – such as toolkits, resource guides, websites, and presentations – describing the projects or programs funded in whole or in part with HHS funds, the recipient must clearly state:

- the percentage and dollar amount of the total costs of the program or project funded with federal money; and
- the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

The NoA may provide further instructions and language to use.

Acknowledgement of Support

When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents – such as tool-kits, resource guides, websites, and presentations (hereafter "statements") – describing the projects or programs funded in whole or in part with U.S. Department of Health and Human Services (HHS) federal funds, the recipient must clearly state:

- the percentage and dollar amount of the total costs of the program or project funded with federal money; and,
- the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement.

• If the HHS Grant or Cooperative Agreement is NOT funded with other non-governmental sources: This [project/publication/program/website, etc.] [is/was] supported by the [full name of the OPDIV/STAFFDIV] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$XX

with 100 percent funded by [OPDIV/STAFFDIV]/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [Name of the Awarding Agency]/HHS], or the U.S. Government. For more information, please visit [Award Agency Stevens Amendment website, if available].

The HHS Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

• This [project/publication/program/website, etc.] [is/was] supported by the [full name of the HHS Awarding Agency] of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$XX with XX percentage funded by [full name of the HHS Awarding Agency]/HHS and \$XX amount and XX percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by [Awarding Agency]/HHS, or the U.S. Government. For more information, please visit [Award Agency's Stevens Amendment website, if available].

Oversight and Monitoring

Subrecipient Flow-Down Requirements

The GPS applies to subrecipients and contractors. This includes consortium agreements where the recipient collaborates with other organizations.

The terms and conditions of awards flow down to subawards and subrecipients unless a particular GPS policy or award term and condition specifically says otherwise.

You have to have a formal written agreement with each subaward recipient. You must include applicable GPS requirements in your subaward agreements. Agreements must meet programmatic, administrative, financial, and reporting requirements. At a minimum, the subaward agreement must include:

- the PI or PD and subrecipient staff responsible for the program activity, including roles and responsibilities
- program administration and monitoring procedures
- policies and process for subrecipient funding, such as allowable costs, expenditure approval, funding caps, payment method and schedule, required documentation
- travel, salaries, and fringe benefit policies and procedures
- applicable public policy requirements and applicable assurances and certifications and provisions indicating the intent of the subrecipient to comply, including submission of applicable assurances and certifications
- conflict of interest requirement
- provisions regarding property, program income, publications, reporting, record retention, and audit

Reporting

You must submit financial, performance, and other reports. Not meeting reporting requirements could result in enforcement actions. These actions include those in the Remedies for Noncompliance section of the GPS_including 45 CFR §§ 75.371-.380, and reporting to Responsibility/Qualification in SAM.gov (formerly FAPIIS).

Federal Financial Reports

You submit Federal Financial Reports (FFRs) through the Payment Management System (PMS).

How often you need to submit an FFR is in the NoA. This can range from quarterly to annually. Higher risk recipients may report more often.

Updated information on FFRs is at the **Program Support Center for PMS**.

You may need to revise your FFR in some cases. You must submit a revised FFR to HHS immediately for overcharges. You also must submit revised FFRs as soon as possible for expenditures that you did not report before. You must explain why the revision is necessary and how you will prevent this in the future. For annual FFRs, revisions are due no later than 9 months from the end date. For final FFRs, revisions are due no later than 6 months after the end date. The agency will tell you how your award will be updated if revised FFRs are accepted.

PLEASE NOTE: The GMS may not accept a revised interim FFR submitted by the recipient that claims additional expenditures after one year from the end of the reporting period (regardless of when the original report was actually submitted).

Progress Reports

You submit progress reports through <u>GrantSolutions</u> or <u>NIH eRA</u>.

The reporting schedule and requirements are in the NoA. Schedules can range from quarterly to annually. Higher risk recipients may report more often.

See 45 CFR § 75.342(b)(1).

Other Reporting

Intellectual Property Reporting

If you have a research award, you must report on patents and inventions through iEdison (<u>iEdison</u> | NIST).

Each competing continuation application and progress report (when used in lieu of a non-competing continuation application) must indicate whether or not any subject inventions were made during the preceding budget period.

Invention Reporting

You must report on inventions. The <u>iEdison website</u> includes information on invention reports. See also 37 CFR part 401.

You must also submit an annual invention use report for:

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- all inventions to which title has been elected, and
- inventions that have been licensed but not patented (research tools).

The utilization report provides a way to evaluate the extent of commercialization of subject inventions, consistent with the objectives of the Bayh-Dole Act.

Contact the GMS for questions, including:

- if inventions under a career development award is a subject invention
- the extramural technology transfer policy
- reporting and use of inventions

Real Property Reporting

Construction awards must report the status of real property each year for as long as the federal government retains an interest, up to 15 years. If the federal interest lasts beyond 15 years, the awarding agency or pass-through entity may require the recipient to report at various multi-year frequencies.

Non-Compliance

Failure to Submit Reports

When you fail to submit required reports within the time allowed, the awarding agency may take enforcement actions including those in the Remedies for Noncompliance section of the GPS.

Overdue Reports

An awarding agency may give a waiver, if permitted by law, or extension if a report is overdue and the reason is beyond your control.

Failure to meet a new date may result in the awarding agency taking enforcement actions.

Submission of a required report does not necessarily fulfill your obligation. Reports must meet content requirements. You must provide the revised report by the indicated due date to avoid enforcement actions.

Fraud, Waste, and Abuse

Fraud, waste, or abuse related to HHS awards or use of award funds should be reported to HHS. Fraud, waste, and abuse may be reported:

- By telephone at 1-800- HHS-TIPS (1-800-447-8477) or TTY at 1-800-377-4950
- Fax at 1-800-223-8164. Forms for use are available at the OIG website.
- E-mail at HHSTips@oig.hhs.gov
- USPS mail at U.S. Department of Health and Human Services, Office of Inspector General, Attn: OIG Hotline Operations, P.O. Box 23489, Washington, DC 20026.

If you report, you are not required to give your name, but if you do, your identity is kept confidential.

Fraud, waste, and abuse includes embezzlement, misuse or misappropriation of award funds or property, and false statements or claims. Examples include:

- theft of award funds for personal use
- using funds for non-award-related purposes
- theft of federally owned property or property acquired or leased under an award
- charging inflated building rental fees for a building owned by the recipient
- submitting false financial report
- submitting false financial data in bids submitted to the recipient

The federal government may pursue administrative, civil, or criminal action under a variety of statutes that relate to fraud and false statements or claims. Even if no award is made, you may be subject to penalties if information submitted as part of an application is found to be false, fictitious, or fraudulent. See the statutes referenced in Appendix D and Appendix E for statutes related to fraud, waste, and abuse.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA), 44 USC 35, as implemented by 5 CFR part 1320, is designed to:

- Reduce, minimize, and control burdens
- Maximize the practical use and public benefit of the information created, collected, disclosed, maintained, used, shared, and disseminated by or for the federal government

OMB clearance is required for awarding agency collection of information. This includes all application or reporting forms, whether paper or electronic. Below is information about how the PRA is implemented.

Federally Sponsored Surveys

Recipients may use award funds to collect information through surveys or questionnaires:

- When the collection of information is not a primary objective of the award but is incidental to, or is an integral part of, an award-supported activity
- When the collection of information is a primary objective of the award, but such information is not intended primarily for use by the federal government, or a party designated by the federal government

When information is collected, according to either of the two conditions above, you may not represent what the information is being collected for, or in association with, unless:

- You receive awarding agency approval, and
- You follow OMB report clearance procedures, when required. When OMB approval is required, the awarding agency, rather than the recipient, will obtain the necessary clearance.

OMB clearance is required whenever the HHS awarding agency sponsors the use of a reporting form or plans to collect identical kinds of information or data from 10 or more people.

Information collection is considered HHS awarding agency-sponsored when any of the following circumstances exist:

- The awarding agency allows you to state that the information is being collected for, or in association with, the awarding agency.
- You use the report form or collect information that an awarding agency has requested for the planning, operation, or evaluation of its program.
- The award terms and conditions provide awarding agency approval of the study design, questionnaire content, or data collection procedure.
- The award terms and conditions provide for either submission of the data for individual respondents or the preparation and submission of special requested tabulations to the awarding agency.

HHS and OMB approval may also be required if the use of a report form or plan presents a relatively high risk of unwarranted privacy invasion.

Collection of the following types of information is not subject to the clearance requirements at <u>5 CFR §</u> 1320:

- health professions data as described in Section 708 of the Public Health Service (PHS) Act
- tests or examinations of individuals for determining knowledge, abilities, or aptitudes, and the collection of information for identification or classification in connection with such tests
- information from patients to be used exclusively for research of or direct treatment of a clinical disorder; for the interpretation of biological analyses of body fluids, tissues, or other specimens; or for identification or classification of such specimens

See 5 CFR § 1320 for additional clearance requirement exemptions.

Remedies for Noncompliance

If you do not comply with award terms and conditions, the awarding agency or pass-through entity may take enforcement actions, in accordance with applicable statutes, regulations and policy.

You usually have an opportunity to correct the deficiencies unless there is a serious threat to public health or welfare concerns. The awarding agency may take necessary proactive steps to protect the federal government's interests. Awarding agencies may take any action allowed by law, including those below. See 45 CFR §§ 75.371-.380.

Implementation of Specific Award Conditions

An awarding agency or pass-through entity may place specific conditions on an award. The purpose is corrective. This remedy may be used if you:

- fail to comply with the terms and conditions of an award
- fail to meet expected performance goals

• are not otherwise responsible

When the awarding agency or pass-through entity imposes specific award conditions, they will notify you of:

- the nature of the conditions
- the reason why
- the type of corrective action needed
- the time allowed for completing corrective actions
- the method for requesting reconsideration of the conditions

Examples of specific award conditions are removing a PD/PI, converting your award from advance payment to reimbursement, and adding reporting requirements.

See 45 CFR § 75.207.

Disallowed Costs

HHS may disallow all or part of the cost of an activity or action determined not in compliance. This can happen at any time during the award or after closeout.

You must repay disallowed costs with non-federal funds or an offset from future year funds. You may appeal disallowed costs.

Other Remedies

Depending on the nature of the deficiency, an awarding agency also may:

- temporarily withhold payment
- withhold further awards for the project or program

Suspending Award Activities or Termination

Consistent with 45 CFR § 75.372(a), an awarding agency or pass-through entity may suspend, pending corrective action, or terminate all or part of your award activities pending your corrective action if you fail to materially comply with the award terms and conditions. See 45 CFR part 75 D – Remedies for Noncompliance.

The HHS awarding agency generally will suspend, rather than immediately terminate, a federal award. This allows you an opportunity to take appropriate corrective action before making the decision to terminate. The HHS awarding agency may decide to terminate the federal award if you do not take appropriate corrective action during the period of suspension.

Under a suspension, the HHS awarding agency will provide you:

- What project activities, if any, will take place during the period of suspension.
- What costs the HHS awarding agency will reimburse if the enforcement action is ultimately lifted and the award resumed.
- What corrective actions must occur during the enforcement action.

• The HHS awarding agency's intent to terminate the award if the non-federal entity does not meet the conditions of the enforcement action.

The HHS awarding agency may terminate without first suspending the federal award if the problem is serious enough or if public health or welfare concerns require immediate action. Termination for cause may be appealed under the HHS awarding agency and HHS's federal award appeals procedures.

A federal award also may be terminated, in whole or partially, by the recipient or by the HHS awarding agency with the consent of the recipient. If you decide to terminate a portion of a federal award, the HHS awarding agency may determine that the remaining portion will not accomplish the original purpose. In this case, you will be advised of the possibility of termination of the entire federal award and will be allowed to withdraw your termination request. If you do not withdraw your request for partial termination, the HHS awarding agency may terminate the entire federal award for cause. See 45 CFR § 75.372.

When an HHS awarding agency terminates a federal award prior to the end of the period of performance due to the non-federal entity's material failure to comply with the federal award terms and conditions, the HHS awarding agency must report the termination to the OMB-designated integrity and performance system accessible through the Responsibility/Qualification System in Sam.gov. This information will be reported after the non-federal entity has exhausted its opportunities to object or challenge the decision or has not within 30 calendar days after being notified of the termination informed the HHS awarding agency that it intends to appeal the decision to terminate. For full information on reporting termination in FAPIIS, see 45 CFR § 75.372(b).

HHS applies appeal rights in line with <u>45 CFR § 75.374</u>. Appeals rights exist for termination actions that are a remedy for non-compliance.

Suspension or Debarment

An awarding agency may initiate suspension or debarment proceedings under <u>2 CFR part 180</u> and HHS awarding agency regulations at <u>2 CFR part 376</u>. A pass-through entity may recommend that the awarding agency do so for a subaward.

Closeout

To close an award, you do several steps to include submitting a final report. Ask your GMS and review the closeout provisions HHS now follows at $2 \text{ CFR} \S 200.344$. The awarding agency will resolve any amounts due to them or to you.

Upon the completion date of an award, you have 120 days to liquidate all financial obligations and submit all required reports, including a final FFR, final progress report, tangible and real property reports (if needed), and Final Invention Statement and Certification (if needed). The GMO or their delegate may give an extension upon a written request. Not submitting timely and accurate reports can affect future funding. HHS may close out your award on its own if you fail to provide your reports on time.

HHS may still disallow costs or recover funds based on an audit or review after your award is closed out. After closeout, you still have to return any funds due to HHS because of refunds, corrections, indirect cost rate adjustments, or other transactions.

You still need to account for property acquired on your award and follow disposition and record retention requirements after close out. HHS adopted two 2 CFR § 200 provisions about equipment and salary disposition:

- 2 CFR § 200.313(e) Equipment: Increases from \$5,000 to \$10,000 the value of equipment that at the end of the grant period "may be retained, sold, or otherwise disposed of with no further responsibility to the Federal agency." The provision also clarifies that Indian Tribes may use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.
- <u>2 CFR § 200.314(a)</u> Unused Supplies: Increases from \$5,000 to \$10,000 the value of unused supplies that recipients of Federal funds are required to sell at the end of the grant award period as well as clarifying that this amount is the total amount of remaining unused supplies, not just like items.

See <u>45 CFR §§ 75.317-323</u> for other disposition requirements. See <u>45 CFR §§ 75.361-75.365</u> for record retention requirements. Keep in mind the above changes in equipment and supply costs adopted by HHS in 2 CFR § 200.

Final Federal Financial Report (FFR)

A final FFR is required for all of the following:

- terminated awards
- awards transferred to new recipients
- awards at the end of a period of performance

Final FFRs must:

- account for all funds awarded during the period of performance
- have no unliquidated obligations
- say the exact unobligated balance

In some cases, you may need to submit a revised FFR. When a revised final FFR results in additional recipient claims, the awarding agency will consider approval if:

- You show why the revision is needed, explains, and implements internal controls to avoid similar future situations
- The charge is allowable under the award
- There is an unobligated balance for the budget period that can cover the claim
- The funds are still available

 The awarding agency receives the revised FSR within 6 months of its original due date

Final Progress Report

A final progress report is required for all of the following:

- terminated awards
- awards at the end of the performance period

Submit final progress reports as directed in your NoA.

Use the awarding agency instructions. At a minimum, they include:

- a summary of progress towards achieving the stated aims
- significant results, positive or negative
- publications

If you submit a competing continuation application, the final progress report requirement may be met by the information included in that application.

Final Invention Statement

For research awards, you must submit a Final Invention Statement and Certification (HHS 568). HHS requires this statement even if the award does not result in any inventions. The HHS 568 is at the iEdison Web site at iEdison | NIST.

The HHS 568 lists all inventions conceived or initially reduced to practice under the award. The form must be signed by the PI or PD and AOR. The form covers the period from the original award start date through the award end date. If there were no inventions, the form should indicate "None."

Post-Closeout

After award closeout, you still have obligations for record retention, property accountability, and financial accountability. See $\underline{45}$ CFR $\underline{\$\$}$ 75.317-.323 and $\underline{75.343}$.)

Record Retention and Access

You must keep financial, supporting, and statistical records, and all other records considered pertinent to an award.

The retention periods are three years after sending:

- the final FFR for closed awards
- quarterly or annual reports for awards renewed quarterly or annually

These periods are extended until the conclusion of any litigation matters, claims, or audits and audit findings are fully resolved.

You must allow records access to the:

- HHS Awarding Agency
- Inspector General
- Comptroller General
- Pass-through Agency

See:

- Retention requirements for records (45 CFR § 75.361)
- Access to records (45 CFR § 75.364)
- Restrictions on public access to records (45 CFR § 75.365)

Debt Collection

During or after closeout, HHS may find that you received more than the correct amount or that you misspent funds. This may result from disallowed costs, recovery of funds, unobligated balances, or other situations. In these cases, HHS will send you a request for repayment. Debts to HHS agencies are considered delinquent 30 days after you are notified. You have 90 calendar days to repay the amount.

If you do not pay back the funds in 90 calendar days, the HHS awarding agency may reduce your debt by:

- making an administrative offset against payments on other HHS awards
- withholding advance payments
- taking other action allowed by law

HHS must, by law, collect debts due to the federal government. Unless prohibited by law, HHS is also required to charge interest on delinquent debts.

See Collection of Amounts Due (45 CFR § 75.391) for more.

You may appeal a request for repayment. If appealed, HHS suspends the collection pending a final appeal decision. If denied, in whole or in part, HHS will charge interest on the debt starting with the date of the original request for repayment.

Refer to the HHS Claims Collection (45 CFR part 30) and the Program Support Center's Debt Management Collection System at https://pms.psc.gov/ for more on collection of debts.

Appeals

Awarding agencies may have their own appeals procedures. See also the procedures of the Departmental Appeals Board (45 CFR part 16).

Awarding agencies and recipients may use alternative dispute resolution (ADR). ADR can reduce the cost, time, and level of dispute involved in appeals.

For more information on appeals, see Opportunities to Object, Hearings, and Appeals (45 CFR § 75.374) and the Departmental Appeals Board website.

Single Audit

An audit is a review to verify if accounting and control systems reasonably assure:

- proper financial operations
- timely, fair, and correct financial reports
- compliance with applicable laws, regulations, and terms and conditions of award
- resources are managed and used economically and efficiently
- desired results and objectives are being achieved effective
- recipients and subrecipients follow the audit requirements of <u>45 CFR part 75</u>, subpart F.

Audit Requirements

As of October 1, 2024, you and your subrecipients must have an audit if either spends \$1,000,000 or more in federal awards during its fiscal year (see 2 CFR \$200.501). Even if an audit is not required, keep records available for review by federal officials.

You must use an independent auditor who must follow the <u>Government Auditing Standards and the</u> <u>audit requirements in 45 CFR 75, subpart F</u>. Audit costs are allowable and often covered by the indirect cost rate.

Pass-through entities are responsible for establishing audit requirements, to ensure compliance by subrecipients.

HHS may request more audits, if necessary.

Types of Audits

Program Specific Audit: test a single program. Refer to 45 CFR § 75.507.

- Single Audit: The auditor uses a risk-based approach to identify major programs which the auditor tests and provides an opinion on compliance. See 45 CFR part 75, subpart F.
- Financial Related Audit: Specific to for-profit organizations. Must be conducted in accordance with the Government Auditing Standards.

Audit Options

If an audit is required, the following options are available:

For Governments, Indian Tribes, Institutions of Higher Education, and Non-Profits

- Only one program: If federal awards are expended in only one program, the program-specific audit is an option.
- Multiple programs: If federal awards are expended from more than one program, a single audit is required.

For-Profit Organizations

- Only one program: If federal awards are in only one program, then they may opt for a program-specific audit or financial related audit of the award.
- Multiple programs: If federal awards are in more than one program, then they must have a single audit or financial related audit of all awards.

Contractors

Audit requirements for federal awards do not apply to contractors with annual HHS awards less than \$1,000,000. See 2 CFR § 200.501.

Foreign Entities

Audit requirements and processes for foreign entities will be addressed in your NOFO and NoA.

Recipient Responsibilities

- Procure or otherwise arrange for the required audit and make sure it is performed properly. See 45 CFR § 75.509.
- Provide the auditor with access to needed personnel, accounts, books, records, supporting documentation, and other information.
- Prepare financial statements, including the schedule of federal award expenditures.
 See 45 CFR § 75.510.
- Make sure the audit is submitted within 9 months after your fiscal year end. See <u>45</u> CFR § 75.512.
- Promptly follow up and take corrective action on audit findings.

See 45 CFR § 75.508 for a listing of auditee responsibilities.

Audit Findings and Resolution

Non-Federal entities and their subrecipients must follow up and take corrective action on all audit findings. This includes preparing:

- a summary schedule of prior audit findings. See 45 CFR § 75.511(b).
- a corrective action plan. See 45 CFR § 75.511(c).

Requirements

The summary schedule and the corrective action plan must include:

- reference numbers the auditor assigns to audit findings under 45 CFR § 75.516(c)
- the fiscal year in which the finding initially happened
- findings relating to the financial statements required to be reported under Government Auditing Standards

See 45 CFR § 75.511.

Report Submission

Reports for non-profit recipients are submitted to the Federal Audit Clearinghouse (FAC). For-profit and foreign recipients submit reports to ARD or the Centers for Disease Control (CDC) (if CDC is the awarding agency).

The HHS assignment system receives single audit reports from the FAC and assigns audit findings to the awarding agencies for resolution.

Both you and your auditors must complete and submit your portions of the reporting package to FAC. They are due within 30 calendar days after receipt of the auditor's report or nine months after the end of the auditee's fiscal year.

See 45 CFR § 75.512.

Delinquent Audits

HHS will follow up to obtain audit reports that are delinquent.

If required audits are not completed or do not follow <u>2 CFR part 200</u> and <u>45 CFR part 75</u>, audit costs may be disallowed or other sanctions may be taken.

HHS Office of Inspector General

The HHS Office of Inspector General (OIG) audits programs and their recipients to ensure funds are used correctly and guard against fraud and waste. The OIG:

- can freely access records and information
- can request information and documents through subpoenas
- acts as the National Single Audit Coordinator, giving audit guidance to HHS agencies and recipients

You need to have strong internal controls and guidelines must be in place to ensure proper use of federal funds.

Documentation

Ensure that the basis for valuing services, materials, equipment, buildings, and land can be verified. Make sure your records, including those from your subrecipients, can support the value. If using volunteer services, document their time and attendance as you would for regular employees.

Additional Information

Cooperative Audit Resolution and Management Decisions

Cooperative audit resolution is a structured approach that brings the appropriate stakeholders together to address audit findings and proposed corrective actions. Non-federal entities must follow this approach to ensuring timely and appropriate resolution of audit findings and recommendations. The non-federal entity must initiate and proceed with corrective action as quickly as possible and corrective action should begin no later than upon receipt of the audit report.

The HHS awarding agency will coordinate with the non-federal entity during the cooperative audit resolution process. The HHS awarding agency will:

- Follow-up on audit findings to ensure the non-federal entity takes appropriate and timely corrective action.
- Issue a management decision, on all assigned reporting packages with audit findings within six months of the date the FAC accepts the reporting package.
- Issue sanctions when the non-federal entity fails to correct conditions identified by audits that are likely to cause improper payments, fraud, waste or abuse.

The HHS awarding agency or pass-through entity responsible for issuing a management decision must do so within 6 months of acceptance of the audit report by the FAC. The management decision provides timely information to the non-federal entity regarding where the HHS awarding agency is in evaluating findings and related corrective actions. The HHS awarding agency management decision will include:

- whether or not the audit finding is sustained
- the reasons for the decision
- the expected action the non-federal entity must take to repay disallowed costs, make financial adjustments, or take other action
- a timetable for follow-up if then non-federal entity has not completed corrective action
- a description of the appeal process available to the non-federal entity

Appendix A: Awarding Agencles Overview

Below is an overview of HHS awarding agencies. Visit HHS Organization Chart | HHS.gov for more.

GPS refers to "Public Health Service (PHS) agencies." We have marked them below.

Agency	Overview	Support
Administration for Children and Families (ACF) www.acf.hhs.gov	Promotes economic and social well-being of children, families, and communities.	 childcare for low-income families foster care and adoption child abuse and domestic violence prevention
Administration for Community Living (ACL) www.acl.gov	Advocates for older adults, people with disabilities, families, and caregivers to help all people live independently and participate in their communities.	 health, wellness, and nutrition self-advocacy connecting people to services retirement planning American Indian, Alaska Native, and Native Hawaiian nutrition and older adult support
Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov PHS agency	Improves quality, safety, accessibility, equitability, and affordability of US health care.	 digital healthcare research <u>PSNet</u> (Patient Safety Network) quality indicators
Administration for Strategic Preparedness and Response (ASPR) www.aspr.hhs.gov	Assists the country in preparing for, responding to, and recovering from public health emergencies and disasters.	 development and stockpiling of medical countermeasures pandemic preparedness
Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP) www.healthit.gov	Administers health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide, standards-based health information exchange to improve health care.	 advance development and use of health IT capabilities establish expectations for data sharing
Centers for Disease Control and Prevention (CDC) www.cdc.gov PHS Agency	Protects against health and public health, safety, and security threats. Their focus is both foreign and domestic.	 immunization services monitoring and preventing disease outbreaks disease prevention strategies workplace safety

Centers for Medicare & Medicaid Services (CMS) www.cms.gov	Advances health equity, expanding coverage, and improving health outcomes.	 clinical standards and quality minority health equity meaningful measures
Food and Drug Administration (FDA) www.fda.gov FDA Grants and Cooperative Agreements Page PHS Agency	Protects public health by ensuring the safety of human and veterinary drugs, biological products, medical devices, cosmetics, and food.	 food safety animal feed safety laboratory systems scientific conferences
Health Resources and Services Administration (HRSA) www.hrsa.gov PHS Agency	Provides access to essential health care services for people who are low-income, uninsured, or live in areas with limited access.	 rural health maternal and child health opioid response health workforce training telehealth
Indian Health Service (IHS) www.ihs.gov PHS Agency	Ensures comprehensive, culturally appropriate personal and public health services are available to American Indians and Alaska Native people.	 community health behavioral health environmental stability school health
National Institutes of Health (NIH) grants.nih.gov PHS Agency	Seeks knowledge about the nature and behavior of living systems. Applies it to enhance health, lengthen life, and reduce illness and disability.	 biomedical and behavioral research research training research infrastructure and communications
Office of the Assistant Secretary (OASH) www.hhs.gov/ash PHS Agency	Seeks to serve the public through responsive public health actions to promote healthy and safe environments and prevent harmful exposures.	 minority health family planning adolescent health women's health infectious disease and HIV/AIDS policy research integrity
Office of the Inspector General (OIG) www.oig.hhs.gov	At the forefront of the Nation's efforts to fight waste, fraud and abuse and to improving the efficiency of Medicare, Medicaid and more than 100 other Department of Health & Human Services (HHS) programs.	 Medicare/Medicaid oversight improved efficiency fraud, waste, abuse detection

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Substance Abuse and Mental Health Services Administration (SAMHSA) www.samhsa.gov PHS Agency	Improves the quality and availability of substance abuse prevention, addiction treatment, and mental health services.	substance abuse and mental health services.
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For awarding agency staff and recipient roles and responsibilities, see the <u>Introduction and General Information</u> section.

Appendix B: Abbreviations and Glossary

Abbreviations

Please see <u>abbreviations listed in 45 CFR part 75</u>. The abbreviations are used by the HHS Financial Assistance Community. Although not all of the terms are in the GPS, they may be useful to applicants and recipients.

Glossary

This glossary defines terms commonly used in the HHS GPS. These definitions are for purposes of clarity and do not replace controlling definitions in applicable statutes and regulations.

The total invoice price of items, counting costs for changes or accessories or additions to make them work for their intended use. Costs like setup, shipping, taxes, and insurance can be included or excluded based on the recipient's usual accounting methods. The term doesn't cover rental or property modification costs. 45 CFR § 75.2 Acquisition cost		
Accrual accounting records revenue and expenses when the transaction happens, not when money is paid.		
Common practices in managing awards like financial accountability, reporting, equipment management, and records retention.		
A payment made to a recipient before they spend the money or based on set payment schedules. 45 CFR § 75.2 Advance payment		
An allocable cost relates to a specific project or activity based on the relative benefits it provides. It's allocable to a federal award if:		
It's specifically for the award.		
 It benefits both the award and other tasks, and can be distributed based on those benefits. 		
 It's needed for the organization's overall functioning. 		
45 CFR § 75.405 Allocable costs		
Allowable costs are:		
Reasonable for the award's purpose.		
Allocable.		
Within the federal cost principles or NoA guidelines.		
 In line with the recipient's consistent policies, covering both federal and non-federal activities. 		
Consistently treated as either a direct or indirect cost.		
Based on standard accounting principles.		
 Not used in another federal award, unless statute says otherwise. 		
45 CFR § 75.403 Factors affecting allowability of costs		

alteration and renovation (A&R)	Alteration and renovation involve changing the inside or features of a facility or installed equipment to enhance its current use or adapt it for a new purpose. It can include improvements, remodeling, or modernization but is different from construction or major permanent upgrades.	
alternative dispute resolution (ADR)	A method to solve disagreements without going to court. It aims to resolve issues faster, cheaper, and in a less confrontational way, preventing them from becoming bigger problems that need formal legal action.	
applicable credit	Receipts that offset or reduce direct or indirect costs. Typical examples include purchase discounts, rebates, or allowances; recoveries or indemnities on losses; insurance refunds; and adjustments of overpayments or erroneous charges.	
	45 CFR § 75.406 Applicable credits	
application	A request for financial support of a project or activity submitted on specified forms and in accordance with awarding agency instructions. See <u>Types of Applications</u> .	
approved budget	The spending plan for a project funded by an award. This budget has both federal funds and, if applicable, non-federal funds like cost-sharing. If both types of funds are in the budget, the recipient must spend them in the same ratio as they appear in the total budget See also 45 CFR § 75.2 Budget	
assurance	A written statement by an applicant, normally included with the application, that it will follow a particular requirement if there is an award.	
audit resolution	The process of resolving audit findings, including those related to management and system deficiencies and monetary findings like questioned costs.	
	See also 45 § CFR 75.2 Cooperative audit resolution.	
award	The document that provides the awarding agency funds to a recipient to carry out an approved project, based on an approved application. In the GPS, award means both grants and cooperative agreements.	
	45 CFR 75.2 Federal award	
awarding agency	The agency responsible for making, monitoring, and overseeing awards. For changes in award terms or for approval requests, the reference may be to the GMS.	
	See also 45 § CFR 75.2 Federal agency.	
award-supported project	Activities described in an application or in a subsequent submission that are approved by an awarding agency for funding, even if federal money isn't the sole financial support for them.	
award terms and conditions	The legal requirements set by the awarding agency for the award. These can come from laws, regulations, policies, or the NoA. The NoA might also add specific conditions to ensure the award's goals are met, enable post-award management, save funds, or protect federal interests.	
budget periods	The period of time (usually 12 months each) into which a period of performance is divided for budgetary and funding purposes. Funding of individual budget periods sometimes is referred to as "incremental funding."	

carryover	Unspent federal funds from a particular budget period that can be transferred and used in the next budget period used to cover allowable expenses in that subsequent period. Funds that have been committed but not yet spent (obligated but unliquidated) are not classified under carryover.	
cash basis	An accounting method in which revenue and expenses are recorded on the books of account when received and paid, respectively, without regard to the period in which they are earned or incurred. It is different than accrual basis.	
change of recipient	Transfer of the legal and administrative responsibility for an award from one legal entity to another before the end of the period of performance.	
closeout	The process used by an awarding agency to determine whether all administrative actions and work required under the award have been completed by the recipient and the awarding agency.	
	2 CFR § 200.344	
cognizant agency	The federal agency that, on behalf of all federal agencies, reviews, negotiates, and approves cost allocation plans, indirect cost rates, and similar rates. They monitor non-federal audit reports; conduct federal audits as necessary; and resolve cross-cutting audit findings.	
	The cognizant agency under applicable cost principles and under <u>45 CFR part 75, subpart F</u> may be different for a given recipient.	
	45 CFR § 75.2 Cognizant agency for indirect costs	
competition	A process in which applications undergo a merit review and are evaluated against established evaluation criteria in the NOFO.	
completion date	The date on which all work under an award is completed or the date in the NoA (as amended) on which federal sponsorship ends (i.e., the end of a period of performance).	
consortium agreement	A formal agreement whereby a project is carried out by a recipient and one or more other organizations that are separate legal entities. Under the agreement, the recipient must perform a substantive role in the conduct of the planned project and not merely serve as a conduit of funds to another party or parties. Consortium agreements are considered subawards.	
contract under an award	A written agreement between a recipient and a third party to acquire commercial goods or services.	
	45 CFR § 75.2 Contract	
construction	A project to support the initial building or major alteration and renovation like large-scale modernization or permanent improvement of a facility.	
consultant	An individual who provides professional advice or services for a fee, but normally not as an employee of the engaging party. Also includes a firm that provides paid professional advice or services.	
cooperative agreement	A financial assistance support mechanism used when there will be substantial federal programmatic involvement. Substantial involvement means that the awarding agency's program staff will collaborate or participate in project or program activities as specified in the NoA.	
	45 CFR § 75.2 Cooperative agreement	

copyright	Protection provided by statute (Title 17, U.S. Code) to the authors of "original works of authorship," including literary, dramatic, musical, artistic, and certain other intellectual works, including computer programs. This protection applies to both published and unpublished works.	
cost analysis	The systematic review of a budget proposal to:	
	Detail and assess cost components.	
	Ensure costs are necessary, reasonable, and allocable.	
	 Confirm alignment with federal guidelines, ensuring no unallowable expenses. 	
cost sharing	See "matching or cost sharing."	
Departmental Appeals Board	The DAB is a board within HHS that impartially addresses disputes from HHS assistance programs. It offers a fair hearing process for challenges to certain grants management decisions, with its role and rules outlined in 45 CFR part 16.	
	45 CFR § 75.2 Departmental Appeals Board	
direct costs	Costs directly linked to a specific project, instructional activity, or other institutional activities, which can be accurately and easily allocated to those activities.	
	45 CFR § 75.413 Direct costs	
domestic organization	A U.Sbased public or private entity, subject to U.S. laws, responsible for the legal and financial management of awarded funds and the execution of the supported activities.	
Entity Identification Number (EIN)	A 12-character code in PMS comprising three parts: the first character indicates if the recipient is an organization or individual; the following 9 characters represent the TIN for organizations or the SSN for individuals; the final 2 characters differentiate between organizational entities with the same or multiple EINs, denoting subsidiaries, branches, or other subdivisions.	
equipment	A tangible item with a lifespan exceeding 1 year and a cost of \$5,000 or more per unit, or below the recipient's capitalization threshold, whichever is lower.	
	2 CFR § 200.1 Equipment	
excess property	Property that, as decided by the head of the awarding agency or its representative, is no longer needed for the agency's functions or responsibilities.	
	45 CFR § 75.2 Excess property	
exempt property	Tangible personal property bought either entirely or partly with federal funds, where the awarding agency has the legal authority to vest title to the recipient without additional obligations to the federal government.	
	45 CFR § 75.319 Federally owned and exempt property	
expanded authorities	Permissions granted to recipients that eliminate the need for prior approval from the awarding agency for certain activities.	
expiration date	The specified date in the NoA marking the conclusion of the current budget period, beyond which the recipient is not authorized to obligate award funds.	

facilities and administrative costs (F&A)	See <u>indirect costs</u>	
federal institution	A Cabinet-level department or independent agency within the executive branch of the federal government, or any of its sub-entities.	
federal share	The proportion, usually expressed as a percentage of the total project costs, that represents the financial and other direct contributions provided by the awarding agency, as detailed in the NoA.	
	45 CFR § 75.2 Federal share	
fee	A sum paid beyond the actual allowable costs to an entity delivering goods or services in line with standard commercial practice, often referred to as "profit."	
financial assistance	The provision of funds, property in place of funds, or other direct aid to a qualified recipient to encourage or further a public purpose authorized by law.	
foreign component	The execution of a major part or component of a project outside the United States by the recipient or by a researcher affiliated with a foreign institution, regardless of whether award funds are used.	
foreign organization	An entity situated in a country outside of the United States and its territories, governed by the laws of that nation, regardless of the nationality of the proposed Principal Investigator/Project Director.	
	45 CFR § 75.2 Foreign organization	
for-profit organization A legal entity formed for the purpose of generating profit for its shareholders This type of organization is also known as a "commercial organization."		
	See also 45 § CFR 75.2 Commercial organization.	
grant	A funding mechanism given to an eligible entity to support a public-purpose project or activity without significant involvement from the awarding agency. Unlike direct benefits for the government, a grant provides financial assistance or other resources to accomplish approved objectives.	
	See also 45 § CFR 75.2 Grant agreement.	
high risk	A recipient with a history of subpar performance, financial instability, or inadequate management, placing them at risk of financial or operational failure.	
human subject	An individual from whom an investigator collects data via intervention, interaction, or acquisition of identifiable private information, including organs, tissues, body fluids, or any related graphic or recorded details. Regulations govern the use of human subjects.	
Indian tribal government	The governing body overseeing an Indian tribe, group, or community, including Alaska Native villages per the Alaska Native Claims Settlement Act of 1971. This body is recognized by the Secretary of the Interior for access to specific programs and services via the Bureau of Indian Affairs and the Indian Health Service.	
	See also 45 CFR § 75.2 Indian tribe.	
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indirect costs	Costs incurred by a recipient for shared purposes and not tied to a specific project or program. They are also referred to as "facilities and administrative costs."	
	45 CFR § 75.2 Indirect (Facilities and Administration or F&A) costs	
institutional review board (IRB)	A committee that safeguards the rights and well-being of human subjects in research. The IRB can approve, modify, or disapprove research activities under its jurisdiction.	
intangible property	Property without physical form, such as copyrights, patents, and other intellectual property rights acquired under awards. It also encompasses loans, notes, leases, stocks, and other ownership instruments. However, intellectual property created, rather than purchased, under awards is excluded. 45 CFR § 75.2 Intangible property	
international organization	An organization with members from multiple countries, representing their interests, regardless of whether its headquarters or activities are located within or outside of the US.	
invention	A potentially patentable or protectable discovery or invention made by an awardee during work funded by a contract, grant, or cooperative agreement. The term "subject invention" refers to inventions specifically conceived or first reduced to practice as part of the funded work.	
key personnel	The PI/PD and other individuals who contribute to the programmatic development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the award.	
local government	A local government entity such as a county, city, town, township, school district, or council of governments, among others. This includes regional or interstate government entities and local public authorities, but excludes institutions of higher education and hospitals. 45 CFR § 75.2 Local government	
matching or cost sharing	The value of non-federal contributions to a federally assisted project, including third-party in-kind donations. These costs must adhere to the same allowability policies as other costs in the approved budget.	
	45 CFR § 75.2 Cost sharing or matching	
merit review	An unbiased evaluation of discretionary applications by experts in the relevant field. Also known as objective review.	
	See also 45 CFR § 75.204 HHS funding agency review of merit of proposals.	
monitoring	A method of evaluating an award's programmatic and business management performance using data from reports, audits, site visits, and other sources.	
non-competing extension	An additional timeframe beyond the original period of performance, granted by the awarding agency or recipient (under expanded authority), to finalize project activities.	
non-federal share	The portion of allowable project costs not borne by the Federal government.	
notice of funding opportunity (NOFO)	An official announcement from the awarding agency that outlines the availability of federal funds for a specific program. This announcement invites applications and provides essential details such as eligibility requirements, evaluation criteria, and guidelines for application preparation and submission.	
objective review	See merit review.	

obligations	The value of commitments made by a recipient during a budget period for orders, contracts, subawards, and received goods and services, that will need payment within the current or later budget periods.	
	45 CFR § 75.2 Obligations	
outlays or expenditures	The charges made to the federally sponsored project or program. They may be reported on a cash or accrual basis.	
	45 CFR § 75.2 Expenditures	
patent	A property right awarded by the federal government that grants the right to exclude others from making, using, or selling the invention for a period of years.	
peer review	A method of evaluating the merit of applications based on assessment by individuals of equal scientific or technical expertise (peers). This review ensures that applications meet high scientific or technical standards, as determined by experts in the relevant field.	
period of performance	The total time for which support of a project has been programmatically approved.	
	45 CFR § 75.2 Period of performance	
pre-award costs	Costs incurred before the official start date of an award, expected to be covered by the award but undertaken at the applicant's own risk, given there's no guarantee of reimbursement unless later approved.	
	45 CFR § 75.209 Pre-award costs	
prior approval	Written approval from the awarding agency's CGMO, or their delegate, granted in response to a recipient's request, to incur a specific cost or action requiring such approval. If these costs/actions are detailed in an application, the award's issuance based on that application serves as the authorization. For indirect cost components, prior approval must come from the relevant agency or as per the associated cost principles.	
	45 CFR § 75.2 Prior approval	
profit	See <u>fee</u>	
program income	Income directly produced by a project, program, or activity funded by the award, or earned due to the award.	
	45 CFR § 75.2 Program income	
progress report	Regularly submitted reports, typically annually, from the recipient to the awarding agency to evaluate progress and determine funding for the next budget period, excluding the final report.	
real property	Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment.	
	45 CFR § 75.2 Real property	
recipient	The entity or individual awarded a grant or cooperative agreement by the awarding agency. They are accountable for the funds and the execution of the project or activity. Even if a specific component is mentioned in the NoA, the recipient refers to the complete legal entity.	
	45 CFR § 75.2 Recipient	
reimbursement	A payment made to a recipient upon its request after it makes cash disbursements.	
	1	

research	A comprehensive study aimed at expanding knowledge or addressing a specific need. It involves the application of knowledge to produce materials, devices, systems, or methods, including the design and enhancement of prototypes and processes. Often referred to as "research and development."	
	45 CFR § 75.2 Research	
	45 CFR § 75.2 Research and Development (R&D)	
research patient care	Standard and supplementary hospital services given to research participants. The expenses for these services are typically allocated to individual research projects using established research patient care rates.	
subaward	Financial assistance given as money or property under an award by a recipient to a qual subrecipient (or by a subrecipient to a lower-tier subrecipient). This aid can be provided through any legal agreement, even if termed a contract, but excludes procurement of goods/services or any assistance other than grants and cooperative agreements. Consortium agreements are included.	
	45 CFR § 75.2 Subaward	
subrecipient	An entity that receives a subaward from a recipient or another subrecipient under a financial assistance award and is responsible to that recipient or subrecipient for the proper use of the federal funds provided by the subaward.	
	45 CFR § 75.2 Subrecipient	
substantive programmatic work	The primary project activities for which award support is provided.	
supplies	Tangible items that are not classified as equipment, intangible property, or debt instruments. While some items in the "supplies" category might resemble equipment, they don't meet the specific criteria or cost threshold to be categorized as such.	
	2 CFR § 200.2 Supplies	
suspending award activities	A temporary halt on a recipient's ability to use award funds until they take corrective as directed by the awarding agency or until the agency decides to end the award. This definition of "suspension" is distinct from its use in the context of debarment and suspension procedures.	
	45 CFR § 75.2 Suspension of award activities	
tangible personal property	Tangible assets including equipment and supplies, excluding intangible property like intellectual property.	
termination	The awarding agency's permanent removal of a recipient's right to commit previously granted funds before the initial authority ends, which can include the recipient willingly giving up that right.	
	45 CFR § 75.2 Termination	
total project costs	The total allowable costs (both direct and indirect) that the recipient incurs to carry out a project supported by the award. This includes costs billed to the award itself and costs that the recipient covers as part of a matching or cost-sharing agreement.	
	45 CFR § 75.2 Total Costs	

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unallowable cost	A cost specified by law or regulation, federal cost principles, or term and condition of award that may not be reimbursed under a grant or cooperative agreement.
unliquidated financial obligations	If using a cash basis, the amount of obligations made by the recipient that have yet to be paid. If using an accrual basis, the sum of obligations made by the recipient for which a disbursement or expense hasn't been recorded. 45 CFR § 75.2 Unliquidated obligations
unobligated balance	The amount of the funds authorized by the federal agency that the recipient has not obligated.
	45 CFR § 75.2 Unobligated balance
vertebrate animal	Any live animal having a backbone or spinal column used or intended for use in research, research training, experimentation, biological testing, or related purposes.
withholding cash payment	The awarding agency, after following necessary steps, limits a recipient's access to funds until they make the needed corrections.

Appendix C: Post-Award Considerations by Type of Program, Activity, or Recipient

Services Provided by Affiliated Organizations

Universities and other organizations (parent organizations) sometimes create affiliated organizations.

The parent organization often provides considerable support services. These include administration, facilities, equipment, accounting, and other services. The affiliated organization includes the costs of these services in its indirect cost proposal.

In some cases, the awarding agency may reimburse these costs. This happens only when the affiliated organization satisfies any of the following:

- It is charged for, and must legally pay for, the costs.
- It is subject to state or local law that sets out how to spend the federal reimbursement and a state or local official approves the expenditures.
- A formal agreement allows the affiliated organization to keep the related federal reimbursement. The parent organization may direct the expenditure of the funds or allow the affiliated organization to decide.

If these conditions don't apply, the awarding agency cannot reimburse the costs. However, the services may be acceptable for cost-sharing purposes.

Data Sharing for Research and Demonstration Projects Considerations

Expectations

Sharing data and research tools is important to quickly turn research into useful products and knowledge to improve human health. This includes things like cell lines and software. Also sharing information about demonstration projects helps others use and duplicate projects. If you are an NIH recipient, reminder to please go to the NIH GPS at:

https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf

HHS encourages researchers to share their findings promptly.

If you enter into subawards, including consortium agreements, and you want access to third-party data or research tools, include a provision in the third-party agreement. There may be times the HHS awarding agency requires you to do so They can also access third-party data or tools. Please check the NoA.

You must also share copies or samples of materials developed under the award. You can charge a small fee for shipping and handling these items. Any income earned from this is considered program income.

If you think you can't meet these expectations, talk to the GMS before getting an award.

Timely Release of Research Data and Tools

Investigators should share their final research data and tools either when their main findings are accepted for publication or when they submit findings to the awarding agency. This ensures timely sharing.

Protection of Certain Data

HHS knows data sharing can be complicated due to various rules and laws, including the <u>HIPAA Privacy</u> <u>Rule</u>, <u>Human Research Protections</u>, and others. We must always protect the privacy of project participants and their data.

For wider use, data must not include any indicators that could reveal the identity of individual participants. Researchers need to ensure that data from human cells or tissues also can't reveal the identity of the original donors.

Researchers can share materials through their lab or organization or submit them to a repository. They should send unique biological data, like DNA sequences, to the appropriate data banks. When sharing unique resources, investigators must provide details about the nature, quality, or characterization of the materials.

Conference Awards

If you have questions about conference awards or what's allowed under your award, ask your GMS.

Here are definitions and details about costs related to conference awards:

- Conference: Events like meetings, retreats, or seminars that share technical information. They must be necessary and reasonable for the award's success.
- International conference: A meeting open to attendees from at least two countries other than the U.S. or Canada. It can be anywhere, even in the U.S. But, if it's outside the U.S. or Canada, award funds can't cover general support. They can cover specific parts, like a workshop or panel.
- Domestic conference: A meeting in the U.S. or Canada mainly for attendees from these two countries. Award funds can support these conferences, whether they're domestic or international.

Equity in Representation

For HHS-supported meetings, ensure diverse participation. Recipients of HHS financial assistance awards must make sure all those eligible for the HHS funded project are able to participate and receive the benefits from the project. When administering HHS-funded meetings, programs, activities, projects, assistance, and services, the recipient must make sure no one able to participate is discriminated against, to the extent doing so is prohibited by Federal statute. Please see 45 CFR § 75.300 and Advancing Equity at HHS for more information.

Funding Requirements

The NoA will include any specific requirements. A change in conference focus is a change in scope and needs prior approval.

Acknowledgment of Support and Disclaimer

All conference materials, like agendas or media promotions, must mention HHS support, whether in whole or in part. Refer to Appendix D for the exact wording of this acknowledgment.

If you're releasing a press statement about activities supported by an HHS award, inform the awarding agency beforehand to coordinate, which may include a review of mate

Allowable and Unallowable Costs and Activities

Please refer to 45 CFR part 75, subpart E, your NOFO/NoA, and the HHS awarding agency.

Other Cost Considerations

If you don't have a written travel policy, follow the <u>Federal Travel Regulation</u>. Always adhere to the U.S. foreign travel restrictions in place at the time, which may include restrictions on countries or limits on funds for travel.

When attending a conference:

- Only claim per diem for days you attend and the actual travel time, taking the most direct route.
- Local travel costs can be covered for local attendees only.
- If meals or lodging cost are nominal or free, like within a registration fee, adjust your per diem accordingly.
- Travel costs shouldn't exceed coach fares. Always choose U.S. carriers when possible.

Intellectual Property: Publications, Copyright, and Public Disclosure

If you publish something using HHS funds, you can distribute it for free. If you sell it, the money earned is considered program income and should be reported as directed in your NoA and on the FFR. More details can be found in the Program Income section of the GPS Program section After the Award.

You can seek copyright for publications from an HHS-supported conference unless your award says otherwise. However, HHS still has rights to the materials, as mentioned in the Irrevocable and the Royalty-Free License GPS section After the Award.

Construction and Modernization of Facilities Awards

Applicability and Definitions

Note that construction and modernization activities must be allowed by law; that law may provide more specifics about allowable construction and modernization activities. However, as a general matter, this section applies to the following HHS award-supported activities:

- Construction: constructing a new building, structure, or facility that provides new space. It also includes installing fixed equipment in such space. It excludes purchasing land and ancillary improvements like parking lots, roads, or fencing.
 Constructing shell space is not allowed as a construction activity as it does not provide usable space.
- Modernization: altering, renovating, remodeling, improving, expanding, or repairing an existing building. Also includes completing existing shell space. Activities must make the building suitable for the purposes of a particular program. This can include space used for storage or by people. It can range from updating flooring to replacing everything except for the existing frame and foundations. If the main award purpose is modernizing a biomedical research facility, the award can't also support research.
- Alteration and renovation (A&R) activities: These are modernization activities and can be under research awards where the primary purpose of the award is other than construction or modernization.

Refer to the NoA for additional related requirements.

Allowable and Unallowable Costs and Activities

This section outlines costs and activities generally allowable and unallowable under construction awards. (The final decision is based on the decision of the HHS awarding agency and the program.)

These policies apply to the use of federal funds and cost sharing or matching funds. The lists are not all-inclusive. Consult program guidelines and award terms and conditions for specific costs allowable under a program or award.

Allowable Costs and Activities

- Acquisition and installation of fixed equipment.
- Architectural and engineering services.
- Bid advertising.
- Bid guarantees and performance and payment bonds as provided in 45 CFR § 75.334.
- Contingency funds for unanticipated charges included in the initial cost estimates for construction contracts. Before you receive bids, the budgeted amount can't exceed five percent of expected construction costs. You must reduce it to not more than two percent after you award a construction contract.
- Filing fees for recording the Notice of Federal Interest (NFI).
- Force accounts to provide funding for your own construction and maintenance staff
 used in carrying out modernization activities. These are allowable if you can
 document that a force account is less expensive than if you were to competitively
 bid the work. You must substantiate costs with receipts for the materials and
 certified labor pay records. Use of a force account requires awarding agency prior
 approval.

- Compliance with the National Historic Preservation Act. This can include:
- hiring special consultants to research and document the historic value of proposed performance sites
- costs to prepare and present required materials to inform the public and others.
- Incentive costs for contractors consistent with contract type as specified in the solicitation of bids or proposals and in the contract. Incentive costs must be reasonable and documented, including that conditions to earn the incentive were met. Incentive-type contracts may also contain a penalty provision. Other types of bonus payments are not allowable.
- Inspection fees.
- Insurance costs of title insurance, physical-destruction insurance, and liability insurance are generally allowable. Physical destruction and liability insurance are usually treated as F&A costs. However, you can treat it as a direct cost if your established policy does so and you consistently do so. You may charge title insurance, if required, to the award in proportion to the amount of awarding agency participation in the property. See Real Property —Insurance.
- Legal fees related to obtaining a legal opinion about title to a site.
- Relocation expenses.
- Sidewalks necessary for use of facility.
- Site clearance costs are allowable if reflected in the bid.
- Site survey and soil investigation costs.
- NEPA analysis costs to evaluate the environmental effects and produce the Environmental Impact Statement (EIS).
- Pre-award costs for architect and consultant fees needed for planning and design are allowable if the project is later approved and funded.
- Project management costs.
- Threat-risk assessment costs for a site-specific or project-specific assessment of security risk by a qualified professional. The threat-risk assessment identifies and quantifies potential threats, both internal and external to the building, its contents, the personnel working in it, and the general public. The analysis also includes examination and evaluation of the physical aspects of the proposed facility, along with operational issues.

Unallowable Costs and Activities

- Bonus payments other than earned incentive payments to contractors under formal incentive arrangements.
- Construction of shell space designed for completion at a future date.
- Consultant fees not related to actual construction.
- Damage judgment suits.
- Equipment purchased through a conditional sales contract.

- Indirect/F&A costs.
- Fund-raising expenses.
- Land acquisition.
- Legal services not related to site acquisition.
- Movable equipment.
- Off-site improvements such as parking lots.

Prior-Approval Requirements

You must get awarding agency prior approval for the following types of project or budget changes:

- Any applicable changes as specified in the Prior Approvals section of the GPS.
- Change in the use of the facility. See Use of Facility and Disposition in this section.

You must provide enough details in your approval request to explain why you need the change. Once approved, you can make the changes. For smaller changes to construction contracts, you don't need prior approval. But keep copies of all changes as part of your award records.

Procurement Requirements

Construction activity usually is conducted through one or more contracts. All such procurement must use the methods described in 45 CFR §§ 75.327 through 75.335, as applicable.

Equal Employment Opportunity, Labor Standards, and Other Contract Requirements

You must provide equal employment opportunity and labor standards requirements for federally assisted construction and modernization to potential bidders/offerors and include them in the resulting contract. See 45 CFR part 75, Appendix II (C) and 41 CFR chapter 60. The Davis-Bacon Act or the Copeland "Anti- Kickback" Act apply only if specifically required by the program's authorizing statute. The NoA will show if they apply.

Equal Employment Opportunity Requirements

Construction contracts (and subcontracts) awarded under HHS awards must follow the requirements of <u>EO 11246</u> and implemented in <u>41 CFR § 60-1</u>. Recipients must:

- Include the "Equal Opportunity Clause" at <u>41 CFR § 60-1.4(b)</u> in any construction contract under the award. You must direct the contractor to include this clause in any applicable subcontracts.
- Follow solicitation and contract requirements for affirmative action specified in <u>41</u>
 <u>CFR § 60-4</u> for contracts in specified geographical areas that will exceed \$10,000.
 These requirements are specified in <u>EO 11246</u>.
- Notify the Office of Federal Contract Compliance Programs regional, area, or field office when you expect to award a construction contract over \$10,000.

Labor Standards Requirements

- Under <u>EO 13202</u>, as amended by <u>EO 13208</u>, you must ensure that bid specifications, project agreements, or other controlling documents for construction services contracts:
- Ensure that bidders, offerors, contractors, or subcontractors are able and willing to enter into or adhere to agreements with one or more labor organizations on the same or other related construction projects.
- Refrain from discrimination against bidders, offerors, contractors, or subcontractors for initiating, refusing to initiate, or adhering to agreements with one or more labor organizations, on the same or other related construction projects.

Under $41 \text{ CFR } \S 60-1.8$, segregated facilities are not permitted for any contract for construction services that will exceed \$10,000. The recipient must require each prospective contractor to submit a certification that the contractor:

- Maintains all facilities provided to employees in a non-segregated manner
- Prohibits its employees to perform services at any location, under the contractor's control, that maintains segregated facilities
- Obtains a similar certification before awarding any covered subcontract

Awards, contractors, and subcontractors with construction contracts or subcontracts over \$100,000 must follow the Contract Work Hours and Safety Standards Act, 40 USC 3701–3708. Among other provisions, the statute covers standards listed below. Consult the statute for proper interpretation and guidance.

- Work hours
- Report of violations and withholding of amounts for unpaid wages and liquidated damages
- Health and safety standards in building trades and construction industry
- Safety programs
- Limitations, variations, tolerances, and exemptions
- Contractor certification or contract clause in acquisition of commercial items not required
- Criminal penalties

Other Requirements

Liquidated Damages

Invitations for bids must supply a date or timeframe to complete the project for each prime contract. You may include a liquidated damages provision in the contract. It allows you to assess damages when the contractor does not complete the construction or modernization by the specified date. Liquidated damages must be real, justified, and approved by the awarding agency before solicitation. Where damages are assessed, any amounts paid belong to the recipient.

Disposition of Unclaimed Wages

If an employee doesn't claim wages from an HHS-supported construction contract, the recipient might need to pay HHS back. Here's the process:

- Check that the contractor tried to find the employee. This might include forwarding mail or contacting their union.
- If the contractor's search fails but seems incomplete, try to find the employee.
- Open an escrow account in the employee's name. Keep it for two years after the contract ends, or longer if local laws say so. Tell the GMS about this account.
- If you pay wages from the account to the employee or their representative, report to the GMS when you close the account.
- If money is still unclaimed after two years, refund the awarding agency based on the award's contribution to those wages.

Use of Facility and Disposition

Unless a statute or instructions from your awarding agency say otherwise, here's how to manage real property:

- Keep using the property for its intended purpose. Don't sell or encumber the title without approval.
- If you don't need it for the initial purpose, get written approval from the awarding agency to use it for a similar federally funded project.
- If you no longer need the property, follow the rules in <u>45 CFR 75.318</u>. Your options include:
- Keep it and pay the awarding agency their fair share based on their contribution and the property's market value.
- Replace it. If buying new property under the same award, use any sales money to reduce the new property's cost.
- Sell it and pay the awarding agency based on a formula in 45 CFR 75.318(c)(2).
- Transfer it to the awarding agency or their approved third party. They'll pay you your fair share based on your contribution and the property's current market value.

Foreign Organizations, International Organizations, and Domestic Recipients with Foreign Components

The GPS generally applies to awards to foreign organizations and international organizations. You can find the definitions of these terms in Appendix B of the GPS. In this section, we refer to them as foreign awards.

The AOR must contact the GMS if their organization can't follow these requirements. This section includes:

- Exceptions and modifications to GPS requirements for foreign awards
- Highlights of other related policies
- Policies that apply to awards with a foreign component

Public Policy Requirements and Objectives

Requirements in Appendix D apply to foreign awards, unless otherwise noted here, the NoA, or in awarding agency policies. Exceptions include:

- Civil rights: The civil rights requirements do not apply to foreign awards.
- Debarment and suspension: These rules and the certification requirement do not apply to:
- foreign governments and foreign recipients
- public international organizations
- entities that are foreign-government-owned or controlled, in whole or in part

All other foreign organizations and international organizations are subject to these rules.

- Drug-Free workplace: The awarding agency may exempt foreign awards from these requirements. To do so, they must find that the requirements are not consistent with U.S. international obligations or the laws and regulations of a foreign government.
- Environmental requirements: A foreign award isn't subject to environmental requirements that would not otherwise apply to it.

Funding and Payment

These policies apply:

- All application budgets, fund requests, and financial reports must be in U.S. dollars.
- If exchange rates change, extra costs might be covered, depending on the awarding agency's available funds.
- You only need prior approval for rate changes if they lead to needing more federal funds or if they will reduce project scope significantly.
- Review local currency gains to determine if you will need additional federal funding before the award ends.
- Adjustments for currency increases may be allowable only when you provide the awarding agency with adequate source documentation from a commonly used source in effect at the time you made the expense.

Allowable and Unallowable Costs

The cost principles that apply to foreign organizations depend on the type of organization. See <u>Cost Principles</u>. There are some exceptions:

- Major A&R are unallowable under foreign awards and domestic awards with foreign components, except where allowed by the governing statute and as indicated in the NoA.
- Minor A&R are generally allowable on awards made to foreign organizations or to a
 foreign component of a domestic award, unless prohibited by the governing statute
 or implementing program regulations. You may include and justify minor A&R costs
 in the detailed application budget. Rebudgeting to accommodate minor A&R
 requires prior approval.
- F&A Costs under foreign awards, including foreign recipients with a domestic component, are at a fixed rate of eight percent of modified total direct costs. These are direct costs minus tuition and related fees, equipment, and subawards in excess of \$25,000. See 45 CFR 75.414(c)(1)(ii). These funds are to support the costs of compliance with federal requirements.
- Capital expenses (facilities) are not allowable, except where allowed by the governing statute and as indicated in the NoA. The awarding agency will not support the acquisition cost or provide for depreciation.
- Equipment is an allowable direct cost.
- Patient care costs are provided only in exceptional circumstances or where allowed by the statue setting up the award program.
- Travel Visas (including short-term) are generally allowable:
 - As a direct cost as part of recruiting costs if the institution has an employeeemployer relationship with the individual
 - When identified in specific NOFOs
 - o If within the scope of an approved research project

Administrative Requirements

Expanded authorities generally apply to foreign awards. Review the NoA to determine the specific award requirements. See the Prior Approvals and Expanded Authority sections of the GPS. These requirements also apply to subawards to foreign entities under financial assistance arrangements, rather than acquisition of goods or services.

If you make a subaward to a foreign entity, to comply with audit requirements, you must include oversight methods. These may include reviewing reports, on-site reviews, or alternatives to a single audit, if one will not be available during the period of the subaward.

Federal Institutions and Payments to or on Behalf of Federal Employees Under Awards

Most policies contained in the GPS apply to awards made to federal institutions. This section includes specific exceptions and modifications of general GPS requirements for federal recipients. It also highlights other related policies.

Eligibility

Specific eligibility is in each NOFO. An awarding agency may not issue an award to any component of its own organization.

PHS organizational segments, other than IHS hospitals, may receive award support under exceptional circumstances only. Such circumstances may include when the work cannot be supported within the mission of the PHS agency and cannot be performed elsewhere.

The federal agency or department is the official applicant, regardless of where within it the work is to be performed. A federal institution must ensure that its own authorizing legislation allows it to receive awards and to be able to comply with the award terms and conditions.

A document that assures both the assumption of responsibility and authority to receive an award must accompany each new and competing continuation application. The assurance must be signed by the head of the responsible federal department or independent agency or a designee who reports directly to the department or agency head. This assurance is in addition to those made by the AOR's signature on the face page of the application. The assurance requirement does not apply to VAMCs, Bureau of Prisons' (Department of Justice) hospitals, IHS hospitals, or other PHS organizational segments.

For-Profit Organizations

General

Terms and conditions for for-profit organizations vary from standard ones. Also, terms and conditions for SBIR and STTR programs vary from those usually applied to for-profit organizations.

Cost Principles

Usual cost principles do not specifically apply to for-profit organizations. As a result, use:

- For for-profit organizations: FAR, 48 CFR § 31.2.
- For private hospitals: 45 CFR part 75, appendix IX.

Allowable and Unallowable Costs

Allowable Costs

- Indirect costs
- Travel that does not exceed costs established by the Federal Travel Regulation (FTR).

Unallowable Costs

- Independent research and development costs, as provided in 45 CFR § 75.476.
- Profits or fees, except for awards under the SBIR and STTR programs and funds paid to a contractor for routine goods or services.

Consult the GMS for questions on costs.

Administrative Requirements

For-profit organizations generally are subject to the same administrative requirements as non-profit organizations, including those relating to personal property title and management.

- Equipment: For-profit groups must track equipment. You can't use award-funded equipment to compete unfairly by offering paid services. Any fees charged for using the equipment count as program income and you must report it on the FFR.
- Intellectual property: All for-profit groups, regardless of size, follow the intellectual property rules in <u>37 CFR § 401</u>. For-profit organizations have different invention reporting rules than non-profits. For-profit organizations can assign invention rights to others without agency approval, but they must still report each invention. The federal government will keep information about federally supported inventions confidential, as allowed by law.
- Program income: See <u>Program Income</u>.
- Operating authorities: Standard award terms apply to for-profit organizations. However, some policies do not allow automatic carryover of unobligated fund balances. The NoA specifies the disposition of the reported unobligated balance.
- Audit: Requirements for non-federal audits of for-profit organizations are in <u>45 CFR</u> § 75.501. For-profit organizations are subject to requirements for non-federal audits. See Audit Requirements.
- Labor distribution requirements: Salary and wage amounts charged to awards for personal services must:
 - Be based on an adequate labor distribution system that distributes payroll costs in line with generally accepted practices of like organizations.
 - Align to industry standards.
 - Track time spent on award activities. The time and-effort reporting system used must:
 - Be for both professional and other staff
 - Reflect daily reporting
 - Track time by individual projects and indirect activities
 - Record both hours worked, and hours absent
 - Enable the AOR to meet the requirement to certify time entries at least every pay period.
 - The GMS must approve any alternative system.

Small Business Innovation Research and Small Business Technology Transfer Programs

The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs have three stages. Some projects might not be eligible for all three.

Phase I

Before providing Phase II support, this phase assesses:

- The technical merit and feasibility of proposed research or R&D
- The quality of the applicant's performance

Phase II

This phase advances efforts started in Phase I. These policies apply:

- Funding is based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application.
- Only Phase I recipients can apply for Phase II funding.
- You can only submit Phase II applications before a Phase I award if using the Fast-Track application process (see below).
- You must submit non-Fast-Track Phase II applications within the first six receipt dates after the end of your Phase I budget period. This is typically two years.

Phase III

The SBIR and STTR programs do not fund Phase III. This phase is for the SBC to work to commercialize the results of the research or R&D done in Phases I and II. In some cases, a federal agency may:

- Use non-SBIR and STTR funds to continue the work.
- Contract for items for federal use.

SBIR and **STTR**

STTR

The STTR program focuses on teaming a Small Business Concern (SBC) with a non-profit research body for a project that might be turned into a product.

The program requires:

- The SBC collaborates with a single non-profit research institution.
- The SBC must do at least 40% of the research. A domestic non-profit organization does at least 30%. This rule is the same for both Phase I and Phase II.
- Eligible research partners include universities, non-profit hospitals, other non-profits research organizations, and federally funded Research and Development Centers.
- The award goes to the SBC. It disperses funds to the research institution.
- The PI must spend at least 10% of their time on the STTR project.

SBIR

The SBIR program requires that SBC employ the PI at least half-time at the time of award and during the project.

Fast-Track Process

The Fast-Track process speeds up decisions and funding for SBIR and STTR Phase II applications. Policies include:

- To be eligible, the project must be scientifically meritorious with a high potential for commercialization.
- Not every agency lets SBCs use Fast-Track. Talk to the agency first before applying.
- If you aren't approved for Fast-Track, your application might go through the regular review.
- With Fast-Track, Phase I and Phase II applications are handled together and usually get one overall score.

For more details, check the SBIR and STTR NOFOs.

Place of Performance and Sources of Materials

All project activities for Phase I and Phase II of SBIR and STTR must be done in the United States. Using a foreign site for research is rare and needs a solid scientific reason. An example includes testing specific patient groups only available abroad. You must attempt to get alternate funding for the part of the work to be done abroad.

If you must buy materials from another country, you must have a good reason and clearly explain it. Approval of such a waiver is rare. The awarding agency reviews each request individually. If you'll need to do this, talk to the GMS before you apply.

GMSs decide waiver requests. The NoA will clearly state if it is approved.

Change in Organization Status & Change of Recipient Institution Actions

The awarding agency makes eligibility decisions at the initial award time.

A later event like a merger or successor-in-interest could alter the organization's status. If the change makes the organization ineligible for the SBIR or STTR program:

- Any current awards can still proceed unless the small business concern makes a
 material misstatement that the agency decides poses a risk to national security; or
 there is a change in ownership, change to entity structure, or other substantial
 change in circumstances of the small business concern that the Federal agency
 decides poses a risk to national security
- After that, the organization will not qualify for new SBIR or STTR awards

If an SBIR or STTR award needs to be transferred to a different institution or organization, this new entity must also fulfill the eligibility requirements of the SBIR or STTR program.

Contact the awarding agency to discuss options when considering a move to a new organization.

Minimum Level of Effort

Congress requires minimum levels of effort for these programs.

SBIR required levels of effort:

Program and Phase:	SBC level of effort:	Aggregate payments to others may not exceed:
SBIR Phase I	67%	33%
SBIR Phase II	50%	50%

STTR minimum levels of effort:

Program and Phase:	SBC minimum level of effort:	Single, non-profit research institution minimum LOE:
STTR Phase I	40%	30%
STTR Phase II	40%	30%

Policies include:

- Waivers are not allowed.
- The basis for establishing the percentage of work to be done by each participant is the entire cost (including direct, indirect costs, and fee) related to each party.
 However, if described and justified under the "Consortium/Contractual Arrangements" section of the application, a different basis might be used.

Multiple Program Director or Principal Investigator Applications and Awards

Team science efforts may use a multiple program director or principal investigator (Multi PD/PI) option. The following policies apply:

- The SBC is always the applicant or recipient organization. Other participants are subcontractors.
- Each PD or PI must commit at least 1.2 calendar months (10% effort) to the project.
- SBIR Phase I and II projects: The contact PD or PI must meet the primary employment requirement. Other PDs or PIs do not have to meet the requirement.
- STTR Phase I and II projects: The PI listed must have a formal appointment with, or commitment to, the SBC. This must be an official relationship but does not require pay.
- Phase IIB Multi PD/PI competing renewal applications: If previously supported through a single PD/PI award, the new application must state the changes in the project's management that led to the proposed Multi PD/PI model.

Public Policy Requirements

Requirements in Appendix D: Administrative and National Policy Requirements apply, unless otherwise noted here or in awarding agency policies.

- Disclosure of financial conflicts of interest does not apply to Phase I of the SBIR and STTR programs.
- Under an SBIR or STTR award, the SBC should purchase only American-made equipment or products when possible.

Allowable Costs and Fees

Program Levels (Total Costs)

The <u>SBA SBIR and STTR Policy Directive</u> provides program levels for SBIR and STTR programs based on statutory guidelines. The directives allow awarding agencies to exceed these levels up to 50% over the guideline when the proposed budget and requested period of support are justified and scientifically appropriate for the proposed research.

In some cases, Phase II SBIR or STTR recipients may apply for Phase IIB competing renewal awards. These are available for projects that require extraordinary time and effort for R&D. Only those SBCs awarded a Phase II may apply for the Phase IIB award.

Applicants must request an appropriate level in the competing application. The awarding agency will not adjust it after submission.

Profit or Fee

SBCs can earn a reasonable profit or fee under Phase I and II of the SBIR and STTR programs.

- This profit or fee must be in the application budget.
- The profit or fee isn't considered a cost for determining allowable use, program income accountability, or setting audit thresholds.
- The SBC can use the profit or fee for any purpose, including investment into the awarded project.
- The intent is to provide a reasonable profit consistent with normal profit margins for for-profit organizations for R&D work. Typically, the profit or fee will not surpass seven percent of the total project costs for each phase.
- The profit or fee should be drawn from PMS in proportion to the drawdown of funds for direct and indirect costs.
- The profit or fee is exclusively for the SBC that receives the award. However, in line with regular commercial practices, the SBC can pay a profit or fee to a contractor that provides routine goods or services under the award.

Indirect Costs

If the applicant SBC has a currently effective indirect cost rate with a federal agency, the rate should be used when calculating proposed indirect costs for an application. The rates must be adjusted for IR&D expenses, which are not allowable under HHS awards.

If that applicant does not have an approved indirect cost rate, one can be proposed in the application. See below for specific requirements for each phase. If awarded at a rate, indirect costs cannot exceed the awarded rate unless the SBC negotiates an indirect cost rate with a federal agency. The awarding agency will not negotiate indirect cost rates for Phase I awards.

If you do not have an effective negotiated indirect cost rate, you may propose estimated indirect costs at a rate not to exceed 40 percent of the total direct costs. You can charge only actual indirect costs to projects.

Phase II

If you do not have an effective negotiated indirect cost rate, you may propose an estimated indirect rate in the application.

If the requested rate is 40 percent of total direct costs or less, you do not need to provide further justification. You can charge only actual indirect costs to projects.

If you choose to negotiate an indirect cost rate greater than 40%, DFAS is the appropriate agency. Upon request, provide DFAS with an indirect cost proposal and supporting financial data for your most recently completed fiscal year. If you do not have financial data for the most recently completed fiscal year, submit a proposal showing estimated rates with supporting documentation.

Administrative Requirements

Market Research

HHS will not support market research, including studies of the literature that lead to a new or expanded statement of work.

No SBIR or STTR funds, direct or indirect, can be used to support commercialization.

For SBIR and STTR programs, market research is the systematic gathering, editing, recording, computing, and analyzing of data relating to the sale and distribution of the research subject. It includes research on:

- The size of potential markets and potential sales volume
- Identifying consumers most apt to purchase the products
- The advertising media most likely to stimulate their purchases

Market research does not include activities that include a public survey to determine the research subject's impact on the behavior of individuals.

Intellectual Property

The recipient keeps rights to data and software created with award funding. However, the federal government has a royalty-free, nonexclusive, and irrevocable license to reproduce, publish or otherwise use the material and to authorize others to do so for Federal purposes.

For SBIR and STTR awards, unlike other commercial awards, such data cannot be released outside the Federal government without the recipient's permission for a period of 20 years from completion of the project.

Data Rights

Section 9 of the Small Business Act, as amended ($\underline{15~USC~638}$), allows SBC's under an SBIR or STTR award to retain their data rights for at least four years. The SBIR/STTR Policy Directive applies the following data rights:

- The Act allows small business concerns (SBCs) to keep the rights to data they create while working on an SBIR/STTR award. This helps encourage SBCs to participate in Federally funded research and supports them in commercializing their technology. The Federal Government will have access to this data to assess the projects and use the results, but it cannot use the data in ways that would hurt the SBC's rights or economic opportunities. The SBIR/STTR data rights provisions and definitions ensure that the Federal Government effectively protects properly marked SBIR/STTR data during the SBIR/STTR protection period just as well as it protects data developed at private expense.
- Federal agencies that participate in SBIR/STTR awards must make sure that SBC recipients keep appropriate proprietary rights to data generated while working on an award. In general, this means the Federal Government will have rights to that data during the protection period, except for certain types of data that are not subject to such data rights restrictions.
- SBIR/STTR data rights apply to all SBIR/STTR awards, including subcontracts, for all phases of the program (I, II, or III) as defined by the SBA Policy Directive from May 2, 2019. The rights for Phase III awards are the same as those for Phases I and II.
- SBIR/STTR data rights restrict the Federal Government's use and release of properly marked SBIR/STTR data only during the SBIR/STTR protection period. After the protection period, the Federal Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for government purposes. At this time, the Federal Government is relieved of disclosure prohibitions related to such government purposes and assumes no liability for unauthorized use of these data by third parties. The Federal Government receives unlimited rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR data.

SBIR/STTR Data Rights - Main Elements:

- An SBC retains title and ownership of all SBIR/STTR data it develops or generates in the performance of an SBIR/STTR award. The SBC retains all rights in SBIR/STTR data that are not granted to the Government in accordance with the SBA Policy Directive. These rights of the SBC do not expire.
- The Government receives SBIR/STTR data rights during the SBIR/STTR protection period on all appropriately marked SBIR/STTR data. These rights enable the Federal Government to use SBIR/STTR data in limited ways within the Government, such as for project evaluation purposes. These rights are intended to prohibit use and disclosure of SBIR/STTR data that may undermine the SBC's future commercialization of the associated technology. The Government receives unlimited rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR data.
- After the SBIR/STTR protection period has expired, the Federal Government may
 use, and authorize others to use on its behalf, for government purposes, SBIR/STTR
 data that was subject to SBIR/STTR data rights during the SBIR/STTR protection
 period.
- The SBIR/STTR protection period begins with award of an SBIR/STTR funding agreement. It ends twenty years, or longer at the discretion of the participating agency, from the date of award of an SBIR/STTR award (either Phase I, Phase II, or Federally-funded SBIR/STTR Phase III) unless the agency and the SBC negotiate for some other protection period for the SBIR/STTR data subsequent to the award.
- Any SBIR/STTR data that is delivered must be marked with the appropriate SBIR/STTR data rights legend or notice to receive the protections given to SBIR/STTR data pursuant to SBIR/STTR data rights. The Government is not liable for the access, use, modification, reproduction, release, performance, display, disclosure, or distribution of SBIR/STTR data that is not appropriately marked in line with agency procedures. If SBIR/STTR data is delivered without the required legend or notice, the SBIR/STTR recipient may, within 6 months of such delivery (or a longer period approved by the agency for good cause shown), request to have an omitted SBIR/STTR data legend or notice, as applicable, placed on qualifying data. If SBIR/STTR data is delivered with an incorrect or nonconforming legend or notice, the agency may correct or permit correction at the recipient's expense.

Negotiated Rights:

- An agency must not, in any way, make issuance of an SBIR/STTR award conditional on the SBC negotiating or consenting to negotiate a special license or other agreement regarding SBIR/STTR data. The negotiation of any such specially negotiated license agreements shall be permitted only after award.
- After issuance of an SBIR/STTR award, the SBC may enter into a written agreement
 with the agency to modify the license rights that would otherwise be granted to the
 agency during the SBIR/STTR protection period. However, the agreement must be

entered into voluntarily, by mutual agreement of the SBC and agency. The agreement cannot be a condition for additional work under the funding agreement or the exercise of options. The agreement must be entered into only after the SBIR/STTR award, which must include an appropriate SBIR/STTR data rights clause, has been signed. Any such specially negotiated license must be in writing under a separate agreement after the SBIR/STTR funding agreement is signed. A decision by the recipient to relinquish, transfer, or modify in any way its rights in SBIR/STTR data must be made without pressure or coercion by the agency or any other party. Any provision in a competitive non-SBIR or SBIR solicitation that would have the effect of diminishing SBIR/STTR data rights shall have no effect on the provision of SBIR/STTR data rights in a resulting Phase I, Phase II, or Phase III award.

- To ensure that SBIR/STTR recipients receive the applicable data rights, all SBIR and STTR NOFOs and resulting funding agreements must fully implement all of the policies, procedures, and requirements set forth in the SBA Policy Directive in appropriate provisions and clauses incorporated into the SBIR/STTR NOFOs and awards. The SBA Policy Directive provides a sample SBIR/STTR data rights clause containing the key elements that must be reflected in the clause used in Federal Agency solicitations. SBA will report to the Congress any attempt or action by an agency, that it is aware of, to condition an SBIR or STTR award on the negotiation of lesser data rights or to exclude the appropriate data rights clause from the award.
- The STTR program requires that the SBC and the single, non-profit research institution execute an agreement allocating between the parties intellectual property rights and rights, if any, to carry out follow-on research, development, or commercialization of the subject research.

SBIR and STTR recipients are covered by <u>35 USC 200-212</u> and <u>37 CFR § 401</u> with respect to inventions and patents.

Data Sharing

For SBIR Phase II funding over \$500,000 in a year in direct costs, applicants must follow the GPS on data sharing, unless the Small Business Act conflicts. If the data is proprietary or sensitive, the SBC should explain it in the application. Whether or not the award meets the threshold for data sharing under Intellectual Property, HHS won't share data outside the federal government without recipient approval for a period of 20 years from completion of the project.

For more information, please see NIH's SBIR/STTR information page.

Research Awards

Human Subjects in Research

The regulation for all HHS awards involving human subjects research is <u>45 CFR part 46</u>, Basic HHS Policy for Protection of Human Subjects. Subpart A is also known as the Common Rule. These regulations

implement Section 491(a) of the Public Health Service (PHS) Act. These regulations apply to both domestic and foreign organizations.

The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is the office with HHS-wide responsibility for research involving human subjects under this policy.

All NOFOs will clearly state:

- The parameters of human subject use
- The information and assurances required from you prior award

There is a single version of the Federal-wide Assurance (FWA) form and Terms of Assurance for domestic and international institutions.

Recipients, whether domestic or international, must safeguard the rights and welfare of human subjects in HHS-conducted or -supported activities (45 CFR § 46.101(a) and 45 CFR § 46.103(a)).

Recipients must ensure that subrecipients follow these requirements, as applicable. Recipients must facilitate the process for obtaining prior approval for subrecipients if not approved in the award.

Exemptions

Some human subject research is exempt from the requirements of the HHS regulations.

The categories of research that qualify for exemption are found at $\underline{45 \text{ CFR } \S 46.104(d)(1)-(8)}$. HHS has final authority to decide if a particular research study supported by HHS is exempt from the HHS regulations. OHRP is the only component of HHS with the delegated authority to interpret and enforce the regulatory requirements in $\underline{45 \text{ CFR } \S 46.101(c)}$ regarding whether a particular activity is regulated by $\underline{45 \text{ CFR part } 46}$. Contact OHRP for questions.

Policies for Non-Exempt Human Subjects Research

The recipient, including any collaborating organization under a subaward, must:

- Hold or obtain an OHRP-approved FWA (45 CFR § 46.103(a)).
- Certify to the awarding agency, within the time frame specified, that the research has been reviewed and approved by an Institutional Review Board (IRB) designated in the FWA (45 CFR § 46.103(d)).

The OHRP website contains a listing of those organizations with OHRP-approved assurances.

The awarding agency must make sure an applicant and any collaborating organizations have the required assurance and certification in place, before:

- Making an award unless there is a specific condition in the NoA restricting expenditures for this purpose.
- You initiate human subjects research, and the awarding agency removes any related NoA specific condition.
- Approving a post-award change in scope that will result in human subjects research.

The specific award condition must indicate that:

- You may not draw down funds, obligate or expend federal funds, or claim required cost sharing or matching costs for research involving human subjects at any site engaged in research until you meet all requirements.
- Failure to comply within the stated time may result in full or partial termination of the award.

The prohibition on expenditures may extend to the whole project if that activity can't be isolated.

Research Involving Animals and Their Welfare

Requirements for using live, vertebrate animals apply to all PHS agencies and other research-related awards. PHS agencies include AHRQ, CDC, FDA, HRSA, IHS, NIH, OASH, and SAMHSA. These requirements apply to recipients, subrecipients, and contractors, whether foreign or domestic.

The requirements:

- Are included in the <u>Public Health Service Policy on Humane Care and Use of Laboratory Animals</u> (PHS Policy).
- Incorporate the <u>U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing</u>, Research, and Training.
- Require the recipient to maintain an animal care and use program based on the Guide for the Care and Use of Laboratory Animals.
- Require compliance, as applicable, with the <u>Animal Welfare Act</u> and other federal statutes and regulations relating to animals.

You must establish appropriate policies and procedures to ensure the humane care and use of animals, and you are ultimately responsible for compliance with the PHS Policy.

You can get information about animal welfare topics from the Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, National Institutes of Health.

Before engaging in any HHS award-supported research using animals, applicants must:

- Have a current Animal Welfare Assurance approved by OLAW. The list of organizations with approved assurances is on the OLAW website for both <u>domestic</u> <u>institutions</u> and <u>foreign institutions</u>.
- Verify, as part of the application or before award, current Institutional Animal Care and Use Committee (IACUC) approval of the animal activities. PHS Policy requires that IACUC approval must have happened within three years of the period of performance start date for new or renewal awards and at least every three years after that.
- Comply with the awarding agency's internal IACUC requirements if a cooperative agreement.

If you do not have a current Animal Welfare Assurance (or made alternative arrangements, like an inter-institutional assurance acceptable to OLAW) or has not provided the required verification by the

time an award is to be made, the awarding agency will notify the PO and the applicant. The awarding agency may:

- Delay the award until the recipient and all performance sites are operating in accordance with approved Animal Welfare Assurances and the organization has provided verification of IACUC approval of those sections of the application that involve use of animals.
- Include a specific condition in the NoA restricting expenditures.

The award condition must state that:

- You may not draw down funds, obligate or expend federal funds, or claim required cost sharing or matching costs for research involving animals at any site engaged in research until you meet all requirements.
- Failure to comply within the stated time may result in full or partial termination of the award.
- The prohibition on expenditures may extend to the whole project if that activity can't be isolated.

Before approving changes involving animal research after award, the awarding agency needs to confirm that there's a proper Animal Welfare Assurance with OLAW. They also need verification from the IACUC.

Reporting

Reporting requirements under the PHS Policy include an annual report to OLAW describing:

- Any updates in your animal care program as mentioned in the Assurance.
- Changes in IACUC membership
- The dates when the IACUC reviewed your program and facilities.

Lastly, the IACUC must quickly report any serious issues or breaches in policies, guidelines, or any suspensions through the official who signed the Assurance.

Foreign Applicants

Foreign applicant organizations applying for awards for activities involving animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

This includes providing OLAW with an Animal Welfare Assurance for Foreign Institutions, which includes:

- Institutional assurance and certification of compliance with the applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted
- A commitment to follow the <u>International Guiding Principles for Biomedical</u> Research Involving Animals.

Awards to Individuals

No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy.

Appendix D: HHS Administrative and National Policy Requirements

Please go to the following page to see updated HHS requirements: https://www.hhs.gov/sites/default/files/hhs-administrative-national-policy-requirements.pdf

Additional Information on Uniform Administrative Requirements

As stated in the information linked above, the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (45 CFR § 75) apply to all HHS awards, unless specifically exempted by 45 CFR § 75.101(d) or (e).

As of October 1, 2024, the following provisions from 2 CFR part 200 are effective for all new HHS awards or monetary actions (new, continuation, and supplements):

2 CFR § 200.1 Definitions: Modified Total Direct Cost (MTDC), which increases the exclusion threshold of subawards from \$25,000 to \$50,000 for modified total direct costs, definition of Equipment, which increases the threshold for determining equipment from \$5,000 to \$10,000, definition of Supplies, which increases the threshold for determining supplies from \$5,000 to \$10,000;

2 CFR § 200.313 (e) Equipment: Increases from \$5,000 to \$10,000 the value of equipment that at the end of the grant period "may be retained, sold, or otherwise disposed of with no further responsibility to the Federal agency" (see 2 CFR section 200.313(e)(1)). The provision also clarifies that Indian Tribes may use their own procedures for use, management, and disposal of equipment. If they do not have procedures, then they must follow the ordinary guidance.

<u>2 CFR § 200.314(a)</u> Unused Supplies: Increases from \$5,000 to \$10,000 the value of unused supplies that recipients of Federal funds are required to sell at the end of the grant award period as well as clarifying that this amount is the total amount of remaining unused supplies, not just like items (see 2 CFR section 200.314).

<u>2 CFR § 200.320</u> Micro-purchase Threshold: Increases the micro-purchase threshold to \$50,000 (see 2 CFR 200.320).¹

<u>2 CFR § 200.333</u> Fixed Amount Awards Subawards: Increases from \$250,000 to \$500,000 the amount of fixed amount subawards that a recipient may provide with prior written approval from the Federal agency (see 2 CFR section 200.333).

<u>2 CFR § 200.344</u> Closeout: Increases the time period for recipients to submit final reports in support of closeout of the award from 90 to 120 days (*see 2 CFR 200.344*).²

2 CFR § 200.414(f) De Minimis Indirect Rate: Increases from 10% to 15% the rate that recipients of Federal funds may use for indirect costs without negotiating an alternative rate with the relevant

¹ This provision has already been adopted by HHS by operation of law, Pub. L. No. 115-91, and OMB Memorandum 18-18. It is included to be clear that this regulation is in force for HHS.

² This provision has already been adopted by HHS. See 88 FR 63591 (Sept. 15, 2023). It is included to be clear that this regulation is in force for HHS.

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Federal agency (see 2 CFR section 200.414). Note that this does not apply to HHS Training or Foreign awards, for which HHS proposes to maintain a modification that caps the de minimis at 8%.

2 CFR § 200.501 Single Audit: Increase from \$750,000 to \$1,000,000 the level at which a recipient of Federal funds is required to conduct a single audit or a program specific audit (*see 2 CFR section 200.501*).

Appendix E: Financial Assistance General Certifications and Representations

In almost all instances, applicants must have a SAM.gov registration. Agreement to a list of general certifications and representations is required for registration.

Please go to the following page to see updated Certifications and Representations:

https://www.hhs.gov/sites/default/files/financial-assistance-general-certification-representations.pdf

EXHIBIT E

	Grant/Co	operative /	Agreement Modificat	ion
1. AWARD NO. FA9550-22-1-0267	2. MODIFICATION NO. P00006	3. EFFECTIVE DATE 28 FEB 2025	PURCHASE REQUEST NO. See Block 9	PAGE OF 1 2
5. ISSUE BY AFRL/RBKR2 USAF, AFRL DUNS 143574 AF OFFICE OF SCIENTIFIC 875 N. RANDOLPH ST. RO ARLINGTON VA 22203 JAMES R. DECATUR 66 JAMES.DECATUR@US.AF	726 C RESEARCH OM 3112 319029925	CODE FA9550	6. AWARDED TO CAGE REGENTS OF THE UNIVERS THE 1608 4TH ST STE 201 BERKELEY CA 94710-1749 (510) 643-3891	CODE 50853 ITY OF CALIFORNIA,

9. ALLOCATED FUNDING: The following funds with associated Accounting Classification reference number(s) (ACRNs) are allotted to this agreement:

ACRN FUND CITATION(s)

AMOUNT

SPECIAL INSTRUCTIONS: Payment will be made by Electronic Funds Transfer (EFT).

PAYING OFFICE INSTRUCTIONS: Use Earliest Cited Funds First for Payment.

PAYMENT SCHEDULE (if applicable): N/A. Submit a SF 270 Request for Reimbursement through WAWF at https://piee.eb.mil for payment.

10. FUNDING HISTORY:	Government Share	11. Recipient Share	12. Total
Previously Obligated:	\$1,421,208.00	\$0.00	\$1,421,208.00
Obligated by this Action:	\$0.00	\$0.00	\$0.00
Total Obligated to date:	\$1,421,208.00	\$0.00	\$1,421,208.00
13.TOTAL AWARD AMOUNT CHANGE	\$0.00	\$0.00	\$0.00

14. DESCRIPTION OF MODIFICATION

The subject grant award no longer effectuates the program goals or agency priorities as found in 2 CFR 200.340(a)(4) as incorporated into the DoD Research and Development General Terms and Conditions for grants by reference. This Grant is hereby terminated.

All costs incurred up to the date of this notification must be submitted no later than 30 calendar days from the termination date.

As a result, the period of performance is reduced from 36 months to 31.5 months as follows: FROM: 15 JUL 2022 through 14 JUL 2025 TO: 15 JUL 2022 through 28 FEB 2025

As the subject grant no longer effectuates the program goals or agency priorities, the closeout requirement for a final technical report is hereby waived. Reporting requirements are revised on the continuation page (pg. 2).

All other closeout requirements remain unchanged. All other terms and conditions remain the same.

	FOR THE RECIPIENT		FOR THE UNITED STATE	ES OF AMERICA
15. SIGNATORE			16. SIGNATURE //signed//	
17. NAME AND TITLE		18. DATE SIGNED	19. NAME AND TITLE LEXCIE A. POTTER GRANTS OFFICER	20. DATE SIGNED 28 FEB 2025

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BLOCK 14 CONTINUED

REPORTING REQUIREMENTS (REVISED)

The following reports must be submitted. Reports are due on or before the following dates.

TYPE OF REPORT	DUE DATE	SUBMIT TO
Interim Research Performance Progress	14-Jul-2023	Pgm Mgr* &
Reports		https://community.apan.org/wg/afosr/p/deliverables
Interim Research Performance Progress		Pgm Mgr* &
Reports		https://community.apan.org/wg/afosr/p/deliverables
Final Invention Report	29-May-2025	afrl.afosr.pkcontracting@us.af.mil
Final Federal Financial Report, including	29-Mar-2025	Grant Admin Office (Block 12 of Grant Award
line item 11		Form) & afrl.afosr.pkcontracting@us.af.mil
Quarterly Federal Financial Report (SF	*See below	Grant Admin Office (Block 12 of Grant Award
425)		Form)

^{*} The Program Manager/Officer is shown on page 1 of the basic Grant award in Block 15.

Quarterly Federal Financial Reports (SF 425) are not required if all payments are by reimbursement.

AFOSR prefers Performance Reports be submitted electronically, however, if the awardee does not have access to electronic means, send paper copies of Performance Reports to the appropriate Program Manager and office symbol listed in Block 15 of page 1 of the basic grant award at the following address: 875 N. Randolph Street Room 3112, Arlington VA 22203-1954.

All records pertinent to this award must be retained for a period of at least three years from the date of submission of the Final Federal Financial Report.

SCHEDULE FA9550-22-1-0267 P00006

^{**} SF 425 Quarterly Federal Financial Reports are required if any payment is made by an advance. The quarterly end dates that must be used are 31 Mar, 30 Jun, 30 Sep, and 31 Dec. The reports must be submitted within thirty (30) days after the end of each reporting period.

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OBLIGATED BY THIS ACTION:						\$(0.00		
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GRANT TOTAL:						\$321,58	4.00		
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703-696-2593 v		ESS: CEY.CIV@US.NA	VY.MIL						
4. SUBMIT PAYMENT REQUEST	TO: 25a.	PAYING OFFICE		25b. CC N34		26a. PA1	TENT O	FFICE:	26b. CODE: N00014
See FMS Article II, S C.2.b of the ONR Adde to the DoD R&D Genera Terms and Conditions	endum N3 al us fm	34291				ATTN: Intel One I 875 N	ONR lectu ibert Jorth	Naval Resea Office of C al Property y Center Randolph St VA 22203-1	rch ounsel Section reet, Suite 1425

AWARD NO.			MODIFICATION NO.	
N000142512110	AWARD/M	ODIFICATION	P00001	
27. SPECIAL INSTRUCTIONS:			1	
First Year Indirect Cost Rate: 59.00%				
See Special Requirements on Page 5				
28. DELEGATIONS: The administration duties listed below make their full text available. Please direct questions to the		e administrative office (block 23	a). Upon request the awardin	g office contact (block 22) will
https://www.onr.navy.mil/work-with-us	_	d/onr-regional-office	S	
This award provides full delegation t				
includes the functions described in t functions related to payments describ			ministrative grants	officer
20 TERMS AND CONDITIONS The fill with the said of		L	6 and -66 an if all	
29. TERMS AND CONDITIONS: The following terms and c request the awarding office contact named in block 22 will in				were given in full text. Opon
DOCUMENT		URL		
The following documents may be found	at:			
https://www.nre.navy.mil/work-with-us		d/manage-grant-award/	grants-terms-condit	ions
- DOD RESEARCH AND DEVELOPMENT GENERA	L TERMS AND CONDI	FIONS (OCT 2024)		
- UAWA AWARD A (SEP 2017)				
- ONR ADDENDUM TO THE DOD R&D GENERAL EDUCATION AND SYMPOSIUM PROJECTS (JUL		IONS AND ONR PROGRAMM	ATIC REQUIREMENTS -	- DOMESTIC
	,			
30. OPTIONS	AMOUNT	PERIOD		
(1)				
(2)				
(3)				
(4)				
31. REPORTS: The reporting requirements under this awa	I rd are specified in the artic	Les of part 5 (Financial, Program	matic. and Property Reporting	g) to the General Terms and
Conditions and in any additional language for Part 5 in an				<i>5,</i>
32. FOR THE RECIPIENT		33. FOR THE UNITED STATE	S OF AMERICA	
32a. SIGNATURE OF PERSON AUTHORIZED TO SIGN		33a. SIGNATURE OF AWARI	DING OFFICER	
		Digitally signed by Dated: 2025.04.23	y VERONICA LACEY 12: 18:44:29 EST	31655901
32b. NAME AND TITLE OF SIGNER	32c. DATE SIGNED	33b. NAME AND TITLE OF A	WARD OFFICER	33c. DATE SIGNED
		VERONICA LACEY		1
		VERONICA LACEI		04/23/2025
NAVONR 4206 (1-2022)		VERONICA EACEI		04/23/2025

Page 2 of 5

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DATE:	BY DATE:	for COMPTROLLER, ONR CONTRACT REVIEWED
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AWARD NO.		MODIFICATION NO.
N000142512110	SPECIAL REQUIREMENTS	P00001
Equity, and Inclusion (DEI) or DEI-re	lly terminate the award by mutual agree lated terms and efforts, in accordance nt DEI Programs." Block 10, proposal dat email on March 24, 2025.	with the Executive Order titled
The DoD Research and Development Gene showing in Block 29.	ral Terms and Conditions (March 2025) r	eplace the DoD terms and conditions
* DoD Research and Development General https://www.onr.navy.mil/media/docume	Terms and Conditions (March 2025) nt/dod-research-and-development-rd-gene	ral-terms-and-conditions-march-2025

NAVONR 4206 (1-2022)

Office of Naval Resear	24		FICE OF RESEAR RD / MODI	CH		875	ce o N. R	OFFICE: f Naval Rese andolph St, N VA 22203-	Suite 1425
S'i nce & Technolog		INSTRUMEN Grant Awa AUTHORITY:	ard:			12.33 3c. DUNS	NUME	ER or UEI:	ER AND TITLE: Outreach and Workford
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3a. ADDRESS: 50854 UNIVERSITY OF CALIFOR UC SAN DIEGO HEALTH 9500 GILMAN DR LA JOLLA CA 92093-00 UNITED STATES OF AMER	NIA, SAN DIEC	N/A GO							
3d. BUSINESS OFFICE CONTACT Michael Kusiak	Γ:			1					
	EMAIL ADDRESS			1					
5. RESEARCH TITLE AND/OR DE Termination-STEM Enha	SCRIPTION OF PR	OJECT AND/			and Reten	tion			
6. FUNDING	ACTIVITY/AGEI	NCY SHARE	RECIPIENT S	HARE	т	OTAL		17. CURRENT F	UNDING PERIOD
PREVIOUSLY OBLIGATED:						\$70,000	.00	N/A	THROUGH N/A
OBLIGATED BY THIS ACTION:						\$0	.00	1 .,,	1771
TOTAL OBLIGATED ON AWARD:						\$70,000	.00	18. PERIOD OF	PERFORMANCE
FUTURE FUNDING:			7			\$0	.00	01/01/2025	THROUGH 08/31/2025
GRANT TOTAL:						\$70,000	.00		
 ACCOUNTING AND APPROPRI See Attached Financia 		Data Shee	et(s)						
0a. PRINCIPAL INVESTIGATOR/R ECHNICAL REPRESENTATIVE:	ECIPIENT				:HNICAL REP ME: Chad A				21b. CODE : 35
Miroslav Krstic				AIR 875	DRESS: WARFARE N. Rando ington VA	lph Str	eet	T DEPT	
0b. TELEPHONE NUMBER: 20c ml	:. EMAIL ADDRESS				LEPHONE N (3) 696-04			MAIL ADDRESS	
2. POC FOR THIS ACTION 2a. NAME: VERONICA Y LACE		22b. COD	DE:		MINISTRATIV			a.scorezenavy	23b. CODE: N62879
2c.ADDRESS: Office of Naval Resea 875 N. Randolph Stree Arlington VA 22203-19	t Suite 1425			Ema va. 495	REG Offi il:usn.pe mbx.onr-b Summer S TON MA 02	ntagon. oston@u treet,	cnr-a s.nav Room		
	. EMAIL ADDRESS ERONICA.Y.LACEY		VY.MIL						
4. SUBMIT PAYMENT REQUEST	TO: 25a. PA	YING OFFICE		25b . CC		26a. PATI	ENT O	FICE:	26b. CODE: N00014
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AWARD NO.			MODIFICATION NO.	
N000142512110	AWARD/M	ODIFICATION	P00003	
27. SPECIAL INSTRUCTIONS:			-	
First Year Indirect Cost Rate: 59.00%				
See Special Requirements on Page 5				
28. DELEGATIONS: The administration duties listed below		e administrative office (block 23	a). Upon request the awardin	g office contact (block 22) will
make their full text available. Please direct questions to the https://www.onr.navy.mil/work-with-us	_	d/onr-regional-office	:S	
This award provides full delegation t	2 2	-		ll delegation
includes the functions described in t	he DoDGARs at 32 (CFR 22.715 and the ac		
functions related to payments describ	ed in 32 CFR 22.8.	10.		
29. TERMS AND CONDITIONS: The following terms and or request the awarding office contact named in block 22 will				were given in full text. Upon
DOCUMENT		URL		
The following documents may be found	at.			
https://www.onr.navy.mil/work-with-us		d/manage-grant-award/	grants-terms-condit	tions
- DOD RESEARCH AND DEVELOPMENT GENERA	L TERMS AND CONDI	FIONS (OCT 2024)		
- UAWA AWARD A (SEP 2017)			AMERICA DEGLETORISMENTA	DOMEGRETA
- ONR ADDENDUM TO THE DOD R&D GENERAL EDUCATION AND SYMPOSIUM PROJECTS (JUL		IONS AND ONR PROGRAMM	ATIC REQUIREMENTS -	- DOMESTIC
30. OPTIONS	AMOUNT	PERIOD		
(1)	1			
(2)				
(3)				
(4)				
31. REPORTS: The reporting requirements under this awa				g) to the General Terms and
Conditions and in any additional language for Part 5 in an 0	ONR Addendum to the Ger	ieral Terms and Conditions spe	cified in Block 29.	
32. FOR THE RECIPIENT		33. FOR THE UNITED STAT	ES OF AMERICA	
32a. SIGNATURE OF PERSON AUTHORIZED TO SIGN		33a. SIGNATURE OF AWAR		
		Digitally signed by Dated: 2025.05.23	y VERONICA LACEY 12 14:25:31 EST	31655901
32b. NAME AND TITLE OF SIGNER	32c. DATE SIGNED	33b. NAME AND TITLE OF A	WARD OFFICER	33c. DATE SIGNED
		VERONICA LACEY		05/23/2025
NAVONR 4206 (1-2022)		•		

Page 11 of 15

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1. CONTRACT NUMBER (CRITICAL)	(CRITICAL)	2. SPIIN (CRITICAL)	TICAD		3. MOD (CRITICAL)	CRIT	ICAL)	4	4. PR NUMBER	8						
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Page 12 of 15

FINANCIAL ACCOUNTING DATA SHEET - NON-NAVY DOD ACTIVITIES RITICAL) 2. SPIIN (CRITICAL) 3. MOD (CRITICAL) 4. PR NUMBER 4. PR NUMBER 4. 720012442	7. ACCOUNTING CITATION AMOUNT USE ONLY (CRITICAL) REF DOCACRN	PAGE TOTAL	GRAND TOTAL	. INVOGGG A GT LOGTAMOO
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AWARD NO.	ODEOLAL DEOLUDEMENTO	MODIFICATION NO.
N000142512110	SPECIAL REQUIREMENTS	P00003
The purpose of this modification is to	o document the termination of this awar	d under mutual agreement.
The end date is changed to August 31,	2025	
* The grant total award value is reduced	d to \$70,000.00	
* End of modification		
		1

AMENDMENT OF SOLICITA	ATION/MODIF	ICATION OF CONTRACT	1.0	CONTRACTID	CODE	PAGE OF PAGES 1 2
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.		5	.PROJECT I	NO (Ifapplicable)
P00001	27-Mar-2025	0011949993				
6. ISSUED BY CODE	W911NF	7. ADMINISTERED BY (Ifother than item6)		CODE	N6601	8
US ARMY ACC-APG-RTP W911NF 800 PARK OFFICE DRIVE SUITE 4229 RESEARCH TRIANGLE PARK NC 27709		ONRRO SAN DIEGO 140 SYLVESTER ROAD BLDG 140 ROOM 218 SAN DIEGO CA 92106-3521				
8. NAME AND ADDRESS OF CONTRACTOR UNIVERSITY OF CALIFORNIA IRVINE 160 ALDRICH HALL	(No., Street, County, S	State and Zip Code)				LICIT ATION NO.
IRVINE CA 92697-0001				DATED (SEE		,
			^ W91	1NF2310209)	T/ORDER NO.
CODE OVIM O	T. CT. ITT. CO.	<u> </u>		DATED (SE un-2023	EE II EM	13)
CODE 0VWL0	FACILITY COL	<u>DE</u> PPLIES TO AMENDMENTS OF SOLI	10.0			
The above numbered solicitation is amended as set fort			is exte		is not exten	4.4
Offer trust acknowledge receipt of this amendment price (a) By completing Items 8 and 15, and returning or (c) By separate letter or telegram which includes a re RECEIVED ATTHE PLACE DESIGNATED FOR TH REJECTION OF YOUR OFFER. If by virtue of this ar provided each telegramor letter makes reference to the 12. ACCOUNT ING AND APPROPRIATION DA	copies of the amendment ference to the solicitation of the RECEIPT OF OFFERS. mendment you desire to chat solicitation and this amendment	nt; (b) By acknowledging receipt of this amendmand amendment numbers. FAILURE OF YOUR APRIOR TO THE HOUR AND DATE SPECIFIEI nge an offer already submitted, such change may	ent on each c ACKNOWL DMAY RES be made by t	copy of the offer EDGMENTTC SULT IN elegramor letter	BE	
		TO MODIFICATIONS OF CONTRACT	SWIDER	<u>c</u>		
IT MOD	IFIES THE CONTRAC	CT/ORDER NO. AS DESCRIBED IN IT	EM 14.		DE IN TI	T
A. THIS CHANGE ORDER IS ISSUED PURSU CONTRACT ORDER NO. IN ITEM 10A.	JANT TO: (Specify a	utnority) THE CHANGES SET FORTH	INTIEM	1 14 ARE MA	DE IN 11	1E
B. THE ABOVE NUMBERED CONTRACT/O office, appropriation date, etc.) SET FORT	TH IN ITEM 14, PUR	SUANT TO THE AUTHORITY OF FA			changes in	n paying
C. THIS SUPPLEMENT AL AGREEMENT IS	SENTERED INTO PU	JRSUANT TO AUTHORITY OF:				
D. OTHER (Specify type of modification and Unilateral; IAW 2 CFR 200.340(a)(4)	authority)					
E. IMPORTANT: Contractor X is not,	is required to sig	n this document and return	copies to	the issuing o	office.	
14. DESCRIPTION OF AMENDMENT/MODIF where feasible.) Modification Control Number: creechw 2: Proposal: 81510 Pl: Dr. Darryl Preece The purpose of this modification is termination	51508			·		ill
be issued to deobligate funding and reduce the		* * * *			neadon N	
SEE CONTINUATION PAGEs. Except as provided herein, all terms and conditions of the d	ocument referenced in Item!	9A or 10A, as hereto fore changed, remains uncha	nged and in	full force and ef	lect.	
15A. NAME AND TITLE OF SIGNER (Type or	print)	16A. NAME AND TITLE OF CO	ANTS OFFICI	ER		,
	les - :	TEL: (919) 549-4387		L: william.a.cree		
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNE	16B. UNITED STATES OF AME		eech		C. DATE SIGNED 7-Apr-2025
(Signature of person authorized to sign)		(Signature of Contracting Of	ficer)		"	
EXCEPTION TO SE 30		20.10.		CVTLAN	DADD DO	DM 20 (D 10 02)

APPROVED BY OIRM 11-84

DEFSDOD_00013

Prescribed by GSA FAR (48 CFR) 53.243

W911NF2310209 P00001 Page 2 of 2

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for CLIN 0001 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 01-JUN-2023 TO 31-MAY-2027	N/A	ARMY RESEARCH OFFICE SHIPPING ADDRESS ONLY (NO MAIL) 800 PARK OFFICE DRIVE SUITE 4229 RESEARCH TRIANGLE PARK NC 27709 (919) 549-4289 FOB: Destination	W36QYT

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 01-JUN-2023 TO 27-MAR-2025	N/A	ARMY RESEARCH OFFICE SHIPPING ADDRESS ONLY (NO MAIL) 800 PARK OFFICE DRIVE SUITE 4229 RESEARCH TRIANGLE PARK NC 27709 (919) 549-4289 FOB: Destination	W36QYT

(End of Summary of Changes)

EXHIBIT F



Public Health Service
National Institutes of Health
National Institute on
Alcohol
Abuse and Alcoholism
67008 Rockledge Drive
Bethesda, MD 20892-6902

February 28, 2025

Elizabeth Carrillo Sponsored Projects Analyst The Regents of the University of California, Santa Barbara 3227 Cheadle Hall, 3rd Floor Santa Barbara, CA 931062050

Dear Elizabeth Carrillo,

Funding for Project Number 5 R21 AA029513-02 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement, and 2 C.F.R. § 200.340(a)(2) (2024). This letter constitutes a notice of termination.

The 2024 Policy Statement applies to your project because NIH approved your grant on 08/18/2023, and "obligations generally should be determined by reference to the law in effect when the grants were made." ³

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards." According to the Policy Statement, "NIH may ... terminate the grant in whole or in part as outlined in 2 CFR Part 200.340." At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Your project does not satisfy these criteria. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide

https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

^{2 2} C.F.R. § 200.341(a); 45 C.F.R. § 75.373

³ Bennett v. New Jersey, 470 U.S. 632, 638 (1985).

^{4 2024} Policy Statement at IIA-1.

⁵ Id. at IIA-155.

Case: 25-4249 07/22/2025 DktEntry: 11.1 Page 269 of 475 Case 3:25-cv-04737-RFL Document 48-6 Filed 06/19/25 Page 3 of 3

low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision," no corrective action is possible here. The premise of Project Number 5 R21 AA029513-02 is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable. Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAs pending.gov*. 8

Administrative Appeal

You may object and provide information and documentation challenging this termination. NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board. 10

You must submit a request for such review to Matthew J. Memoli, MD, MS, Acting Director, National Institutes of Health no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Matthew J. Memoli, MD, MS, Acting Director, National Institutes of Health may grant an extension of time.¹¹

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.¹²

Sincerely,

Judy S. Fox - Digitally signed by Judy S. Fox - S Date: 2025.02.28 18:13:05 - 05'00'

⁶ 2024 Policy Statement at IIA-156.

⁷ See 2 C.F.R. § 200.343 (2024).

⁸ 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

⁹ See 45 C.F.R. § 75.374.

¹⁰ See 42 C.F.R. Part 50, Subpart D.

¹¹ *Id.* § 50.406(a).

¹² *Id.* § 50.406(b).

EXHIBIT G

Case: 25-4249 07/22/2025, DktEntry: 11.1, Page 271 of 475 Case 3:25-cv-04737-RFL Document 48-7 Filed 06/19/25 Page 2 of 3



UNITED STATES DEPARTMENT OF EDUCATION OFFICE OF SECONDARY AND ELEMENTARY EDUCATION OFFICE OF ADMINISTRATION

2/12/25

Tonikiaa Orange Project Director UNIVERSITY OF CALIFORNIA, LOS ANGELES 1320 Moore Hall Box 951521 Los Angeles, CA 90095

RE: Grant Award Termination

Dear Tonikiaa Orange

This letter provides notice that the United States Department of Education is terminating your federal award, <u>S336S230050</u>. See 2 C.F.R. § 200.340-43; see also 34 C.F.R. § 75.253.

It is a priority of the Department of Education to eliminate discrimination in all forms of education throughout the United States. The Acting Secretary of Education has determined that, per the Department's obligations to the constitutional and statutory law of the United States, this priority includes ensuring that the Department's grants do not support programs or organizations that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that unlawfully discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Illegal DEI policies and practices can violate both the letter and purpose of Federal civil rights law and conflict with the Department's policy of prioritizing merit, fairness, and excellence in education. In addition to complying with the civil rights laws, it is vital that the Department assess whether all grant payments are free from fraud, abuse, and duplication, as well as to assess whether current grants are in the best interests of the United States.

The grant specified above provides funding for programs that promote or take part in DEI initiatives or other initiatives that unlawfully discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic; that violate either the letter or purpose of Federal civil rights law; that conflict with the Department's policy of prioritizing merit, fairness, and excellence in education; that are not free from fraud, abuse, or duplication; or that otherwise fail to serve the best interests of the United States. The grant is therefore inconsistent with, and no longer effectuates, Department priorities. *See* 2 C.F.R. § 200.340(a)(4); *see also* 34 C.F.R. § 75.253. Therefore, pursuant to, among other authorities, 2 C.F.R. § 200.339-43, 34 C.F.R. § 75.253, and the termination provisions in your grant award, the Department hereby terminates grant No. S336S230050 in its entirety effective 2/12/25

400 MARYLAND AVE., S.W., WASHINGTON, DC 20202 www.ed.gov

The Department of Education's mission is to promote student achievement and preparation for global competitiveness by fostering educational excellence and ensuring equal access.

Case 3:25-CV-04737-RFL Document 48-7: 11.1 Page 272 of 475 Page 3 of 3

If you wish to object to or challenge this termination decision, you must submit information and documentation supporting your position in writing within 30 calendar days of the date of this termination notice. Objections and challenges must be sent by email and first-class mail and addressed to the component head that oversees the grantmaking unit, which will typically be the Assistant Secretary of that unit. In this case, please address your objection or challenge to Ruth Ryder, Acting Assistant Secretary; Office of Elementary and Secondary Education; 400 Maryland Ave., SW; Washington, D.C. 20202; ruth.ryder@ed.gov.

Your appeal should contain the following:

- 1. a copy of the written notice of termination;
- 2. the date you received written notice of termination;
- 3. a brief statement of your argument and the disputed factual, legal, or other issues;
- 4. the amount of funds or costs in dispute, if any; and
- 5. any other relevant documents.

See id. § 200.342.

Costs incurred by you after this termination are allowable only if (a) those costs were properly incurred by you before the effective date of this termination, and not in anticipation of it; and (b) those costs would be allowable if your federal award was not suspended or expired normally at the end of the period of performance in which the termination takes effect. See 2 C.F.R. § 200.343. You are encouraged to carefully review and discharge your closeout responsibilities set forth in 2 C.F.R. § 200.344-45 and your award agreement. Those responsibilities include, but are not limited to, your obligation to "promptly refund any unobligated funds" that have been paid out but "are not authorized to be retained." See 2 C.F.R. § 200.344(g). Failure to do so will result in the Department filing a report documenting your "material failure to comply with the terms and conditions of" this award on SAM.gov and taking any other appropriate enforcement actions. See id. § 200.344(i).

Finally, you are reminded of your duties under your agreement and Department of Education guidance regarding retention of grant records for at least three years.

Respectfully,

MARK
WASHINGTON
Digitally signed by MARK
WASHINGTON
Date: 2025.02.12
21:24:12 - 05'00'

Deputy Assistant Secretary for Management and Planning

cc: Ruth Ryder

400 MARYLAND AVE., S.W., WASHINGTON, DC 20202 www.ed.gov

EXHIBIT H



<Authorized Rep> <Organization> <Address line 1> <Address line 2> <City> <State>, <Zip>

RE: Grant Termination

Dear AmeriCorps Award Recipient:

Effective immediately, the AmeriCorps award subrecipient(s) included in the attached spreadsheet is/are being terminated per 2 CFR 200.340(a)(4) because it has been determined that the award no longer effectuates agency priorities. You must immediately cease all award activities. This is a final agency action and is not administratively appealable.

The provisions at <u>2 CFR 200.343</u> - <u>Effects of Suspension and Termination</u> apply. This process ensures the equitable settlement of costs, proper disposition of government property, and mitigation of negative impacts on stakeholders. AmeriCorps staff will initiate an amendment to change the end date of the period of performance effective immediately.

Please immediately notify subrecipients and/or community partners, if applicable, and initiate your internal termination and closeout procedures.

Please review <u>Closeout Instructions for Grantees</u> to close out this Federal award within 120 days. Please note, there are some close-out actions that indicate that you must submit information to your portfolio manager. Instead of submitting to those individuals, you must instead submit to the following regional mailboxes:

- MidAtlantic@americorps.gov (DC, DE, MD, NJ, PA, PR, VA, VI, WV)
- Midwest@americorps.gov (IL, IN, KY, MI, OH)
- Mountain@americorps.gov (AZ, CO, ID, MT, NM, UT, WY)
- NorthCentral@americorps.gov (IA, MN, WI, ND, SD, NE, KS, MO)
- Northeast@americorps.gov (CT, MA, ME, NH, NY, RI, VT)
- SouthCentral@americorps.gov (AR, LA, MS, OK, TX)
- Southeast@americorps.gov (AL, FL, GA, NC, SC, TN)
- West@americorps.gov (AK, AS, CA, CNMI, GU, HI, NV, OR, WA)

Costs after termination are allowable if:

(a) The costs result from financial obligations which were properly incurred before the effective date of termination, and

Case 3:25-cv-04737-RFL Document 48-8 11.1 Page 275 of 475 Page 3 of 3



(b) costs are for necessary and reasonable termination and closeout activities.

Please follow the program specific instructions below, based on the type of award that is being terminated.

AmeriCorps State and National

State commissions and prime grantees should immediately notify subgrantees, operating sites, and members and follow grant close-out procedures. All member activities should cease immediately. Members should be exited for compelling personal circumstances (CPC). The program should document that the member was exited for compelling personal circumstances due to the agency's termination of the grant and program closure. If possible, the program should try to have the member transferred to another program. If this is not possible, the program should note in the CPC documentation that member reassignment was not an option.

Jennifer Bastress Tahmasebi Interim Agency Head

EXHIBIT I

Name Title Organization Address

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Dear	· · · · · · · · · · · · · · · · · · ·	•
Dear		•

This letter provides notice that the United States Department of Agriculture is terminating your federal award, (Federal Award Identification Number [FAIN], Project Title), in accordance with the terms and conditions of your award, which include applicable regulations relating to termination. See 2 C.F.R. §§ 200.340-343.

It is the policy of the Department to establish a return to American principles and realign its focus towards its original objectives of maximizing and promoting American agriculture; ensuring a safe, nutritious, and secure food supply; enhancing rural prosperity; and managing our National Forests. This policy prioritizes multiple use management; conservation of our Nation's natural resources; and a focus on serving the American people in furtherance of those policies. The Department's resources must be conserved and focused upon its original objectives, as well as its obligations under the Constitution and laws of the United States. The Department's priorities include ensuring that its grants, cooperative agreements, and other similar arrangements do not support programs that promote or take part in climate change or environmental justice initiatives. It is vital that the Department assess both whether all award payments are free from fraud, abuse, and duplication and whether they are in the best interests of the United States.

<u>Termination</u>. The award specified above provides funding for programs that promote or take part in climate change or environmental justice initiatives; that conflict with the Department's policies and priorities; that are not free from fraud, abuse, or duplication; or that otherwise fail to serve the best interests of the United States. The award is therefore inconsistent with, and no longer effectuates, Department priorities. See 2 C.F.R. § 200.340(a)(4). Pursuant to, among other authorities, 2 C.F.R. §§ 200.339-343, which are applicable to your award, the Department hereby terminates award No. (FAIN) in its entirety effective (insert date of letter).

<u>Closure</u>. You must submit all final reports and a final payment request no later than 120 calendar days after the date of this notice. You will be reimbursed for costs incurred up to the date of this notice that are determined to be consistent with 2 C.F.R. § 200.343, *Effects*

of suspension or termination. Any open balance remaining 120 days after the date of this notice will be unavailable for payment.

If you do not submit all reports in accordance with the terms and conditions of the Federal award within one (1) year of the effective termination date, (Agency) must proceed to close out the award with the information available. In these circumstances, in accordance with 2 C.F.R. § 200.344, (Agency) must report your material failure to comply with the terms and conditions of the award in SAM.gov using the Contractor Performance Assessment Reporting System (CPARS). In this way, failure to submit timely and accurate final reports may affect your future funding.

Recipients are required by Federal regulation to retain all Federal award records consistent with 2 C.F.R. § 200.334. (Include the following if any payments were made to recipient)

Termination of the agreement does not affect a Federal agency's or a pass-through entity's right to disallow costs and recover funds based on a later audit or other review. In addition, termination does not affect a recipient's obligation to return any funds due as a result of later refunds, corrections, or other transactions, including final indirect cost rate adjustments (refer to 2 C.F.R. § 200.345).

Appeal Process. [Insert applicable appeal process]

If you have questions, contact your (Agency) Program Contact at (insert email address).

Sincerely,

(insert signatory official name) (Insert signatory official title)

CC: (insert name, Title, Office)

Date

Name Title Organization Address

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Dear	· · · · · · · · · · · · · · · · · · ·	•
Dear		•

This letter provides notice that the United States Department of Agriculture is terminating your federal award, (Federal Award Identification Number [FAIN], Project Title), in accordance with the terms and conditions of your award, which include applicable regulations relating to termination. See 2 C.F.R. §§ 200.340-343.

It is a priority of the Department of Agriculture to eliminate discrimination in all forms throughout the United States. The Secretary of Agriculture has determined, per the Department's obligations to the Constitution and laws of the United States, that priority includes ensuring that the Department's awards do not support programs or organizations that promote or take part in diversity, equity, and inclusion ("DEI") initiatives or any other initiatives that discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic. Such DEI policies and practices can violate both the letter and purpose of Federal civil rights laws and conflict with the Department's policy of maximizing and promoting American agriculture, ensuring a safe, nutritious and secure food supply, enhancing rural prosperity, and protecting our National Forests. In addition to complying with the letter and spirit of the civil rights laws, it is vital that the Department assess whether all awards are free from fraud, abuse, and duplication, as well as to assess whether current awards are in the best interests of the United States.

Termination. The award specified above provides funding for programs that promote or take part in DEI initiatives or other initiatives that unlawfully discriminate on the basis of race, color, religion, sex, national origin, or another protected characteristic; that violate either the letter or purpose of Federal civil rights laws; that conflict with the Department's policies and priorities; that are not free from fraud, abuse, or duplication; or that otherwise fail to serve the best interests of the United States. The award is therefore inconsistent with, and no longer effectuates, Department priorities. See 2 C.F.R. § 200.340(a)(4). Pursuant to, among other authorities, 2 C.F.R. §§ 200.339-343, which are applicable to your award, the Department hereby terminates award No. (FAIN) in its entirety effective (insert date of letter).

<u>Closure</u>. You must submit all final reports and a final payment request no later than 120 calendar days after the date of this notice. You will be reimbursed for costs incurred up to the date of this notice that are determined to be consistent with 2 C.F.R. § 200.343, *Effects of suspension or termination*. Any open balance remaining 120 days after the date of this notice will be unavailable for payment.

If you do not submit all reports in accordance with the terms and conditions of the Federal award within one (1) year of the effective termination date, (Agency) must proceed to close out the award with the information available. In these circumstances, in accordance with 2 C.F.R. § 200.344, (Agency) must report your material failure to comply with the terms and conditions of the award in SAM.gov using the Contractor Performance Assessment Reporting System (CPARS). In this way, failure to submit timely and accurate final reports may affect your future funding.

Recipients are required by Federal regulation to retain all Federal award records consistent with 2 C.F.R. § 200.334. (Include the following if any payments were made to recipient)

Termination of the agreement does not affect a Federal agency's or a pass-through entity's right to disallow costs and recover funds based on a later audit or other review. In addition, termination does not affect a recipient's obligation to return any funds due as a result of later refunds, corrections, or other transactions, including final indirect cost rate adjustments (refer to 2 C.F.R. § 200.345).

Appeal Process. [Insert applicable appeal process]

If you have questions, contact your (Agency) Program Contact at (insert email address).

Sincerely,

(insert signatory official name) (Insert signatory official title)

CC: (insert name, Title, Office)

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Name Title Organization Address

Dear	
Dear	٠

This letter provides notice that the United States Department of Agriculture is terminating your federal award, (Federal Award Identification Number [FAIN], Project Title), in accordance with the terms and conditions of your award, which include applicable regulations relating to termination. See 2 C.F.R. §§ 200.340-343.

<u>Termination</u>. The award specified above has been determined to not align with the foreign assistance objectives of the Department. The award is therefore inconsistent with, and no longer effectuates, Department priorities. See 2 C.F.R. § 200.340(a)(4). Pursuant to, among other authorities, 2 C.F.R. §§ 200.339-343, which are applicable to your award, the Department hereby terminates award No. (FAIN) in its entirety effective (insert date of letter).

<u>Closure</u>. You must submit all final reports and a final payment request no later than 120 calendar days after the date of this notice. You will be reimbursed for costs incurred up to the date of this notice that are determined to be consistent with 2 C.F.R. § 200.343, *Effects of suspension or termination*. Any open balance remaining 120 days after the date of this notice will be unavailable for payment.

If you do not submit all reports in accordance with the terms and conditions of the Federal award within one (1) year of the effective termination date, (Agency) must proceed to close out the award with the information available. In these circumstances, in accordance with 2 C.F.R. § 200.344, (Agency) must report your material failure to comply with the terms and conditions of the award in SAM.gov using the Contractor Performance Assessment Reporting System (CPARS). In this way, failure to submit timely and accurate final reports may affect your future funding.

Recipients are required by Federal regulation to retain all Federal award records consistent with 2 C.F.R. § 200.334. (Include the following if any payments were made to recipient)

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later refunds, corrections, or other transactions, including final indirect cost rate adjustments (refer to 2 C.F.R. § 200.345).

Appeal Process. [Insert applicable appeal process]

If you have questions, contact your (Agency) Program Contact at (insert email address).

Sincerely,

(insert signatory official name) (Insert signatory official title)

CC: (insert name, Title, Office)

EXHIBIT J



INSTITUTE OF MUSEUM AND LIBRARY SERVICES ACTION MEMORANDUM

April 8, 2025

FROM: Keith Sonderling, Acting Director

SUBJECT: Authorization for Termination of Grant(s)

Purpose:

This memorandum authorizes the termination of federal grants administered by the Institute of Museum and Library Services (IMLS), effective April 8, 2025, in alignment with the agency's updated priorities and the President's Executive Order 14238 ntinuing the Reduction of the Federal Bureaucrassued on March 14, 2025.

Action:

I hereby authorize the termination of the attached federal grant(s), effective April 8, 2025, pursuant to the terms in the attached exhibit(s).

Attachment:

See the attached hibit Grant Notice to be issued to each of the grantees.

Contact:

Questions regarding this action may be directed to-greating estimates@imls.gov.

Sincerely,

Keith Sonderling
Acting Director
ksonderling@imls.gov

Keith Sonderling

955 L'Enfant Plaza SW #4000, Washington, DC 20024

Attachment: Exhibit Grant Notice



INSTITUTE OF MUSEUM AND LIBRARY SERVICES

NOTICE OF GRANT TERMINATION

April 8, 2025

Tim Dennis, Melina Perez, Eleanor Forbes

tdennis@library.ucla.edu, mduenas@library.ucla.edu, eleanor.forbes@research.ucla.edu

Dear IMLS Grantee,

This letter provides notice that the Institute of Museum and Library Services (IMLS) is terminating your federal grant (Grant Application No. RE-252335-OLS-22) effective April 8, 2025, in accordance with the termination clause in your Award Agreement.

Upon further review, IMLS has determined that your grant is unfortunately no longer consistent with the agency's priorities and no longer serves the interest of the United States and the IMLS Program. IMLS is repurposing its funding allocations in a new direction in furtherance of the President's agenda. Independently and secondly, the President's March 14, 2025 executive order mandates that the IMLS eliminate all non-statutorily required activities and functions. *See Continuing the Reduction of the Federal Bureaucracy*, E.O. 14238 (Mar. 14, 2025). Therefore, the IMLS hereby terminates your grant in its entirety effective April 8, 2025.

Please remember that your obligations under the Grant Agreement continue to apply. An audit may be conducted by IMLS after the termination of the agreement.

Please contact <u>grant-notices@imls.gov</u> with only urgent questions. We wish you well.

Sincerely,
s/ Keith Sonderling
Keith Sonderling

Acting Director

ksonderling@imls.gov

955 L'Enfant Plaza SW #4000, Washington, DC 20024

Case: 25-4249, 07/22/2025, DktEntry: 11.1, Page 286 of 475

EXHIBIT - 4

1	Erwin Chemerinsky (<i>pro hac vice</i> forthcoming) echemerinsky@law.berkeley.edu	
2	Claudia Polsky (CA Bar No. 185505)	
3	cpolsky@law.berkeley.edu U.C. BERKELEY SCHOOL OF LAW	
4	Law Building Berkeley, CA 94720-7200	
5	Telephone: 510.642.6483	
6	Elizabeth J. Cabraser (CA Bar No. 83151) ecabraser@lchb.com	
7	Richard M. Heimann (CA Bar No. 63607) rheimann@lchb.com	
8	LIEFF CABRASER HEIMANN & BERNSTEIN, LLP	
9	275 Battery Street, 29th Floor San Francisco, CA 94111	
10	Telephone: 415.956.1000	
11	Anthony P. Schoenberg (CA Bar No. 203714) tschoenberg@fbm.com	
12	FARELLA BRAUN + MARTEL LLP One Bush Street, Suite 900	
13	San Francisco, CA 94104 Telephone: 415. 954.4400	
14	Attorneys for Plaint, fs and the Proposed Class [Additional counsel listed on signature page]	
15	[Additional counsel fisica on signature page]	
1.6	UNITED STATES DIS	STRICT COURT
16	UNITED STATES DIS	SIRICICOURI
17	NORTHERN DISTRICT	
	NORTHERN DISTRICT	OF CALIFORNIA
17	NORTHERN DISTRICT NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST,	
17 18	NORTHERN DISTRICT NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST, CHRISTINE PHILLIOU, and JEDDA FOREMAN, on behalf of themselves and all	Case No. 3:25-cv-04737-RL
17 18 19	NORTHERN DISTRICT NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST, CHRISTINE PHILLIOU, and JEDDA FOREMAN, on behalf of themselves and all others similarly situated,	OF CALIFORNIA
17 18 19 20	NORTHERN DISTRICT NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST, CHRISTINE PHILLIOU, and JEDDA FOREMAN, on behalf of themselves and all	Case No. 3:25-cv-04737-RL DECLARATION OF NEETA
17 18 19 20 21	NORTHERN DISTRICT NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST, CHRISTINE PHILLIOU, and JEDDA FOREMAN, on behalf of themselves and all others similarly situated, Plaintiffs, v.	Case No. 3:25-cv-04737-RL DECLARATION OF NEETA
17 18 19 20 21 22	NORTHERN DISTRICT NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST, CHRISTINE PHILLIOU, and JEDDA FOREMAN, on behalf of themselves and all others similarly situated, Plaintiffs, v. DONALD J. TRUMP, in his official capacity as President of the United States;	Case No. 3:25-cv-04737-RL DECLARATION OF NEETA THAKUR
17 18 19 20 21 22 23	NORTHERN DISTRICT NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST, CHRISTINE PHILLIOU, and JEDDA FOREMAN, on behalf of themselves and all others similarly situated, Plaintiffs, v. DONALD J. TRUMP, in his official capacity as President of the United States; DEPARTMENT OF GOVERNMENT EFFICIENCY ("DOGE");	Case No. 3:25-cv-04737-RL DECLARATION OF NEETA THAKUR
17 18 19 20 21 22 23 24	NORTHERN DISTRICT NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST, CHRISTINE PHILLIOU, and JEDDA FOREMAN, on behalf of themselves and all others similarly situated, Plaintiffs, v. DONALD J. TRUMP, in his official capacity as President of the United States; DEPARTMENT OF GOVERNMENT EFFICIENCY ("DOGE"); AMY GLEASON, in her official capacity as Acting Administrator of the Department of	Case No. 3:25-cv-04737-RL DECLARATION OF NEETA THAKUR
17 18 19 20 21 22 23 24 25	NORTHERN DISTRICT NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST, CHRISTINE PHILLIOU, and JEDDA FOREMAN, on behalf of themselves and all others similarly situated, Plaintiffs, v. DONALD J. TRUMP, in his official capacity as President of the United States; DEPARTMENT OF GOVERNMENT EFFICIENCY ("DOGE"); AMY GLEASON, in her official capacity as	Case No. 3:25-cv-04737-RL DECLARATION OF NEETA THAKUR
17 18 19 20 21 22 23 24 25 26	NORTHERN DISTRICT NEETA THAKUR, KEN ALEX, NELL GREEN NYLEN, ROBERT HIRST, CHRISTINE PHILLIOU, and JEDDA FOREMAN, on behalf of themselves and all others similarly situated, Plaintiffs, v. DONALD J. TRUMP, in his official capacity as President of the United States; DEPARTMENT OF GOVERNMENT EFFICIENCY ("DOGE"); AMY GLEASON, in her official capacity as Acting Administrator of the Department of Government Efficiency;	Case No. 3:25-cv-04737-RL DECLARATION OF NEETA THAKUR

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_	BRIAN STONE, in his official capacity as	
2	Acting Director of the National Science Foundation;	
3	NATIONAL ENDOWMENT FOR THE HUMANITIES;	
4	MICHAEL MCDONALD, in his official	
5	capacity as Acting Chairman of the National Endowment for the Humanities;	
	UNITED STATES ENVIRONMENTAL	
6	PROTECTION AGENCY; LEE ZELDIN, in his official capacity as	
7	Administrator of the U.S. Environmental	
8	Protection Agency; UNITED STATES DEPARTMENT OF	
0	AGRICULTURE;	
9	BROOKE ROLLINS, in her official capacity as Secretary of the U.S. Department of Agriculture;	
10	AMERICORPS (a.k.a. the CORPORATION	
11	FOR NATIONAL AND COMMUNITY SERVICE);	
	JENNIFER BASTRESS TAHMASEBI, in her	
12	official capacity as Interim Agency Head of AmeriCorps;	
13	UNITED STATES DEPARTMENT OF	
14	DEFENSE; PETE HEGSETH, in his official capacity as	
	Secretary of the U.S. Department of Defense;	
15	UNITED STATES DEPARTMENT OF EDUCATION;	
16	LINDA MCMAHON, in her official capacity as	
17	Secretary of the U.S. Department of Education; UNITED STATES DEPARTMENT OF	
	ENERGY;	
18	CHRIS WRIGHT, in his official capacity as Secretary of Energy;	
19	UNITED STATES DEPARTMENT OF	
20	HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., in his official	
	capacity as Secretary of the U.S. Department of	
21	Health and Human Services; UNITED STATES CENTERS FOR DISEASE	
22	CONTROL;	
23	MATTHEW BUZZELLI, in his official capacity as Acting Director of the Centers for Disease	
	Control;	
24	UNITED STATES FOOD AND DRUG ADMINISTRATION;	
25	MARTIN A. MAKARY, in his official capacity	
26	as Commissioner of the Food and Drug Administration;	
	UNITED STATES NATIONAL INSTITUTES	
27	OF HEALTH; JAYANTA BHATTACHARYA, in his official	
28	capacity as Director of the National Institutes of	

DECLARATION OF NEETA THAKUR

Case No.: 3:25-cv-04737-RL

Case: 25-4249, 07/22/2025. DktEntry: 11.1 Page 289 of 475 Case 3:25-cv-04737-RFL Document 10 Filed 06/05/25 Page 3 of 11

1 Health; INSTITUTE OF MUSEUM AND LIBRARY 2 SERVICES; KEITH SONDERLING, in his official capacity 3 as Acting Director of the Institute of Museum and Library Services; UNITED STATES DEPARTMENT OF THE 4 INTERIOR: 5 DOUG BURGUM, in his official capacity as Secretary of the Interior; 6 UNITED STATES DEPARTMENT OF STATE; MARCO RUBIO, in his official capacity as Secretary of the U.S. Department of State; 7 DEPARTMENT OF TRANSPORTATION; SEAN DUFFY, in his official capacity as 8 Secretary for the U.S. Department of 9 Transportation, 10 Defendants. 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28

DECLARATION OF NEETA THAKUR

Case No.: 3:25-cv-04737-RL

DECLARATION OF NEETA THAKUR

I, Neeta Thakur, declare as follows:

- 1. I have personal knowledge of the facts contained in this declaration and, if called as a witness, could and would testify competently to those facts.
- 2. I am a pulmonary and critical care specialist at the University of California, San Francisco (UCSF) who examines the role of social and environmental stressors on asthma and COPD in historically marginalized communities. I currently serve as Medical Director of the Zuckerberg San Francisco General Hospital Chest Clinic. I am also an associate professor of medicine and pulmonary and critical care at UCSF.
- 3. I completed dual degrees in public health and medicine at the University of Arizona, where I earned MPH and MD degrees in 2007. I came to UCSF for a residency in Internal Medicine (2007-10) and stayed to complete a Pulmonary and Critical Care Medicine fellowship (2010-13). From 2013 to 2015, I was a clinical instructor at UCSF and joined faculty in 2015. Since then, I have worked at UCSF as a clinician, professor, and academic researcher.
- 4. My research focuses on (1) defining obstructive lung disease phenotypes that exist in racially and ethnically diverse communities and how these are shaped by social and environmental stressors; (2) identifying community-specific drivers that place individuals at high risk for poor outcomes; and (3) co-developing place-based and targeted interventions aimed at social and environmental stressors to improve respiratory outcomes in historically marginalized populations. My research is transdisciplinary and employs community-engaged approaches that enable community stakeholders to help shape research questions and propose locally relevant interventions to promote public health.
- 5. Articles illustrative of my focus on social determinants of pulmonary health include (among many others) an article on *Early life air pollution and asthma risk in minority children* published in the American Journal of Respiratory and Critical Care Medicine 188 (3), 309-318 (2013); and an article on *Associations between historical residential redlining and current age-acjusted rates of emergency department visits due to asthma across eight cities in California,* published in The Lancet Planetary Health 4 (1), e24-e31 (2020).

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UC Berkeley School of Law (510)642-5398

- 6. My research, which frequently involves collaboration with other universities and community based organizations, has been supported by state grants, federal grants from the National Institutes of Health (NIH) and Environmental Protection Agency (EPA), foundation grants, and other sources.
- 7. In recognition of my research leadership, I was this year (2025) selected as the faculty director of Clinical Research Operations for the Clinical Trials Operations Unit at UCSF's Clinical & Translational Science Institute after a competitive search process.
 - 8. A true and correct copy of my curriculum vitae is attached as Exhibit A.

Grant Application to EPA

- 9. In November 2021, I submitted a grant application to EPA in response to its announcement of funding opportunity EPA-G2021-STAR-H1. This opportunity, made available through the agency's Science to Achieve Results (STAR) program, focused on "Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/Lifestages: Community-Based Research for Solutions."
- 10. My research team's Grant Application, titled "Partnering for Resilient Opportunities To Eliminate Toxic (PROTECT) Health Effects from Wildfire PM2.5 in Environmental Justice Communities," addressed the potential to intervene to prevent adverse health effects to environmental justice (EJ) communities from the fine particulate matter (PM) characteristic of wildfire smoke. Due to their small size (2.5 microns), PM2.5 particles can penetrate deeply into human lung tissue and do considerable damage. A true and correct copy of our Grant Application is attached as Exhibit B.

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11. The premise of our grant research was that the increase in wildfire smoke in California has had a widespread and cascading impact on EJ communities, because environmental pollution and the social adversity that magnifies adverse health outcomes are concentrated in communities of color and low-income communities. Our proposal aimed to (1) estimate the health effects of sub-daily exposure to wildfire-specific PM2.5 in California, including across social vulnerability factors, with particular focus on effects within EJ communities: (2) understand community recovery from short-term health effects following exposure; (3) understand indoor infiltration of wildfire smoke and the mitigating effect of housing quality and behaviors on health effects; and (4) identify acceptable, community-relevant interventions to mitigate exposure.

- 12. Our grant proposal, on which I was Principal Investigator, encompassed nine investigators spanning three institutions: UCSF, UC Berkeley, and California's Office of Environmental Health Hazard Assessment. Our team's expertise spanned exposure and building science, environmental engineering, atmospheric modeling, epidemiology, implementation science, and community-based participatory research.
- 13. Our proposal also contemplated work with community-based organizations and local government partners in the intended study areas of Fresno, Richmond, and San Francisco, and remuneration to community participants for same.
- 14. The Grant Application requested funding commensurate with our cumulative 3year budget of \$1,330,536 to support our multi-campus, multi-agency, multi-nonprofit research collaboration.

EPA's Grant Award

- 15. On November 22, 2022, an EPA Senior Grants Management Specialist, Jennifer Brooks, transmitted to me a Notice of EPA Award and the Grant Agreement. The Agreement indicated that our team was authorized to proceed for Project Period 12/01/2022-11/30/2025, and that EPA would make an initial grant of \$690,000 (i.e., approximately half of project costs).
- 16. A true and correct copy of the 2022 Notice and Grant Agreement are attached as Exhibits C and D respectively.

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- 17. On June 21, 2023, an EPA Senior Grants Management Specialist, Jennifer Brooks, transmitted to me a second Notice of EPA Award and an Assistance Amendment. The Amendment likewise indicated that our team was authorized to proceed for Project Period 12/01/2022-11/30/2025. It stated that EPA was awarding \$640,536, bringing our total federal funding award to \$1,330, 536.
- 18. A true and correct copy of the 2023 Notice and Grant Agreement are attached as Exhibit E and F respectively.
- 19. To date, we have subcontracted \$297,487 to UC Berkeley and \$40,000 to our nonprofit partner Central California Asthma Collaborative.

EPA's Grant Termination

- 20. On April 28, 2025, EPA sent to the UC Regents a document styled as an "Assistance Amendment." A true and correct copy of the Assistance Amendment is attached as Exhibit G.
- 21. The Amendment instructed our research team to "stop work; terminate the [grant] agreement; reduce performance period duration; [and] curtail scope of work," while waiving certain reporting requirements. *Id.* at 1. It stated that "(EPA) hereby awards \$0.00" towards any unfunded, as-yet-unincurred costs of the previously awarded \$1,330,536. *Ibid*.
- 22. The Assistance Amendment stated: "The Agency is asserting its right under 2 C.F.R. 200.340 and the Termination General Term [stet] and Condition of this agreement to unilaterally terminate this award." *Id.* at 4.
- 23. The Amendment was accompanied by memorandum from EPA to the Director of Contracts and Awards at UCSF titled "Termination of EPA Assistance Agreement RD 84048101 under 2 CFR 200.340." A true and correct copy of this memo is attached as Exhibit H.
 - 24. The memo stated that EPA terminated our grant for the following reasons:

[T]he award no longer effectuates the program goals or agency priorities. The objectives of the award are no long consistent with EPA funding priorities.

(510)642-5398

The EPA Administrator has determined that, per the Agency's obligations to the constitutional and statutory law of the United States, this priority includes ensuring that the Agency's grants do not conflict with the Agency's policy of prioritizing merit, fairness, and excellence in performing our statutory functions. In additional to complying with the law, it is vital that the Agency assess whether all grant payments are free from fraud, abuse, waste, and duplication, as well as to assess whether current grants are in the best interests of the United States.

The grant specified above provides funding for programs that promote initiatives that conflict with the Agency's policy of prioritizing merit, fairness, and excellence in performing our statutory functions; that are not free from fraud, abuse, waste, or duplication; or that otherwise fail to serve the best interests of the United States. The grant is inconsistent with, and no longer effectuates, Agency priorities.

Id. at 1.

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Harm from EPA's Grant Termination

25. I and my project team have suffered immediate harm as a result of the cancellation of the grant. Specifically:

- a) I have been unable to complete the health analyses with our UC Berkeley colleagues as well as identify promising health-protecting strategies to help protect communities across California during wildfire smoke events. Instead, I have had to spend significant time seeking alternate funding sources. This includes unexpected grant writing, and reaching out to other funding sources, including philanthropy groups. In addition, to support staff and avoid layoff of two individuals, I needed to use my own discretionary funds to support team members.
- b) As my own time was also financially supported by this grant, I also needed to find new funding sources to fill this unexpected funding gap.
- c) The abrupt loss of funding has additionally impacted the overall training environment for my research team, which has had to endure a funding gap for a post-doctoral fellow, the letting go of a student intern with our team, and uncertainty over whether we can accept new trainees on our team.
- d) The UCSF and UC Berkeley researchers on this grant have been unable to complete the proposed analyses of the health impacts of wildfire smoke events across the state of California. This is after considerable work by UCB researchers to develop an unprecedented, highly temporally spatially resolute map of wildfire smoke at the hourly level. As a consequence, at least three research publications will go unpublished that have the potential for high impact both for science and public health.

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- e) The now-terminated grant also supported new collaborations as well as early career investigators at UC Berkeley. The loss of this funding has impacted the pay plan for a recently hired graduate student at UC Berkeley, support for a post-doctoral fellow, and productivity for an early career investigator.
- f) Lastly, the unrealized objectives of this transdisciplinary grant have important public health impacts that include:
 - Generation of a temporally and geographically resolute map of wildfire smoke PM2.5 for the time period 2017 to 2022. This unprecedented modeling approach of using ground-level measures over an extended time period was to be used to provide more accurate estimates of exposure during future wildfire smoke events.
 - Improved understanding of the health impacts of wildfire smoke, and specifically, how long after an event we expect health harms and for what health conditions. This has direct clinical and public health relevance.
 - Identification of relevant thresholds for public health guidance during wildfire events. To our team's knowledge, all studies to date on the health effects of wildfire smoke use daily exposure averages. However, this is not how individuals experience adverse air quality: there are time periods where smoke exposure may be very high, and this is not reflected in the daily mean exposure. With our team's hourly exposure measurements, we are uniquely able to identify relevant thresholds for public health guidance during wildfire events.

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- g) Grant termination has compromised the trust-building necessary for community-engaged participatory action research. It has taken years for effort for me to develop relationships with the community based organizations and community-engaged individuals who wrote letters in support of our grant application. They did so notwithstanding their scare time and resources, with the expectation that our project would deliver tangible benefits to their low income communities in the form of improved respiratory health. Through this EPA grant we were able to build partnerships with fifteen community based organizations and the work with these groups was abruptly stopped due to this termination. This is after significant efforts by these partners to co-design a survey, and also after my team had made a commitment to better understand how health impacts were being experienced in their communities and barriers to health protective resources during wildfire smoke events. The EPA's termination of this grant will make it more difficult for me to partner with organizations such as the Central California Asthma Collaborative in Fresno and Brightline in San Francisco, and with a community-trusted scientist in Richmond (Dr. Omoniyi Omotoso).
- h) Additionally, even if we were eventually to find replacement funding for this project (a difficult proposition given the sums at stake), they would no longer be adequate to cover our expenses. This includes costs of staff, finding and training post-doctoral fellows to carry out proposed analyses, and reestablishing partnerships.

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- i) These personal and financial harms are ongoing.
- j) These harms are in addition to the loss of value to the public from my research team's inability to complete work on studying health risks from the fine particulate matter associated with wildfire, and inability to design health-protective interventions for three of California's most health-vulnerable communities.

Appeal of Grant Termination

- 26. The EPA memo regarding grant termination provided that UCSF could submit a "Dispute" to a named Disputes Decision Official at EPA within 30 days from the date EPA transmitted the termination notice.
 - 27. UCSF is currently preparing such a Dispute.
- 28. The Award of Grant Funding will remain unavailable to our project pending the outcome of the appeal.

Role of Class Representative

- 29. I am ready to assume the responsibilities of serving as a class representative. I understand that I must stay informed regarding developments in the lawsuit, communicate regularly with my attorneys, and act in the best interests of the class. I have no conflicts that would prevent me from assuming this responsibility.
- 30. I have been in communication with other UC researchers, who would be members of the class, who have suffered the same general type of harm as I describe above, from the abrupt termination of their previously approved research grants. This harm is widespread and I believe it will only increase in scope and impact if classwide relief is not granted.

I declare under penalty of perjury under the laws of the State of California and the United States that the foregoing is true and correct.

Executed this $\frac{28}{2}$ day of May, 2025.



EXHIBIT A

University of California, San Francisco CURRICULUM VITAE

Name: Neeta Thakur, MD, MPH

Position: Associate Professor In Residence, Step 3

Medicine

School of Medicine

Address: Box 0841

505 Parnassus Ave

University of California, San Francisco

San Francisco, CA 94143 Voice: 415 378-6594

Pager Number: 415 443-9259 Email: Neeta.Thakur@ucsf.edu

EDUCATION

1998 - 2002	University of Arizona, Tucson, AZ	B.S.	Physiological Sciences, Magna Cum Laude
2002 - 2007	University of Arizona, Tucson, AZ	M.D./M.P.H.	
2007 - 2008	University of California, San Francisco	Intern	Medicine
2008 - 2010	University of California, San Francisco	Resident	Medicine
2010 - 2013	University of California, San Francisco	Fellow	Pulmonary and Critical Care Medicine
2012 - 2013	University of California, San Francisco	Certificate	Advance Training in Clinical Research
2012 - 2015	University of California, San Francisco	Fellow	Clinical Pharmacology
2015 - 2019	University of California, San Francisco	Certificate	Implementation Sciences
2019 - 2019	Zuckerberg San Francisco General Hospital, UCSF	Program	ZSFG Clinical Leaders Professional Development Program

LICENSES, CERTIFICATION

2009 California Medical Licensure A107658

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2010	Internal Medicine Board Certification		
2013	Pulmonary Medicine Board Certification		
2015	Critical Care Medicine Board Certification		
PRINCIPAL PO	OSITIONS HELD		
2004 - 2005	Arizona AIDS Education and Training Center, Tucson, AZ	Research Assistant	
2005 - 2005	California STD/HIV Prevention Training Center, Oakland, CA	Program Assistant	
2013 - 2015	University of California, San Francisco, CA	Clinical Instructor	Medicine
2015 - 2017	University of California, San Francisco, CA	Assistant Adjunct Professor	Medicine
2017 - 2021	University of California, San Francisco, CA	Assistant Professor in Residence	Medicine
2021 - present	University of California, San Francisco, CA	Associate Professor in Residence	Medicine
OTHER POSIT	TIONS HELD CONCURRENTLY		
2013 - 2014	Health and Environmental Resource Center, San Francisco, CA	Medical Director	
2017 - present	Zuckerberg San Francisco General Hospital	Medical Director of the Chest Clinic	Medicine
2020 - 2022	Zuckerberg San Francisco General Hospital	Founder, Medical Director of the Critical Illness Recovery Clinic	Medicine
2020 - 2022	UCSF Partnership for Research in Implementation Science for Equity (PRISE) Center	Program Director for Sub-specialty Care	Epidemiology and Biostatistics and Medicine
2021 - 2022	EPA Clean Air Scientific Advisory Committee Particulate Matter	Committee Member	
2021 - present	Zuckerberg San Francisco General Hospital	Director of Diversity and Social Justice	Division of Pulmonary and Critical Care Medicine

2022 - present	NHLBI National Asthma Education and Prevention Program Coordinating Committee	Committee Member	
2023 - present	Health Effects Institute	Research Committee Member	
2023 - present	UCSF PRISE Center	Co-Diector	Epidemiology and Biostatistics and Medicine
2024 - 2024	EPA Clean Air Scientific Advisory Committee NOx	Committee Member	
2024 - present	UC Center for Climate, Health and Equity	Interim Co-Chair of Research	UC-wide position
2025 - present	Clinical Research Operations/Clinical Trials Operation	Faculty Director	Office of the Associate Vice Chancellor for Clinical Research (AVC- CR) Clinical and Translational Science Institute (CTSI)

HONORS AND AWARDS

2002	Magna Cum Laude	University of Arizona
2009	Clinical and Translational Science Institute Resident Research Funding Award	UCSF CTSI
2010	Clinical and Translational Science Institute Travel Award	UCSF CTSI
2010	Environmental and Occupational Health Travel Award	American Thoracic Society
2012	Walter Travel Fund	Breathe California
2012	Social and Behavioral Health Sciences Travel Award	American Thoracic Society
2013	Social and Behavioral Health Sciences Travel Award	American Thoracic Society
2013	2nd Place for oral presentation, The Ninth Annual Respiratory Disease Young Investigators' Forum.	Respiratory Disease Young Investigators' Forum

2014	Podell Hewett Fellowship in Airways Disease Research, 2014-15	UCSF Division of Pulmonary and Critical Care Medicine Fellowship Program
2014	Social and Behavioral Health Sciences Travel Award	American Thoracic Society
2014	American Thoracic Society Recognition Award for Early Career Investigators	American Thoracic Society
2015	Parker B. Francis Fellow	Parker B. Francis Fellowship Program
2017	Nina Ireland Program for Lung Health Faculty	UCSF Division of Pulmonary and Critical Care Medicine
2018	Selected American Thoracic Society Representative for the 23rd Congress of the Asian Pacific Society of Respirology	American Thoracic Society
2019	Michael S. Stulbarg Outstanding Teaching Award	UCSF Division of Pulmonary and Critical Care Medicine Fellowship Program
2019	PEARLS tool recommended for ACEs screening in pediatric primary care. Only pediatric screening tool to be financially reimbursed by Medicaid.	California Department of Health Care Services
2020	Haile T. Debas Academy of Medical Educators Excellence in Teaching Award	UCSF
2021	Assembly on Behavioral Science and Health Services Research Early Career Achievement Award	American Thoracic Society
2021	V. Courtney Broaddus Service Award	UCSF Division of Pulmonary and Critical Care Medicine
2022	The Outstanding Mentor Award	UCSF Division of Pulmonary and Critical Care Medicine
2024	John Murray Humanitarian Award	UCSF ZSFG Department of Medicine

KEYWORDS/AREAS OF INTEREST

Social determinants of health, environmental justice, implementation sciences, health disparities, racism, asthma, COPD, acculturation, race/ethnicity, adverse childhood experiences, biomarkers, systems of care, pulmonary rehabilitation, representation in research

CLINICAL ACTIVITIES

CLINICAL ACTIVITIES SUMMARY

I work in both the outpatient and inpatient clinical settings at Zuckerberg San Francisco General Hospital (ZSFG). Since 2017. I have served as the Medical Director of the Chest Clinic. In this role, I have significantly expanded access to key treatments and services for our vulnerable patient population. This include establishing a shot clinic for our severe asthma patients to receive biologic therapies such as omalizumab and mepolizumab, developing and implementing a pipeline to access special pharmacies for anti-fibrotic therapies for our interstitial lung disease patients, and developing and piloting a community-based pulmonary rehabilitation program for symptomatic patients with COPD that is accessible for all patients within the SF Community Health Network - now a R01 trial to test for effectiveness. For each of these services, I had to develop good understanding of current health system barriers and reimbursement processes while also addressing important patient barriers (health literacy and numeracy, costs, and care access/transportation issues) prior to implementation. Programs were iteratively developed with cross-disciplinary input to ensure seamless integration into clinical flow. I have also developed relationship with investigators across campuses to gain critical access to pulmonary research trials, including those for asthma, pulmonary fibrosis, MAC treatment, COPD, and pulmonary rehabilitation.

In my role as Medical Director, I have worked to significantly enhance the clinical and educational experience for our six pulmonary fellows in our ACGME training program. This includes developing a case series of outpatient pulmonary cases, curating relevant ACGME board exam questions, organizing a weekly didactic series of high yield pulmonary topics, and precepting with fellows in our outpatient Chest clinic. Our ZSFG Chest Clinic is now the highest-rated clinic among our fellows and considered a high-yield learning opportunity by residents. In addition to my role as Medical Director, I see my own patients one half-day per week in the outpatient clinic. These clinical experiences (both in the inpatient and outpatient settings) at ZSFG gives me first-hand insight on how social and environmental stress negatively affect outcomes in patients with obstructive lung disease.

I also attend for three weeks on the pulmonary consult service and for three weeks in the Medical Intensive Care Unit (MICU). In these settings, I work with different trainee levels ranging from medical students to fellows and with trainees from different disciplines.

CLINICAL SERVICES

2013 - 2016	Parnassus Chest Faculty Practice Preceptor	Half a day per month
2014 - 2015	Parnassus Critical Care Attending	6 weeks per year
2013 - present	ZSFG Chest Clinic Provider and Preceptor	Half a day per week
2015 - present	ZSFG Medical Intensive Care Attending	3 weeks per year
2015 - present	ZSFG Pulmonary Consult Attending	3 weeks per year

PROFESSIONAL ACTIVITIES

MEMBERSHIPS

2010 - present American Thoracic Society

2022 - present International Society for Environmental Epidemiology

SERVICE TO PROFESSIONAL ORGANIZATIONS

2014 - 2023	American Thoracic Society	Health Equity and Diversity Committee Member
2014 - 2018	American Thoracic Society	Environmental, Occupational and Population Health Assembly s Early Faculty and Fellows' Working Group Member
2017 - 2020	American Thoracic Society	Behavioral Science and health Service Research Program Committee Member
2018 - 2019	American Thoracic Society	Health Equality and Diversity Committee, Vice Chair
2019 - 2022	American Thoracic Society	Health Equality and Diversity Committee, Chair
2023 - present	American Thoracic Society	Ethnic, Conflicts of Interest Committee Member

SERVICE TO PROFESSIONAL PUBLICATIONS

2015 - present	American Journal of Respiratory Critical Care Medicine, ad hoc reviewer (4-5 manuscripts per year)
2016 - present	Plos One, ad hoc reviewer (1-2 manuscripts per year)
2016 - present	Pediatrics, ad hoc reviewer (1-2 manuscripts per year)
2019 - present	Thoracic, ad hoc reviewer (0-1 manuscripts per year)
2019 - present	Journal of Allergy and Clinical Immunology, ad hoc reviewer (2-3 manuscripts per year)
2021 - present	AJPH, ad hoc reviewer (0-1 manuscripts per year)

2021 - present Lancet, ad hoc reviewer (0-1 manuscripts per year)

2022 - present JAMA Network, ad hoc reviewer (2-3 manuscripts per year)

INVITED PRESENTATIONS - INTERNATIONAL

2013	American Thoracic Society International Conference "The Impact of Socioeconomic Status On Asthma Outcomes Among Black Youth", Philadelphia, PA.	Abstract, Podium
2013	American Thoracic Society International Conference "Decreased Asthma Diagnosis, Report of Symptoms and Medication Use Among Children of Mothers with Low Language Acculturation", Philadelphia, PA.	Abstract, Podium
2014	American Thoracic Society International Conference "Asthma and Discrimination The GALA II And SAGE II Studies", San Diego, CA.	Abstract, Podium
2015	American Thoracic Society International Conference "Diversity of the Healthcare Workforce," Denver, CO.	Invited Speaker, Podium
2017	American Thoracic Society International Conference "Racial Discrimination Affects Drug Response in African American Youth with Asthma," Washington, DC.	Abstract, Podium
2018	American Thoracic Society International Conference "Expanding Care Coordination to Outside the Health Care System:Addressing Unmet Social Needs," San Diego, CA.	Speaker and organizer of session
2018	23rd Congress of the Asian Pacific Society of Respirology "A Multi-level Approach to Asthma Health Disparities: from Biomarkers to Geocoded Data," Taipei, Taiwan. (Award)	Abstract, Podium
2019	American Thoracic Society International Conference "Adverse Childhood Experiences are Associated with Pediatric Asthma," Dallas, TX.	Abstract, Podium
2019	American Thoracic Society International Conference "Clinical Year in Review: Health Disparities," Dallas, TX.	Invited Speaker, Podium
2019	American Thoracic Society International Conference "Climate Change and Respiratory Health: Widening US Disparities," Dallas, TX.	Organizer of session
2021	American Thoracic Society International Conference "Removing barriers to clinical research" Virtual presentation.	Invited Speaker
2021	American Thoracic Society International Conference "Disparities Across Grantee Populations", Post-graduate course. Virtual presentation.	Invited Speaker

2021	Society for Prevention Research "Use of biological and context data to inform prevention: Opportunities, challenges and future directions", Virtual presentation.	Invited Speaker, Plenary Session	
2021	26th Congress of the Asian Pacific Society of Respirology "Respiratory Health Inequities and the Compounding Impact of Climate Change" Virtual presentation.	Invited Speaker	
2022	American Thoracic Society International Conference "Improving Representation in Clinical Studies" San Francisco, CA.	Invited Speaker	
	American Thoracic Society International Conference "How to Build a Diverse Pipeline of PCCM Clinicians Going Forward?" San Francisco, CA.	Invited Speaker	
2022	American Thoracic Society International Conference "The Role of Psychosocial, Neighborhood, and Contextual Factors as Environmental Stressors on Asthma Exacerbations" San Francisco, CA.	Invited Speaker	
2022	International Society of Environmental Epidemiology "Bridging Implementation Science and Health Equity to Mitigate Climate Change Impacts" Session speaker. Athens, Greece.	Invited Speaker	
2023	American Thoracic Society International Conference "Improving Representation in Biomedical Studies" Washington DC.	Invited Speaker	
2023	American Thoracic Society International Conference "Utilizing a Community Based Participatory Approach in Environmental Justice Research" Washington DC.	Invited Speaker	
2024	Pediatric Academic Societies Meeting "Moving Beyond PEARLS: Towards Sustainable Models for Addressing Early Life Adversity" Toronto, CA.	Invited Speaker	
2024	American Thoracic Society International Conference. NHLBI Workshop, "Inclusive Practices in Clinical Trial Recruitment". San Diego, CA.	Invited Speaker	
INVITED PRESENTATIONS - NATIONAL			
2015	California Asthma Summit, "The Impact of Adversities on the Development and Management of Asthma", Los Angeles, CA.	Invited Speaker, Podium	
2016	University of Arizona, College of Medicine, "A Multilevel Approach to Understanding Asthma Health Disparities", Tucson, AZ.	Invited Speaker, Podium	

2016	ACEs Conference and Symposium: Pediatrics Symposium."ACEs and Asthma", San Francisco, CA.	Invited Speaker, Podium
2017	University of Illinois, Chicago, Medicine Grand Rounds. "What's Race Got to do with it? A Multilevel Approach to Examining Health Disparities", Chicago, IL	Invited Speaker, Podium
2017	University of Illinois, Chicago, Pulmonary Conference. "A Multi-Level Approach to Understanding and Improving Outcomes in Obstructive Lung Disease", Chicago, IL	Invited Speaker, Podium
2019	State of the Science: A National Research Meeting on Medical and Social Care Integration. "Should there be a common health outcome metric for social care intervention research? Use of biomarkers", SIREN UCSF Network, Portland, OR	Invited Speaker, Podium
2020	Mount Sinai, Division of Pulmonary and Critical Care Medicine Grand Rounds. "A Multi-Level Approach to Understanding the Role of Racism in Asthma" New York, New York. (virtual)	Invited Speaker, virtual presentation
2021	Mount Sinai, Department of Medicine T32 Virtual Retreat. "Issues of health equity in research and ways to reduce barriers to engagement by addressing SDOH" New York, New York. (virtual)	Invited Speaker, virtual presentation
2021	Thomas Jefferson University, World Asthma Day. "Addressing Asthma Health Disparities in 2021". Pittsburg, PA.(virtual)	Keynote Speaker, virtual presentation
2022	University of Washington, Pulmonary Grand Rounds. "Implementation Science in Action: Rehabilitation in Safety Net Environments (RISE) COPD", Virtual presentation	Invited Speaker
2022	Beth Israel, Pulmonary Grand Rounds. "Implementation Science in Action: Rehabilitation in Safety Net Environments (RISE) COPD", Virtual presentation.	Invited Speaker
2023	Children's Hospital of Philadelphia (CHOP) Center for Health Equity "CBPR Workshop", Virtual workshop.	Invited Speaker and Workshop organizer
2023	Regional Asthma Management & Prevention (RAMP) and the National Center for Healthy Housing (NCHH). "Racism, Housing, and Asthma: A Conversation" Webinar.	Panel Discussant
2024	ACEs Aware. "Pediatric ACES and Related Life Events Screener (PEARLS) and Health in a Safety-net Practice". Webinar.	Invited Speaker
2024	University of California, Irvine Medical Grand Rounds. "Engaging Community: Identifying & Prioritizing Placebased Interventions for Asthma". Virtual Presentation	Invited Speaker

2024	UIC ReCOVery Long COVID Summit, "Barriers to Long COVID Care for Minoritized Populations" Panel Discussion. Chicago, Illinois	Invited Panelist
2024	U Colorado Excellence in Respiratory and Critical Care Seminar Series, "Engaging Community: Identifying & Prioritizing Place-based Interventions for Asthma". Invited Professorship. Denver, Colorado	Invited Speaker
INVITED PRE	SENTATIONS - REGIONAL AND OTHER INVITED PRE	SENTATIONS
2010	Internal Medicine R3 Talk "The Economics of Tobacco: the business and political strategy", University of California, San Francisco	Presenter
2010	Pulmonary Grand Rounds "UPDATE: Factors associated with exacerbations in COPD", University of California, San Francisco	Invited Speaker, Podium
2012	Critical Care Medicine Grand Rounds "I survived, but am I living?' Long-term Outcomes of ICU Hospitalizations", University of California, San Francisco	Invited Speaker, Podium
2013	Annual Pulmonary Research Retreat "Socioeconomic Status and Asthma Susceptibility: The GALAII and SAGE II Studies", University of California, San Francisco. Abstract selected for oral presentation	Abstract, Podium
2014	UCSF MTPCCR "The Social Determinants and Asthma: How chronic stress affects asthma in minority youth." San Francisco, CA	Guest Lecturer
2014	Health Disparities Research Symposium, UCSF "Increased Asthma Risk with Perceived Discrimination", San Francisco, CA	Abstract, Podium
2015	Annual School Symposium on Asthma, SEHAC. "The Impact of Adversities on the Development and Management of Chronic Illnesses". Oakland, CA.	Invited Speaker, Podium (Community Event)
2015	San Francisco State University, Fall Colloquial. "The heterogeneity of Asthma: What is the role of Poverty?" San Francisco, CA	Invited Speaker, Podium
2016	Medicine Grand Rounds. "What's Race Got to do with it? A Multilevel Approach to Examining Health Disparities", University of California, San Francisco. San Francisco General Hospital.	Invited Speaker, Podium
2016	Stanislaus County Asthma Coalition. "The Impact of Adversities on the Development and Management of Asthma", Modesto, CA.	Invited Speaker, Podium (Community Event)

2016	Medicine Grand Rounds. "The heterogeneity of Asthma: What is the role of Poverty?" University of California, San Francisco. Parnassus Campus.	Invited Speaker, Podium
2016	SF Build Dialogue. "The heterogeneity of Asthma: What is the role of the environment?" San Francisco State University. San Francisco, CA.	Invited Speaker, Podium and Panelist
2016	White Coats for Black Lives. "Exploring Race-based Medicine." University of California, San Francisco. Parnassus Campus.	Invited Speaker, Podium and Panelist
2016	Asthma Forum. "Asthma Phenotypes", Kaiser Permanente, San Francisco, CA.	Invited Speaker, Podium (Community Event)
2017	Medicine Grand Rounds. "COPD Update: Identifying Patients and Optimizing Treatment in Vulnerable Populations", University of California, San Francisco. San Francisco General Hospital.	Invited Speaker, Podium
2017	Asthma Forum. "Discrimination, Psycho-Social Stress and the Relationship to Non-Atopic Neutrophilic Asthma and Other Asthma Phenotypes", Kaiser Permanente, San Francisco, CA.	Invited Speaker, Podium and Panelist (Community Event)
2017	Koret Institute for Precision Prevention. "A Multilevel Approach to Understanding Asthma Health Disparities", UC Berkeley. Berkeley, CA.	Invited Speaker, Podium
2017	CME Care of the Vulnerable Patient. "Approach to an Underserved Patient with COPD", Zuckerberg San Francisco General, UCSF. San Francisco, CA.	Invited Speaker, Podium
2018	American Lung Association. "State of the Air 2018 and New Research" UCSF Mission Bay Campus. San Francisco, CA.	Invited Speaker, Podium (Community Event)
2018	CME UCSF 46th Annual Advances in Internal Medicine. "Asthma Updates", UCSF, San Francisco, CA.	Invited Speaker, Podium
2019	Asthma Summit. "Asthma and the Indoor Environment: The Who, What, and How (we can help). Sacramento, CA	Invited Speaker, Podium and Panelist
2019	Annual Tri-hospital Pulmonary Retreat. "A Multi-level Approach to Examining and Addressing Asthma Health Disparities". Presidio. San Francisco, CA.	Invited Speaker, Podium
2019	UCSF School of Medicine: Adverse Childhood Experiences Speaker Series. "Stress and ACEs: risk factors for poor health . San Francisco, CA.	Invited Speaker, Podium

2021	UCSF School of Medicine. Racism and Race: The Use of Race in Medicine and Implications for Health Equity Event Series, Session 2: Case Studies: Race, Racial Categorization, and Racism in Medicine Today. San Francisco, CA	Panelist, virtual presentation
2022	UCSF Department of Pediatrics Grand Rounds. PEARLS: Screening for Social Adversity in Primary Care: the Why & How. San Francisco, CA.	•
2022	California Thoracic Society Meeting. "Wildfires and Effects on Obstructive Airways Disease". Carmel, CA	Invited Speaker
2022	CME UCSF 27th Annual Management of the Hospitalized Patient. "Management of Hospitalized Patient with Asthma and COPD". San Francisco, CA	Invited Speaker
2023	AIM Youth Mental Health Conference. "Research Findings from the Pediatric Adverse Childhood Experiences ACEs Study" Monterrey, CA	Invited Speaker and Panel Discussant
2023	California Department of Public Health Research Updates. "Historical Redlining and COVID-19 cases and deaths in California", Virtual Presentation	Invited Speaker

GOVERNMENT AND OTHER PROFESSIONAL SERVICE

2019 - present	SFDPH Climate Change Coordinating Committee	Member
2021 - 2022	Environmental Protection Agency (EPA) Clean Air Scientific Advisory Committee for PM2.5	Committee Member
2022 - present	NHLBI National Asthma Education and Prevention Program Coordinating Committee	Committee Member
2024 - present	Environmental Protection Agency (EPA) Clean Air Scientific Advisory Committee for NOx	Committee Member

UNIVERSITY AND PUBLIC SERVICE

SERVICE ACTIVITIES SUMMARY

Division Service: I play an active role in the UCSF Division of Pulmonary and Critical Care Medicine and serve on several division-specific committees and have served on several search committees for faculty and leadership positions within our division. On the Clinical Competency Committee, I evaluate the progression of our clinical fellows and ensure they are meeting core competencies. In my position on the Fellowship Selection Committee, I review applications, interview prospective fellows, and participate in the final selection meeting. I value this position as it provides an opportunity to ensure our fellows represent diverse interest and are from diverse backgrounds.

I also serve on the Nina Ireland Program for Lung Health (NIPLH) Executive Advisory Board in the Division of Pulmonary and Critical Care Medicine. This program was established in 2010

after a large gift and provides an endowment to support pulmonary medicine. One main area of focus is the unrestricted grant program which awards over \$500,000/year of pilot funding to pulmonary and critical care medicine focused projects. The NIPLH Executive Advisory Board sets the research agenda for the granting program and reviews and provides recommendations for funding of applications. As a member, I have expanded the scope of the research program to include health disparities and implementation sciences as priority areas. I am also working with Dr. Golden (Director of the NIPLH) to develop a community-academic partnership grant program to promote and facilitate community-engaged research.

Lastly, I am the ZSFG Pulmonary Director of Diversity and Social Justice. In this role, I chaired the NI Scholars Pilot program from 2019-2022, which was intended to promote increased diversity within the pulmonary fellowship program, including recruitment of applicants from groups traditionally excluded from medicine. This program is targeted at applicants with a track record in scholarly activities, including clinical, translational, and basic science. In this role, I developed selection criteria and facilitated a group of six faculty members in selecting scholars for the last two fellowship applicant seasons. My other areas of focus are to increase the use of diversity supplements across the ZSFG Pulmonary Division (and the division as a whole) and to develop clinical equity markers across our clinical footprints at ZSFG extending from the outpatient to the ICU setting.

Department and Campus Service: I have served on several search committees for faculty and leadership positions across the School of Medicine, extending from the recruitment of basic scientists and epidemiologists to interventionists. At the start of 2024, I joined the CTSI Clinical Trials Advisory Committee (CTAC), which reviews and provides feedback on clinical research processes at UCSF. In addition, I recently joined the Academic Senate Committee on Equal Opportunity.

Service to Professional Societies: I chaired the American Thoracic Society (ATS) Health Equity and Diversity Committee from 2019-2022 and was a member of this committee since 2014 and rotated off in 2023 to join the Ethics and COI committee. The ATS is the leading professional association for pulmonary and critical care medicine and research with over 16,000 members worldwide. As chair, I oversaw several successes: expansion of a dedicated fellowship to 2 positions, establishment of an ALA-ATS-CHEST RWJF Harold Amos Fellow, partnering with the PFT committee to establish new guidelines removing the use of race from spirometry equations, providing scholarships to support URM medical students at the ATS conference, highlighting work on health disparities at the annual International ATS conference, and providing recommendations to the ATS leadership on diversifying committee representation.

Government Service: Over the past five years, I have increasingly served on several federal government expert panels, including the EPA Clean Air Scientific Advisory Committee PM and NOx Panel and the NHLBI National Asthma Education and Prevention Program Coordinating Committee. Locally, I am an active member of the SFDPF Climate Coordinating Committee, which discusses the health impacts of climate-related events across the city and county, how to leverage available resources in a coordinated fashion, and identify resource gaps.

Public Service: To increase awareness of respiratory health and provide disease supports and education, I started Asthma and COPD Health Days in San Francisco and Richmond, CA. These health fairs are directed at patients with lung disease receiving care within the SF Community Health Network and Lifelong Medical Care. These health fairs are supported through funding from the NIPHL, SF Department of Public Health, and research grants. At the

health fairs, participants received asthma inhaler teaching, information sheets and short Q&A sessions on environmental supports, learn how stress effects disease, and a tool kit which includes a spacer and environmental controls (e.g. dust mite pillow covers). In addition to these health fairs, I present at a variety of community events targeted at patients and Community Health Workers on asthma and COPD two to three times a year. Most recently, I am a member of the Technical Advisory Committee to the Bayview Hunters Point AB617 Community Steering Committee, which is developing a community emissions reduction plan to address traffic related pollution burden as well as climate change impact in Bayview Hunters Point.

UCSF CAMPUSWIDE

2024 - present	Clinical Trials Advisory Committee	Member
2024 - present	Committee on Equal Opportunity	Member
SCHOOL OF	MEDICINE	
2021 - 2022	Family and Community Medicine Faculty Search Committee	Committee Member
2022 - 2022	Epidemiology and Biostatistic Faculty Search Committee	Committee Member
DEPARTMEN [*]	TAL SERVICE	
2011 - 2015	Pulmonary and Critical Care Medicine Program Evaluation Committee	Fellow representative
2017 - 2018	Pulmonary Fellowship Program Director Search Committee	Member
2017 - 2018	Pulmonary Division Status of Women and UIM	Member
2014 - present	SFGH Chest Leadership Committee	Member
2015 - present	Nina Ireland Program for Lung Health Executive Advisory Board	Member
2016 - present	Pulmonary and Critical Care Medicine Fellowship Selection Committee	Member
2017 - present	Pulmonary and Critical Care Medicine Program Evaluation Committee	Member
2017 - 2019	Faculty Retreat Planning Committee	Member
2018 - 2020	Severe Asthma Clinical Trialist Search Committee	Member
2018 - present	Pulmonary and Critical Care Medicine Fellowship Clinical Competency Committee	Member
2020 - 2022	Nina Ireland Scholars Subcommittee	Chair
2022 - 2023	ZSFG Chief of Nephrology Search Committee	Member
2023 - present	Pulmonary and Critical Care Medicine Nina Ireland	Member

Endowed Chair Search Committee

COMMUNITY AND PUBLIC SERVICE

1999 - 2002	Alternative Breaks - Service Learning organization, University of Arizona	Director
2000 - 2004	Fostering and Achieving Cultural Equity and Sensitivity (FACES) in Medicine, University of Arizona	President
2003 - 2004	Commitment to Underserved People (CUP) Program, University of Arizona College of Medicine	Referral Coordinator
2014 - present	Bay Area Research Consortium on Toxic Stress	Member
2014 - present	Present on topics related to asthma and COPD to community health workers and first line medical workers (e.g. school nurses, medial assistants)	Presenter
2016 - present	Asthma and COPD Day: Health Fair directed at patients with lung disease receiving care within the Community Health Network and ZSFG	Organizer
2018 - present	American Lung Association medical expert - provide testimony and meet with legislature regarding the negative impact of air pollution on lung health.	Medical Expert
2019 - present	National Consortium on Asthma and Toxic Stress	Member
2024 - present	AB617 Bayview Hunters Point Community Emissions Reduction Plan	Technical Advisor

CONTRIBUTIONS TO DIVERSITY

CONTRIBUTIONS TO DIVERSITY Contributions to Diversity, Equity & Inclusion Guidance

My research program, approach to mentoring, and the leadership positions I have elected to pursue are all tied to my commitment to diversity, equity, and inclusion. Over the last decade, my **research program** has contextualized how risk factors operate within and across communities (DOD, NHLBI K23) to contribute to health inequities, built upon these findings to create interventions with community perspectives and partnerships (EPA, PCORI), and, most recently, test these interventions through rigorous trial design in and with the communities they were co-designed (state-funded CAIPM, NHLBI R01). Through this work, we have taken steps to include community members as partners and ensure our research is representative of the populations most burdened by the disease or exposure of interest. As a result, all of our current studies have community partners as co-investigators, and greater than 70% of recruited study populations are composed of individuals historically excluded from research. Our work is purposeful in its design and constructs research questions that have clear community and policy targets for intervention.

I am dedicated to **supporting and mentoring** students, trainees, and early career faculty who identify as being from historically marginalized groups. This includes developing and supporting scholarship programs for trainees and junior faculty from marginalized backgrounds (ATS Health Equity and Diversity Fellowship, NI Scholar Program, YPAR Summer Intern Program), providing formal recommendations on diversifying the research field (Thakur

AJRCCM 2014, invited ATS presentations in 2015 and 2020, 2022, 2023), and providing support and mentorship in an inclusive, safe environment for trainees at every level (high school, undergraduate, graduate and medical school, and post-doctoral). The program that most exemplifies my commitment to students and trainees from marginalized backgrounds is our YPAR Summer Intern Program. In 2019, as part of my research program, we launched the Youth Participatory Action Research (YPAR) program targeted at teens from historically marginalized communities. In its first year, we hired six student interns (ages 14-17) from Richmond, CA. The paid internship program provided basic needs, such as meals, social support, and financial support, while also providing career development skills and fostering an interest in science. We have had promising results: supported 25 high school interns over the last five years, supported students to successfully obtain two grants (Community Art Mural and Community Air Monitoring Project), 100% retention in high school, and >97% of those eligible, attend college. In addition, by actively involving our pulmonary and post-doctoral fellows from marginalized groups as peer mentors, we have provided a setting where our high school students can see themselves in science while also enriching the training of our fellows.

Lastly, my leadership positions have been largely driven to address diversity, equity, and inclusion. Most exemplary was my role as Chair of the American Thoracic Society (ATS) Health Equality and Diversity Committee. The ATS is the leading professional association for pulmonary and critical care medicine and research with over 16,000 members worldwide. We have had several successes, including; dedicated fellowship, providing scholarships to support URM medical students at the ATS conference, highlighting work on health disparities at the annual International ATS conference, and providing recommendations to the ATS leadership on diversifying committee representation. In my role as chair: 1) I led a workshop, including researchers and individuals from the NHLBI, NIMHD, and FDA, to develop recommendations for increasing minority participation in clinical research. This work was published in the form of a Research Statement published in the American Journal of Respiratory and Critical Care Medicine (2020) and has resulted in several invited presentations Nationally; 2) hosted a Town Hall on Addressing Racism and Health Disparities with the leaders within ATS (inc. over 40 individuals) on how to shape and expand existing priorities of the ATS towards an equity lens. This has involved on-going meetings (2-3/months) with the executive leadership and committee leadership to ensure progress on set benchmarks and re-evaluation of guideline recommendations; and, 3) overseen the development of a mentoring and networking program for URM early career faculty and trainees in the ATS, including sponsoring URM students at the ATS conferences.

TEACHING AND MENTORING

TEACHING SUMMARY

My teaching experiences span the spectrum from bedside, clinical teaching to the development of educational programs. Examples include:

-As part of the K12 IMPACT Program, I developed the health system embedded experience for the K12 Scholars. This included working with key stakeholders at UCSF and ZSFG to determine alignment across training opportunities, identifying learning objectives based on aligned experiences across the two health systems, and regular biweekly check-ins with Scholars during their embedded experience.

-In 2019, I started the YPAR Summer Internship program. This program focuses on developing research and career development skills for teens from historically disadvantaged communities by employing a Youth Participatory Action Research (YPAR) curriculum (yparhub.berkeley.edu). Informed by their own experiences living in the community, coupled with introductory lectures of stress and the environment, the teens are encouraged to formulate

their own research question regarding neighborhood quality and determine the best way to answer the developed question. The summer experience cumulates with the students participating in the analysis of collected data and presenting their results to public officials in Richmond, including the District Supervisor, representatives from the City of Richmond, DPH, Air District, Food Banks, and other youth groups. In the past, their work was also submitted as an abstract to the Yes Conference, a research conference for high school students across the SF Bay Area focused on science and the environment and has resulted in two youth-led minigrant applications to local organizations.

-As medical director of the Chest Clinic at ZSFG, I have transformed the educational curriculum for the pulmonary fellows assigned their longitudinal clinic at ZSFG. This includes designing the Outpatient curriculum, developing accompanying ACGME-board questions for lectures, and personally delivering several didactics on several topics including asthma, COPD, and addressing unmet social needs in practice.

In addition, I guest lecture 3-4 times per year in a variety of setting to discuss health disparities and asthma, including in the Schools of Pharmacy and Medicine, UC Berkeley School of Public Health, and San Francisco State University. Lastly, I teach informally as an attending in the ZSFG Chest Clinic weekly and on the Medical Critical Care and Pulmonary Consult service 6 weeks per year, where I work with fellows, residents, and medical students from multiple departments.

FORMAL TEACHING

Academic Yr Course No. & Title		Teaching Contribution	School	Class Size
2015 - 2020	SF BUILD Scholars Program: NIH funded collaboration between SF State University and UCSF to diversify the biomedical sciences.	Guest Lecturer		10
2016 - 2021 UCSF-UCB Joint Medical Program - Asthma Block		Guest Lecturer	Medicine	15
2017 - 2021	lmS K12 Learner Health System Embedded Experience Program	Director	Grad	4
2018 - 2019	PUMCH Designing Clinical Research	Section Leader	Grad	7
2018 - present	UCB PH-270 Seminar Introduction to Environmental Health Sciences	Guest Lecturer	Grad	30

Academic Yr	Course No. & Title	Teaching Contribution	School	Class Size
	ImS Individual Level Behavioral Interventions	Section Leader	Grad	10

INFORMAL TEACHING

- 2013 present Teaching of pulmonary fellows on outpatient pulmonary medicine during chest clinic at ZSFG and Parnassus. Occurs weekly.
- 2014 present Bedside teaching of critical care medicine to residents and critical care fellows during attending time in ICU
- 2015 present Bedside teach of pulmonary medicine to medical students, residents, and pulmonary fellows during attending time on the pulmonary consult service at ZSFG

MENTORING SUMMARY

I provide mentorship for trainees extending from the undergraduate level to early career faculty. I am the primary mentor for 1 undergraduate student, 2 graduate/medical students, 2 post-doctoral/pulmonary fellows, and 4 early career faculty. My mentorship activities demonstrate my dedication to providing opportunities for students and trainees from groups underrepresented in medicine and science. My mentees have a track record of productivity and success, including 16 publications in peer-reviewed journals, and 7 research-related grants (including 4 career development awards and one R21). One of my mentees, Dr. de la Rosa, recipient of the California Presidential Post-Doctoral Fellow, successfully obtained a tenured faculty position at UC-Berkeley starting in July 2021.

For each of my mentees, I provide one-on-one teaching on the disparities relevant to our study population and on statistical methods, help mentees formulate their research question and plan, and provide oversight and input on statistical analyses and manuscript preparations. This is carried out through daily to weekly one-on-one meetings with each mentee. In addition, I help identify training gaps and opportunities for professional development. As I have personally benefited from having a team of mentors, I encourage my trainees to seek out other content experts and career mentors. In this vein, I mentor several pulmonary fellows and faculty who are interested in health disparities research, but in different pulmonary fields such as interstitial lung disease, transplant medicine, and critical care medicine.

Lastly, I started the KIPP Summer Internship program for teens from historically disadvantaged communities, which provides a structured environment for learning research methods while also cultivating personal development.

PREDOCTORAL STUDENTS SUPERVISED OR MENTORED

Dates	Name	Program or	Mentor Type	Role	Current	
		School			Position	

Dates	Name	Program or School	Mentor Type	Role	Current Position
2011 - 2011	Christine Jalluri	University of California, San Francisco ZSFG	Project Mentor	Supervised research	Physician, Sutter Health
2012 - 2012	Melissa Martin	University of California, San Francisco School of Medicine	Project Mentor	Supervised research	Pediatric Gastroenterol ogist, Sutter Health
2014 - 2016	Nicolas Barcelo	University of California, San Francisco, School of Medicine	Research/Schola rly Mentor,Project Mentor	Supervised research	National Clinical Scholars Fellow, UCLA Psychiatry
2015 - 2017	Sonia Carlson	University of California, San Francisco, School of Medicine	Research/Schola rly Mentor,Project Mentor,Career Mentor	Supervised research	Gynecologist, Cleveland Clinic, Weston, FL
2014 - 2019	Jessica An	University of California, Berkeley, School of Public Health	Research/Schola rly Mentor,Project Mentor,Career Mentor	Supervised research	Staff Researcher, Kaiser
2017 - 2018	Sonya Chalaka	University of California, San Francisco, Global Health	Project Mentor	Supervised research	Associate, Health & Senior Care Section at HansonBridg ett
2016 - 2020	Emilia Patrick	University of California, San Francisco, School of Nursing	Research/Schola rly Mentor,Project Mentor,Career Mentor	Supervised research	Nurse Educator, ZSFG

Dates	Name	Program or School	Mentor Type	Role	Current Position
2017 - present	Vedaja Surapaneni	University of California, Berkeley	Research/Schola rly Mentor,Project Mentor,Career Mentor	Supervised research	Medical Student, Emory Medical School (Class of 2024)
2017 - 2022	Anthony Nardone	University of California, San Francisco, School of Medicine	Research/Schola rly Mentor,Project Mentor,Career Mentor	Supervised research	Joint Medical Program Student
2018 - 2019	Andrea Munoz	San Francisco State University, SFBUILD	Project Mentor	Supervised research	Nursing Student, USF
2019 - present	Savannah Sturla	University of California, Berkeley/Univ ersity of Michigan	Project Mentor	Supervised research	Doctoral Student
2020 - 2022	Michelle Williams	University of California, Berkeley	Research/Schola rly Mentor,Project Mentor	Supervised research	Master Student in Public Health and City Planning Program
2021 - 2022	Carlos Vera	University of California, Berkeley	Project Mentor	Supervised research	Data and Evaluation Specialist, Monterey County
2022 - present	Jocylene Arenalles	Contra Costa College	Research/Schola rly Mentor	Supervised research	Undergraduat e student
2024 - present	Sara Alavi	University of California, San Francisco, School of Medicine	Research/Schola rly Mentor	Supervised research	Joint Medical Program

POSTDOCTORAL FELLOWS AND RESIDENTS MENTORED

Dates	Name	Fellow	Mentor Role	Faculty Role	Current Position
2017 - 2019	Tyronda Elliot	Pulmonary Fellow	Career Mentor	Member of Research Committee and meet with fellow regular to discuss career and research opportunities	Intensivist, Highland Hospital
2018 - 2022	Bhavika Kaul	Pulmonary Fellow	Career Mentor	Member of Research Committee and meet with fellow regular to discuss career and research opportunities	Assistant Professor, Baylor
2019 - present	Katherine Sullivan	Chief Resident	Project Mentor,Career Mentor,Co- Mentor/Clinical Mentor	Co-mentor/Content Mentor	Pulmonary Fellow
2019 - present	Adali Martinez	Resident	Research/Schola rly Mentor,Project Mentor,Career Mentor	Primary mentor	Pulmonary Fellow
2020 - 2022	Nick Murphy	Resident	Project Mentor	Research mentor	Pulmonary Fellow
2021 - 2023	Ernesto Casillas	Pulmonary Fellow	Research/Schola rly Mentor,Project Mentor,Career Mentor	Primary mentor	Assistant Professor, UCSF
2023 - present	Rebecca Sugrue	Post-doctoral Fellow	Research/Schola rly Mentor,Project Mentor,Career Mentor	Primary mentor	Post-doctoral Fellow

FACULTY MENTORING

Dates	Name	Position while	Mentor Type	Mentoring Role	Current
		Mentored			Position

Dates	Name	Position while Mentored	Mentor Type	Mentoring Role	Current Position
2019 - present	Rosemarie de la Rosa	Post-doctoral Fellow	Research/Schola rly Mentor,Project Mentor,Career Mentor	Primary mentor	Assistant Professor, UC Berkeley
2018 - present	Alison DeDent	Post-doctoral Fellow	Research/Schola rly Mentor,Project Mentor,Career Mentor	Primary Mentor	Assistant Professor, UCSF
2019 - present	Aaron Baugh	Post-doctoral Fellow	Research/Schola rly Mentor,Project Mentor,Career Mentor	Primary mentor	Assistant Professor, UCSF
2020 - present	Leslie Seijo	Post-doctoral Fellow	Research/Schola rly Mentor,Project Mentor,Career Mentor	Primary mentor	Assistant Professor, UCSF
2022 - present	Jamuna Krishnan	Assistant Professor	Research/Schola rly Mentor,Co- Mentor/Clinical Mentor	Co-mentor	Assistant Professor, Cornell
2022 - present	Marissa Boeck	Assistant Professor	Research/Schola rly Mentor,Co- Mentor/Clinical Mentor	Co-mentor	Assistant Professor

RESEARCH AND CREATIVE ACTIVITIES

RESEARCH AND CREATIVE ACTIVITIES SUMMARY

I am a physician-scientist with specialty training in pulmonary and critical care medicine and advanced training in clinical research methods, social epidemiology, and implementation sciences (MPH in Community Health, Certificate in Clinical Research and Implementation Sciences). From my time as an undergraduate student and now as faculty, I have been interested in the role of opportunity, or lack thereof, in health outcomes. Opportunity plays a large role in determining where people live, how individuals are treated, and their overall socioeconomic wealth; each of which is an important risk factor for developing lung disease and contributes to morbidity. This has informed my research program, which is dedicated to understanding and addressing the contributors to respiratory health disparities in populations disproportionately exposed to social stressors and environmental hazards. Over the past decade, I have developed a novel research agenda and my primary goals are directed towards

1) defining obstructive lung disease phenotypes that exist in racially and ethnically diverse communities and 2) identifying community-specific drivers that place individuals at high risk for poor outcomes and 3) co-developing place-based and targeted interventions aimed at social and environmental factors to improve respiratory outcomes in historically marginalized populations. To successfully achieve these goals, I employ community-engaged methods ranging from querying community stakeholders for input on scientific questions and study design to participatory action research through our Youth Participatory Action Research program and our environmental justice portfolio.

RESEARCH AWARDS - CURRENT

1. OPR20142 PI 15 % effort Thakur (PI)
California Initiative to Advance Precision Medicine 09/16/2021 06/30/2025
Collaborative approach to examining Adversity and \$ 1,000,000 \$ 3,000,000 total building REsilience (CARE) direct/yr 1

Under this award, we will build upon three studies and align efforts across Northern and Central California. Applying a Precision Medicine approach, we will expand upon the existing Pediatric ACEs and Resiliency Study (PEARLS) cohort (n=350) by adding a 3-year follow up biomarker testing and analysis point (Aim 1). This will allow us to identify early effects of adversity and pinpoint heterogeneity, including identifying factors that are protective or stress-buffering, which may allude to intervention. Under Aim 2, we have aligned three caregiver-child intervention studies and, using a randomized wait-list controlled trial design (n=300), will test effect of intervention on caregiver stress, behavioral and biologic outcomes. Under Aim 3, led by Futures Without Violence and informed by Aims 1 and 2, we will develop and pilot a community-vetted Resilience Toolkit for low-resourced primary care settings that is scalable and of value across California. The proposed activities under CARE will accelerate our understanding of how to best identify those at greatest risk, enhance protective factors, and intervene to bolster resilience across the care continuum.

PI of grant

2. R01HL161049	PI	20 % effort	Thakur (PI)
NHLBI		12/31/2021	12/30/2026
Rehabilitation in Safety- to improve outcomes in COPD	net Environments (RISE) vulnerable patients with	\$ 499,000 direct/yr 1	\$ 2,495,000 total

The proposed study will directly test the benefit of the COPD Wellness and Plus+ Program relative to usual care and estimate the added benefit of the HA in COPD Wellness Plus+ to COPD Wellness alone in a three-arm, randomized waitlist-controlled trial (n=387) conducted in three geographically isolated urban primary care sites that provide care for some of the most socially vulnerable patient populations with COPD. In this Type 1 effectiveness-implementation hybrid design, we aim to 1) determine the effectiveness of COPD Wellness and Plus+ to improve functional and symptom outcomes; and, using a mixed-methods approach 2) to evaluate the implementation of COPD Wellness and Plus+ across study sites applying the RE-AIM and CFIR frameworks to identify additional barriers and enablers of intervention implementation and patient acceptance and adherence.

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3. Grant13504839 PI 15 % effort Thakur (PI)

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Prepared: May 10, 2025

EPA 12/30/2022 12/29/2025

Partnering for Resilient Opportunities To Eliminate \$ 1,350,000 total Cumulative Toxic (PROTECT) Health Effects from

Wildfire PM2.5 in Environmental Justice

Communities

This proposal seeks to 1) estimate the health effects of sub-daily exposure to wildfire-specific PM2.5 in California, including across social vulnerability factors, with particular focus on effects within EJ communities; 2) understand community recovery from short-term health effects following exposure; 3) understand indoor infiltration of wildfire smoke and the mitigating effect of housing quality and behaviors on health effects; and, 4) identify acceptable community-relevant mitigation interventions.

PI of gran	١t
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4. U01HG013276	MPI	10% % effort	Christensen/Thakur (PI)
NIH		07/01/2023	06/30/2028
EXposomic Profiling in Airway disease to uNravel Determinants of disease in Asthma (EXPAND-Asthma) Center		\$ 500,000 direct/yr 1	\$ 2,500,000 total

Goals: To improve our understanding of heterogeneous asthma pathobiology associated with socio-environmental exposures, relevant to marginalized populations, allowing us to better discriminate individuals at high risk for poor outcomes and identify place-based targets for intervention.

MPI of grant to standardize social and environmental measures, oversee community-based research infrastructure, and lead community-engaged research partnerships.

5. 1R01MD019027	Co-I	10% % effort	Best (PI)
NIMHD		09/24/2023	09/23/2028

Factors Influencing Pediatric Asthma into Adulthood (FIPA2)

Major Goals: To examine the complex interplay between social, environmental and immunological response to viral respiratory infections as contributory to asthma and asthmarelated morbidity in American Indian (AI) populations with asthma. Specifically, we will test the hypothesis that AI children with asthma have alterations in immunological response to several viral respiratory infections as compared to those without asthma. We will also investigate whether social and environmental factors (SEF) significantly contribute to this disparity through stressed-induced modification of immune state. We will explore the role of viral respiratory infections (RSV, rhinovirus C, and influenza A and B) and SEF on asthma severity, including frequency of exacerbations, ER visits/hospitalizations, and use of asthma medications.

Asthma expertise as well as expertise on measuring social adversity measures, including ACEs.

6. R01ES035504	PI	15% % effort	Thakur (PI)
NIEHS/NIH		08/01/2024	07/31/2029

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Prepared: May 10, 2025

\$ 2,500,000 total

Driving Environmental Justice: Community \$ 500,000

Monitoring of Diesel Truck Emissions and Impacts direct/yr 1

on Asthma Morbidity in Immigrant Communities.

To increase our understanding of the short-term respiratory health effects of residing near diesel exhaust pollution sources, including frequented truck routes, for Latino/x/e children with asthma and to identifying and co-prioritizing mitigation strategies for adoption and policy change.

PI of grant (scored 8th Percentile, assigned for funding)

7	. R0S1716943471093	Research Project PI	10% % effort	Weiser (PI)
	NIH/NIEHS		09/01/2024	08/31/2029
	Equity and Climate Opportunit	ies for Health (ECO-	\$ 918,024	\$ 2,764,734 total
	Health) Center		direct/vr 1	

Major Goals: The proposed Equity and Climate Opportunities for Health (ECO-Health) Center at the University of California will generate rigorous scientific evidence about how climate change leads to poor health outcomes within communities that are heavily impacted by structural injustices. The Center will also partner with these communities to use this evidence to co-develop and co-implement climate adaptation interventions that improve health and reduce health inequities. Ultimately, the ECO-Health Center will help generate equitable solutions that build resilience to the health risks of climate change in California communities and beyond.

Research Project PI

RESEARCH AWARDS - SUBMITTED

1. Grant14259129	PI	10 % effort	Thakur (PI)
EPA		01/01/2025	12/31/2027
Healthy Homes Throug	gh Every Door	\$ 4,911,546 direct/yr 1	\$ 15,297,705 total

This collaborative project integrates decarbonization efforts with health-targeted programs, addressing the underutilization of these initiatives in disadvantaged communities, particularly communities of color and low-income households. Our proposal focuses on three San Francisco Bay Area counties (Alameda, San Francisco, and San Mateo), aiming to enhance local capacity and engagement with Healthy & Efficient Home Initiatives to improve health outcomes. This initiative aligns with climate and pollution reduction strategies by targeting energy-efficient housing, workforce development, and indoor air quality improvements, aiming to decarbonize low-income households and create green job opportunities. Our proposed action areas include: Action Area 1: Increase access and engagement by partnering with Community-Based Organizations (CBOs) to provide coordination services to 400 households and foster a community of practice. Action Area 2: Incorporate these initiatives into Asthma Home Visit programs, extending services to an additional 225 households. Action Area 3: Deliver comprehensive remediation services, including solar installation and green job training, to 150 households, with a subset receiving free solar installations.

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2.	UCSF Lead	2.5% % effort	Preble (PI)	
California Air Resource Bo	ard	03/01/2025	02/28/2027	

Reducing Exposure with Air Cleaners and Technology (REACT) in At-Risk Communities

\$ 54,940 direct/yr 1 \$ 109,880 total

Communities with historical and persistent divestment face disproportionate air pollution and health burdens. This study aims to mitigate these exposures by evaluating the impact of air filtration devices on indoor fine particulate matter (PM2.5) and respiratory health using an interrupted time series design. Additionally, a multistage randomized control trial will assess how indicators from low-cost PM2.5 sensors and technical assistance can enhance the use and effectiveness of air cleaners. We will recruit 100 households in Bayview Hunters Points (BVHP) and monitor them for 90 days. The study will determine how air quality indicators, air cleaner usage, and targeted assistance improve indoor air quality and health outcomes, guiding future policy and advocacy to protect over-exposed communities. This collaborative effort involves UC Berkeley, UC San Francisco, and local environmental justice organizations, BVHP Community Advocates, and Brightline Defense.

UCSF Lead, will oversee recruitment with partnering community organizations and lead the health outcome analyses.

RESEARCH AWARDS - PAST

NIH/NHLBI 1K12	Career Development	75 % effort	Burchard/Erle (PI)
HL119997-01	Award Recipient		
•	Program in Omics of Lung	07/01/2015	12/31/2015
The Use of High Dimension	al Data to Identify Asthma	\$ 86,500	\$ 259,500 total
Phenotypes Susceptible to	Social Adversities	direct/yr 1	
	HL119997-01 UCSF Career Development Diseases The Use of High Dimension	HL119997-01 Award Recipient UCSF Career Development Program in Omics of Lung	HL119997-01 Award Recipient UCSF Career Development Program in Omics of Lung 07/01/2015 Diseases The Use of High Dimensional Data to Identify Asthma \$86,500

This proposal aims to identify asthma phenotypes in disadvantaged, minority populations and their interaction with social determinants using an omics approach. This will allow for the uncovering of relationships previously missed due to biases brought into analyses.

2.	Principal Investigator	16.6 % effort	Thakur (PI)
American Thoracic Outstanding Early (Society: Recognition Award for Career Investigators	11/01/2014	10/31/2015
Allostatic Load and Asthma in Minority	Asthma: Chronic Stress and Children	\$ 40,000 direct/yr 1	\$ 40,000 total

The goal of the Recognition Award is to fund researchers who had a Career Development Award that was near fundable level but not awarded from the National Institute of Health or an equivalent organization. This support will be used for ancillary supplies to measure cytokines in African American study participants to better elucidate the inflammatory response to social stressors.

3.	PR141896	Principal Investigator	20 % effort	Thakur (PI)
	Peer Reviewed Medical Research Program Discovery Award		09/30/2015	3/31/2017
Pathways to Disease: The Social Adversity on Asthm		Biological Consequences of a In Minority Youth	\$ 130,000 direct/yr 1	\$ 200,000 total

The goal of this award is to better delineate the biological pathways of stress related to socioeconomic and environmental stress among urban, minority of youth with asthma. This study will examine 1) the immune and neuro-endocrine response and 2) the microbiome in response to chronic exposure to psychosocial stress.

4.	A125633	Principal Investigator	33 % effort	Thakur (PI)
	Francis Family Foundation: Fellowship Program	Parker B. Francis	07/01/2015	06/30/2018
	Social Adversity and Asthm	a: A new Phenotype?	\$ 50,000 direct/yr 1	\$ 156,000 total

The goal of this award is to 1) identify risk factors for poor asthma outcomes in African American and Latino children that are related to social and environmental exposures, 2) test a limited set of inflammatory biomarkers to determine if they are elevated in the presence of specific stress exposures, and 3) Determine if there is an asthma phenotype susceptible to social and environmental stress.

5.	15 % effort	Thakur (PI)
Nina Ireland Program in Lung Health	01/01/2017	12/31/2018
Rehabilitation in Safety-Net Environments (RISE) for	\$ 50,000	\$ 100,000 total
COPD	direct/yr 1	

The goals of the project are to conduct a pilot study of 1) low-intensity pulmonary rehabilitation, COPD Wellness, for individuals with moderate-to-severe COPD seeking care through ZSFG; and determine if 2) adding a program that addresses unmet social needs improves adherence to the exercise program.

6.	A126349A	Principal Investigator	13 % effort	Thakur (PI)
	Tara Health/Center for You	th Wellness	09/1/2015	02/28/2020
	Pediatric ACEs and Resilie	nce Study (PEARLS)	\$ 151,000	\$ 755,000 total
			direct/yr 1	

The goals of this award are to 1) develop and validate a screening tool for ACEs for use in pediatric primary care; 2) further understand the longitudinal relationship of ACEs and health in children; and 3) identify biologic markers that may help identify children at greater risk from poor health due to high ACEs exposure.

I am the Lead-PI for objectives 2 and 3 for this grant and the co-I for objective 1. Since 2019, I have served as the primary contact to the funder and have overseen all scientific inquiry and day-to-day operations for PEARLS. This includes finding additional funding to support the continuation of the PEARLS cohort.

7.	K23HL12551-01A1	Principal Investigator	75 % effort	Thakur (PI)
	NHLBI		01/01/2016	12/31/2020
	Social Adversities and Asth	nma: A New Phenotype	\$ 165,000	\$ 625,000 total
			direct/yr 1	

The goals of this project are to 1) identify individual- and community-level risk factors for asthma among disadvantage, minority youth; 2) define a profile of characteristics, which includes biomarker data, that will better identify individuals at high risk for poor asthma outcomes who are from communities burdened by social adversities; and 3) examine the asthma-related outcomes in individuals with the identified phenotype.

8.	Awarded	PI	15 % effort	Thakur (PI)
	TARA Health		02/28/2020	07/31/2021
	PEARLS Extension		\$ 184,734 direct/yr 1	\$ 184,734 total

Complete follow up, biomarker analysis, and analysis from PEARLS.

I lead the health outcomes and biomarker aim for this proposal. This includes overseeing and contributing to all analysis and manuscript preparations for the study, including examining for associations between ACEs and health, biological health, and intervention response.

9.	Project PI	3.5 % effort	Cohen (PI)
Koret Foundation		09/01/2017	08/31/2022
The Koret Institute	for Precision Prevention at the		\$ 614,246 total
Berkeley Global Ca	mpus		

This is a Center Grant to UC-Berkeley and includes an environmental, health, and training focus. UCSF is leading the Health Project of the Koret Institute for Precision Prevention (KIPP). The study will examine the social and environmental contributors to asthma in vulnerable populations.

I am the Project PI of this R01 equivalent award. I established the Richmond Environment and Asthma Community Health (REACH) Study to study the joint effect of psychosocial stressors and ambient air pollution on asthma morbidity in children from high-risk communities.

10.	PI	2.5% % effort	Thakur (PI)
Genentech Corporate	Giving	09/16/2020	09/15/2022
ACES and Resilience Community (ARC)	from Biologic-Response to the	\$ 200,000 direct/yr 1	\$ 400,000 total

To study the longitudinal effect of ACEs on pediatric health outcomes in children in PEARLS. This provides funding for an additional time point of collection.

I am the PI of the study and oversee all aspects of the study design, recruitment, methods of data collection, and data analysis.

11.	PI	10 % effort	Thakur (PI)
Robert Wood Johnson Fou	ndation	06/15/2020	06/30/2022

Title: Social and Economic Barriers to Public Health and Clinical Interventions for COVID-19 in Vulnerable Populations

To understand and address barriers to public health and clinical interventions for COVID-19 in vulnerable populations across ten sites in the US. Identifying key intervention targets will require detailed information regarding the drivers of barriers to both health care access and ability to self-isolate, with special attention to barriers to COVID-19 testing and treatment; telemedicine; and shelter in place regulation adherence.

I am the PI of this multi-center trial that includes 10 sites across the US. As PI, I have personally recruited each site to participate, determined the study design, and overseen recruitment, methods of data collection, and data analysis.

12. EACB-23028	PI	5 % effort	Thakur (PI)
Patient Centered Outcome (PCORI)	s Research Institute	12/21/2021	02/28/2024
Building Capacity for Rese Impacted Health Condition			\$ 249,974 total

Extreme heat and wildfire smoke events have significant health impacts in communities with the least economic, social, or political resources to respond. This project will engage a diverse group of stakeholders in San Francisco to understand priority health conditions, identify relevant patient-centered outcomes affected by climate, and collect information on the barriers to existing migration strategies.

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SIGNIFICANT PUBLICATIONS

1. 2013

N Thakur, Oh SS, Nguyen EA, Martin M, Roth LA, Galanter J, Gignoux CR, Eng C, Davis A, Meade K, Lenoir MA, Avila PC, Farber HJ, Serebrisky D, Brigino-Buenaventura E, Rodriguez-Cintron W, Kumar R, Williams LK, Bibbins-Domingo K, Thyne S, Sen S, Rodriguez-Santana JR, Borrell LN, Burchard EG. Socioeconomic Status and Childhood Asthma in Urban Minority Youths: The GALA II and SAGE II Studies. Am J Respir Crit Care Med. 2013 Nov 15; 188(10):1202-9. PMID: 24050698; PMCID: PMC3863734.

Socioeconomic Status (SES) and Asthma: Individuals living in poverty are thought to be at higher risk for asthma as they have greater exposure to known risk factors to asthma. Yet, when we examine the role of socioeconomic status within each racial/ethnic group, the effects vary. With the GALA II and SAGE II studies, two parallel, case-control studies of asthma designed to examine the complex interplay of genetics and socioenvironmental factors, we demonstrated that the risk factors for asthma differ among racial/ethnic groups: poverty increases the odds of asthma in African Americans, yet decreases it in Mexican Americans. This is the first study to demonstrate this different in effect and now has been replicated by other studies. Moreover, we were able to demonstrate that this risk held true across the SES gradient (i.e. not limited to high vs. low SES) regardless of race/ethnicity. Given the significance of these findings, this paper was selected for an editorial. The observed heterogeneity in exposure effect has also deeply informed my research program and formed the basis of my K23 award. For this specific manuscript, I developed the research question and analytic approach, performed all data analyses, interpreted the results, drafted and revised the final manuscript as published.

2. 2015

Pino-Yanes M, **Thakur N**, Gignoux C R, Galanter J M, Roth L A, Eng C, Nishimura K K, Oh S S, Hita Vora, Huntsman S, Nguyen E A, Hu D, Drake K A, Conti DV, Moreno A, Sandoval K, Winkler CA, Borrell LN, Lurmann F, Islam T S, Davis A, Farber H J, Meade K, Avila P C, Serebrisky D, Bibbins-Domingo K, Lenoir M A, Ford J G, Brigino-Buenaventura E, Rodriguez-Cintron W, Thyne S M, Sen S, Rodriguez-Santana J R, Bustamante C, Williams L K, Gilliland F D, Gauderman W J, Kumar R, Torgerson D G, Burchard E G. Genetic ancestry influences asthma susceptibility and lung function among Latinos. J Allergy Clin Immunol. 2015 Jan;135(1):228-35. PMID 25301036. PMCID: PMC4289103.

Genetic Ancestry and Asthma: Asthma prevalence varies across Latino subgroups, which have varying levels of Native ancestry. Prior studies suggest that Native ancestry is protective. Here we show that Native ancestry is associated with reduced odds of asthma and improved pulmonary function. I critically reviewed and provided interpretation of the results, revised several iterations of the manuscript, and approved of the final version as published.

3. 2015

N Thakur*, Barcelo N*, Oh SS, Nguyen EA, Eng C, Davis A, Meade K, Lenoir MA, Avila PC, Farber HJ, Serebrisky D, Brigino-Buenaventura E, Rodriguez-Cintron W, Kumar R, Bibbins-Domingo K, Thyne S, Sen S, Rodriguez-Santana JR, Borrell LN, Burchard EG. *These authors contributed equally to this work. Discrimination is predictive of asthma in some racial/ethnic groups: The GALA II and SAGE II Studies. Chest.2017;151(4):804-812. PMID 27916618

Discrimination and Asthma: Psychosocial stress is an important predictor of poor health outcomes. In this work, we demonstrated that perceived racial discrimination is associated with asthma and worse morbidity among African American children. In Latinos, this association varied by socioeconomic status. For this manuscript, I conceived the research question, designed the analytical approach, and performed the analysis. I would with a medical student to draft the first and subsequent iterations of the manuscript, and approved of the final version as published.

4.

S. Carlson, Borrell N, Eng C, Nguyen M, Thyne S, LeNoir MA, Burke-Harris N, Burchard EG*, **Thakur N***. *These authors contributed equally to this work. Self-reported racial/ethnic discrimination and bronchodilator response in African American youth with asthma. PLoS ONE 12(6): e0179091. PMID 28609485

Discrimination and Asthma: Among children with asthma, we found that consideration of experiences of discrimination when examining asthma phenotypes helped improved our ability to identify children who may benefit from further asthma controller therapy in a group of children with an asthma types thought to be more drug resistant (TNF-alpha high asthma). These results support the need to screen for racial/ethnic discriminatory experiences among those with moderate-severe asthma as it may help to reclassify asthma type and identify more precise treatments for high-risk population. For this manuscript, I conceived the research question, worked with Dr. Carlson to develop the analytical approach, directly supervised the analysis and assisted with interpretation of results, and revised and approved the final manuscript. This project was supported by independent funding I obtained from the Department of Defense and represents the output of one of my first mentorship opportunities.

5. Koita K, Long D, Hessler D, Benson M, Daley K, Bucci M, **Thakur N**, Burke Harris N. Development and implementation of a pediatric adverse childhood experiences (ACEs) and other determinants of health questionnaire in the pediatric medical home: A pilot study. PLoS One. 2018; 13(12):e0208088. PMID: 30540843.

Adverse Childhood Experiences: Early-life trauma and related adversities are prevalent and associated with negative childhood and adulthood health outcomes. These adverse childhood experiences (ACEs) are especially common in low-income communities. Early identification and targeted treatment of trauma in childhood is critical for reducing the long-term behavioral, mental, and physical health outcomes in children and adults. This manuscript is the output of our pilot study for to develop a questionnaire for screening for ACEs within pediatric primary care. This screener was selected by the California Department of Public Health for ACEs screening in pediatric primary care, the only tool to be available for financial reimbursement. For this pilot study, I co-designed the study and the semi-structured interview guide and reviewed the coded data and help interpret the results. I also participated in finalizing the questionnaire, revised several iterations of the manuscript, and approved of the final version as published.

CONFERENCE ABSTRACTS

- 2009 Blumenthal E, Kalanithi L, Keet K, Kern R, Kneeland P, Mikosz C, Neinstein A, Osterhoff R, Pierce R, Ponce P, Thakur N, and Yong C. Teaching Leadership and Quality Improvement: A Resident-Led Initiative to Improve Anticoagulation Safety at UCSF Medical Center. American Association of Medical Colleges: Integrating Quality Meeting, June 15-16, 2009.
- 2011 C. Jalluri, Thakur N, Seligman H. Average travel time to clinic in underserved patients with and without lung disease. Health Disparities Research Symposium V at UCSF 2011.
- 2012 N Thakur, EG Burchard, H Seligman. Risk Factors Associated With Missed Appointments Among Patients With Chronic Lung Disease In A Safety-Net System. Am. J. Respir. Crit. Care Med. 2012; 185: A5139.
- 2012 N Thakur, C Jalluri, EG Burchard, and H Seligman. Average Travel Time To Clinic In Patients With And Without Lung Disease Utilizing A Safety-Net Clinic. Am. J. Respir. Crit. Care Med. 2012; 185: A2865.
- V Surapaneni, J DeVore, EC Patrick, G Su, **N Thakur.** Barriers and Facilitators to Low-Intensity Pulmonary Rehabilitation in a 'Safety-Net' Setting. American Journal of Respiratory and Critical Care Medicine 2018;197:A2167

M Ye. LN Borrell, S Oh. K Bibbins-Domingo, R Kumar, EG Burchard, N

Prepared: May 10, 2025

2010	Thakur . Allergen Sensitization Patterns by Socioeconomic Class in Children with and Without Asthma. American Journal of Respiratory and Critical Care Medicine 2019;199:A7052. Oral Presentation, Podium.
2019	Munoz Vera A, Andrade A, Athavale P, Chalaka S, Thakur N . Barriers and Facilitators to ACEs Screening Tools in Low-income Community Health Facilities. Health Disparities Research Symposium at UCSF. 2019. San Francisco, CA.
2020	R de la Rosa, M Ye, D Zablotny, D Hessler, M Benson, R Gilgoff, K Koita, M Bucci, DLong, N Thakur. Unmet Social Needs Increases Emergency Department Visits And Exercise Wheeze In Children With Eosinophilic Asthma. 2020 International American Thoracic Society Meeting. Philadelphia, PA. Rapid Oral Poster Presentation (Deferred due to COVID-19 Pandemic).
2020	Ye M, Andrade A, Munoz Vera A, Obasi C, Guzman E, Gonzalez E, Rayon C, Madriz S, Hernandez J, De La Rosa R, Morello-Frosch R, Noth B, Hammond SK,; Smith MT, Balmes J1, Cohen R, Thakur N . Neighborhood Physical and Social Attributes by Systemic Social Observation and Asthma Emergency Department Visits. 2020 International American Thoracic Society Meeting.

A Martinez, M Ye, R de la Rosa, D Hessler, M Benson, R Gilgoff, K Koita, M Bucci, DLong, **N Thakur.** Adverse Childhood Experiences Increases Severe Asthma Symptoms in Children Receiving Care within a Safety Net Setting. 2020 International American Thoracic Society Meeting. Philadelphia, PA **Oral Presentation, Podium.** (Deferred due to COVID-19 Pandemic).

Philadelphia, PA (Deferred due to COVID-19 Pandemic).

ACADEMIC LEADERSHIP

2019

At ZSFG, I am the Medical Director of the Chest Clinic, where I also serve and chair the ZSFG Chest Leadership Committee. This multidisciplinary committee is composed of nursing, respiratory therapy, and Chest providers, including a trainee representative, and meets quarterly to identify quality improvement projects for clinic (past projects include the biologic shot clinic for severe asthma and streamlining the oxygen prescribing process), reviews quality metrics for clinic, and ensures the clinic environment provides a well-rounded educational opportunity for the fellows. As an emerging Clinical Leader at ZSFG, in 2019 I was invited to participate in the inaugural ZSFG Clinical Leadership Professional Developmen Program, a six-month program that included content on ZSFG and Department of Medicine operations, personality type and leadership training, change management, and developing your people skill training.

EXHIBIT B

OMB Number: 4040-0004 Expiration Date: 12/31/2022

Application for	Application for Federal Assistance SF-424 G21H113504839							
* 1. Type of Submiss Preapplication Application Changed/Corr		* 2. Type of Application: New Continuation Revision * If Revision, select appropriate letter(s): * Other (Specify): Revision						
* 3. Date Received:		4. Applicant Identifier:						
5a. Federal Entity Identifier: 5b. Federal Award Identifier:								
State Use Only:								
6. Date Received by	/ State:		7. State Application	lder	ntifier:			
8. APPLICANT INF	ORMATION:							
* a. Legal Name:	The Regents of	the Uni	versity of Cal	ifo	ornia San Francisco			
* b. Employer/Taxpa	* b. Employer/Taxpayer Identification Number (EIN/TIN): * c. Organizational DUNS:							
d. Address:								
* Street1: Street2: * City:		UCSF Office of Sponsored Research 490 Illinois Street, 4th Floor San Francisco						
County/Parish: * State: Province:	San Francisco CA: California	San Francisco CA: California						
* Country: * Zip / Postal Code:	USA: UNITED ST	TATES						
	94143-0000							
e. Organizational Unit: Department Name: Medicine Division Name: School of Medicine								
f. Name and contact information of person to be contacted on matters involving this application:								
Prefix: Middle Name: * Last Name: Buffix:	tchinson]	* First Name	e: 	Sharon			
Title: UCSF Contracts and Grants Officer								
Organizational Affilia	ation:							
* Telephone Numbe	er: 415-260-6443				Fax Number:			
*Email: shutchinson@ucsf.edu								

Application for Federal Assistance SF-424					
* 9. Type of Applicant 1: Select Applicant Type:					
H: Public/State Controlled Institution of Higher Education					
Гуре of Applicant 2: Select Applicant Type:					
Type of Applicant 3: Select Applicant Type:					
* Other (specify):					
* 10. Name of Federal Agency:					
Environmental Protection Agency					
11. Catalog of Federal Domestic Assistance Number:					
66.509					
CFDA Title:					
Science To Achieve Results (STAR) Research Program					
* 12. Funding Opportunity Number:					
EPA-G2021-STAR-H1					
* Title:					
Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/Lifestages: Community-Based Research for Solutions					
13. Competition Identification Number:					
Title:					
14. Areas Affected by Project (Cities, Counties, States, etc.):					
1234-Areas_Affected.pdf Add Attachment Delete Attachment View Attachment					
* 15. Descriptive Title of Applicant's Project:					
Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from					
Wildfire PM2.5 in Environmental Justice Communities					
Attach supporting documents as specified in agency instructions.					
Add Attachments Delete Attachments View Attachments					

Application	Application for Federal Assistance SF-424						
16. Congressi	onal Districts Of:						
* a. Applicant	CA-012		* b. Program/l	Project CA-012			
Attach an addit	onal list of Program/Project Congressional Distric	cts if needed.					
1235-Congr	1235-CongressionalDistricts.pdf Add Attachment Delete Attachment View Attachment						
17. Proposed	Project:						
* a. Start Date: 07/01/2022 * b. End Date: 06/30/2025							
18. Estimated Funding (\$):							
* a. Federal	1,330,536.00						
* b. Applicant	0.00						
* c. State	0.00						
* d. Local	0.00						
* e. Other	0.00						
* f. Program In	come 0.00						
* g. TOTAL	1,330,536.00						
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Middle Name:							
* Last Name:	Giovannetti						
Suffix:							
* Title:	CSF Contracts and Grants Officer						
* Telephone Number: (415) 260-5861 Fax Number:							
*Email: olive.giovannetti@ucsf.edu							
* Signature of A	authorized Representative:		* Date Signed:	11/16/2021			

OMB Number: 2030-0020 Expiration Date: 04/30/2021

EPA KEY CONTACTS FORM

Authorized Representative: Original awards and amendments will be sent to this individual for review and acceptance, unless otherwise indicated.

Name:	Prefix	x:		First Name:	Shelby			Middle N	ame: [
	Last	Name:	Mayoral					s	uffix:		
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City:		San Fr	ancisco			State:	CA: California				
Zip / F	Postal	Code:	94143-0000			Country:	USA: UNITED STAT	TES			
Phone I	Numb	er:	(628) 224-3	3730			Fax Number:				
E-mail A	Addre	ss:	Shelby.May	oral@ucsf.ed	u						
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	Last	Name:	McCaffrey					S	uffix:		
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Stree	t2:										
City:		San Fr	ancisco			State:	CA: California				
Zip / F	Postal	Code:	94143-0000			Country:	USA: UNITED STAT	ES			
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Name:	Prefix	x:		First Name:	Sharon			Middle N	ame:		
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E-mail A	Addre	ss:	shutchinson	n@ucsf.edu							

EPA Form 5700-54 (Rev 4-02)

EPA KEY CONTACTS FORM

Project Manager: Individual responsible for the technical completion of the proposed work. Name: Prefix: First Name: Neeta Middle Name: Suffix: M.D.Last Name: Thakur Title: UCSF Assistant Professor **Complete Address:** Street1: Zuckerberg San Francisco General Hospital Street2: 1001 Potrero Avenue, 228 City: State: CA: California San Francisco **Zip / Postal Code:** |94143-0841|Country: USA: UNITED STATES **Phone Number:** Fax Number: (415) 476-0735 E-mail Address: Neeta.Thakur@ucsf.edu

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Funding Opportunity: EPA-G2021-STAR-H1, Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/Lifestages: Community-Based Research for Solutions

Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Wildfire PM_{2.5} in Environmental Justice Communities.

Abstract

Investigators: Thakur, Neeta; Balmes, John R.; Holm, Stephanie; Chow, Fontini (Tina); de la Rosa, Rosemarie; Noth, Betsey M.; Chan, Wanyu R.; Kirchstetter, Thomas W.; Basu, Rupa

Institution(s): University of California San Francisco, University of California Berkeley, Lawrence Berkeley National Laboratory, Office of Environmental Health Hazard Assessment

Project Period and Location: December 1, 2022 - November 30, 2025; Fresno, Richmond, and San Francisco Counties, California.

Project Cost: \$1,349,532

Project Summary: Social adversity and environmental pollution are geospatially distributed and concentrated in communities of color and of low socioeconomic status, leading to worse health outcomes in these (Environmental Justice [EJ]) communities. In California, the increase in wildfire smoke events has likely had cascading and widespread impacts in EJ communities. There is a critical need to understand the impact of recurrent and prolonged wildfire smoke exposure on health and how this health risk is distributed across communities.

Objectives: This proposal seeks to 1) estimate the health effects of sub-daily exposure to wildfire-specific PM2.5 in California, including across social vulnerability factors, with particular focus on effects within EJ communities; 2) understand community recovery from short-term health effects following exposure; 3) understand indoor infiltration of wildfire smoke and the mitigating effect of housing quality and behaviors on health effects; and, 4) identify acceptable community-relevant mitigation interventions.

Approach: We will derive an hourly 3km wildfire-specific PM2.5 concentration grid by improving upon the NOAA HRRR Smoke Model with corrections from observation data. Exposure estimates will be assigned to geographic areas of interest. We will use a combination of air infiltration models using housing attributes and meteorological data as inputs combined with new observational studies of infiltration factors of PM_{2.5} to estimate smoke infiltration. We will then examine for health effects of wildfire-specific PM_{2.5} on respiratory, cardiovascular, and cerebrovascular-related emergency department visits and hospitalizations across zip codes (n~1300) in California, factoring for smoke infiltration. We will examine if health effects occur disproportionately across social vulnerability factors, including age, race/ethnicity, composite indices for socioeconomic status, and EJ community designation using CalEnvironScreen 4.0. Lastly, with our community partners, we will quantitatively survey (n=450) residents of EJ communities residing in Fresno, Richmond, and San Francisco about mitigation behaviors during wildfire events and qualitatively assess barriers to existing barriers. Together, these data will be used to co-develop implementation strategies to increase uptake of acceptable community-relevant mitigation interventions.

Expected Results: At the conclusion, we will have a HRRR Smoke model with more accurate estimates for wildfire-specific $PM_{2.5}$ and understanding of smoke infiltration for housing across California; estimated health risk of wildfire PM2.5 across different communities in California; improved understanding of behaviors during wildfire events, including barriers to mitigations; and, co-developed implementation strategies to increase uptake of acceptable interventions.

Supplemental Keywords: Wildfire Smoke, Environmental Justice, Health Effects

Funding Opportunity: EPA-G2021-STAR-H1, Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/ Lifestages: Community-Based Research for Solutions

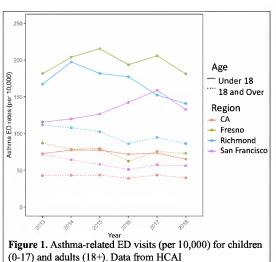
Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Wildfire PM_{2.5} in Environmental Justice Communities.

RESEARCH PLAN

1. Objectives

1.1 Background and Significance: Across the United States and in California, social adversity and environmental pollution are geospatially distributed and concentrated in communities of color and of low socioeconomic status (SES). These environmental justice (EJ) communities carry a disproportionate burden of exposure that has a significant impact on health, including mortality. For example, nationally, 1 in 12 children has asthma. In EJ communities, this number is as high as 1 in 4.5.6 African American and Latinx children have twice as many asthma hospitalizations and are more likely to have severe or difficult-to-control asthma compared to non-Hispanic White children. Similarly striking disparities are observed for cardiovascular and cerebrovascular disease. Similarly striking

Traffic-related air pollution - a mixture of fine particulate matter (PM_{2.5}) and gases (especially nitrogen dioxide [NO₂]) and known contributors to respiratory, ¹⁴ cardiovascular, ¹⁵ and cerebrovascular ^{10,11} morbidity - is 37% higher in communities of color compared with predominantly white communities. ²⁹ African American and Latinx populations are also twice as likely to live in poverty, more likely to live in poor housing conditions, and be exposed to violence and discrimination. These factors - all well-described risks ^{12,13,16} for respiratory, cardiovascular, and cerebrovascular disease - compound the effects of traffic-related air



pollution, contributing to the disproportionate negative health effects in these communities. These conditions are relevant to EJ communities within San Francisco (Bayview-Hunters Point and Tenderloin), Richmond (North Richmond and Triangle). and Fresno (South Central), CA. Figure 1 demonstrates the disproportionate asthma burden in these EJ communities compared to California overall. within these communities also have limited control in changing personal environments to reduce exposure to these risk factors for poor health.^{17–19} This is particularly relevant when considering the rising occurrence of extreme weather events due to climate change.²⁰

In California, the increase in wildfire events has amounted to a 5-fold increase in annual burned area over the last three decades and increased frequency of wildfire smoke events.²¹ For example, for a 4-week period in August-September 2020, San Francisco, Richmond, and Fresno all experienced extremely poor air quality due to PM_{2.5} from wildfire smoke. These events have now become a yearly occurrence (**Figure 2**). This is concerning as major wildfire events have increasingly impacted the public health of urban communities.^{22,23} While many urban communities are not directly affected by advancing fire lines, wildfire smoke travels hundreds of kilometers and is now responsible for 50% of annual PM_{2.5} in the Western US.²⁴ This is alarming as there is mounting evidence associating wildfire smoke exposure

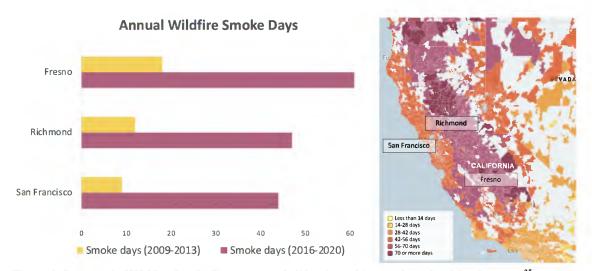


Figure 2. Increase in Wildfire Smoke Days Across California and in our three focal Study Areas 25

with exacerbations of cardiovascular and respiratory disease, ²⁶ including emergency department (ED) visits. ^{10,27,28} With increasing events, the impact of recurrent and prolonged wildfire smoke exposure on health needs to be better understood; simple single day or summative exposure studies are no longer sufficient to understand risk. A recent study examined the health effects of wildfire PM_{2.5} exposures over the course of an extended event and found an increased risk of respiratory hospital admissions when smoke levels were extreme but not when smoke levels were lower. ²⁹ Furthermore, research, including our own, ^{26,30–33} has found that the health impacts of wildfire events, are unevenly distributed, with greater risks for children and those in poor and socially marginalized communities. ^{3,4}

We are just beginning to understand the health effects of wildfire events in individuals living and working in the state of California. Given the increase in frequency and intensity of such events, there is a critical need to understand the effects of immediate (i.e., hours to days) and longer-term (weeks) exposure on health. There is an even greater need to determine the compounding effects of wildfire smoke in EJ communities. While all Californians are vulnerable to the health impacts of PM_{2.5} emissions from wildfires, EJ communities are at increased risk due to their increased exposure (from being essential outdoor workers and/or living in older, substandard housing³⁴ with increased infiltration of outdoor air pollutants), increased sensitivity to climate change, and their decreased ability to adapt to climate change. Risk factors for climate-related morbidity and mortality are often classified as intrinsic (e.g., pre-existing medical conditions, disability, age) or extrinsic (housing that remains cool in high temperatures and has central ventilation, access to resilience center, transportation). EJ communities are disproportionately affected by *both* factors.⁴ These communities are the most exposed, sensitive, and least likely to have the economic, social, or political resources necessary to prepare for or respond to wildfire events.

Health-protective guidance would improve if we better understood the exposure-response relationship for most short-term health outcomes of concern, including respiratory, cardiovascular, and cerebrovascular conditions. Critical data gaps include the effects of sub-daily exposures, understanding community recovery following exposure, understanding indoor infiltration of wildfire smoke, and quantifying the health effects across social vulnerability factors, with particular focus within EJ communities.

1.2 Objectives: To address these gaps, we propose to estimate the sub-chronic effects of short-term exposures (e.g., hourly or daily variations) over days to weeks to wildfire-specific $PM_{2.5}$ on respiratory, cardiovascular, and cerebrovascular outcomes, including ED visits and hospitalizations. Through this proposal (see Fig. 3), we aim to:

Objective 1: Quantify the wildfire-specific fine particulate matter (PM_{2.5}) exposures for the 2016-2020 fire seasons using a high-resolution atmospheric smoke model fused with dense networks of state-wide air quality monitoring data to provide inputs to exposure models.

<u>Hypothesis 1</u>: Integrated model-data products will show improved predictions of $PM_{2.5}$, and exposure to wildfire-specific $PM_{2.5}$ will vary more by geographic region than by vulnerability.

Objective 2: Estimate how housing attributes (e.g., structure type and condition, year built, presence of air conditioning) and human behaviors (e.g., window opening, use of mechanical ventilation and/or filtration system) modify the infiltration of wildfire-specific PM_{2.5} into the indoor environment to provide novel insights that are vital when considering exposure risk and mitigation strategies. We will use a combination of air infiltration models using housing attributes and meteorological data as inputs combined with new observational studies of infiltration factors of PM_{2.5} in California residences to estimate smoke infiltration.

<u>Hypothesis 2</u>: Census tracts within EJ communities will have a greater percentage of housing with attributes that increase the infiltration of wildfire-specific $PM_{2.5}$ compared with housing located in non-EJ communities.

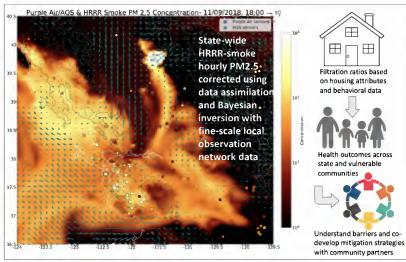
Objective 3: Estimate the added burden of immediate (hours, days) and longer-term (weeks) exposure to wildfire-specific $PM_{2.5}$ on respiratory (COPD and asthma), cardiovascular (myocardial infarction and heart failure), and cerebrovascular (stroke and transient ischemic attack) emergency department (ED) visits and hospitalizations, and how these relationships are modified by social vulnerability factors (race and ethnicity, neighborhood deprivation, EJ community designation) across communities in California (represented by ~1300 zip codes). <u>Hypothesis 3a:</u> The magnitude of the wildfire $PM_{2.5}$ effect on acute health outcomes will be largest for high sub-daily exposures and the magnitude of the effect for subchronic health outcomes will be largest for longer (daily to weekly) exposures.

<u>Hypothesis 3b</u>: The magnitude of the wildfire $PM_{2.5}$ effect on select health outcomes will be greatest in communities with highest vulnerability.

Objective 4. Engage closely with community groups to better understand current mitigation behaviors and to identify place-based mitigation strategies to reduce the short-term effects of wildfire-specific PM_{2.5} while addressing the ongoing health risks that environmental pollution poses in Environmental Justice (EJ) communities.

<u>Hypothesis 4a</u>: EJ communities will have more barriers to adopting mitigation behaviors during wildfire events than non-EJ communities due to social and structural barriers.

<u>Hypothesis 4b</u>: Targeting of health-protective guidance and mitigation will be improved with more specific place-based data and stakeholder engagement.



- Figure 3. Project workflow:

 1) HRRR-Smoke PM_{2.5}
 concentration and wind vectors,
 enhanced by concentrations from
 Purple Air (squares) and AQS
 (circles) observations of PM_{2.5}
 (shown here during the 2018 Camp
 Fire event),
- 2) Indoor/outdoor filtration ratios calculated based on housing attributes and behavior data,
- 3) Statewide respiratory, cardiovascular, and cerebrovascular health outcomes and across social vulnerability.
- 4) Engage EJ community partners to co-develop implementation strategies for adopting mitigation interventions during wildfire smoke events.

2. Approach/Activities

Overview: The PROTECT Health Effects project will address our 4 objectives by estimating the health effects of wildfire-specific PM_{2.5} exposure (i.e., hourly and daily variations) across vulnerable communities in California. We will also examine how housing quality may reduce risk, as a promising intervention to limit wildfire PM_{2.5} health effects and effects from on-going exposures to other pollutants. Lastly, we will engage with EJ communities to understand existing barriers to mitigation interventions and co-develop implementation strategies to increase uptake of acceptable community-relevant mitigation interventions.

2.1 Objective 1: Quantify the wildfire-specific fine particulate matter ($PM_{2.5}$) exposures for the 2016-2020 fire seasons using a high-resolution atmospheric smoke model fused with dense networks of state-wide air quality monitoring data.

Background: High-resolution smoke forecasts are needed to provide reliable spatial and temporal information during extreme wildfire events. The National Oceanic & Atmospheric Administration (NOAA) High-Resolution Rapid Refresh Smoke (HRRR-Smoke) model provides a robust, straightforward dataset with hourly, nationwide smoke coverage, including vulnerable communities which typically lack dense observation data, from 2016-present. ^{35,36} At 3-km resolution, HRRR-Smoke is the highest resolution operational smoke model available. ^{37,38} HRRR-Smoke only includes wildfire smoke emissions (no background emissions), providing a way to isolate smoke contributions to sub-daily PM_{2,5} exposures.

Preliminary Data: We have a wealth of experience using weather prediction models including the state-of-the-art HRRR-Smoke wildfire smoke model to generate PM_{2.5} concentration fields; we will be supported directly by NOAA scientists in the proposed work (see Letter of Support). HRRR-Smoke is a three-dimensional atmospheric model for simulation of mesoscale flows and smoke dispersion over complex terrain.³⁹ HRRR-Smoke is based on the Weather Research and Forecasting (WRF) model, enhanced with rapid assimilation of observation data, making it a very robust numerical weather prediction model. Satellite fire detections of fire radiative power (FRP) are fed into the model to drive smoke transport in the boundary layer and aloft, at high spatial resolution over the entire continental US. HRRR-Smoke is unique in its ability to capture both meteorological and PM_{2.5} fields; the model includes the effect of weather on smoke transport, and the effect of smoke on weather, and at 3-km resolution is able to capture spatial variations and transient patterns of smoke plumes due to complex terrain effects across California.³⁷

Deriving a Statewide Concentration Grid: HRRR-Smoke predictions are highly sensitive to errors in the satellite FRP; PM_{2.5} estimates are also influenced by errors in the driving meteorology, land-surface characterization, and contributions from sources in addition to wildfires. We will enhance the HRRR-Smoke using source inversion and data assimilation of large datasets of surface and satellite PM_{2.5} observations to build a highly spatiotemporally resolved pollutant concentration time series that corresponds to the locations of the residences of the study population. This process will account for model errors in wind speed and direction and satellite fire detection when predicting smoke transport.

Proposed Model: To correct for errors in fire detection source strength, we will use Bayesian inference techniques^{40,41} to adjust emissions. Further errors in model predictions will be reduced using standard data assimilation techniques (three-dimensional variational [3DVar] data assimilation) available with the HRRR model to incorporate sensor network data, ^{42,43} following guidance from data assimilation and other data fusion approaches. ^{44–46} Our goal is to use computationally efficient data science approaches that can be incorporated into real-time forecasts. Thus, we focus on algorithms which can be executed in a time frame on the order of minutes to provide hourly 3-km data for the 2016-2020 period, without requiring new HRRR-Smoke simulations. We summarize the process in **Figure 4**.

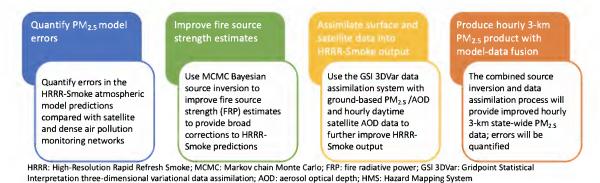


Figure 4. Overview of steps to develop a wildfire-specific PM_{2.5} 3-km statewide surface grid.

Data Sources: The corrections referenced in **Figure 4** will leverage dense observation networks described below to improve the statewide PM_{2.5} concentrations provided by HRRR-Smoke. These networks include:

- *Statewide regulatory monitoring stations*. Data are available from EPA's Air Quality System (AQS) database and include hourly PM_{2.5} and other pollutants.
- **Purple Air PM**_{2.5} **data.** There are 8,700 community-installed Purple Air sensors in California. In Figure 2, we compare a sample of Purple Air data to HRRR-Smoke. In the San Francisco Bay Area alone, the number of sensors grew to 5,615 by 2021, with 38% of them indoors, providing overall excellent temporal and spatial coverage. These low-cost sensors are not as accurate as AQS sensors, but can be easily adjusted using newly established correction factors to capture spatial and temporal trends. 47–49
- Berkeley Atmospheric CO₂ Observation Network (BEACO₂N). A 70-sensor network in the SF Bay Area (2 km apart), measuring 5 sec concentrations of NO, NO₂, O₃, CO, CO₂, size resolved particle number from 100 nm to 10 microns, and boundary layer height.
- Satellite aerosol optical depth (AOD) data. Hourly daytime AOD data from GOES-16/17 can be compared to vertically integrated smoke predictions from HRRR-Smoke and incorporated into the integrated model-data product to constrain wildfire emissions. Smoke emitted from intense wildfires is often extremely thick and satellite algorithms label the smoke plume as a 'cloud' which leads to missing FRP data (which will be the target of the source inversion approach described above) and also missing AOD data (which will be complemented by analogous data sources and/or gap filling measures).
- NASA AERONET (AErosol RObotic NETwork). In addition to the satellite AOD data, ground based hourly AOD measurements are available. All AOD data are for daytime only and may be limited due to cloudiness, but can serve as additional constraints in the data assimilation process.
- Assembly Bill (AB) 617 Surface Monitoring Data. AB617 mandates that community air monitoring and emission reduction plans be developed for designated EJ communities. North Richmond and South Central Fresno, CA are CARB-designated AB617 communities (https://ww2.arb.ca.gov/capp-communities).

Deriving Area Exposure Estimates: We will use the hourly 3-km grid of wildfire-specific PM_{2.5} generated from the HRRR-Smoke model to assign residential outdoor wildfire-specific PM_{2.5} exposures for all census tracts and zip codes in California. Census tract and zip code geographical extent data is available for each year from 2016-2020 from the US Census website. This information will be overlaid on the hourly 3-km grid. We will use tools within ArcGIS to spatially average or extract the wildfire-specific PM_{2.5}, depending on the size of the census tract and zip code. Once the hourly spatial average exposure is derived, we can aggregate the data into sub-daily exposure periods (e.g., daytime, night time) for each geographical area. We will also derive the number of daily exceedance hours and the time of

day at which the peak exposure occurred. The daily exceedance hours will be defined as the number of hours that the hourly average of wildfire PM2.5 was greater than 55.4 micrograms per cubic meter, the level at which the Air Quality Index (AQI) deems PM_{2.5} to be 'unhealthy.'

Differences across geographical areas and communities (e.g., Bayview-Hunters' Point vs. all of San Francisco) will be quantitatively assessed by comparison of annual average daily wildfire-specific PM_{2.5} µg/m3, daily exceedance hours, and timing of peak hours of exposure.

Expected Outcome: This will create an wildfire-specific PM_{2.5} exposure estimate for every census tract and zip code in California between 2016-2020, for each day, with detailed sub-daily exposures and aggregated exposures up to multi-year averages, as needed.

2.2 Objective 2: Estimate how housing attributes and human behaviors modify the infiltration of wildfire-specific $PM_{2.5}$ into the indoor environment.

Background: Another novel element of our proposal is estimating exposure by accounting for indoor concentration differences. During major wildfires, people are advised to shelter indoors to reduce their exposure to outdoor smoke. However, the ability to keep windows closed during wildfires depends on outdoor conditions, and if thermal comfort can be maintained in homes with windows closed. The ability to remove infiltrated wildfire-specific PM_{2.5} using filtration also varies depending on the use and effectiveness of portable air cleaners and furnace air filters (if present). The infiltration of wildfire-specific PM_{2.5} depends on housing characteristics, outdoor conditions, and occupant behaviors, but pin-pointing the effects of these influencing factors is challenging.⁵⁰ New assessments of infiltration factors of wildfire PM_{2.5} using crowdsourced data in California found substantial variability that can be partially explained by building and behavioral factors.^{20,51,52} However, there is an absence of data on the infiltration factors in EJ communities.

Preliminary Data: Dr. Chan has compiled the largest US residential air leakage database to date, ⁵³ and has published work ⁵⁴ to estimate the population exposure to outdoor air pollutants while sheltering in homes. She has led field teams to measure indoor PM in a large number of homes, and has developed mechanistic and statistical approaches to estimate the contribution of exposure from indoor sources and from PM of outdoor origin.

Proposed Model: The wildfire PM₂₅ infiltration factor will be calculated at the census-tract level using this model: (AER*P)/(AER+k). The penetration coefficient of infiltrating particles P and loss rate k of indoor particles by surface deposition and other mechanisms will be sampled from published distributions.⁵⁵ Empirical and physics-based models relate to the air infiltration portion of the air exchange rate (AER) which will be computed using meteorology and building attributes for single-family homes.⁵⁶ AER of multi-family dwellings will be estimated based on California datasets.⁵⁷ Increases in AER from window opening and use of mechanical systems will be estimated based on published studies.⁵⁸ Distributions of AER, P, and k will be adjusted according to community-wide responses to reflect the behavioral influence during wildfires. The modeled infiltration factor for wildfire-specific PM_{2.5} (as defined in Objective 1) will be compared with the measured distribution from crowdsourced data to constrain the models. 51,52 This final step will be assisted by additional indoor PM data collection efforts within EJ communities that coincide with the study period for this proposal. The total number of homes included in this parallel study is n=150 within the three study areas (Fresno, Richmond, and San Francisco). The goal of these already funded projects is to gather multiple months of data from each home such that infiltration factors can be calculated when indoor sources are minimal while outdoor PM concentrations vary.

Data Sources

• *Housing Attributes*: We purchased a dataset with attributes of all residential and commercial buildings in California in both urban and rural counties in 2016, ⁵⁹ including

type (single-family, multi-family), year built, and year of retrofit, which may indicate weatherization upgrades. The data can be evaluated at the census tract level to examine across EJ and non-EJ communities and at the zip code level to match the resolution of the ED visit and hospitalization data.

- **Behavioral Data:** We will modify estimates using survey data collected under Objective 4 (see section 2.4), which will include mitigation behaviors during wildfire events.
- *Indoor PM Data:* We will have consumer-grade PM monitoring data from 150 homes in EJ communities; monitors will be similar to the ones used in crowdsourced studies. ^{51,52} This data will supplement published infiltration factors from existing crowdsourced data that do not reflect the house and household characteristics of EJ communities.

Expected Output: We will derive indoor infiltration estimates for wildfire-specific PM_{2.5}, adjusting for housing attributes, outdoor conditions, and other behavioral factors informed by Objective 4, averaged over census tracts, zip codes, and neighborhoods in California. In addition, we will calculate infiltration factors using measured data collected from EJ communities, in order to compare differences and for constraining the model.

2.3 Objective 3: Estimate the added burden of immediate and long-term exposure to wildfire-specific PM_{2.5} on respiratory, cardiovascular, and cerebrovascular emergency department visits and hospitalizations to identify critical exposure windows and examine how these relationships are modified by vulnerability factors across communities in California.

Background: There is robust evidence that short-term PM_{2.5} exposure is associated with increased cardiorespiratory hospital admissions. ^{10,27,60} Unlike PM_{2.5}, wildfire smoke generated PM_{2.5} is not regulated under the Clean Air Act and the health impacts of wildfire-specific PM_{2.5} are not well understood, particularly in vulnerable communities chronically exposed to higher levels of ambient air pollution and other psychosocial stressors that may confer greater susceptibility to pollutants. Most studies on wildfire smoke have used 24-hour average PM_{2.5} concentrations in the analysis of health outcomes. ⁶¹ There is also emerging evidence that

sub-daily non-wildfire fine particulate exposures may be associated with myocardial infarction (MI) and ischemic events and should similarly be examined for wildfire-specific PM_{2.5}.⁶² Furthermore, research thus far has exclusively focused on acute effects of wildfire smoke and further investigation on long-term health impacts is warranted. We also aim to identify critical exposure periods that occurred before ED visits and hospitalizations. These approaches will allow us to explore whether the window of susceptibility to wildfire-specific PM_{2.5} is longer and if health effects are greater in vulnerable populations due to individual- and structural- level factors (**Figure 5**).

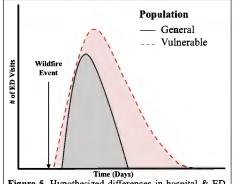


Figure 5. Hypothesized differences in hospital & ED visits between general (black solid line) and vulnerable (red dashed line) populations after a wildfire event.

Preliminary Data: Drs. Balmes, Holm and Noth have a collective experience of over 60 years examining the health effects of non-wildfire and wildfire-specific PM_{2.5}. We have extensively published on the health impacts of wildfire smoke, with an emphasis on susceptible populations such as children and people with pre-existing disease. ^{26,30–32} Our specific contributions/expertise include health effects in wildland firefighters, ³¹ indoor PM_{2.5} in both the developing ⁶³ and developed ⁶⁴ world, and effects of ambient pollution on respiratory ^{65–67} and metabolic ⁶⁸ health of children. Furthermore, Drs. Thakur and Balmes demonstrated co-occurrence of social and environmental exposures by demonstrating higher rates of asthma ED visits and diesel exhaust exposure in historically redlined census tracts across California. ⁶⁹

Data Sources: From the California Health Care Access and Information (HCAI), we will obtain respiratory-, cardiovascular-, and cerebrovascular-related ED visits and hospitalization at the zip code level for the period extending from 2016-2020. For each event, we will have age, sex, and race/ethnicity data. This will allow us to examine the rate of ED visits and hospitalizations during (days) and following (weeks, up to eight weeks) peak smoke exposure, providing a better understanding of how wildfire smoke acutely and subacutely contributes to poor health in pediatric and adult populations across California.

Available Data Elements:

- *ED visits and hospitalizations*: We will obtain daily counts that will be aggregated at the zip code level. ED visits and hospitalizations will be converted to rates by dividing counts by the population. Health conditions to be included are as follows:
 - Respiratory events, visits will be identified by ICD-9 codes 460:519 or ICD-10 codes J00:J99 (excluding J95) which include pulmonary diagnoses, such as asthma, COPD, pneumonia, and interstitial lung disease.
 - Cardiovascular events, visits will be identified by ICD-9 codes 410:414 or ICD-10 codes I20:I25 which include acute myocardial infarction (MI) or other acute or chronic ischemic heart disease and ICD-9 code 428 and ICD10 code I50 which is for congestive heart failure.
 - Cerebrovascular events, visits will be identified by ICD-9 codes 430:438 or ICD-10 codes I60:I69 which include hemorrhagic stroke, ischemic stroke, and occlusion of the precerebral and cerebral arteries.
- *Demographics*: Age, sex, race/ethnicity for each ED visit and hospitalization.
- *Vulnerability Factors:* There is a paucity of studies examining what factors increase susceptibility to the health impacts of wildfire smoke. Understanding what factors are associated with increased susceptibility to wildfire-specific PM_{2.5} will assist with identifying and implementing potential interventions to protect these subgroups. We will examine if identified associations are modified by the following vulnerability factors:
 - Age: We will examine how associations with wildfire-specific PM_{2.5} differ between adults ≥65 years vs <65 years and children 0-5 years vs both older children and adults <65 years. These age groups (≥65 years and <5 years) had higher rates of asthma hospitalizations compared to younger adults (<65 years) after California wildfires.⁷⁰
 - **Sex**: Emerging evidence suggest women may be more susceptible to wildfire-specific PM_{2.5} for respiratory-related hospitalizations; this will be further explored. ^{33,62}
 - *Race/Ethnicity*: Majority Black, Hispanic, and Indigenous census tracts have 50% greater vulnerability to wildfire smoke compared to other census tracts.⁷¹ We will examine if wildfire-specific PM_{2.5}-associated hospitalizations differ by race/ethnicity.
 - o *Baseline PM*_{2.5} *Exposure*: High baseline PM_{2.5} exposure will be defined as having an annual mean concentration > $12\mu g/m^3$. Average <u>baseline</u> PM_{2.5} concentrations will be estimated using month-of-year average PM_{2.5} on non-smoke days across all years in the sample. This geoscience-based model incorporates ground monitor data, satellite observations, chemical transport model predictions, and other features. ^{72,73}
 - *Healthy Places Index* (HPI): We will use the California Healthy Places Index,⁷⁴ a composite risk assessment of social vulnerability associated with mortality, to estimate health effects from wildfire-specific PM_{2.5} across communities, comparing the highest and lowest quartiles. This tool was used by the California Department of Public Health to inform equitable resource allocation in response to COVID.
 - CalEnviroScreen 4.0 (CES4.0): We will use the same definitions as CalEPA to
 designate disadvantaged communities in California based on census tracts that score in
 the highest quartile for this indicator along with census tracts in the top 5 percentile for
 the Pollution Burden sub-indicator.

o *Indoor Filtration*: We will explore the degree to which indoor filtration of wildfire-specific PM_{2.5} changes risk for ED visits or hospitalization. We hypothesize that for communities where indoor penetration ratio estimates are high (i.e. >0.5), ED visits and hospitalizations will be highest.

<u>Wildfire-specific PM_{2.5} exposure estimates</u>: From our models in Objective 1, we will have the daily (average), hourly (average), and sub-daily (number of exceedance hours) concentrations of wildfire-specific PM_{2.5}, including exposure estimates to the zip code level. These concentrations will be aggregated for relevant windows of exposure, starting from 8 weeks prior to the start of the study period, through the end of the study period.

Main Analysis Plan: We will use a distributed lag mixed (DLM) model to flexibly analyze the contribution of smoke exposure over the prior two months, and how exposures at different lags (from 0 through 8 weeks prior) affect daily ED visit and hospitalization rates. Distributed lag models allow us to control for exposures at all the different time frames simultaneously, and a random term will be added to the models to control for repeated use of the same census tract over the study interval. These models will use the following structure:

$$y_{ij} = a + a_k x_{ik} + u_{ij} \gamma_{ij} + \sum_{s=0}^{l} \beta_s \delta_{ijs},$$

where y_{ij} is ED or hospitalization rate on the jth day of the study interval for zip code i, a_k (where $k=1,\ldots$) are the coefficients for the fixed effects, x_{ik} are the values of covariates for the ith geographic area (where $k=1,\ldots$), u_{ij} is the coefficient for the random effect, γ_{ij} is an indicator for the jth day in ith geographical area), β_s are the coefficients for each daily exposure lag relative to the date of the ED or hospitalization rate, and δ_{ijs} are the exposure values for the jth day in the ith area, for lag s. Analyses will be adjusted for confounders, including age, sex, race/ethnicity, temperature, and season. This approach will allow us to compare results across a large range of exposures that may be used to develop relative risk ratios comparing exposed and non-exposed areas. A false discovery rate will be applied to account for multiple comparisons.

<u>Subgroup Analyses:</u> We will identify sensitive periods with the main DLM and then use a linear model with an interaction term between vulnerability factors and wildfire-specific $PM_{2.5}$ to evaluate for effect modification of the PM-health relationship. In a sensitivity model, we will run DLM restricted to EJ communities to explore whether the sensitivity periods to wildfire-specific $PM_{2.5}$ may be different in these communities.

Limitations: While DLMs allow us to consider all lag periods simultaneously, they are unable to answer questions about the effect of repeated exposures. We hope to explore this important question in further study.

Power: Of California's 1741 active zip codes, we estimate that we likely be able to get health data for 75% of these (1300 zip codes), with overrepresentation from more densely populated areas. Using the wildfire-specific $PM_{2.5}$ estimates from Aguilera et al. (mean 2.46, range 0-18 µg/m3), as well as their mean rate of respiratory visits (2.5/100,000 population), we simulated outcome data (10,000 repetitions for n=1300) following a Poisson distribution. With data from 1300 zip codes, looking only at data for a single lag, we would have 80% power to detect a difference if a 1 µg/m³ increase in wildfire $PM_{2.5}$ increases respiratory visits by 1.7% or more. Given that we will be assessing multiple lags within a single model for each year of the study period (2016-2020), over 5 years of data, we should be able to detect small to moderate effects in the DLMs.

Expected Outcome: Estimated effects of wildfire-specific PM_{2.5} across pediatric and adult relevant health outcomes across communities and vulnerability factors in California.

2.4 Objective 4: Engage closely with community groups to better understand current mitigation behaviors and to identify acceptable place-based mitigation strategies that address short-term health risks of wildfire-specific $PM_{2.5}$ while addressing the ongoing threat of environmental pollution in Environmental Justice (EJ) communities.

Background: We have a good sense of the communities who are most vulnerable and sensitive to wildfire-specific PM_{2.5} in California and their associated risk for health conditions, both of which will be further explored through this award. There are also now a number of evidence-based mitigation strategies that support vulnerable populations during extreme heat and wildfire smoke events.⁴ These mitigations vary in invasiveness -- ranging from steps to increase awareness and educate communities about protective behavior, to fan distribution, opening resilience centers, to home and building weatherization.¹¹ What is lacking from current research efforts of mitigation interventions is the consideration of unique community attributes that may lead an intervention to be successful in one community or neighborhood, but not another. For example, for communities that experience power outages during wildfire events (a common occurrence in Richmond, CA), passive approaches (i.e., not dependent on electrification), such as adding cool roofs to improve thermal comfort and make window closure a viable option, may be preferred over portable filtration devices.

History of Community Partnerships within EJ Communities: Our team has an extensive track-record of community research partnerships, including with the EJ communities included in this award (Table 1). Most relevant, is a recently funded award from the Patient Centered Outcomes Research Institute (PCORI, EACB-23028). Under this award, we have already started this engagement effort with local community and neighborhood organizations located in Bayview/Hunters Point and the Tenderloin, two EJ neighborhoods in SF. We will extend this purposeful method of community engagement to North Richmond and South Central Fresno, two EJ communities with AB 617 designation. We are optimistic of success, as we already have established partnerships in these communities (see Letters of Support from Dr. Omotoso [Lifelong Medical] and Central California Asthma Collaborative).

Table 1. Examples of Past and Current Academic-Community Partnerships

Academi -Community Partners	Nature of Partnership
Lawrence Berkeley National Laboratory (LBNL) Association for Energy Affordability, Inc. (AEA)	AEA mission is to achieve energy efficiency to foster and maintain affordable and healthy housing and communities, especially those of low-income. LBNL and AEA partnered and completed a field study (2017-2019) sampling indoor air quality, ventilation, and other parameters in low-income apartments. (San Francisco, Southern CA)
UCB (Chow) and Little Manila Rising (Community-based Organization [CBO] in AB 617 community)	Co-teaching of UCB course to create local design plans to help tackle air quality issues and climate change. Students engaged and attended regular meetings with EJ communities in Stockton, who are actively participating in the AB 617 process to improve local air quality (see this CARB EJ blog post, and project website with student design projects).
UCB (Noth), UC Merced (Bradman) with Little Manila Rising and Central California Asthma Collaborative, both CBOs that serve AB 617 communities.	San Joaquin Valley Pollution and Health Environmental REsearch (SPHERE) study aims to conduct field studies in 120 households assessing total exposures to air pollutants and noise to residents in Stockton and South Central Fresno (AB 617 communities).
UCB (Balmes, Holm, Noth) and Central California Asthma Collaborative (CBO that serves AB 617 community)	Collaborating on a study of ambient air pollution and children's health in the greater Fresno area. This productive ongoing collaboration has followed multiple cohorts of children, and resulted in many research papers linking air pollution with asthma outcomes as well measures of metabolic health and glucose dysregulation.

(Noth) and Lifelong Medical William Jenkins (Community Health Center in AB 617 Community)	Co-lead a Youth Participatory Action Research (YPAR) Internship with high school students residing in North Richmond on place-based social and environmental issues important while training in research skills that allow youth to improve their lives and community. Students have competitively obtained two grants: Richmond City Art's Community Art Mural and Air District's Community Air Monitoring Project.
San Francisco Department of Public Health and Office of Resilience and	PCORI-engagement award will build on the cross-municipality efforts through the Heat and Air Quality Resilience Project to authentically bring in community stakeholders into the City's cross-sector planning on building climate resilience in socially vulnerable neighborhoods.

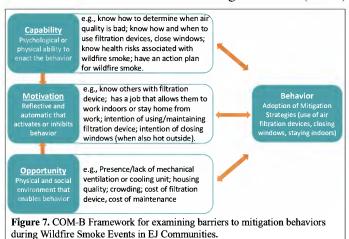
Framework for Engagement: Our approach incorporates principles of community-based participatory action research (CBPAR). 75,76 PAR deviates from traditional research models where line of inquiry is dictated by the subject matter expert and research is completed on or for a specific community. In these traditional models, the researcher determines the research question, the study design, and analysis plan, leaving the community as a passive player in the process, even when the conducted research may confer benefits for the community. When facing complex social problems, such as combating the disproportionate health effects from wildfire smoke, this traditional model breaks down. Rather, we have adopted an approach where research questions, study design, and analysis are ground-truthed with community partners and strategies addressing social and structural barriers to mitigation are co-developed and tailored to meet the community's specific needs. To accelerate our understanding of which climate mitigation interventions should be translated into wide-spread implementation and incorporated into policy, it is imperative that community stakeholder voices and priorities are at the center of the research agenda. Through purposeful strategies (intentional spaces for bi-directional learning, skill building and leadership training, and prioritization of community engagement, see Community Engagement Plan), we aim to level the power imbalance and build trusting, fruitful relationships that foster a productive, group dynamic. We will have a multi-stakeholder process to systematically build a mitigation agenda that centers on community priorities, with the shared goal of improving wildfire-impacted health disparities.

SEED Method for Engagement: Implementation of our logic model depends on successful engagement. The SEED (Stakeholder Engagement in question Development and Prioritization) Method is a systematic, iterative approach to engaged stakeholders in health intervention research. ¹⁵ Zimmerman and colleagues have demonstrated successful implementation of this method across variety of health concerns and partnerships, including those involving community and local governmental stakeholders. ¹⁶ The SEED Method is based in participatory research principles nested within the socio-ecological model that are action oriented, aligning well with our proposal goals of engaging community stakeholders around adoption of evidence-based mitigation interventions.

Formation of Community Stakeholder Group: We will proactively engage community-based organizations who meet one of the following criteria: located within and/or actively engages within the included EJ communities in Fresno, Richmond, and San Francisco; interest or mission aligns with wildfire smoke-impacted health conditions; or, interests or mission align with mitigation strategies for wildfire smoke events. To ensure the process of stakeholder identification is comprehensive, we will use the SEED Stakeholder Identification and Recruitment Matrix (available: https://tinyurl.com/n8wfs7bw). We will set up "coffee-break meetings" with prospective community groups and stakeholders. The purpose of these meetings will center around information exchange. To ensure community partners feel adequately prepared prior to the meetings, each group will receive an overview document of the purpose of the engagement and a list of questions for discussion. Each meeting will follow the following structure: brief overview of EPA proposal and reason for engagement, purpose and goals of meeting, space for stakeholder to state their goals for

meeting, discussion. We will have two dedicated note-takers to capture discussion. Each meeting will end asking stakeholders 1) if they would like to move on to the next steps to be formally part of the Community Stakeholder Group, and 2) who else they recommend us to meet with until no further community stakeholders are identified or until we have at least five partners within each community wanting to move forward. Meetings will take place virtually, at a community center, or at the organization's location site. The final Community Stakeholder Group will include at least three stakeholders from each EJ community (n=9).

Identifying Barriers to Acceptable and Promising Mitigation Strategies in EJ Communities: Implementation Science frameworks are increasingly being recommended to develop complex behavior change interventions. While there is "no magic bullet" for changing behavior, passive dissemination of guidelines and broad, non-specific messaging are known to be largely ineffective at changing practice. Similarly, success is limited when the choice of intervention lacks an explicit rationale. Theory can be used to understand which mitigation behaviors need to be changed, the factors that influence the behaviors being targeted, and which potential behavior change techniques and modes of delivery are likely to be effective. The Behavior Change Wheel (BCW) is a comprehensive intervention



development framework derived from 19 behaviour change frameworks to holistically address the "behavior system". 77 The BCW framework uses the Capability **Opportunity Motivation Behavior** (COM-B) model to understand behavior (Figure 7). Thus, the framework BCW provides coherent basis for considering all potential barriers to behavior change and the interventions expected to overcome those barriers in a given context/population.

Survey Development, Distribution, and Analysis. Using this COM-B framework, academic researchers in partnership with the Community Stakeholder Group will co-develop a community-wide survey to gain understanding of the current use and barriers to existing mitigation strategies for wildfire smoke and which potential strategies are viewed as acceptable. Surveys will be distributed through social and community networks of the community stakeholder groups and through the network developed through the "coffee break" meetings. Survey will be anonymized with no participant identifying information shared. We aim to survey 150 individuals within each EJ community (total n=450). Results

will be used to develop conceptual models to identify potential targets for acceptable mitigation strategies. Sample questions provided in **Table 2**. This survey is intended to garner descriptive data only and the provided sample size will allow for sufficient variability to adjust infiltration models (Objective 2) and inform focus group discussion.

<u>Focus groups</u>. After preliminary conceptual models are developed for each identified acceptable mitigation intervention, the community stakeholder group and the academic research team

Table 2. Sample Survey Questions

- 1. What are your experiences of wildfire smoke?
- 2. How often do you use these strategies during wildfire events?*
- 3. What are some reasons you do not use these strategies during wildfire events?*
- 3. What strategies do you think could address wildfire smoke in your community? Which ones do you not think would be effective?
- *In actual survey, will provide list of strategies and Likert option response

will co-develop specific questions for each focus group relevant to their experience/area of expertise. From these generated questions an interview guide will be developed. Each focus group will include 5-7 participants. Interested Community Stakeholder Group members will be trained by Dr. Thakur's team to co-moderate focus groups. Focus groups will be audio recorded and transcribed.

Thematic Analysis. Themes will be categorized according to the COM-B framework (Figure 7) as Capability, Opportunity, and Motivating barriers and enablers to implementation of mitigation strategies. We will further characterize subcategories of barriers and enablers across several levels reflecting, for example, community views on structural and systems factors affecting mitigation success, those that relate to skills required to enact mitigation efforts, and those that affect motivation to engage with the mitigation strategy. Additionally, themes that relate to pre-existing drivers of mitigation challenges experienced by community members (such as poorly ventilated housing) versus those that are emerging factors (such as power outages affecting the ability to cool), will be characterized.

Revise and Prioritize Strategies. Resulting themes will be used to help identify and revise implementation strategies to move forward for pilot testing. The process of prioritization will be facilitated by Dr. Thakur's team using guides from the SEED Toolkit and by applying the APEASE (Acceptability, Practicability, Effectiveness, Affordability, Side-effects, and Equity) Criteria. 7817 The SEED Toolkit include a process of multiple rounds of voting until a preset number of strategies is identified (for example, 15-20 strategies may be presented, but only 5 will be moved forward for pilot testing). The APEASE criteria will be used to help determine feasibility and relevance of each of the proposed mitigation strategies. These criteria query whether the proposed strategy exhibits Affordability (Cost to implement?); Practicality (Intervention feasible?); Effectiveness (Evidence for the intervention?); Acceptability (Intervention acceptable to those receiving/delivering the intervention?); Side-effects (Unintended consequences of the intervention?); and Equity (Will the intervention increase disparities?). One example is the do-it-yourself box filter fan. This intervention is low cost (affordable), easy to assemble (practical), and shown to reduce indoor concentration of PM_{2.5} (effective). However, concerns have been raised about its actual use as it requires windows to be closed which is not possible in buildings without central ventilation (feasibility?) and concerns of causing a fire if left in use for too long (side-effects). Further, fans do not address the exposure to chronic sources of PM_{2.5} as they are intended for short-term use (equity).

Expected Outcome: In addition to forming a cross-county community stakeholder group, we will have increased understanding of the existing barriers to uptake of mitigation interventions for wildfire-specific $PM_{2.5}$ across multiple counties, allowing us to uniquely identify common barriers that are ripe for intervention. Lastly, with our stakeholder partners we will co-develop implementation strategies to target these identified barriers.

- **2.5 Environmental Justice:** Central to the PROTECT Health Effects proposal is partnerships with stakeholders who live and serve Environmental Justice communities. In addition to being equipped to answer important quantitative questions regarding the cumulative effect wildfire-specific PM_{2.5} has across EJ communities, we uniquely have established partnerships with local governmental agencies and community organizations in EJ communities that will allow for co-development of strategies to mitigate the negative health effects of wildfire-specific PM_{2.5} that are informed by local contexts to address barriers.
- **2.6 Innovation**: Our proposal features multiple dimensions of innovation targeted to yield impactful outcomes. First, our focus on sub-daily effects of wildfire-specific PM_{2.5} on relevant pediatric and adult health outcomes is both highly important and innovative. This proposal is one of the first to attempt to quantify exposures on this level and at this scale. Furthermore, we will examine these effects across socially vulnerable communities. Second,

our assessment of how housing attributes and mitigation behaviors modify indoor filtration of wildfire-specific PM_{2.5} across California is also highly important and innovative, especially with regard to vulnerable communities that likely have poorer housing stock. Lastly, our application of an *Implementation Science* approach to examine health inequities due to the disproportionate burden of exposure to PM_{2.5} through community collaboration is a new approach to environmental health effects research and focuses on sustainability as a key feature of adoption for considering strategies that increase uptake of mitigation interventions.

2.6 Expected Results, Benefits, Outputs and Outcomes: The results generated from this proposal will have multiple targets of influence. We have shaped our research questions to fill important gaps in developing State and Federal guidelines and policies - specifically, our analyses on the sub-daily effects of wildfire-specific PM_{2.5} on health outcomes will help inform decisions around public building closures, including schools. Our proposed work with community partners will provide much needed information on existing challenges to accessing mitigation efforts - for example, high upfront cost of retrofitting vs. on-going cost of portable air filtration devices. Lastly, at the conclusion of this award, we will have promising, community-led implementation strategies to push forward evidence-based mitigation strategies at a cross-county level.

2.8 Project Management

Research Team: We have assembled leading researchers from University of California San Francisco (UCSF, Thakur [PI], Balmes, and Holm), UC Berkeley (UCB, Chow, de la Rosa, and Noth), Lawrence Berkeley National Laboratory (LBNL, Chan, Kirchstetter), and the California Office of Environmental Health Hazard Assessment (OEHHA, Basu). Our interdisciplinary team includes expertise spanning exposure and building science, environmental engineering, atmospheric modeling, epidemiology, and implementation science, and community-based participatory research. Dr. Thakur (PI) is a physician-scientist who is PI of multiple grants with strong community engagement components, including from PCORI on capacity building for climate change in socially vulnerable populations. She is an expert at bridging disciplines and leading diverse teams - including, incorporating community groups onto the leadership team - to conduct science with clear policy relevance. Dr. Balmes is a world-renowned expert on the health effects of environmental pollution and is the Physician Member of the California Air Resources Board (CARB) and thus is in a position to advocate for policy initiatives at the state level that can benefit communities impacted by wildfire smoke. Dr. Holm is an environmental pediatrician and epidemiologist who works in the Children's Environmental Health Center within California EPA, and who has been heavily involved in wildfire smoke guidance for children at the national level.

From UCB, <u>Dr. Chow</u> is a leader in the development and application of atmospheric transport modeling over complex terrain and in urban areas. She brings this experience to community-engaged air pollution mitigation work in her teaching and to wildfire smoke modeling in collaboration with the HRRR-Smoke team at NOAA. <u>Dr. de la Rosa</u> is an environmental health scientist and toxicologist with expertise on approaches to assess cumulative risk from combined exposure to chemical and non-chemical stressors. <u>Dr. Noth</u> is an experienced exposure scientist with over 20 years of experience in air pollution exposure assessment; she has collaborated extensively with Dr. Balmes on air pollution studies, including wildfire smoke studies in Fresno and California state-wide for many years. From LBNL, <u>Dr. Chan</u> is an expert in indoor air quality and building science with deep knowledge in estimating housing stock air infiltration and experience leading studies of indoor PM. <u>Dr. Kirchstetter</u> has studied air pollutant emissions and controls for 30 years. He has recently been leading research to invent and deploy low-cost air pollution sensors to study air quality in partnership with underserved communities. <u>Dr. Basu</u> is a senior scientist at the OEHHA, a

sister agency to CARB in Cal/EPA and can also assist in the development of state-level policy initiatives to reduce exposures to wildfire smoke.

Our team of academic researchers and policymakers/scientists in state government is uniquely positioned to not only fill scientific gaps in our understanding of the health risks of wildfire-specific PM_{2.5} across communities, but also to ensure that our analyses provide policy-relevant information that will enhance public health guidance. To this cross-sector team, we add our local community and governmental partners (see Letters of Support) from Fresno (Central California Asthma Collaborative), Richmond (Contra Costa Health System, Dr. Omotoso), and San Francisco (Brightline, San Francisco Department of Public Health and the Office of Resilience and Capital Planning). Our team has a strong and extensive history of productive research relationships in the involved communities (see Table 1 and the Community Engagement Plan).

Project structure and management. The overall structure of the academic team includes the following groups: (a) UCSF, (b) UCB, (c) LBNL, and (d) OEHHA. Our community partner team includes Central California Asthma Collaborative, San Francisco Department of Public Health and Office of Resilience and Capital Planning, Contra Costa Health Services, and Dr. Omotoso (member of the North Richmond AB 617 Community Monitoring Group); we will add members to this team through this award. UCSF will serve as the primary coordinating center for the grant activities. Principal Investigator Thakur will take overall responsibility for the project, including setting and monitoring milestones and target dates, overseeing the budget, and tracking progress toward the project outputs and outcomes (see Timeline below). Leah Murphy will support Dr. Thakur in these tasks. Dr. Chow (UCB) will oversee and guide the process for deriving an hourly 3-km statewide grid of wildfire-specific PM_{2.5} from NOAA HRRR Smoke model with adjustments from observational data. Dr. Noth (UCB) will oversee and guide the process for assigning area unit exposure estimates, including daily exceedance measures, that will be used in the health analyses. Drs. Kirchstetter and Chan (LBNL) will guide and oversee trainees to generate the infiltration estimates for wildfire-specific PM_{2.5}. Dr. Holm (UCSF) and Dr. de la Rosa (UCB) will oversee the health analyses, including examining health effects across socially vulnerable groups. Dr. Basu (OEHHA) will advise on health analyses, including planned approach. Drs. Thakur and Balmes (UCSF), working with the community partner team, will oversee the recruitment of members to the community stakeholder group, survey administration, and focus group conduct. The core project team (Thakur, Chow, Noth, Kirchstetter, Chan, Holm, de la Rosa, and Balmes) will meet biweekly to report progress and ensure coordination across the institutions and project tasks. Drs. Thakur and Balmes will meet monthly for the first six months of the award and then quarterly (after the community stakeholder group is established) with the community partner team to report progress of deliverables under Objective 4. All investigators on the core project team will assist with the interpretation of findings and plans for dissemination.

Table 3. PROTECT Health Effects Timeline

Study Activity		Year 1			Ye	Year 2		Y	Year 3		
1-1 Derive statewide 3-km concentration grid											
1-2 Derive area level exposure estimates											
2-1 Derive infiltration ratios, adjusting for housing attributes											
2-2 Derive infiltration ratios, adjusting for behavior											
3-1 Primary health analysis											
3-2 Health analysis across vulnerable groups											
4-1 Form community stakeholder group				3							
4-2 Conduct community surveys											
4-3 Conduct focus groups											
Refine analyses and publish results											

Funding Opportunity: EPA-G2021-STAR-H1, Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/Lifestages: Community-Based Research for Solutions

Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Wildfire PM_{2.5} in Environmental Justice Communities.

Quality Assurance Statement

(1) QA/QC personnel

<u>Neeta Thakur</u> MD, MPH, Assistant Professor in the Division of Pulmonary Critical Care Medicine at UCSF will serve as project Principal Investigator (PI), with overall responsibility for project management, quality oversight, and financial oversight. She will also have lead oversight for the establishment of the analysis plan and analysis methods, identification of applicable data, analysis of the data, and authorship of the study report and/or paper.

<u>Fotini (Tina) Chow</u>, PhD, Professor and Vice Chair for Graduate Studies in the Department of Civil and Environmental Engineering at UC Berkeley will guide the selection of the analysis methods, identification of applicable data, and analysis of the data for Objective 1, which are to generate estimates for hourly wildfire-specific PM_{2.5}, and lead and/or co-author resulting manuscripts.

Wanyu (Rengie) Chan, PhD, Research Scientist in Indoor Environment Group at Lawrence Berkeley National Laboratory will advise on the selecting the analysis methods, identification of applicable data, and analysis of the data for Objective 2, which are to generate indoor Wildfire PM_{2.5} filtration ratios, and lead and/or co-author resulting manuscripts.

Stephanie Holm, MD, MS PhD, Assistant Professor in the Department of Pediatrics at UCSF will have responsibility for selecting the analysis methods, identification of applicable data, and analysis of the data for Objective 3, which are to calculate the estimate health risk of wildfire-specific PM_{2.5}, and lead and/or co-author resulting manuscripts.

Together, this team has extensive experience in the types of analyses planned for this project.

(2) **Project Objectives**

The objectives of the PROTECT Health project are to estimate the health burden of Wildfire-specific PM_{2.5} across communities in California with a specific focus of understanding the disproportionate burden experienced by environmental justice (EJ) communities; to determine how housing quality and mitigating behaviors may modify this risk; and, to increase our understanding of current behaviours during Wildfire events and barriers to existing mitigation strategies in EJ communities.

The hypotheses for this study include: 1) That exposure to wildfire-specific PM_{2.5} increases risk of respiratory-, cardiovascular-, and cerebrovascular-related emergency department (ED) visits and hospitalizations; 2) These effects will be greater in socially vulnerable communities and 3) modifiable by housing quality and adoption of mitigation behaviors. These hypotheses will be tested using a combination of data assimilation techniques and regression-based models and through qualitative (focus groups) and quantitative (surveys) information obtained from residents living in EJ communities. All aspects of the work will be reviewed by our Community partner group comprised of scientists, health officials, and stakeholders from local departments of public health and community-based organizations.

(3) Collection of Data

The PROTECT Health project does not include the collection of primary environmental data, method development, or the development or operation of environmental technology; therefore, sections (a), (c), and (e) are not applicable and not included.

(b) Use of Existing/Secondary Data

Data obtained will overlap the study period (2016-2020), except where noted, for all secondary data sources. The secondary data applicable to the project are as follows:

- *NOAA HRRR-Smoke Model* hourly PM_{2.5} estimates, available across California at 3-km grid resolution from 2016-present.
- **Statewide regulatory monitoring stations.** Data are available from EPA's Air Quality System (AQS) database and include hourly PM_{2.5} and other pollutants.
- *Purple Air PM_{2.5} data*. There are 8,700 community-installed sensors in California. These low-cost sensors are not as accurate as AQS sensors, but can be easily adjusted using newly established correction factors and capture spatial and temporal trends. ^{1–3}
- Berkeley Atmospheric CO₂ Observation Network (BEACO₂N). A 70-sensor network in the SF Bay Area (2 km apart), measuring 5 sec concentrations of NO, NO₂, O₃, CO, CO₂, size resolved particle number from 100 nm to 10 microns, and boundary layer height.
- Satellite aerosol optical depth (AOD) data. Hourly daytime AOD data from GOES-16/17.
- *NASA AERONET (AErosol RObotic NETwork)*. Hourly daytime ground-based AOD measurements, may be limited due to cloudiness.
- California Tax Assessor County Office data. Attributes of all residential and commercial buildings in California as geospatial files from data vendor ParcelQuest.
- *Emergency department visits and hospitalization data*. Data will be available from the California Health Care Access and Information as daily counts across zip codes.
- *U.S. Census and American Community Survey.* Provides population demographic and social data, including factors such as crowding, vacancy rates, and poverty. 2015-2019 Five-year estimates will be used for analyses.
- *Healthy Places Index*. Composite index of social and population data used to identify socially vulnerable communities across California.
- *CalEnvironscreen 4.0.* Composite index of environment, social, and health data used to identify Environmental Justice Communities across California.

OUALITY OF SECONDARY DATA

Environmental data: Secondary data sources will be used to adjust the HRRR-Smoke model wildfire PM2.5 estimate (*see section d: modify existing model*)

Sociodemographic and health data: Key sources of data are from state or federal departments. When multiple sources of such data are available, they will be compared for consistency. Results from the scientifically strongest sources will be used if the strongest sources can be identified, otherwise suitable averages will be used based on the data from the multiple sources. Non-referred sources will be used as a last resort. Non-referred sources (e.g., housing attribute data) needed to estimate indoor filtration of wildfire PM_{2.5} will be compared with other published data sources, such as the American Housing Survey (U.S. Census), to check for consistency. The resulting infiltration factors will also be cross checked with Purple Air observational data from indoor air sensors located within diverse housing types (single family homes, multiple unit housing, dense housing, and those located within and outside of EJ communities).

- d) <u>Development or Refinement of Models</u>: HRRR-Smoke data is available in a public archive and support will be provided by the HRRR-Smoke modeling team from NOAA (see letter of support). Data quality will be assessed by quantitative evaluation and comparison with surface and satellite based observations, then creating a new model-data fusion product with higher accuracy. The following step wills be taken to ensure accuracy of the model:
- The PM_{2.5} model errors using the HRRR-Smoke atmospheric model will be quantified by detailed comparison with satellite data and dense air pollution monitoring networks.
- Bayesian source inversion will be performed using the highly efficient Markov chain Monte Carlo (MCMC) approach to retrieve improved fire radiative power (FRP)

estimates; these will be used to adjust plume source strength and to better constrain biomass burning fluxes. The MCMC approach will create a probabilistic composite smoke field which indicates the 90% confidence intervals for PM_{2.5} concentration levels. When more than one fire is burning, NOAA's Hazard Mapping System (HMS) will be used to identify separate plumes, then MCMC source inversion can be applied separately to correct for FRP detections within each wildfire cluster. These corrections to FRP are critical for adjusting the overall fire source strength and for improving estimates for biomass burning fluxes. To further improve accuracy of the predicted PM_{2.5} and correct for additional model errors, such as boundary layer processes, turbulence, topography-driven effects etc., data assimilation can be used to correct model predictions.

• Data assimilation (a form of machine learning) will be used to incorporate surface observations and hourly daytime surface and satellite aerosol optical depth (AOD) data to improve smoke plume and biomass burning flux accuracy. The NOAA Gridpoint Statistical Interpretation (GSI) is a 3-dimensional variational data assimilation system (3DVar) which is available for use with HRRR. 43,79,80 We propose to use GSI as a tool for assimilating both ground based PM_{2.5} and AOD data, as well as satellite AOD, to correct the historical PM_{2.5} model products from HRRR-Smoke. GSI 3DVar is being used to assimilate satellite retrievals of AOD into NCEP's Next-Generation Regional Air Quality Forecasting System in the development of the new Rapid Refresh Forecast System (RRFS) which will replace HRRR in the future. 81,82

This process will result in a prototype PM_{2.5} "analysis product" (a term used in weather forecasting for data-model fusion) based on HRRR-Smoke, to be input into the health exposure models. Various alternatives will be explored using either source inversion and machine learning/data assimilation techniques to improve the skill of the smoke pollution product. Subsets of observation data will be incorporated, and the analysis product will be validated with comparisons to other data using standard statistical measures.

- (f) <u>Conducting Surveys</u>: We will administer 450 surveys across three study areas to elicit information on current mitigation behaviors used during wildfire events and on acceptable mitigation interventions. This survey is intended to garner descriptive data only, inform infiltration models, and inform the focus group discussions. Data will be entered into the Research Environment Data Capture (REDCap) system.
- (4) Data management activities: Survey data will be recorded in REDCap, a HIPPA compliant system that includes a suite of software tools, supported by UCSF, which enables the collection, cleaning and viewing of research data. Data can be entered and changed only by those with the rights to do so. Varying interfaces allow for multiple study teams to access, view, and/or enter data, depending on access rights, into the database, while allowing for research participants to respond to questionnaires directly through electronic data capture. (e.g., record-keeping procedures, data-handling procedures and the approach used for data storage and retrieval on electronic media). Health data will be stored and only accessed in a secure data hosting and computer service, UCSF Research Analysis Environment (RAE) after a DUA is in place. Sociodeomographic and environmental data will be uploaded to the RAE for analyses. This HIPAA compliant desktop environment is hosted on servers housed at the UCSF Data Center on Minnesota Street. The MvResearch environment is hosted on six Dell PowerEdge R710s and Five Equal Logic PS6100E SAN, which are located inside the locked rack. There are two layers of physical redundant Cisco firewalls that protect the servers and SAN. To facilitate archiving of journal publications, Open Access choices will be made whenever possible.

Funding Opportunity: EPA-G2021-STAR-H1, Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/Lifestages: Community-Based Research for Solutions

Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Wildfire PM_{2.5} in Environmental Justice Communities.

Protection of Human Subjects

1. Risks to Human Subjects

a. Human Subjects Involvement, Characteristics and Design

Objectives 1 and 2 do not involve human subjects, rather we propose to estimate the ground level wildfire-specific PM_{2.5} over a 3-km grid over the state of California (objective 1) and estimate the indoor filtration ratio of wildfire-specific PM_{2.5} adjusted on housing characteristics (objective 2) and behavioral data (objective 4).

For Objective 3, we will estimate the sub-daily and daily effects of wildfire-specific PM_{2.5} on respiratory, cardiovascular, and cerebrovascular ED-visits and hospitalizations across zip codes in California. This is an ecological study design, i.e., no personal identifying information obtained, and all analyses will be performed at the zip code level. Below, we will refer to this study as the "ecological health analysis".

For Objective 4, human subjects are involved as participants in surveys, focus groups, and interviews. Eligible participants are age 18 year and older and representative of one of the following three groups: lives within and/or actively engages with an identified climate change vulnerable community; represents an organization whose interest or mission aligns with climate-impacted health conditions; or, represents an organization whose interests or mission align with mitigation strategies for wildfire smoke events. It is anticipated that all participants will be able to speak English. However, all study materials including recruitment scripts, consent forms, surveys, focus group and interview guides will be available in English, Spanish, and Chinese.

Vulnerable populations. Participants recruited for Objective 4 will be residents or with community-based organizations that support Environmental Justice (EJ) communities, i.e., communities that are exposed to disproportionate environmental pollution and experience an excess of social stress. We believe it is necessary to focus our engagement with this vulnerable population when attempting to understand current behaviors and barriers to mitigation strategies for wildfire smoke within these communities.

b. Sources of Materials

Research Material. For the ecological health analysis, we will obtain a dataset from the California Health Care Access and Information (HCAI) that includes daily ED-visits and hospitalizations for respiratory (ICD9 codes: 460:519 or ICD10 codes: J00:J99, excluding J95), cardiovascular (ICD9 codes: 410:414, 428 or ICD10 codes: I20:I25, I50), and cerebrovascular (ICD9 codes: 430:438 or ICD10 codes: I60:I69) events aggregated at the zip code level. Events will be appended with age, sex, and race/ethnicity data. Research materials collected under Objective 4 from human subjects include participants' responses to focus groups, interview questions, and responses to surveys. Focus groups and interviews will be audio recorded and transcribed.

Data Collection, Management, and Protection. Only research team members who have appropriate training and certification in human subject research will have access to any research material. The ecological health dataset will be transferred to UCSF only after a DUA is in place and stored and accessed in a secure data hosting and computer service, UCSF Research Analysis Environment (RAE). All focus group and interview data will contain minimal subject identifiers (i.e., age, sex, language spoken, role in community and relation to climate mitigation strategies). Survey data will be linked to consented participants only through study ID. All survey data will be entered into Research Electronic Data Capture (REDCap), a secure and HIPPA-compliant web-based system for building and managing web-based research projects. All other data, including audio recordings, will be kept on secure, password protected servers in locked rooms and separated from the file linking study ID to participants, which will also be kept in a secure, password protected computer.

c. Potential Risks

Potential Risks. The main potential risks to patients are loss of confidentiality and invasion of privacy. There may be some psychological risk such as anxiety generated by the questions.

Alternative Procedures. The alternative procedure for all participants is not to participate in focus groups, interviews, or surveys. Potential Stakeholders who wish to not participate in the evaluation study on engagement efforts will still be allowed to complete trainings and be on the Community Stakeholder Group. There is no loss of any patient or employee privileges and rights for not participating in the study.

2. Adequacy of Protection Against Risk

a. Recruitment and Informed Consent

Ecological Health Study. As no patient-identifying information is collected for this analysis, all the health data has already been collected, and that the level of the analysis is at the zip-code level, this qualifies as exempt research.

Recruitment of Community Stakeholder Group. Working with our local partners (SFDPH, SFORCP, and Brightline in San Francisco, CCHS and Lifelong Medical in Richmond, and CCAC in Fresno), we will proactively engage community-based organizations who meet one of the following criteria: located within and actively engages with an identified climate change vulnerable community; interest or mission aligns with climate-impacted health conditions; or, interests or mission align with mitigation strategies for wildfire smoke events. Given the role of this group as a research partner, potential participants need to be English-proficient. Identified groups will be approached by a local partner, who will set up a "coffee-break" meeting which will include a research partner, a local partner, and a community stakeholder to determine interest in partnering. Those expressing interest, will be invited to take part in Participatory Action Research Training sessions. As we will be collecting satisfaction and engagement data, participating stakeholders will be informed that we will collect information on the engagement process and asked to participate in this evaluation study using a standardized recruitment script. Interested participants will be given written informed consent in English. Participants will be given an opportunity to ask questions before signing the informed consent. This process will be repeated with the formed Community Stakeholder Group to allow for ongoing assessment of engagement efforts. No additional compensation will be provided for participating in the evaluation study. However, community stakeholders will be compensated at a rate \$100/meeting for their time and efforts on the Community Stakeholder Team.

Survey Participants. Identification of potential participants will be led by the Community Stakeholder Group and local community partners on this grant. The recruitment script will be standardized to state that we are recruiting for a study to understand how wildfire events impact their health and gather information on behaviors during wildfire and which mitigation strategies they already use and/or find acceptable. Interested participants will be directed to a private, secure website to read the informed consent and respond to the survey in the participant's preferred language. Incentive for participation in a survey is \$20.

Focus Group Participants. Identification of potential participants will be led by the Community Stakeholder Group and local community partners on this grant. The recruitment script will be standardized to state that we are recruiting for a study to understand the ways in which they use mitigation strategies and why or why not they may decide to use one strategy over another. After ascertaining eligibility, the community liaison will then schedule the participant for a focus group meeting. At the focus group, all participants will be given written informed consent in English, Spanish, or Chinese per the participant's preference. Participants will be given an opportunity to ask questions before signing the informed consent. All participants will sign the consent form. Incentive for participation in focus groups is \$40 per person.

b. Protection Against Risk

Protection Against Loss of Confidentiality and Invasion of Privacy. Only research team members who have appropriate training and certification in human subject research will have access to any research material. Researchers will not identify any participant in any publication or presentation, and all research data will be presented in aggregate.

All focus group, interview, and survey data will contain minimal subject identifiers (i.e., age, sex, language spoken, ethnicity, neighborhood). During focus group or interviews, participants will be addressed using first names only. Notes and transcripts will not include names or other identifying information. Once the data on the audiotapes has been transcribed, the tapes will be destroyed.

Protection Against Psychological Risk. We recognize that participants may experience discomfort or distress with some of the questioning. Participants will be informed that they do not have to discuss, answer, or do anything they are uncomfortable with and can withdraw from the study at any time.

Protection for Children. All participants will be 18 years of age or older.

3. Potential Benefits of the Proposed Research to Human Subjects and Others

There will be no direct benefit to survey and focus group participants. Stakeholder participants may confer some personal benefit from leadership training. The potential risks in this project in terms of loss of privacy and discomfort from questioning are minimal.

4. Importance of the Knowledge to be Gained

The knowledge to be gained from this study is a better understanding of the health risks associated with wildfire-specific PM_{2.5} and how this risk is distributed across communities. In addition, at the conclusion we will have increased understanding of the barriers to mitigation strategies and, with community stakeholders, would have identified acceptable strategies to move forward for implementation. This has the potential impact of improving the design of interventions that will reduce the health effects of wildfire smoke events.

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Scientific Data Management Plan

Data generated under this project will be administered in accordance with both University and EPA policies.

- 1. Types of Data Produced: Data capture will occur in several ways. Modeled data for exposure concentration and estimates, participant-administered questionnaires, and through focus groups. A summary of the data products include:
- **Integrated model-data smoke product** (hourly, 3km grid): Concentrations will be estimated by fusion of HRRR-Smoke model output and surface and satellite observations of PM2.5.
- Wildfire-specific PM2.5 exposure estimates: Using concentrations from the fused model-data smoke product, area level estimates at the census tract and county level will be derived. Estimates will be as daily means (to allow for comparability to other methods for estimation) and as hours in exceedance of daily thresholds (set at 55µg/m³, the upper boundary of the AQI orange zone). For this second measure, estimates will be expressed in mean hourly exposure and number of hours over threshold.
- Indoor Wildfire PM_{2.5} Filtration Ratio estimates: Hourly distribution of infiltration factors in homes averaged over census tracts.
- **Survey Data:** Current use and behaviors, in addition to acceptability of mitigation strategies from 450 residents from included study areas (Fresno, Richmond, and San Francisco, California).
- Qualitative Data: Focus group themes on barriers to promising mitigation strategies from 45 residents from included study areas.

2. Data Format

The data formats of our collaborative research will include:

- Fused model-data products from HRRR-Smoke and observations will be output in netCDF format. We will also produce a library of graphics comparing simulation results to observed data to facilitate case browsing. NetCDF is a set of software libraries and self-describing, machine-independent data formats that support the creation, access, and sharing of array-oriented scientific data (direct quotation from http://www.unidata.ucar.edu/software/netcdf/).
- Wildfire PM_{2.5} infiltration factors distribution estimates will be developed using a statistical software package, such as R. Results and the key influencing parameters, such as housing attributes and occupant behaviors, will be outputted as R data objects.
- Survey data will be entered into the Research Electronic Data Capture (REDCap) system, a HIPAA-compliant web-based system. All data will be verified for accuracy (i.e. double entered and merged). REDCap supports several data output downloads, including .csv, .dta, .xml, etc.
- Audio recordings (.mpa) of focus groups will be transcribed and destroyed. Transcripts will be stored as .pdf and/or .doc files and as coded files after thematic analysis.
- 3. Access to data, and data sharing practices and policies
- Integrated model-data smoke product: We will establish a publicly-available data archive for the fused model-data smoke product. The original data produced from the

- simulation code, HRRR-Smoke, are already available in a public web archive. Our new data will be provided to the data archive within one year of the project end date for international public access.
- Deidentified dataset: We will create (de-identified) public use datasets of survey data from Objective 4, which would be available without restriction to any member of the public. Any such datasets would be made publicly available through DataShare (http://datashare.ucsf.edu), which was developed by a partnership of the UCSF Clinical & Translational Science Institute, UCSF Library, and UC Curation Center at the California Digital Library. This service provides public access via persistent URLs, tools for long-term data management, and permits permanent storage options. Data will be discoverable by either searching or browsing the website. Each dataset will be required to include the following metadata: title of dataset, creator, description, technical description, subject headings, and related publications. All required fields will be searchable as will optional fields.

Beyond the sharing of observations, our data sharing policy will include:

- Providing code, post-processing files, and datasets to any journal that requires data posting
- Code, post-processing files, datasets, and graphics being made available to qualified investigators within one year after completion of our investigators' data analyses and publication of papers presenting the results of those analyses, whichever is later.
- A process for sharing data that will be dependent on University policies and likely require a Data Use Agreement, pending the data types requested. To facilitate the process we will develop a proposal submission process. This includes submitting a request in writing identifying the requestors and their affiliated institution, indicate what they plan to do with the data, include assurances that they will not share the data with others without the written permission of the project principal investigator and agree to give proper credit to the project/investigators who collected the data in publications resulting from the data.

4. Policies and provisions for re-use, re-distribution and production of derivatives

- Results will be disseminated widely through journal publications and conference presentations. Our results will therefore be subject to peer review. We have requested funding to make presentations at the American Geophysical Union, American Meteorological Society, Society for Epidemiologic Research, and the American Thoracic Society meetings.
- Journal publications will be archived in pdf format and Open Access choices will be made whenever possible.
- All publications, presentations, and results from this project will be available through the main project website, creating an integrated internet resource where scientific results will be available to the public.

5. Storage and Archiving of data

We anticipate that the fused model-observation analysis product will generate a few terabytes of data that will need to be archived for further processing and data analysis during the course of the project. The data will be stored on a parallel file server most likely hosted by UC Berkeley through the Berkeley Research Computing Center, with copies on local disks. Final health data for this project will be archived in UCSF's Secure Research Analysis Environment (RAE).

Funding Opportunity: EPA-G2021-STAR-H1, Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/Lifestages: Community-Based Research for Solutions

Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Wildfire PM_{2.5} in Environmental Justice Communities.

Community Engagement Plan

Our approach incorporates principles of community-based participatory action research (CBPAR) as a mechanism for addressing the negative effects of climate change. ^{13,14} PAR deviates from traditional research models where line of inquiry is dictated by the subject matter expert and research is completed on or for a specific community. Based in PAR, our logic model for engagement (**Figure 1**) begins with the context in which relationships with the community will be formed. Wildfire smoke events have significant, cascading, and compounding health impacts on the people who live, work, and recreate across California. Health impacts are not evenly distributed; the neighborhoods that carry the heaviest health burden are the ones most exposed and least likely to have the economic, social, or political resources needed to prepare for or respond to them. However, historic and present-day decision making by local and federal governments on climate issues have *not* consistently placed these environmental justice (EJ) communities' interests central. It is within this context renewed partnerships will be formed with community partners, with transparency and acknowledgement of past actions.

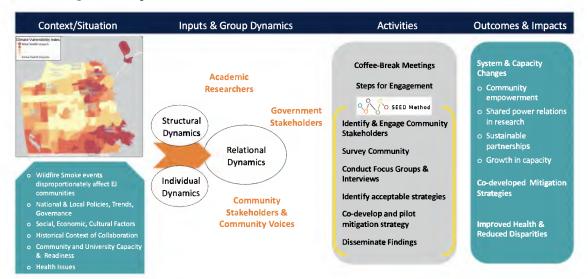


Figure 1. Logic Model for Engaging Community Stakeholders to Address Climate-Impacted Health Conditions For authentic partnerships to occur, several barriers must be addressed. 1) Acknowledgement of historic and current actions that have contributed to ongoing mistrust of climate change efforts. 2) Address socio-cultural differences and skill-set imbalances that contribute to overt and unconscious power imbalances when partnering with a community. 3) Emphasis of a community-first model that brings community stakeholders to the table at the start of planning and increases transparency of the decision-making process.

1. **Provide neutral spaces to facilitate bidirectional informational exchange.** Lack of transparency and parachute research within socially vulnerable communities continues to foster mistrust. Research may be seen as contractual without consideration of community needs or priorities. In addition, historic and present-day decision making by local and

federal government on climate issues have not consistently placed socially vulnerable interests central; at times having a downstream effect of worsening climate impact. Programs that happen to align with community priorities or interest are limited in impact as they lack vital input from community stakeholders and are subject to closure as grant funding ends. To counter, we must offer neutral spaces where community stakeholders are able to openly share concerns and opine on preferred methods of engagement. Neutral spaces are those that are in the community. We, as the "researchers", are invited to these community spaces, shifting power dynamics. Under the current proposal, we will set up "coffee-break" meetings with community stakeholders that allow for information sharing in a neutral space that is not tied to a particular agenda. This network can later be leveraged for forming a community stakeholder group, co-development of mitigation strategies, and for dissemination of research findings and public health messages around wildfire events.

- 2. Equip community stakeholders with necessary skills to off-set power imbalances. Community members and organizations hold historic and current knowledge and perspective of how wildfire smoke exposures impact their community. The addition of this knowledge helps ground truth the results that will be generated under Objective 1-3 of this proposal. These stakeholders are also key in identifying barriers to potential mitigation interventions and where levers may exist to facilitate implementation of promising strategies. As mitigation is complex, crossing multiple sections and social conditions, it is critical to bring in community partners on equal footing. Equipping stakeholders with the necessary research literacy and leadership skill development will move us towards leveling the research-community power dynamic and have a more equitable partnership. Specifically, during the first six months of the award, we will host monthly 1.5hour meetings around research methods and skill building with interested partners. Sessions will center on building research vocabulary for stakeholders and provide training on certain skills, including an overview of the SEED Method (see below), how to develop a research question, data types, and methodologies for querying the community (i.e., qualitative interview techniques vs. quantitative surveys).
- 3. Prioritize community-stakeholder engagement on the community-academic team. By bringing stakeholders into the Research Agenda at the start of the proposal, as opposed to when quantitative analyses proposed under Objective 1-3 are already completed, ensuring community perspective is prioritized and incorporated at every stage of the project. Furthermore, we have laid out an intentional plan to engage community members extending from enriching our analyses with behavioral data, actively discussing community-specific barriers to mitigation interventions, to co-developing implementation strategies to increase uptake of acceptable mitigation strategies. The community stakeholder group will be a key partner on the research team.

These steps are foundational to authentically incorporating community voices into the research agenda. To ensure success, we will use the Stakeholder Engagement in question Development and Prioritization (SEED) Method, developed through PCORI funding by investigators at the Virginia Commonwealth University Center on Society and Health. The SEED Method is an evidence-based systematic, iterative process that brings in community stakeholders as equal creators of a research agenda. Through this partnership between community stakeholders, local and state governmental stakeholders, and academic researchers, we will build capacity for research related to climate and health that centers on community concerns and priorities, furthering the capacity and reach of this proposal in a way that is centered on health equity.

Evaluation of Engagement: We will take several steps to ensure authentic engagement with community partners around climate and health impacts. The SEED Method incorporates several points of evaluation to ensure initial engagement and successful output of such engagement. We have adapted this evaluation scheme for the present proposal, focusing on community stakeholder engagement with the process and satisfaction (Table 1). Briefly, after forming the Community Stakeholder Group, we will survey all partners to ask if there are additional community partners missing from the discussion. This will occur at month 9 and again at month 18 understanding that priorities may shift over time. To evaluate engagement, we will anonymously survey community partners regarding satisfaction with the process and query for suggestions to improve the process. These surveys (Group Dynamics Questionnaire) will immediately follow every group-wide community-academic meeting to capture immediate reactions to the process with built-in time for follow-up in 1:1 meetings with community partners, which will be facilitated by Dr. Thakur's team. In addition, after each co-developed product (survey, focus interview guide, pilot project), the community partner will complete an activity log documenting the level of engagement by all stakeholders (providing a time for self-reflecting on their own engagement in the process). We will also debrief with the Community Stakeholder Group to elicit process feedback to help improve upon the process of engagement.

Table 1. Evaluation activities

	Activities	Evaluation Tool*
Identify and engage (months 2-8)	 "Coffee Break Meetings" Participatory Action Research skill building and leadership training Form Community Stakeholder Group 	Training Satisfaction Questionnaire Group Dynamics Questionnaire
Consult #1 (months 9-18)	Community-academic team co-design survey Administer survey to participants (broader community engagement)	Activity Log – Question Development Debrief: After Action Review & Questionnaire
Conceptualize (month 19-21)	- Co-generate preliminary conceptual models based on community survey	Activity Log – Conceptual Model Debrief: After Action Review & Questionnaire
Generate strategies (month 22-24)	- Co-generate preliminary mitigation strategies based on community survey	
Consult #2 (month 24-28)	 Co-develop Interview guide for focus groups Community Stakeholder Group co-facilitated focus group Co-identification of themes from focus groups 	Activity Log – Guide Development Debrief: After Action Review & Questionnaire
Prioritize and finalize strategies (Month 29)	Use voting process to prioritize strategies Finalize strategies for focus based on community needs and APEASE criteria	Activity Log – Prioritize strategies Debrief: After Action Review & Questionnaire
Pilot Development (Month 30-36)	- Prototype and pilot implementation strategy for increasing uptake	Activity Log – Pilot Development Debrief: After Action Review & Questionnaire
Wrap up/next steps (Month 24)	- Develop a sustainability plan and action steps for implementation	After Action Review

^{*}Adapted from SEED Method Toolkit84

Coordination with Complementary Activities in Planned Study Areas: Several members of the research team have active collaborations with community and local governmental partners that are relevant to this proposal. Our goal is to not duplicate efforts, but rather build on these collaborations. Below, we provide a detailed description of current work in each EJ community and how this award will complement or enhance current efforts.

Fresno, California

There are two relevant partnerships to highlight, one is specifically with the AB 617 designated EJ community, South Central Fresno.

UCB and Central California Asthma Collaborative: Drs. Balmes and Holm (UCSF) and Dr. Noth (UCB) have been collaborating with the Central California Asthma Collaborative (CCAC) for approximately 4 years on the planning and implementation of the co-funded EPA(83543501) and NIH (R24ES022849) study to retain and follow longitudinally two cohorts of children participating in the Children's Health and Air Pollution Study (CHAPS) in Fresno. CCAC's mission is to provide education and direct services, build regional capacity and advocate for sensible policies that improve health and address inequities by reducing environmental impacts and emphasizing the prevention and management of chronic disease. http://cencalasthma.org The CCAC is currently providing the field office for CHAPS. Dr. Balmes has worked with CCAC for over a decade regarding advocacy for clean air and environmental justice at both the state and local levels. Dr. Balmes is currently the Chair of CARB's AB 617 Consultation Group of which the Director of CCAC, Kevin Hamilton, is a key member. CCAC will be actively involved in the PROTECT Health Effects as a Community Stakeholder Partner and lead engagement efforts in Fresno County.

UCB and South Central Fresno: Drs. Noth (UCB) and Bradman (UC Merced) are implementing a total exposure study to air pollution and noise in the San Joaquin Valley, including South Central Fresno - SPHERE (San joaquin valley Pollution and Health Environmental REsearch study), funded by the California Air Resources Board. We are collaborating with the CCAC in order to recruit community members to our study. We plan to include public health students Fresno State, a Hispanic Serving Institution, in conducting the field studies. Because Fresno State is primarily a teaching university and does not have a large environmental health research portfolio, this would offer the students practical experience in scientific research. In the past, through the CHAPS National Children's Environmental Health Center, we collaborated with Fresno State professors Dr. Zografos, Kwan and Capitman and their students to conduct community mapping of neighborhood social and built environments, 85 as well as air pollution. This work, called a Structured Social Observation, was made available to Dr. Thakur via training from Fresno State, and she applied it very successfully in Richmond, California, as part of the Youth Participatory Action Research Summer Internship in 2019 (below). We expect that our fieldwork for SPHERE will take place in early 2022, and will include collecting matched indoor and outdoor PM_{2.5} measurement data in 120 residences in San Joaquin Valley communities, including South Central Fresno. It is anticipated that these data will be informative for the work proposed in Objective 2.

Richmond, California

There is one relevant partnership to highlight, both of which are located within the AB 617 designated EJ community, North Richmond and focused on youth engagement.

<u>UCSF-UCB</u> and <u>Lifelong Medical William Jenkins Health Center:</u> Since 2016, UCSF-UCB have worked in partnership with Lifelong Medical to increase our understanding of place-based risk factors for asthma in North Richmond, CA. To increase community perspective and engagement with the research agenda, UCSF-UCB-Lifelong Medical

launched a Youth Participatory Action Research Summer Internship in 2019. Over the past three years, we have trained 14 youth in research methods and engagement to empower this group to formulate research questions about their own community and partner on strategies that have the potential to improve health. This rich engagement has already had several successful outputs relevant to the current proposal: mapping of the social riskscape in Richmond, qualitative work that has led to understanding sources of wellness and safety across the community, and, most recently, mapping of perceived environmental hazards in partnership with a grant from the Air District. This group is primed to assist with community surveying activities proposed in Objective 4. The data from this award will also inform these youth researchers on promising strategies to move forward through pilot testing within their community.

San Francisco, California

There are two collaborations to highlight that will increase our likelihood of success in implementing this grant. Furthermore, the information garnered under this award has immediate impact on activities currently being pursued through these collaborations.

Brightline and Lawrence Berkeley National Laboratory: Brightline is a nonprofit organization dedicated to promoting sustainability and empowerment of low-income, frontline communities within and outside of California. In efforts to better understand exposure burden for residents of high-density housing, such as single room occupancies (SROs), Brightline in partnership with Lawrence Berkeley National Laboratory - has successfully obtained funding from the California Air Resource Board (CARB) for hyperlocal community air monitoring for this high-risk population, who are often not included in crowdsourced monitoring studies. The information obtained from their sensors will enrich our wildfire-specific PM_{2.5} model and building infiltration study. Furthermore, Brightline has completed surveys with residents of SROs to understand barriers to use of do-it-yourself box filter fans during wildfire, the data of which will inform the basis of the community survey on barriers to mitigation interventions. Reciprocally, information learned from this survey will be shared with Brightline to further their own intervention efforts.

UCSF PRISE Center and the Heat and Air Quality Resilience Project: Dr. Thakur, as Director of Subspecialty Care of the PRISE Center, recently obtained funding with the San Francisco (SF) Department of Public Health (DPH) and the Office of Resilience and Capital Planning from the Patient Centered Outcome Research Initiative (PCORI) for an engagement award to improve the city-wide response to extreme health and air quality issues, including those associated with wildfire events. The UCSF PRISE Center (PRISE stands for Partnerships for Research in Implementation Science for Equity) was established in partnership with SFDPH to accelerate uptake of evidence-based clinical and public health interventions with a focus on health equity. This award will enhance cross-municipality efforts already underway through the Heat and Air Quality Resilience (HAQR) Project. HAQR includes all municipal departments involved in emergency preparedness and response services, housing, and infrastructure. Using a similar method of engagement proposed here, we are currently underway and recruiting stakeholders to outfit the HAQR Leadership team. This project specifically focuses on implementation and lacks capacity for the type of detailed and informative research to take place under this award. The findings generated from this award will be shared with the HAOR team. This team also provides a ready group for engagement, particularly when at the pilot prototyping stage of the grant proposal.

Funding Opportunity: EPA-G2021-STAR-H1, Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/Lifestages: Community-Based Research for Solutions

Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Wildfire PM_{2.5} in Environmental Justice Communities.

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Budget Justification

<u>PERSONNEL</u>: Pursuant to University of California (UC) policy, salaries in the initial budget period are based on current published UC salary scales and include University mandated range adjustments and merit increases scheduled to occur before the proposed project start date of July 1, 2022.

Position Title	Annual	% of Time to	Year 1	Year 2	Year 3	Total
	Salary	Project				
Neeta Thakur,	\$263,315	10%	\$26,332	\$26,332	\$26,332	\$78,996
Principal Investigator						
Stephanie Holm,	\$167,003	Yr1 = 5%	\$8,350	\$16,700	\$16,700	\$41,750
Co-investigator		Yr 2-3 =10%				
John Balmes,	\$326,342	3%	\$9,790	\$9,790	\$9,790	\$29,370
Co-investigator						
Leah Murphy,	\$122,960	10%	\$12,296	\$12,296	\$12,296	\$36,888
Project Manager						
Total			\$56,768	\$65,118	\$65,118	\$187,004

Neeta Thakur, MD MPH, Principal Investigator, UCSF Assistant Professor. Dr. Thakur will direct and oversee all aspects of the project implementation, including coordination of activities and evaluation activities with grant partners. In addition to overseeing environmental health analyses with Drs. Holm and de la Rosa, Dr. Thakur, in partnership with Community Partners, will lead the Community Stakeholder Group meetings. This includes overseeing the Community Stakeholder Group in administering community survey and carrying out the thematic analysis of focus groups as proposed under Objective 4.

Stephanie Holm, MD, PhD, MPH, co-investigator, UCSF Assistant Professor. Dr. Holm, along with Drs. de la Rosa and Thakur, will oversee the environmental health analyses. This includes building the health analysis model, supervising analyses by the graduate student, and leading interpretation of the results. Dr. Holm will also be responsible for ensuring the data quality of the health data obtained from the California Health Care Access and Information.

John Balmes MD, co-investigator, UCSF Professor. Dr. Balmes will provide technical and expert input for the health analysis, guidance in the implementation of the community engagement study, and participate in the manuscript preparation phases of the study.

Leah Murphy, Project Manager. The project manager will provide direct back-up to the community partners' day-to-day activities and oversight of communications with Local Partners and the Community Stakeholder Group. The project manager will organize and lead the Participatory Action Research (PAR) training session with Dr. Thakur with interested community stakeholder parties. This person will also be responsible for building the developed survey within Redcap, coding of focus group transcripts, and assisting with the completion of the progress reports and the final report.

<u>FRINGE BENEFITS:</u> Consist of two benefit assessments. The UC-managed Composite Benefit Rates (CBR) and the UCSF-managed Faculty Childbearing Childrearing assessment. UC-approved Composite Benefit Rates (CBRs) include retirement, payroll taxes and assessments, and

health & welfare. Employees are assigned to a benefits group based on job code and benefits eligibility. The FY 2020-21 CBRs were reviewed and added to the Federally negotiated rate agreement on June 29, 2020, by the University's Federal cognizant agency, HHS Office of the Inspector General, Office of Audit Services. *For this proposal, the rates are: Tenured, Ladder Rank Faculty = 24.4% with a 1% Faculty Childbearing leave benefit = 25.4%; Non-tenured Faculty = 32.1% with a 1% Faculty Childbearing leave benefit = 33.1%; Partial Benefit (for Emeritus) = 3.7%; Academic and Staff = 42%.

Title	Base Fringe	Costs			Total
	Rate*	Yr 1	Yr 2	Yr 3	
Principal Investigator Thakur	25.4%	\$6,688	\$6,688	\$6,688	\$20,064
Co-investigator Holm	33.1%	\$2,764	\$5,528	\$5,528	\$13.820
Co-investigator Balmes	3.7%	\$362	\$362	\$362	\$1,086
Project Manager Murphy	42%	\$5,164	\$5,164	\$5,164	\$15,492
TOTAL		\$14,978	\$17,742	\$17,742	\$50,462

<u>TRAVEL</u>: We are requesting \$1,067 per year to request travel between sites for community engagement work. We are requesting an additional \$7,900 to provide travel for up to five members of the project team to the annual STAR program progress review. Funds will not be used for foreign travel without approval by the EPA. The total travel request is \$26,751.

Purpose of	Location	Item	Computation	Cost per
Travel				year
EPA STAR	Washington	Lodging	5 people x \$260 per night x 3 nights	\$3,900
Progress	DC			
		Airfare	5 people x \$500/roundtrip	\$2,500
		Per Diem	5 people x \$85 per day for 2 days;	\$1,450
			travel days at \$60 per day	
Subtotal Per	r Year:			\$7,850
In State	Richmond,	Mileage	40 miles roundtrip @ .56/per mile =	\$314
Travel	CA		\$22.4 per trip x 14 trips per yr	
	Fresno, CA	Mileage	380 miles roundtrip @ .56/per mile	\$213
		Lodging	\$150 x 2 persons @ 1 night	\$300
		Per Diem	\$60 per person x 2 persons x 2 days	\$240
Subtotal Per	r Year			\$1,067
TOTAL Per	Year			\$8,917

CONTRACTUAL

CONTRACTED WORK (\$12,480)

To-be-Determined Survey Administration: In years 1-2, we request \$4160 per community organization (n=3) to administer the survey within the three communities for a total of \$12,480. The surveys will be contracted work and not via a subaward agreement.

OTHER(\$845,703)

Publication costs of \$2,000 are requested for year 3 to offset costs to publish "open access" manuscripts to increase access to scientific publications to Environmental Justice communities. **Health Data Pull:** We request \$10,000 in year one for the California Health Care Access and Information data pull request.

Participant Support Costs (\$43,920)

Community Stakeholder Group: For the formed community stakeholder group, we will provide compensation to members (3 per region, total n=9 members, each receive \$100/meeting). We anticipate meeting monthly with this group for a total of 12 meetings/year for all three years, for a total of \$32,400.

<u>Focus Groups and Surveys:</u> We will conduct 3 focus group per community with 5-7 members (total n=63), participants will be compensated \$40 (\$2,520). We will administer 150 surveys/community (total n=450) to assess current behaviors, barriers to, and acceptance of mitigation strategies. Participants will be compensated \$20 (\$9,000). We request \$11,520 for compensation.

Data Network Recharge (\$531/totai) The data network services recharge or data network recharge is a vital component of the University's Enterprise Network Services (**ENS**), which provides funding for critical equipment in support of UCSF's electronic information flow. The Data Network charge for the period of 7/1/22-6/30/23 is \$46/per FTE for a calculation of .28 x \$46 x 12 months = \$155. For the period of 7/1/23-6/30/2024, the cost is \$47 per FTE and \$48 starting 7/1/24 and beyond. The FTE for this project is stated below.

IT Field Services (ITFS) (\$1,105/total) UCSF ITFS is an integral component of the Enterprise Network Services (**ENS**) providing support to campus voice and data technology functions. ITFS includes software installation/updates, internet security, hardware setup/configuration, and centrally managed patching, storage and backup. The ITFS recharge rate is implemented and effective as of 7/1/20 until amended at \$98/month/FTE for premium services

FTE	Year $1 = .28$	Year $2 = .33$	Year $3 = .33$	Total
Data Network	\$155	\$186	\$190	\$531
ITFS	\$329	\$388	\$388	\$1,105
TOTAL	\$484	\$574	\$578	\$1,636

SUBAWARDS (\$788,147)

University of California Berkeley: Over three years, UCSF will award UC Berkeley \$455,710 in direct costs and \$249,337 in indirect costs (60.5% rate) to work collaboratively with UCSF on Objective 1: Quantify wildfire specific fine particulate matter for fire seasons, Objective 2: Estimate magnitude of effect by wildfire PM on health outcomes and Objective 3: Determine indoor penetration based on housing attributes data. Dr. Rosemarie de la Rosa will provide the oversight on the UC Berkeley scope of work with her colleagues, Dr. Fotini Chow and Dr. Elizabeth Noth. Drs. de la Rosa, Chow and Noth, and a postdoctoral scholar and graduate student researcher will receive salary and fringe benefit support as well as computer software and IT services to support their work.

UCB	Year One	Year Two	Year Three	Total
Direct	\$110,575	\$169,837	\$175,298	\$455,710
Indirect	\$66,898	\$89,889	\$92,550	\$249,337
TOTAL	\$177,473	\$259,726	\$267,848	\$705,047

Note: UCB is UCSF's sister campus and its total costs will be excluded from Modified Total Direct Costs (MTDC) Base per Department of Health and Human Services indirect costs rates agreement dated 11/27/2017.

Central California Asthma Collaboration (CCAC): Over three years, UCSF will award CCAC \$54,546 in direct costs and \$5,455 in indirect costs (10% rate) to employ a research coordinator at 25% effort to engagement efforts, including recruiting stakeholders, administrating surveys, and conducting focus groups.

CCAC	Year One	Year Two	Year Three	Total
Direct	\$18,182	\$18,182	\$18,182	\$54,546
Indirect	\$1,818	\$1,818	\$1,818	\$5,454
TOTAL	\$20,000	\$20,000	\$20,000	\$60,000

TBD, Pilot Projects: We request \$7,000 per community (n=3) to allow for stakeholder driven piloting of mitigation strategies. Strategies are to be determined in partnership with the stakeholder group. Examples of possible pilots include targeted distribution of portable air filtration devices, development of an early alert system, etc. UCSF will award TBD community organization \$7,000 in direct costs and \$700 in indirect costs (10% rate) to co-develop and implement a pilot adaptation strategy. Funds will be distribute in years 2 and 3.

TBN	Year One	Year Two	Year Three	Total
Direct		\$10,500	\$10,500	\$21,000
Indirect		\$1,050	\$1,050	\$2,100
TOTAL		\$11,550	\$11,550	\$23,100

FACILITIES AND ADMINISTRATIVE EXPENSES (\$208,136)

UCSF's indirect costs are calculated based on Modified Total Direct Costs (MTDC) as defined in 2 CFR Part 200.68 using facilities and administration (F&A) rates approved by the U.S. Department of Health and Human Services (DHHS). MTDC is comprised of total direct costs less capital equipment, alterations and renovations, patient care costs, off-campus rent, tuition and fee remission, scholarships and fellowships, participant support costs, and that portion of subcontract costs in excess of \$25,000. Additionally, the total amount of subawards to other UC campuses are excluded. Proration is based on the number of days at the applicable rate.

This project will be located On-Campus. UCSF's F&A rate agreement dated November 27, 2017, provides for an escalating rate for on-campus research:

July 1, 2020, until amended: 61.5%

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BIOGRAPHICAL SKETCH

NAME: Thakur, Neeta

eRA COMMONS USER NAME: NThakur

POSITION TITLE: Assistant Professor of Medicine

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Arizona, Tucson, AZ	B.S.	05/02	Physiology
University of Arizona, Tucson, AZ	M.D./M.P.H.	06/07	
University of California, San Francisco	Resident	06/10	Internal Medicine
University of California, San Francisco	Fellow	06/13	Pulmonary and Critical Care Medicine
University of California, San Francisco	Certificate	06/13	Clinical Research
University of Californa, San Francisco	Certificate	9/2019	Implementation Sciences

A. Personal Statement

I am a physician-scientist specialized in pulmonary and critical care medicine with advance training in clinical research methods, social epidemiology, and implementation sciences. My research program focuses on the short and long-term health effects of multilevel stressors, including air pollution, with special focus on economically disadvantaged communities and communities of color. Our group has linked multiple data types (biologic, individual, and environmental) to demonstrate that social risk factors are geo-spatially distributed, disproportionately burden communities of color, and are associated with specific health outcomes in individuals with chronic lung conditions. We are dedicated to community engagement and bringing in stakeholders as equal partners in research. This is evident in our leadership team of the CIAPM ACES award to test early-life interventions to address social stress that includes our community partner as a multiple PI. In addition, I have developed programs targeted at increasing access to STEM fields for individuals from traditionally underrepresented groups in medicine and science (URM) at the local and national-level. This includes bringing community youth voices to science through youth participatory action research. Relevant to this proposal, I am the contact PI for a PCORI engagement grant, a collaboration between academic researchers and local municipality departments, that will bring in community stakeholders from San Francisco neighborhoods that are disproportionately impacted by extreme heat and poor air quality to co-develop acceptable mitigation strategies to reduce the impact of climate-related events on health. We will build on this effort and expand to neighboring counties under this proposal. My longstanding history of community engagement, on-going collaborations with environmental health experts (Balmes, Noth, and de la Rosa), coupled with my history of examining multi-level stressors and health, make me well-suited to lead this proposal.

- 1. Nardone A, Casey JA, Morello-Frosch R, Mujahid M, **Balmes JR**, **Thakur N**. Associations between historical residential redlining and current age-adjusted rates of emergency department visits due to asthma across eight cities in California: an ecological study. Lancet Planet Health 2020 Jan;4(1):e24-e31.
- 2. Martinez A, **de la Rosa R**, Mujahid M, **Thakur N.** Structural racism and its pathways to asthma and atopic dermatitis. JACI *In Press.*

B. Positions and Honors

2013-2015	Clinical Instructor, Medicine, University of San Francisco, San Francisco, CA
2015-2017	Assistant Adjunct Professor, Medicine, University of San Francisco, San Francisco, CA
2017-	Assistant Professor in Residence, Medicine, University of San Francisco, San Francisco, CA
2013-2014	Medical Director, Health and Environmental Resource Center, San Francisco, CA
2016-	Medical Director, ZSFG Chest Clinic, San Francisco, CA
2016-	Nina Ireland Program for Lung Health Executive Advisory Board Member

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2019-2021 National Committee on Asthma and Toxic Stress, member

2020- Program for Research in Implementation Science for Equity Program Director

2019- Health Equality and Diversity Committee Chair, ATS

2014 Podell Hewett Fellowship in Airways Disease Research, 2014-15

2014 American Thoracic Society (ATS) Recognition Award for Early Career Investigators

2015 Parker B. Francis Fellowship Program, 2015-2018

2017 Faculty Position, Nina Ireland Program in Lung Health, University of California, San Francisco, CA

2018 The ATS Asian Pacific Society of Respirology Young Investigator Award

2021 ATS Behavioral Sciences and Health Services Research Early Career Achievement Award

C. Contributions to Science

- 1. <u>Social Stress and Obstructive Lung Disease</u>: We have demonstrated that individual and place-based measures of social stress are associated with having disease and poor health in communities of color.
- a. **N. Thakur**, Oh SS, Nguyen EA, Martin M, Roth LA, Galanter J, Gignoux CR, Eng C, Davis A, Meade K, Lenoir MA, Avila PC, Farber HJ, Serebrisky D, Brigino-Buenaventura E, Rodriguez-Cintron W, Kumar R, Williams LK, Bibbins-Domingo K, Thyne S, Sen S, Rodriguez-Santana JR, Borrell LN, Burchard EG. Socioeconomic Status and Childhood Asthma in Urban Minority Youths: The GALA II and SAGE II Studies. AJRCCM. 2013; 188(10):1202-9. PMID: 24050698; PMCID: PMC3863734.
- b. **N Thakur***, Barcelo N*, Oh SS, Nguyen EA, Eng C, Davis A, Meade K, Lenoir MA, Avila PC, Farber HJ, Serebrisky D, Brigino-Buenaventura E, Rodriguez-Cintron W, Kumar R, Bibbins-Domingo K, Thyne S, Sen S, Rodriguez-Santana JR, Borrell LN, Burchard EG. Perceived Discrimination Associated with Asthma and Related Outcomes in Minority Youth: The GALA II and SAGE II Studies. Chest.2017;151(4):804-812. PMID 27916618. PMCID: PMC5472516.
- c. S. Carlson, Borrell N, Eng C, Nguyen M, Thyne S, LeNoir MA, Burke-Harris N, Burchard EG*, **Thakur N***. Self-reported racial/ethnic discrimination and bronchodilator response in African American youth with asthma. PLoS ONE Jun;12(6): e0179091. PMID 28609485. PMCID: PMC5469454.
- d. **N Thakur**, Borrell LN, Ye M, Oh SS, Eng C, Meade K, Avila PC, Farber HJ, Serebrisky D, Brigino-Buenaventura E, Rodriguez-Cintron W, Kumar R, Bibbins-Domingo K, Thyne S, Sen S, Rodriguez-Santana JR, Burchard EG. Acculturation is Associated with Asthma Burden and Pulmonary Function in Latino Youth: The GALA II Study. JACI. 2019 May;143(5):1914-22. PMID: 30682453.
- e. A Nardone, Casey JA, Morelle-Frosch R, Mujahid M, Balmes JR, **Thakur N.** Associations between historical residential redlining and current-age adjusted rates of emergency department visits due to asthma across eight cities in California: an ecological study. Lancet Planetary Health. 2020 Jan; 4(1):e24-31. PMID 31999951.
- f. **Thakur N**, Hessler D, Koita K, Ye M, Benson M, Gilgoff R, Bucci M, Long D, Burke Harris N. Pediatrics adverse childhood experiences and related life events screener (PEARLS) and health in a safety-net practice. Child Abuse & Neglect. 2020 Oct; 108:104685. PMID: 32898839.
- g. Ejike CO, Woo H, Galiatsatos P, Paulin LM, Krishnan JA, Cooper CB, Couper DJ, Kanner RE, Bowler RP, Hoffman EA, Comellas AP, Criner GJ, Barr RG, Martinez FJ, Han MK, Martinez CH, Ortega VE, Parekh TM, Christenson SA, **Thakur N**, Baugh A, Belz DC, Raju S, Gassett AJ, Kaufman JD, Putcha N, Hansel NN. Contribution of Individual and Neighborhood Factors to Racial Disparities in Respiratory Outcomes. AJRCCM. 2021 Apr;203(8):987-997. PMID: 33007162. PMCID: PMC8048743.
- 2. <u>Air Pollution and Asthma</u>: Through collaborations, we have demonstrated that the health effects of air pollution differ by race/ethnicity and community, stressing the importance of including diverse populations in research and studying risk factors across communities.
- a. Nishimura KK, Galanter JM, Roth LA, Oh SS, **Thakur N**, Nguyen EA, Thyne S, Farber HJ, Serebrisky D, Kumar R, Brigino-Buenaventura E, Davis A, LeNoir MA, Meade K, Rodriguez-Cintron W, Avila PC, Borrell LN, Bibbins-Domingo K, Rodriguez-Santana JR, Sen Ś, Lurmann F, Balmes JR, Burchard EG. Early Life Air Pollution and Asthma Risk in Minority Children: The GALA II & SAGE II Studies. AJRCCM. 2013 Aug 1;188(3):309-18. PMID: 23750510. PMCID: PMC3778732.
- b. Neophytou AM, White MJ, Oh SS, **Thakur N**, Galanter JM, Nishimura KK, Pino-Yanes M, Torgerson DG, Gignoux CR, Eng C, Nguyen EA, Hu D, Mak AC, Kumar R, Seibold MA, Davis A, Farber HJ, Meade K, Avila PC, Serebrisky D, Lenoir MA, Brigino-Buenaventura E, Rodriguez-Cintron W, Bibbins-Domingo K, Thyne SM, Williams LK, Sen S, Gilliland FD, Gauderman WJ, Rodriguez-Santana JR, Lurmann F, Balmes JR, Eisen EA, Burchard EG. Air Pollution and Lung Function in Minority Youth with Asthma in the GALA II & SAGE II Studies. AJRCCM. 2016 Jun 1; 193(11):1271-80. PMID 26734713. PMCID: PMC4910900.
- c. Nardone A, Neophytou AM, Balmes J, Thakur N. Ambient Air Pollution and Asthma-Related Outcomes in Children of Color of the USA: a Scoping Review of Literature Published Between 2013 and 2017. Curr Allergy Asthma Rep. 2018 Apr 16; 18(5):29. PMID: 29663154. PMCID: PMC6198325.

Complete List of Published Work in MyBibliography:

https://www.ncbi.nlm.nih.gov/sites/myncbi/neeta.thakur.1/bibliography/47135371/public/?sort=date&direction=ascending

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

NAME: Balmes, John R., MD

eRA COMMONS USER NAME: BALMES

POSITION TITLE: Professor, University of California, Berkeley and San Francisco

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of Illinois	ВА	06/1972	Psychology
Mount Sinai School of Medicine	MD	06/1976	Medicine
Mount Sinai Medical Center, NYC	Residency	06/1979	Internal Medicine
Yale University	Post-doctoral fellowship	06/1981	Pulmonary Medicine

A. Personal Statement

I am a physician-scientist who has been studying adverse health effects of air pollutants and other environmental toxins on adults and children in both controlled human exposure and epidemiological studies for over 40 years. In my laboratory at the University of California, San Francisco, I have studied the acute effects of exposure to ozone, SO₂, NO₂, and particulate matter on lung function and airway inflammation in adults with asthma as well as cardiovascular effects of exposure to secondhand tobacco smoke and ozone. In Fresno, CA, I have studied the associations between air pollution and respiratory symptoms, lung function, and immune dysfunction in children with and without asthma. I was one of three multiple PIs leading a NIEHS/EPA-funded Children's Environmental Health Center (the Children's Health and Air Pollution Study or CHAPS); my project for CHAPS involved studying associations of exposure to air pollution with metabolic outcomes. Currently, I am the contact PI for an R24-funded 5-year extension of CHAPS. In Fresno, I have a long history of collaboration with the Central California Asthma Collaborative (CCAC). I have also participated in multiple studies of wildfire smoke and respiratory health (see publications listed below). I have a long-time collaborative relationship with both Drs. Thakur and Holm. The papers below provide evidence of these collaborations.

- 1. Nardone A, Casey JA, Morello-Frosch R, Mujahid M, **Balmes JR**, **Thakur N**. Associations between historical residential redlining and current age-adjusted rates of emergency department visits due to asthma across eight cities in California: an ecological study. Lancet Planet Health 2020 Jan;4(1):e24-e31.
- 2. **Holm SM**, Miller MD, **Balmes JR**. Health effects of wildfire smoke in children and public health tools: a narrative review. J Expo Sci Environ Epidemiol 2021 Feb;31(1):1-20.

B. Positions and Honors

Instructor in Medicine, Yale University
Assistant Professor of Medicine, University of Southern California
Assistant Professor of Medicine, University of California, SF
Associate Professor of Medicine, University of California, SF
Professor of Medicine, University of California, SF; Emeritus since 1/1/2021
Professor of Environmental Health Sciences, University of California, Berkeley;
Emeritus since 1/1/2021
Chief, Division of Occupational and Environmental Medicine, SF General Hospital
Director, Human Exposure Laboratory, Lung Biology Center, UCSF
Director, Northern Calif. Center for Occupational and Environmental Health, UC Berkeley
Director, UC Berkeley-UCSF Joint Medical Program
Member, California Air Resources Board, Cal/EPA

Pulmonary Academic Award, NHLBI, 1983-1986

Environmental/Occupational Medicine Academic Award, NIEHS, 1991-1996

Clean Air Research Award, American Lung Association of San Francisco and San Mateo, 1997

Clean Air Award, American Lung Association of California, 1999

Jean Spencer Felton Award for Excellence in Scientific Writing, Western Occupational and Environmental Medicine Association, 2002

Robert A. Kehoe Award of Merit, American College of Occupational and Environmental Medicine, 2006 Carl Moyer Award for Scientific Leadership and Technical Excellence, Coalition for Clean Air, 2006 Rutherford T. Johnstone Award, Western Occupational and Environmental Medical Association, 2010 Robert M. Zweig Memorial Clean Air Hero Award, South Coast Air Quality Management District, 2012 Public Service, American Thoracic Society, 2016

John M. Peters Award, American Thoracic Society Assembly on Environmental, Occupational and Population Health, 2016

Fellow, American Thoracic Society, 2018

Distinguished Achievement Award, American Thoracic Society, 2020

C. Contributions to Science

Epidemiological studies of the respiratory health effects of air pollution in children and adults

I have collaborated on multiple research efforts to assess the relationships between exposure to various air pollutants, including household air pollution from domestic cooking with biomass fuels and wildfire smoke, and respiratory outcomes in children and adults. These studies include respiratory symptoms, the growth of lung function, exacerbations of asthma, and incident asthma.

- 1. Mortimer KM, Neugebauer R, Lurmann F, **Balmes JR**, Tager IB. The effect of prenatal and lifetime exposure to air pollution on the pulmonary function of asthmatic children. Epidemiology 2008;19:550-557. discussion 561-562.
- 2. Neophytou AM, White MJ, Oh SS, Thakur N, Galanter JM, Nishimura KK, Pino-Yanes M, Torgerson DG, Gignoux CR, Eng C, Nguyen EA, Hu D, Mak AC, Kumar R, Seibold MA, Davis A, Farber HJ, Meade K, Avila PC, Serebrisky D, Lenoir MA, Brigino-Buenaventura E, Rodriguez-Cintron W, Bibbins-Domingo K, Thyne SM, Williams LK, Sen S, Gilliland FD, Gauderman WJ, Rodriguez-Santana JR, Lurmann F, **Balmes JR**, Eisen EA, Burchard EG. Air pollution and lung function in minority youth with asthma in the GALA II & SAGE II studies. Am J Respir Crit Care Med 2016;193(11):1271-1280. PMCID: PMC4910900.
- 3. Smith KR, McCracken JP, Weber MW, Hubbard A, Jenny A, Thompson LM, **Balmes J**, Diaz A, Arana B, Bruce N. Effect of reduction in household air pollution on childhood pneumonia in Guatemala (RESPIRE): a randomised controlled trial. Lancet 2011 Nov 12; 378(9804):1717-26.
- 4. Reid CE, Jerrett M, Petersen ML, Pfister GG, Morefield PE, Tager IB, Raffuse SM, **Balmes JR**. Spatiotemporal prediction of fine particulate matter during the 2008 northern California wildfires using machine learning. Environ Sci Technol 2015;49(6):3887-96. PMID: 25648639
- 5. Pope D, Diaz E, Smith-Sivertsen T, Lie RT, Bakke P, **Balmes JR**, Smith KR, Bruce NG. Exposure to household air pollution from wood combustion and association with respiratory symptoms and lung function in nonsmoking women: results from the RESPIRE trial, Guatemala. Environ Health Perspect. 2015 Apr;123(4):285-92. PMCID: PMC4384202 6. Reid CE, Jerrett M, Tager IB, Petersen ML, Mann JK, **Balmes JR**. Differential respiratory health effects from the 2008 northern California wildfires: A spatiotemporal approach. Environ Res 2016;150:227-235. PMID: 27318255
- 7. Reid CE, Brauer M, Johnston FH, Jerrett M, **Balmes JR**, Elliott CT. Critical review of health impacts of wildfire smoke exposure. Environ Health Perspect 2016;124(9):1334-43. PMID: 27082891 PMCID: PMC5010409
- 8. Heinzerling AP, Guarnieri MJ, Mann JK, Diaz JV, Thompson LM, Diaz A, Bruce NG, Smith KR, **Balmes JR**. Lung function in woodsmoke-exposed Guatemalan children following a chimney stove intervention. Thorax 2016;71:421-428. PMID: 26966237.
- 9. *Mortimer K, Ndamala CB, Naunje A, Malava J, Katundu C, Weston W, Havens D, Pope D, Bruce N G, Nyirenda M, Wang D, Crampin A, Grigg J, **Balmes J**, Gordon S. A cleaner burning biomass-fueled cookstove intervention to prevent pneumonia in children under 5 years old in rural Malawi (CAPS): a cluster randomized controlled trial. Lancet 2016;389(10065):167–175. PMID: 27939058 PMCID: PMC5783287
- *Best Environmental Epidemiology Paper of the Year Award International Society for Environmental Epidemiology 10. Rylance S, Jewell C, Naunje A, Mbalume F, Chetwood JD, Nightingale R, Zurba L, Flitz G, Gordon SB, Lesosky M, **Balmes JR**, Mortimer K. Non-communicable respiratory disease and air pollution exposure in Malawi: a prospective cohort study. Thorax. 2020 Mar;75(3):220-226. PMCID: PMC7063402

Complete List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/pubmed/?term=balmes+j

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OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

BIOGRAPHICAL SKETCH

NAME: Holm, Stephanie

eRA COMMONS USER NAME: stephaniemholm

POSITION TITLE: Assistant Clinical Professor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE	Completion Date	FIELD OF STUDY
Overather and Oallana Overather and DA	D.A	MM/YYYY	Oli-t
Swarthmore College, Swarthmore, PA	BA	06/2007	Chemistry
University of Pittsburgh School of Medicine	MD	05/2011	Medicine
Children's Hospital and Research Center Oakland	N/A	09/2014	Pediatric Residency
UCSF Benioff Children's Hospital Oakland	N/A	10/2015	Pediatric Pulmonary Fellowship
University of California Berkeley School of Public Health	MPH	05/2017	Epidemiology
University of California San Francisco Division of Occupational and Environmental Medicine	N/A	06/2018	Occupational and Environmental Medicine Residency
University of California Berkeley School of Public Health	PhD	06/2021	Epidemiology

A. Personal Statement

As a physician board-certified in both pediatrics and occupational-environmental medicine, I am passionate about how environmental exposures contribute to child health, with a particular interest in airborne exposures and their contribution to pediatric lung diseases. I felt the draw of working on problems larger than a single patient encounter, yet my grounding in clinical pediatrics provides a useful launch point from which I pursue research in child health. My long-term goals have been to do research, communicate research findings to the public and do regulatory work, and I have been gratified to see that work evolve as I further launch my career. As a Public Health Medical Officer within the California EPA, I collaborate with multiple boards, departments and offices throughout CalEPA on issues surrounding the role of the environment in the health of California's children. In my role as Co-director of the Western States Pediatric Environmental Health Specialty Unit, I have worked on many education and public health communication projects and have particular expertise in disinfectant exposures and wildfire smoke. Working with Dr. Balmes, I have led the AIM project (Airflow Improvements during Meal-prep) and am a collaborator on the Children's Health and Air Pollution Study (CHAPS). Between my expertise in pediatric lung diseases and pediatric environmental epidemiology and Dr. Thakur and Balmes' expertise in adult lung diseases, we bring a breadth of expertise across the lifecourse.

B. Positions and Honors

2020-present Public Health Medical Officer II, Office of Environmental Health Hazard Assessment, Cal EPA

2020-present Graduate Student Researcher, PI: Balmes

2019-present Co-Director, Western States Pediatric Environmental Health Specialty Unit 2018-present Volunteer Assistant Clinical Professor, University of California San Francisco

2018-2019 Graduate Student Instructor in Epidemiology, Biostatistics and Medicine (UC Berkeley)
2018 Educational video editor (Online MPH Program, School of Public Health, UC Berkeley)

2018 Chief Resident, UCSF Occupational and Environmental Medicine Program

2015-2016 Consulting Researcher at UC Berkeley

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- 2018 American Occupational Health Conference Scholarship
- 2017 American Thoracic Society Assembly on Environmental, Occupational and Population Health Abstract Scholarship
- 2011 Richard L. Day Prize for Pediatrics at the Univ of Pittsburgh School of Medicine.
- 2011 Bert and Sally O'Malley Award for Outstanding Medical Student Research at the University of Pittsburgh School of Medicine.
- 2010 Sleep Research Society 2010 Honorable Mention Abstract Award for Scientific Merit

C. Contributions to Science

Health Effects of Air Pollution in Children: I led a dual-cohort study in the East Bay Area of Northern California, which found that both living with a smoker and cooking without the use of a venting range hood contributed to household particulate matter levels and has led to ongoing work assessing the effect of a ventilation intervention during cooking. I have also actively participated in analyses of study findings from the Children's Health and Air Pollution (CHAPS) cohort, demonstrating links between air pollutant exposure and metabolic functioning in children. I also recently published a systematic review of the effects of ozone exposure on lung function, which focused heavily on pediatric exposures as much of the recent literature has been related to long-term ozone exposure in children.

- 1. **Holm SM**, Gillette D, Balmes JR, Hartin K, Seto E, Lindeman D, Polanco D, Fong E "Cooking Behaviors are Related to Household Particulate Matter Exposure in Children with Asthma in the Urban East Bay Area of Northern California," *Plos One*, 13:6 (2018), e0197199
- 2. Zhang A, Balmes JR, Lutzker L, Mann J, Margolis H, Tyner T, Holland N, Noth E, Lurman F, Hammond SK, **Holm SM**. "Traffic-Related Air Pollution, Biomarkers of Metabolic Dysfunction, Oxidative stress, and CC16 in Children," *JESEE*, 2021 Aug 20
- 3. Mann JK, Lutzker L, **Holm SM**, Margolis HG, Neophytou AM, Eisen EA, Costello S, Tyner T, Holland N, Tindula G, Prunicki M, Nadeau K, Noth EM, Lurmann F, Hammond SK, Balmes JR. "Traffic-Related Air Pollution is Associated with Glucose Dysregulation, Blood Pressure and Oxidative Stress in Children," *Environ Res.* 2021 Apr, *195*, 110870
- 4. **Holm SM**, Balmes JR "Systematic Review of Ozone Effects on Human Lung Function, 2013-2020," *CHEST*, 2021 Aug 10

Environmental Pediatrics:

As Co-director of the Region 9 (Western States) Pediatric Environmental Health Specialty Unit, I have expertise in translating scientific knowledge for diverse audiences and have recently led two major projects: reviewing literature relating to potential effects of exposure to disinfectant products among young children in childcare settings and writing a review paper on the state of the epidemiologic literature regarding children's health and exposure to wildfire smoke, as well as considerations for public health responses to wildfire smoke events. I have also been part of the effort leading working groups of diverse public health stakeholders to reach uniform public health recommendations for wildfire smoke guidance regarding children and have given national webinars on this topic as well. As part of that work, I recently spoke about mask and respirator use by children as part of a National Academies of Science, Engineering and Medicine (NASEM) Workshop, and have since been serving on a NASEM committee addressing respiratory protection for the public.

- 1. **Holm SM**, "Respiratory Protection in Children," National Academies of Science, Engineering and Medicine Workshop: Current Issues in the Assessment of Respiratory Protective Devices, August 4, 2020
- 2. **Holm SM**, Miller MD, Balmes JR. "Health effects of wildfire smoke in children and public health tools: a narrative review." *JESEE*, 2021 Feb; 31(1):1-20
- 3. **Holm SM**, Leonard V, Durrani T, Miller MD. "Do We Know How Best to Disinfect Child Care Sites," *American Journal of Infection Control*, 47:1 (2019), 82-91

Complete List of Published Work in MyBibliography:

https://www.ncbi.nlm.nih.gov/myncbi/stephanie.holm.1/bibliography/public/

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BIOGRAPHICAL SKETCH New/Early Stage Investigator

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Rosemarie de la Rosa

eRA COMMONS USER NAME (credential, e.g., agency login): rmd1025

POSITION TITLE: Assistant Professor

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
BS	06/2010	Biology
MPH	05/2014	Environmental Health Science
PhD	08/2019	Environmental Health Science
Postdoctoral	06/2021	Medicine
	(if applicable) BS MPH PhD	(if applicable) Date MM/YYYY BS 06/2010 MPH 05/2014 PhD 08/2019

A. Personal Statement

I am an Assistant Professor at UC Berkeley in the Division of Environmental Health Sciences. My research aims to understand how the social environment during early and middle childhood influences susceptibility to the toxic effects of chemical exposures. As a doctoral student at UC Berkeley, I was funded by an EPA Science to Achieve Results (STAR) Graduate Fellowship to identify environmental chemicals that interact with glucocorticoid receptor signaling, a stress-induced pathway that has systemic effects on human physiology. I have also published on assessing cumulative risk from multiple environmental stressors using exposomics. I began collaborating with Dr. Thakur as a postdoctoral scholar examining the relationship between adverse childhood experiences and stress-related biomarkers in a diverse and low-income pediatric population. Through this work, I identified a biomarker profile related to metabolic dysregulation among a subset of children that reported high experiences of adverse childhood experiences. Collectively, my training in environmental health, toxicology, and molecular epidemiology has provided me with the foundation to conduct research assessing the independent and joint effect of chemical and non-chemical stressors on human health.

B. Positions and Honors

2010 - 2012	Research Assistant, Children's Hospital Boston
2012 - 2019	Graduate Student Researcher, University of California Berkeley
2019 - 2021	Postdoctoral Scholar, University of California San Francisco
2021 - Present	Assistant Professor, Division of Environmental Health Sciences, School of
	Public Health, University of California Berkeley

Professional Memberships

2016 - Present Member, Society of Toxicology (SOT)2020 - Present Member, American Thoracic Society

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<u>Honors</u>	
2014	Chancellor's Fellowship, University of California, Berkeley
2015	EPA STAR Graduate Fellowship
2017	KC Donnelly Externship Award, National Institute of Environmental Health Sciences
2017	Minority in Cancer Research Award, American Association for Cancer Research
2017	Best Student Paper Award, Environmental and Molecular Mutagenesis
2019	University of California President's Postdoctoral Fellowship
2020	Telomere Research Network Pilot Award

C. Contributions to Science

- 1. <u>Arsenic toxicity and susceptibility</u>. I worked with Dr. Craig Steinmaus to examine the long-term health effects of arsenic exposure. I conducted the first epidemiologic study demonstrating a direct association between genetic differences in AS3MT, the primary enzyme involved in arsenic metabolism, and arsenic-related internal cancer risk. I also found that early-life arsenic exposure was associated with decreased plasma glucocorticoid levels in adulthood, providing preliminary evidence that arsenic may act as an endocrine disruptor of the hypothalamic-pituitary-adrenal axis in humans.
 - a. **de la Rosa R**, Steinmaus C, Akers NK, Conde L, Ferreccio C, Kalman D, Zhang KR, Skibola CF, Smith AH, Zhang L, Smith MT (2017) Associations between arsenic (+3 oxidation state) methyltransferase (AS3MT) and N-6 adenine-specific DNA methyltransferase 1 (N6AMT1) polymorphisms, arsenic metabolism, and cancer risk in a Chilean population. *Environ. Mol. Mutagen.* 58, 411–422.
 - b. Early-life arsenic exposure has a long-term effect on plasma glucocorticoid levels. Society of Toxicology 57th Annual Meeting, San Antonio, TX, March 13, 2018.
- 2. Chemicals and glucocorticoid receptor signaling. The overall objective of my doctoral work was to investigate the effect of environmental chemicals on glucocorticoid receptor signaling. As part of this project, I developed a bioassay to identify environmental chemicals that modulate glucocorticoid receptor activation. I was also a recipient of a KC Donnelly Externship Award from NIEHS to develop additivity models that predict the joint effect of chemical mixtures on glucocorticoid receptor signaling.
 - a. **de la Rosa R**, Vazquez S, Tachachartvanich P, Daniels SI, Sillé F, Smith MT. (2020) Development of a Cell-Based Bioassay to Screen Environmental Chemicals and Human Serum for Glucocorticogenic Activity. *Environmental Toxicology and Chemistry*.
 - b. **de la Rosa R**, Schlezinger JJ, Smith MT, Webster TF. (2020) Application of Generalized Concentration Addition to Predict Mixture Effects of Glucocorticoid Receptor Ligands. *Toxicology in Vitro*.
- 3. Exposome and cumulative risk. Dr. Martyn Smith and I proposed using exposomics to measure cumulative risk in a review paper and book chapter that we co-authored. I contributed to these projects by proposing potential exposomic methods that could be used to measure the combined effect of chronic psychosocial stress and environmental exposures on human health.
 - a. Smith MT, **de la Rosa R**, Daniels SI (2015) Using exposomics to assess cumulative risks and promote health. *Environ. Mol. Mutagen.* 56, 715–723.
 - b. Smith MT, McHale CM, **de la Rosa R** (2019) Using exposomics to assess cumulative risks from multiple environmental stressors. In Dagnino S & Macherone A (Eds.), Unraveling the exposome: A Practical View, 3–22. Springer International Publishing.
- 4. <u>Biological embedding of psychosocial stress</u>. As a Presidential Postdoctoral Fellow, I worked with Dr. Neeta Thakur to explore the association between adverse childhood experiences and stress-related biomarkers during early- and mid- childhood. I characterized allostatic load, or the cumulative burden of stress on the body, in a low-income and predominantly Black pediatric population. I also set up a protocol to quantify telomere length, which allowed us to examine the relationship between various psychosocial stressors and cellular aging.
 - a. Measuring the Biological Impact of Childhood Trauma and Resilience in a Diverse Pediatric Population. UC President's Postdoctoral Fellowship Program Spring Meeting, April 18, 2020.

	BIOGRAPHI	CAL SKETCH	
NAME: Elizabeth M. Noth, PhD MPH		POSITION TITLE	: Associate Researcher
ADDRESS: 2121 Berkeley Way, Berkeley, CA 94	720		
EDUCATION/TRAINING			
INSTITUTION AND LOCATION	DEGREE	MM/YY	FIELD OF STUDY
University of California, Berkeley	B.S.	05/1996	Conservation and Resource Studies
Boston University, School of Public Health	M.P.H.	01/2000	Environmental Health

05/2009

Environmental Health Sciences

PhD

A. Personal Statement

University of California, Berkeley

I am an exposure assessment scientist with over 20 years of experience in air pollution exposure assessment for children's exposures. Over the last 5 years, I have focused on air pollution exposures that are either extremely high (e.g., during light metal manufacturing) or impact vulnerable populations (e.g., children and pregnant women). My contributions on two major environmental epidemiology studies focus on the San Joaquin Valley in California: developing spatial-temporal air pollution models for criteria pollutants and polycyclic aromatic hydrocarbons to calculate daily exposure estimates for every child on every day of an 8-year follow-up period for the Fresno Asthmatic Children's Environment Study, and on every day of a 5-year follow-up period, plus lifetime exposures for children, for the Children's Health and Air Pollution National Children's Environmental Health Center. More recently, in collaboration with Drs. Thakur and Balmes, I have extended my work to Richmond, CA through the REACH study. My research also includes occupational exposure assessment because of my concern for the very high concentrations that workers are exposed to from such air pollutants as particulate matter, polycyclic aromatic hydrocarbons, fluorides and more in hot environments with high physical demand.

B. Positions and Honors

2000-2009	Graduate Student Researcher in Environmental Health Sciences, University of California, Berkeley, CA
2001-2003	Research Scientist on contract to California Environmental Health Investigations Branch, Impact
	Assessment, Oakland, CA
2009-2013	Post-doctoral Scholar, Environmental Health Sciences, School of Public Health, University of California, Berkeley
2013-2019	Assistant Researcher, Environmental Health Sciences, School of Public Health, University of California, Berkeley
2016-present	Consultant on CHEST Foundation/Pulmonary Fibrosis Foundation Clinical Research Grant in Pulmonary
	Fibrosis. (PI: Kerri Johannson, MD., University of Calgary.)
2018-present	Scientific Director, Lecturer and Mentor for Interdisciplinary Global Endeavors in Technology and
	Education (IGNITE) and Project AIR (Action, Innovation, Research)
2019-present	Associate Researcher, Environmental Health Sciences, School of Public Health, University of California,
·	Berkeley
<u>Honors</u>	
1998-2000	Boston University School of Public Health, Dean's Scholarship
2001-2002	University of California, Berkeley, Regent's Fellowship
2004-2005	Marian Rennie Benson Fellowship, University of California Berkeley Public Health Alumni Association.

C. Selected Peer-reviewed Publications – Full bibliography available at

https://www.ncbi.nlm.nih.gov/myncbi/elizabeth.noth.1/bibliography/public/

- 1. Zhang AL, Balmes JR, Lutzker L, Mann JK, Margolis HG, Tyner T, Holland N, **Noth EM**, Lurmann F, Hammond SK and Holm SM. (2021) "Traffic-related air pollution, biomarkers of metabolic dysfunction, oxidative stress, and CC16 in children." *J Expo Sci Environ Epidemiol. In press*
- 2. Mann JK, Lutzker L, Holm SM, Margolis HG, Neophytou AM, Eisen EA, Costello S, Tyner T, Holland N, Tindula G, Prunicki M, Nadeau K, **Noth EM**, Lurmann F, Hammond SK, Balmes JR. (2021) Traffic-related air pollution is associated with glucose dysregulation, blood pressure, and oxidative stress in children. *Environ Research* 195:110870.

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- 3. Prunicki M, Cauwenberghs N, Lee J, Zhou X, Movassagh H, **Noth E**, Lurmann F, Hammond K, Balmes JR, Desai M, Wu JC, Nadeau KC. (2021) Air pollution exposure is linked with methylation of immunoregulatory genes, altered immune cell profiles, and increased blood pressure in children. Nature Scientific Reports 11(4067). Published Feb 18, 2021.
- 4. **Noth EM,** Lurmann F, Perrino C, Vaughn D, Minor HA, Hammond SK. (2020) "Decrease in Ambient Polycyclic Aromatic Hydrocarbon Concentrations in California's San Joaquin Valley 2000-2019." *Atmospheric Environment* 242, 117818.
- 5. Navarro K, Cisneros R, Chowdhary P, **Noth EM**, Balmes J, Hammond SK. (2019) "Incident Command Post Exposure to Polycyclic Aromatic Hydrocarbons and Particulate Matter during a Wildfire." *Journal of Occupational & Environmental Hygiene* 16(11):735-744
- 6. Navarro K, Cisneros R, **Noth EM**, Balmes JR, Hammond SK (2017). "Occupational Exposure to Polycyclic Aromatic Hydrocarbon of Wildland Firefighters at Prescribed and Wildland Fires." *Environmental Science & Technology* 51(11): 6461–6469

D. Research Support (ongoing + completed in last 3 years, sort by relevance)

California Air Resources Board 19RD003(PI: Hammond)

3/15/2020 – 3/14/2023

Air Pollution Measurements, Exposure Assessment, and Evaluation of the Sources of Particulate Matter in Fresno, CA: The objectives of this study are to a) understand the sources of particulate matter (PM) exposures to residents of Fresno and Clovis and b) estimate concentrations of polycyclic aromatic hydrocarbons, black carbon, brown carbon, and PM from each of these sources at the neighborhood level. We will focus on disentangling the sources of PM exposures (PM originating from traffic-related sources from other combustion sources, e.g., residential wood burning, agricultural burning, prescribed burns, and wildfires. Role: Co-Investigator, Key personnel.

NIEHS R01 ES031261 (PI: Padula, UCSF, subaward PI: Noth)

6/18/2020 – 3/31/2025

Wilafires and intentional biomass burning in California and Preterm Birth

Our overall goal is to study how mothers' exposures to wildfire and intentional biomass burning(i.e. prescribed burns, agricultural fires and residential wood burning) during pregnancy may affect whether her baby is born prematurely. We will also evaluate the role of neighborhood deprivation and race/ethnicity may modify the relationship between fire exposures and preterm birth. Role: Principal Investigator (subaward to UCB)

California Air Resources Board 20RD012 (PI: Noth)

4/1/2021 - 3/31/2023

Title: San Joaquin Valley Pollution and Health Environmental Research Study (SPHERE)

This study will be the first in California to measure indoor and outdoor noise levels concurrent with air quality and develop cumulative exposure metrics characterizing exposures to mixtures of air pollutants and noise. The information collected will foster unique insight into how disparities in air quality and noise exposures affect the health of California residents in disadvantaged communities. Role: Principal Investigator

California Office of Environmental Health Hazard Assessment, 19-E0020 (PI: Noth)

05/1/2020 – 04/30/2022

Pilot Air Quality Study for an AB617 Community (PAQS-AB617): The goal of this Pilot Air Quality Study in an AB 617 community is to measure ambient concentrations of selected airborne polycyclic aromatic hydrocarbons (PAHs) at appropriate locations to complement the targeted biomonitoring study being carried out the Office of Environmental

Health Hazard Assessment (OEHHA). Role: Principal Investigator

NIEHS R24 ES030888 (MPIs: Balmes, Holland, Noth)

2/15/2020-2/14/2025

CHAPS Cohort Maintenance: The major goal of this project is to continue longitudinal follow-up of the participants in the Children's Health and Air Pollution Study (CHAPS), an epidemiological study that has focused on the effects of air pollution on children growing up in the San Joaquin Valley of California, one of the most polluted areas in the country. Role: Principal Investigator

NIH NIA 5R01 AG026291-1 (PI: Cullen)

9/1/2017 - 5/31/2022

Disease, Disability and Death in an Aging Workforce: To assess the impact on health and function of ubiquitous physical hazards in the work environment as they relate to the preventable causes of the major chronic diseases of working age adults—ischemic heart disease, asthma, musculoskeletal disorders and COPD. Role: Co-Investigator

FOTINI (TINA) KATOPODES CHOW

PROFESSIONAL PREPARATION

Harvard University	Cambridge, MA	Engineering Science (summa cum laude)	B.S. 1998
Stanford University	Stanford, CA	Civil & Environmental Engineering	M.S. 1999
Stanford University	Stanford, CA	Civil & Environmental Engineering	PhD 2004
		(Environmental Fluid Mechanics &	
		Hydrology)	
Lawrence Livermore	Livermore, CA	Atmospheric sciences, post-doctoral	Aug 2004 –
National Laboratory		researcher	Jun 2005

APPOINTMENTS	
2016-present	Professor, Civil & Environmental Engineering
	University of California, Berkeley
2011-2016	Associate Professor, Civil & Environmental Engineering
	University of California, Berkeley
2005-2011	Assistant Professor, Civil & Environmental Engineering
	Halicanita of California Danieles

University of California, Berkeley

2004-2005 Consulting Assistant Prof., Civil & Environmental Engineering, Stanford

SELECTED HONORS

- UC Berkeley Chancellor's Public Scholar Faculty Fellowship, 2021
- Extraordinary Teaching in Extraordinary Times, 2021 (campus-wide award)
- Henry G. Houghton Award, American Meteorological Society, 2016
- Presidential Early Career Award for Scientists and Engineers (DOE PECASE), 2011
- National Science Foundation CAREER Award, 2007-2012
- UC Berkeley Hellman Family Faculty Fund award, 2007

PUBLICATIONS (published articles available at https://chow.ce.berkeley.edu/)

Related:

Chow, F.K., Yu, K., Young, A., James, E., Grell, G., Csiszar, I.A., Tsidulko, M., Freitas, S., Pereira, G., Giglio, L., and R. Ahmadov. 2021. High-resolution smoke forecasting for the 2018 Camp Fire in California, *Bulletin of the American Meteorological Society,* under review (minor revisions requested). *See also:*

https://agu.confex.com/agu/fm20/meetingapp.cgi/Paper/772370

Chen, B., Chow, F.K., and T. Thompson. 2020. Simulations to support local source apportionment using forward and inverse simulations of urban dispersion at the micro-scale. Abstract A065-0012 presented at 2020 AGU Fall Meeting, online, 1-17 December. https://agu.confex.com/agu/fm20/meetingapp.cgi/Paper/773000 [Paper in prep for submission 12/2021 to Atmospheric Environment]

Wiersema, D.J., Lundquist, K.A. and F.K. Chow. 2020. Mesoscale to microscale simulations over complex terrain with the immersed boundary method in the Weather Research and Forecasting model. *Monthly Weather Review* **148**(2), 577–595.

Michioka, T. and F.K. Chow. 2008. High-resolution large-eddy simulations of scalar transport in atmospheric boundary layer flow over complex terrain. *Journal of Applied Meteorology and Climatology* **47**(12), 3150-3169.

Chow, F.K., Kosovic, B., and S.T. Chan. 2008. Source inversion for dispersion in urban environments using building-resolving simulations and Bayesian inference with stochastic sampling. *Journal of Applied Meteorology and Climatology* **47**(6), 1553–1572.

Other significant products:

- Arthur, R.S., Mirocha, J.D., Marjanovic, N., Hirth, B.D., Schroeder, J.L., Wharton, S. and F.K. Chow. 2020. Multi-scale simulation of wind farm performance during a frontal passage. *Atmosphere* **11**(1), 245, 1-17.
- Chow, F.K., Schär, C., Ban, N., Lundquist, K.A., Schlemmer, L. and X. Shi. 2019. Crossing multiple gray zones in the transition from mesoscale to microscale simulation over complex terrain. *Atmosphere* **10**(5), 274, 1-38.
- Simon, J.S., Zhou, B., Mirocha, J.D., and F.K. Chow. 2019. Explicit filtering and reconstruction to reduce grid dependence in convective boundary layer simulations using WRF-LES. *Monthly Weather Review* **147**(5), 1805-1821.
- Taylor, D., Chow, F.K., Delkash, M., and P.T. Imhoff. 2018. Atmospheric modeling to assess wind dependence in tracer dilution method measurements of landfill methane emissions. *Waste Management* **73**(3), 197-209.
- Bao, J., Chow, F.K., and K.A. Lundquist. 2018. Large-eddy simulation over complex terrain using an improved immersed boundary method in the Weather Research and Forecasting model, *Monthly Weather Review* **146**(9), 2781-2797.

SYNERGISTIC ACTIVITIES

- 1. Expert in development and applications of atmospheric transport modeling over complex terrain and urban areas
- 2. Led community-engaged student design projects to improve air quality for the Stockton AB 617 community in 2021, with Little Manila Rising and other nonprofit organizations.
- 3. Developed micro-scale simulations for local source apportionment, with Environmental Defense Fund, focused in West Oakland, CA.
- 4. Editor for the *Journal of Atmospheric Sciences* (2016-2020)
- 5. NCAR Research Applications Lab Advisory Panel Member (2021)
- 6. AMS Mountain Meteorology Committee Member (2006-2008, 2016-2018)
- 7. Co-taught new graduate seminar on planetary boundaries, the Anthropocene, and systems thinking (2018, 2020, 2021)
- 8. Organized and participated in numerous workshops on diversity, equity and inclusion in engineering education and research (2017-present)
- 9. Vice Chair for Graduate Studies, Civil and Environmental Engineering department (2019-present)
- 10. Program leader for UC Berkeley Environmental Engineering program, including creation of new graduate professional development events (2017-2020).

Wanyu Rengie Chan, Ph.D.

Professional Preparation

Ph.D University of California, Berkeley

Environmental Engineering Program, Civil & Environmental Engineering, 2006

MS University of California, Berkeley

Civil & Environmental Engineering, 2002

BS Carnegie Mellon University, Pittsburgh PA

Chemical Engineering, 2001

Affiliation

Research Scientist, Deputy Group Leader, Indoor Environment Group, Lawrence Berkeley National Laboratory

Expertise

Indoor air quality, indoor air pollutant transport and fate, field studies measuring occupant exposure and indoor environmental quality, building science, building air leakage, filtration

Experience Summary

Dr. Chan is a Research Scientist with 20+ experience studying indoor air quality. Her work focus on characterizing human exposures to indoor air pollutants in buildings, and the implications to energy use and occupant health. She served on a committee organized by the National Academies of Sciences, Engineering, and Medicine on the topic of indoor exposure to fine particulate matter and mitigation. She led field studies to evaluate the role of kitchen and dwelling ventilation on indoor air quality in 90+ new California single-family homes and retrofitted apartments. The projects were funded by California Energy Commission (CEC), involving multiple collaborators. Dr. Chan is part of an ongoing project funded by the Department of Energy, Building America Program to study indoor air quality in new homes across different U.S. regions. Dr. Chan published several papers on the health benefits of improved filtration and ventilation. Dr. Chan joined the Laboratory as a graduate student and worked on the evaluation of shelter-in-place effectiveness. She collaborated with the National Atmospheric Release Advisory Center to develop an operational indoor model that has been applied in advising emergency responders on protecting buildings against accidental or intentional chemical or biological releases.

Publications

Most closely related to the proposed project

- 1. Zhao H., W.R. Chan, S. Cohn, W.W. Delp, I.S. Walker, and B.C. Singer. 2020. Indoor air quality in new and renovated low-income apartments with mechanical ventilation and natural gas cooking in California. *Indoor Air*. DOI: 10.1111/ina.12764.
- 2. Tang H., W.R. Chan, and M.D. Sohn. 2020. Automating the interpretation of PM2.5 time-resolved measurements using a data-driven approach. *Indoor Air*. DOI: 10.1111/ina.12780.
- 3. Chan W.R., J.M. Logue, X. Wu, N.E. Klepeis, W.J. Fisk, F. Noris, and B.C. Singer. 2018. Quantifying fine particle emission events from time-resolved measurements: method description and application to 18 California low-income apartments. *Indoor Air* 28(1), 89–101. DOI: 10.1111/ina.12425.
- 4. Fisk W.J. and W.R. Chan. 2016. Health benefits and costs of filtration interventions that reduce indoor exposure to PM2.5 during wildfires. *Indoor Air* 27(1), 191–204. DOI: 10.1111/ina.12285.

5. Chan W.R., J. Joh, and M.H. Sherman. 2013. Analysis of air leakage measurements of US houses. *Energy and Buildings* 66, 616–625. DOI: 10.1016/j.enbuild.2013.07.047.

Other significant publications

- 1. Laumbach R.J., K.R. Cromar, G. Adamkiewicz, C. Carlsten, D. Charpin, W.R. Chan, A. de Nazelle, F. Forastiere, J. Goldstein, S. Gumy, W.K. Hallman, M. Jerrett, H.M. Kipen, C.S. Pirozzi, B.J. Polivka, J. Radbel, R.E. Shaffer, D.D. Sin, and G. Viegi. 2021. Personal interventions for reducing exposure and risk for outdoor air pollution. *An Cificial American Thoracic Society Workshop Report*. DOI: 10.1513/AnnalsATS.202104-421ST.
- 2. Zhao H., W.R. Chan, W.W. Delp, H. Tang, I.S. Walker, and B.C. Singer. 2020. Factors impacting range hood use in California houses and low-income apartments. *International Journal of Environmental Research and Public Health* 17(23), 8870. DOI: 10.3390/ijerph17238870.
- 3. Fisk W.J., B.C. Singer, and W.R. Chan. 2020. Association of residential energy efficiency retrofits with indoor environmental quality, comfort, and health: A review of empirical data. *Building and Environment* 180. DOI: 10.1016/j.buildenv.2020.107067.
- 4. Fischer M.L., W.R. Chan, W.W. Delp, S. Jeong, V.H. Rapp, and Z. Zhu. 2018. An estimate of natural gas methane emissions from California homes. *Environmental Science & Technology* 52(17), 10205–10213. DOI:10.1021/acs.est.8b03217.
- 5. Chan W.R., W.W. Nazaroff, P.N. Price, M.D. Sohn, and A.J. Gadgil. 2005. Analyzing a database of residential air leakage in the United States. *Atmospheric Environment* 39, 3445–3455.

Synergistic Activities

- 1. PI for Indoor Air Quality Scientific Findings Resource Bank project, sponsored by U.S. Environmental Protection Agency (2018–Current). The goal of this project is to continuedly assess the benefits from specific measure to improve indoor environmental quality through conducting literature reviews and scientific evaluation on the effect to occupant health.
- 2. Work lead for Indoor Air Quality in New Homes study sponsored by Department of Energy, Building America Program (2018–Current). The study goal is to collect indoor air contaminant and building characteristics in a broad range of new homes in different U.S. climates. Results from this study will inform standards and technology development to enable acceptable IAQ and energy goals.
- 3. Project team supporting the proposed rule change for manufactured home (2020–Current). Conduct literature search and modeling of indoor air quality as a result of the proposed rule change on air sealing, duct leakage, and ventilation of manufactured homes. This work is sponsored by the Department of Energy, Building America Program.
- 4. Co-PI for Effective Kitchen Ventilation for Healthy Zero-Net Energy Homes with Natural Gas project, sponsored by California Energy Commission (2017–2019). The project goal is to inform residential codes and standards that protect indoor air quality and health, focusing on kitchen ventilation requirements to enable effective control in homes with gas cooking.
- 5. Field study lead for Healthy Efficient New Gas Home (HENGH) project, sponsored by California Energy Commission (2014–2018). Field study of new California single-family homes evaluated the role of mechanical ventilation on indoor air quality. Results led to better enforcement of mechanical ventilation system labeling to inform occupants and ensure more compliance with standards.

Biographical Sketch: Thomas W. Kirchstetter

Energy Technologies Area • Lawrence Berkeley National Laboratory MS90-4026B, Berkeley, California 94720 • Phone: 510-486-7071 • Email: twkirchstetter@lbl.gov

Department of Civil and Environmental Engineering • University of California at Berkeley 655 Davis Hall, Berkeley, California 94720 • Phone: 510-908-1237 • Email: twkirchstetter@berkeley.edu

(a) Professional Preparation

Alexander Hollaender Distinguished Postdoctoral Fellow, LBNL, 1998 – 2000

Ph.D. Environmental Engineering, University of California at Berkeley, 1998

M.S. Environmental Engineering, University of California at Berkeley, 1994

B.S. Atmospheric Science and Mathematics, State University of New York at Albany, 1991

(b) Appointments

Lawrence Berkeley National Laboratory, Energy Analysis & Environmental Impacts Division Senior Scientist and Scientific Division Director, 2017 – present

Primary steward of research, people, and safety of a scientific division of 160 researchers that connect science and technology with economics and policy by measuring and analyzing energy use and emissions to the environment and providing robust data-driven analysis that informs energy technology development and decision making in the implementation of energy technologies in the transportation, building, electricity, and manufacturing sectors

Previous appointments at Berkeley Lab
Department Head, Sustainable Energy and Environmental Systems, 2015 – 2020
Group Leader, Sustainable Energy Systems, 2015 – 2017
Staff Scientist, 2000 – 2018

University of California Berkeley, Department of Civil & Environmental Engineering Adjunct Professor, 2018 – present

Teach environmental engineering courses • Lead world class research • Principal advisor of graduate student thesis research • PhD student exam committee service

Previous appointments at UC Berkeley: Associate Adjunct Professor, 2011 – 2018; Lecturer, 2005–2011

Research interests: Air pollution science & technology: Pollutant emissions and controls • Climate and environmental impacts of transportation • Pollutant measurement technologies, development of low-cost sensors, and community air monitoring networks • Chemical and optical characterization of biomass burning and carbonaceous aerosols • Environmental impacts of municipal solid waste-to-energy

(c) Selected Other Professional Service and Synergistic Activities

- Co-founder and Chair of Oppenheimer Leadership Network, 2020 present
- Member, LBNL Diversity, Equity and Inclusion, Division Director Accountability Committee, 2019
- Member, SMART Mobility Steering Committee, Vehicle Technologies Office, DOE, 2018 2020
- Editor, Aerosol Science and Technology Journal, 2013 2018
- Organizer, International Conference on Carbonaceous Particles in the Atmosphere, 2000 2018
- Contributor, EPA's Integrated Science Assessment for particulate patter welfare effects 2016
- Editor, Journal of Atmospheric Chemistry and Physics, 2006 2013
- Member, Distinguished Lecture Series Committee, Lawrence Berkeley National Lab, 2011 2013

TW Kirchstetter, Oct 2021

(d) Selected Honors

- Nominated Berkley Lab Participant, Oppenheimer Science & Energy Leadership Program, 2019
- R&D 100 Award Winner, Cool Roof Time Machine, 2017
- Outstanding Mentor Award, DOE, Office of Science Undergraduate Research Program, 2005
- Alexander Hollaender Distinguished Postdoctoral Fellowship, Department of Energy, 1998
- Golden West Section Graduate Scholarship, Air & Waste Management Association, 1994
- Science and Engineering Research Semester Award, Department of Energy, 1992

(e) Patents

- Patent 9,856,383, "Mixture and method for simulating soiling and weathering of surfaces" Inventors: Sleiman, M; Kirchstetter, T; Destaillats, H; Levinson, R; Berdahl, P; Akbari, H, Issued January 2018
- Patent 10,495,573, "Instrument for measuring airborne particulate matter" Inventors: Caubel JJ, Cados TE, Kirchstetter, TW, Issued December 2019

(f) Select Peer-Reviewed Journal Publications (out of 85 total)

(Google Scholar h-index = 49, citations = 10,300; Web of Science h-index = 43, citations = 7,000)

- 85. Singer, BC; Zhao, H; Preble, CV; Delp, WW; Pantelic, J; Sohn, MD; Kirchstetter, TK (2021), Measured Influence of Overhead HVAC on Exposure to Airborne Contaminants from Simulated Speaking in a Meeting and a Classroom, *Indoor Air*, doi.org/10.1111/ina.12917
- 79. Preble, CV; Harley, RA; Kirchstetter, TW (2019) Control Technology-Driven Changes to In-Use Heavy-Duty Diesel Truck Emissions of Nitrogenous Species and Related Environmental Impacts, *Environ. Sci. Technol.*, doi:10.1021/acs.est.9b04763
- 78. Caubel, JJ; Cados, TE; Preble, CV; Kirchstetter, TW (2019) A Distributed Network of 100 Black Carbon Sensors for 100 Days of Air Quality Monitoring in West Oakland, California, *Environ. Sci. Technol.*, doi:10.1021/acs.est.9b00282
- 73. Caubel, JJ; Cados, TE; Kirchstetter, TW (2018) A New Black Carbon Sensor for Dense Air Quality Monitoring Networks, *Sensors*, 18, 738, doi.org/10.3390/s18030738
- 72. Apte, JS; Messier, KP; Gani, S; Brauer, M; Kirchstetter, TW; Lunden, MM; Marshall, JD; Portier, CJ; Vermeulen, RCH; Hamburg, SP (2017) High-resolution air pollution mapping with Google Street View cars: exploiting big data, *Environ. Sci. Technol.*, doi: 10.1021/acs.est.7b00891
- 68. Preble, CV, Dallmann, TR; Kreisberg, NM; Hering, SV; Harley, RA; Kirchstetter, TW (2015) Effects of particle filters and selective catalytic reduction on heavy-duty diesel drayage truck emissions at the Port of Oakland, *Environ. Sci. Technol.*, doi:10.1021/acs.est.5b01117
- 62. Thatcher, TL; Kirchstetter, TW; Malejan, CJ; Ward, CE (2014) Infiltration of black carbon particles from residential woodsmoke into nearby homes, *Open J. Air Poll.*, *3*, doi:10.4236/ojap.2014.34011.
- 54. Hadley, OL; Kirchstetter, TW (2012) Black carbon snow albedo reduction, *Nature Climate Change*, 2, 437-440, doi: 10.1038/NCLIMATE1433.
- 51. Kirchstetter, TW; Thatcher, TL (2012) Contribution of organic carbon to wood smoke particulate matter absorption of solar radiation, *Atmos. Chem. Phys.*, 12, 1-6, doi:10.5194/acp-12-1-2012.
- 31. Kirchstetter, T.W.; Novakov, T. (2007) Controlled generation of black carbon particles from a diffusion flame and applications in evaluating black carbon measurement methods. *Atmos. Environ.*, *41*, 1874-1888, doi:10.1016/j.atmosenv.2006.10.067.
- 24. Kirchstetter, TW; Novakov, T; Hobbs, PV. (2004) Evidence that spectral light absorption by aerosols emitted from biomass burning and motor vehicles is different due to organic carbon. *J. Geophys. Res.*, 109, D21208, doi:10.1029/2004JD004999.

BIOGRAPHICAL SKETCH

NAME Rupa Basu	POSITION TITLE Chief, Air and Climate Epidemiology Section
eRA COMMONS USER NAME (credential, e.g., agency login) rupabasu	
EDITCATION/TDAINING	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
University of California, San Diego, CA	B.S.	06/94	Biology
University of California, Los Angeles, CA	M.P.H.	12/95	Environmental Health
The Johns Hopkins University, Baltimore, MD	Ph.D.	10/01	Epidemiology

A. Personal Statement

I am an epidemiologist and Chief of the Air and Climate Epidemiology Section at the Office of Environmental Health Hazard Assessment (OEHHA), California Environmental Protection Agency with over two decades of experience. My area of expertise is on health effects associated with climate change exposures, such as heat/temperature, air pollutants, and wildfire smoke, while identifying vulnerable subgroups to help prevention efforts. I also focus my research on current methodologic approaches for conducting epidemiologic studies, including the time-stratified case-crossover and times-series study designs. I have collaborated with external agencies such as the Scripps Institute of Oceanography and the Kaiser Division of Research as well as several statewide and national climate change investigators. I have been an invited guest speaker on many occasions from academic settings in addition to governmental leaders, such as former Governor Schwarzenegger. My work is widely cited and has received media attention, including *The New York Times*, *LA Times*, and NPR. I have served as a referee for many health journals and have reviewed several grant proposals and reports for federal and state governmental agencies.

B. Positions POSITIONS

<u> </u>	
2002-2003	Environmental Scientist, U.S. Environmental Protection Agency, Washington, DC
2003-2005	Senior Scientist, Exponent Inc., Washington, DC and Oakland, CA
2005-2014	Research Scientist III, Office of Environmental Health Hazard Assessment, Oakland, CA
2014-	Section Chief, Air and Climate Epidemiology Section, Office of Environmental Health Hazard
	Assessment, Oakland, CA
2018	Lecturer for "Health Implications of Climate Change," UC Berkeley School of Public Health,
	Berkeley, California

PROFESSIONAL AFFILIATIONS AND SERVICE

Professional society memberships: Society International Society for Environmental Epidemiology; Genetic and Environmental Toxicology Association; Society for Epidemiologic Research; Society for Paediatric and Perinatal Epidemiology; American Public Health Association

External committees: U.S. EPA Panel Reviewer for Coarse Particulates and Health Effects; U.S. EPA Panel Reviewer for STAR Fellowship/Global Change; NIH grant proposal reviewer for Temperature and Preterm Delivery; USGCRP Review Editor for Climate and Health Assessment, Chapter on Temperature-Related Death and Illnesses; US EPA Panel Reviewer for Coarse Particulates and Health Effects

Invited Committees: Climate Action Team (2008-), Heat adaptation workgroup (2011-), Governor's climate change conference (2011), Mediterranean Climate Change Conference planning committee and co-chair public health session (2012-), US Climate and Health Alliance (2013-); outside reader for PhD thesis committees at Boston University (2020) and Monash University (2016)

HONORS AND AWARDS

Emmy award for "Years of Living Dangerously" climate change documentary (2014)

Mercury Rising episode featuring Matt Damon http://yearsoflivingdangerously.com/story/mercury-rising/ Travel awards to attend various meetings (2006-2019)

Valued author certificate from the American Journal of Epidemiology (2011)

Director's Award Awarded for outstanding achievement and recognition of peer-reviewed (2010) publications at the Office of Environmental Health Hazard Assessment

"S" Award for superior research contributions at the U.S. Environmental Protection Agency (2003) Johns Hopkins University Summer Epidemiology Program Grant for Dissertation Work (1999-2000) Johns Hopkins University, Epidemiology Department tuition grant for doctoral studies (1998-2001)

C. Contributions to Science

- 1. Fine particulate matter and adverse health outcomes
 - Malig B, Fairley D, Pearson D, Wu X, Ebisu K, Basu R. Examining Fine Particulate Matter and Cause-Specific Morbidity During the 2017 North San Francisco Bay Wildfires. Science of the Total Environment. 787, 147507. https://doi.org/10.1016/j.scitotenv.2021.147507, 2021
 - Nguyen, A-M, Malig B, Basu R. The association between ozone and fine particles and mental health-related emergency department visits in California, 2005-2013. PLOS One. 16(4): e0249675, doi: 10.1371/journal.pone.0249675, 2021.
 - Sarovar V. Malig B. Basu R. A case-crossover study of short-term air pollution exposure and the risk of stillbirth in California, 1999-2009. *Environmental Research*. https://doi.org/10.1016/j.envres.2020.110103, 2020.
 - **Basu R**, Pearson D, Ebisu K, Malig B. Association between PM_{2.5} and PM_{2.5} constituents and preterm birth in California, 2000-2006. *Pediatric and Perinatal Epidemiology*, doi: 10.1111/ppe.12380, 2017.
 - Ostro B, Malig B, Broadwin R, Basu R, Gold E, Bromberger JT, Derby C, Feinstein S, Greendale GA, Jackson E, Kravitz HM, Matthews KA, Sternfeld B, Tomey K, Green RR, Green RS. Chronic PM_{2.5} Exposure and inflammation: determining sensitive subgroups in mid-life women. *Environmental Research*, 132C:168-175, 2014.
- 2. Heat and adverse birth outcomes
 - Bekkar B, Pacheco S, Basu R, DeNicola N. Association of Air Pollution and Heat Exposure With Preterm Birth, Low Birth Weight, and Stillbirth in the US: A Systematic Review. *JAMA Netw Open*. 3(6):e208243. doi: 10.1001/jamanetworkopen.2020.8243, 2020.
 - **Basu R**, Chen H, Li D-K, Avalos LA. The impact of maternal factors on the association between temperature and preterm delivery. *Environmental Research*, 154:109-114. doi: 10.1016/j.envres.2016.12.017, 2017.
 - Sarovar, V, Malig B, **Basu R**. High ambient temperature exposure increases the risk of stillbirth in California. *American Journal of Epidemiology*, 183(10):894-901, 2016.
 - **Basu R**, Malig B, Ostro B. High ambient temperature and the risk of preterm delivery. *American Journal of Epidemiology*, 172(10):1108-17, 2010.
 - **Basu R**, Rau R, Pearson D, Malig B. Temperature and term low birth weight in California. *American Journal of Epidemiology*, 187(11):2306-2314, doi: 10.1093/aje/kwy116, 2018.
- 3. Heat and other health outcomes
 - **Basu R**, Gavin L, Pearson D, Ebisu K, Malig B. Examining the association between temperature and emergency room visits for mental health-related outcomes in California. *American Journal of Epidemiology*, 187(4):726-735. doi:10.1093/aje/kwx295, 2018.
 - **Basu R**, Ostro BD. A multi-county analysis identifying the populations vulnerable to mortality associated with high ambient temperature in California. *American Journal of Epidemiology*, 168(6): 632-7, 2008.
 - **Basu R**, Pearson D, Broadwin R. A case-crossover study of temperature and infant mortality in California. *Paediatric and Perinatal Epidemiology*; doi: 10.1111/ppe.12204, 2015.
 - **Basu R**, Pearson D, Malig B, Broadwin R, Green S. The effect of elevated ambient temperature on emergency room visits, *Epidemiology*, 23(6):813-20, 2012.

Other Support

Thakur, Neeta

EACB-23028 (Thakur)

12/1/2021-11/30/2023

5%

PCORI (Patient-Centered Outcomes Research Institute) \$249,974/total

Building Capacity for Research to Address Climate-Impacted Health Conditions

Goals: Extreme heat and wildfire smoke events have significant health impacts in communities with the least economic, social, or political resources to respond. This project will engage a diverse group of stakeholders in San Francisco to understand priority health conditions, identify relevant patient-centered outcomes affected by climate, and collect information on the barriers to exisiting migration strategies.

#77655 (Thakur) 06/15/2020-06/30/2022 10%

Robert Wood Johnson Foundation \$238,068/total

Project Title: Social and Economic Barriers to Public Health and Clinical Interventions for COVID-19 in Vulnerable Populations

Goals: To understand and address barriers to public health and clinical interventions for COVID-19 in vulnerable populations across ten sites in the US. Identifying key intervention targets will require detailed information regarding the drivers of barriers to both health care access and ability to self-isolate, with special attention to barriers to COVID-19 testing and treatment; telemedicine; and shelter in place regulation adherence.

G-88022(MPI: Thakur, Long)

8/1/2020-7/31/2022

3.5%

Genentech Foundation \$500,000/total

Project Title: ACES and Resilience—from Biologic-Response to the Community (ARC) Goals: Adverse Childhood Experiences (ACES) are associated with behavioral, mental and clinical outcomes in children. Tools that are easy to incorporate into pediatric practice, effectively screen for adversities and identify children at high risk for poor outcomes are lacking. We will establish methods for multiplex assays in diverse pediatric sample types and for telomere length.

OPR20142 (Thakur)

7/1/2021-6/30/2024 \$2,988,695/total

15%

California Governor's

Office of Planning and Research

The Collaborative Approach to Examining Adversity and Building Resilience (CARE) Program Goals: While knowledge of ACEs impact on health has advanced rapidly, two critical gaps persist: 1) sufficient understanding of early childhood specific biological pathways, and 2) how to best bolster resilience. These gaps severely limit identification and effective intervention. To address this crisis, we need to move research and intervention development forward collaboratively and with community partnership, leveraging Precision Medicine. We plan to address these gaps.

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Koret Foundation 9633 (Thakur) 09/01/2017-09/30/2022 5%

UC Berkeley \$701,522/total

Title: The Koret Institute for Precision Prevention at the Berkeley Global Campus Project Title: Richmond Environment and Asthma Community Health Study

Goals: UCSF is leading the Health Project of the Koret Institute for Precision Prevention (KIPP).

The study will examine the social and environmental contributors to asthma in vulnerable

populations.

K23HL12551-01A1 (Thakur) 1/01/2016-12/31/2021 13%

NIH/NHLBI \$1,025,503/total

Title: Social Adversities and Asthma: A New Phenotype?

Goals: To define a profile of characteristics, which includes biomarker data, that will better identify individuals at high risk for poor asthma outcomes who are from communities burdened by social adversities.

K12 HL138046 (Bibbins-Domingo) 09/01/2017-06/30/2022 2% NIH/NHLBI \$2,907,100/total

UCSF Career Development Program in Implementation Research in Heart and Lung Diseases Goals: To develop the careers of post-doctoral scholars interested in using implementation science to improve the delivery of evidence-based care for heart and lung diseases.

Role: Learner Health System Embedded Experience Director

PENDING

R01HL161049 (Thakur) 12/1/2021-11/30/2026 20%

NIH/NHLBI \$3,824,076/total

Title: Rehabilitation in Safety-Net Environments (RISE) for COPD

Goals: Pulmonary rehabilitation is one of the few interventions that has been shown to effectively modify the course of Chronic Obstructive Pulmonary Disease (COPD) and improve health outcomes; however, challenges in implementation and access to this high resource intervention in real-life settings have led to low-availability and engagement due to both healthcare system-level and patient-level barriers. The proposed Type 1 effectiveness-implementation hybrid designed study will test an innovative low-resource, community-based pulmonary rehabilitation program (COPD Wellness) with social supports (Health Advocates) for patients with symptomatic COPD through a three-arm randomized waitlist-controlled trial.



Case 3:25-4249, 07/22/2025. DktEntry: 11 1 Page 407 of 475 Document 10-2 Filed 06/05/25 Page 66 of 101 United States ENVIRONMENTAL PROTECTION

Washington, DC 20460

OMB Control No. 2030-0020 Approval expires 04/30/2021

Current and Pending Support

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.			
Other agencies (including NSF) to which this proposal has been/will be submitted.			
Investigator: John R. Balmes, MD			
Support:			
Project/Proposal: Northern California Education and Research Center			
Source of Support: CDC/NIOSH			
Total Award Amount: 8,995,000.00 Total Award Period Covered: 07/01/2015 to 06/30/2025			
Location of Project: UC Berkeley School of Public Health			
Person-Months Per Year Committed to the Project. Cal: 1.20 Acad: Sumr:			
Support:			
Project/Proposal: CHAPS Cohort Maintenance			
Source of Support: NIEHS			
Total Award Amount: 1,250,000.00 Total Award Period Covered: 02/15/2020 to 02/14/2025			
Location of Project: UC Berkeley School of Public Health			
Person-Months Per Year Committed to the Project. Cal: 0.60 Acad: Sumr:			
Support:			
Project/Proposal: AIM to Improve Asthma in Meal prep			
Source of Support: NIEHS			
Total Award Amount: 416,928.00 Total Award Period Covered: 03/18/2020 to 12/31/2021			
Location of Project: UC Berkeley School of Public Health			
Person-Months Per Year Committed to the Project. Cal: 0.60 Acad: Sumr:			
Support: ✓ Current ☐ Pending ☐ Submission Planned in Near Future ☐ *Transfer of Support			
Project/Proposal: Sustainable Household Energy Adoption in Rwanda [SHEAR]: Promoting Rural Health with Solar and Gas			
Source of Support: NIEHS; subcontract from Colorado State University			
Total Award Amount: 106,667.00 Total Award Period Covered: 09/15/2019 to 05/31/2024			
Location of Project: UCSF			
Person-Months Per Year Committed to the Project. Cal: 0.48 Acad: Sumr:			
Support:			
Project/Proposal. Interventions and Communication Strategies to Neduce Fleatin Nisks of Wildiand File Smoke Exposures			
Source of Support: EPA; subcontract from Public Health Institute (PHI) \$994,482			
Total Award Amount: Total Award Period Covered: 10/01/2021 to 09/30/2024			
Location of Project: PHI			
Person-Months Per Year Committed to the Project. Cal: 0.60 Acad: Sumr:			
*If this project has previously been funded by another agency, please list and furnish information for immediately preceding funding			
period.			

NCER FORM 5 (9/01) For Use with **EPA STAR Grant Applications**

USE ADDITIONAL SHEETS AS NECESSARY



Case 3:25-d249, 07/22/2025. DktEntry: 11.1 Page 408 of 475 Page 67 of 101 United States ENVIRONMENTAL PROTECTION Washington, DC 20460

OMB Control No. 2030-0020 Approval expires 04/30/2021

Current and Pending Support

The following information should be provided for each inverse may delay consideration of this proposal.	vestigator and other senior personnel. Failure to provide this information		
Investigator: Stephanie M. Holm	Other agencies (including NSF) to which this proposal has been/will be submitted.		
Support: Current Pending Project/Proposal: Children's Health and Air Pollution	Submission Planned in Near Future		
Source of Support: National Institute of Environment Total Award Amount: 1,250,000.00 Total Award Location of Project: UC Berkeley	ntal Health Sciences vard Period Covered: 02/14/2020 to 11/29/2024		
Person-Months Per Year Committed to the Project.	Cal: 2.00 Acad: Sumr:		
·	Submission Planned in Near Future **Transfer of Support Meal-Prep to Improve Asthma (AIM to improve Asthma)		
Source of Support: National Institute of Environmenta	al Health Sciences		
	vard Period Covered: 03/31/2020 to 12/30/2022		
Location of Project: UC Berkeley	Value 1 51104 50 Voled. 50/01/2020 10 12/00/2022		
Person-Months Per Year Committed to the Project.	Cal: 1.00 Acad: Sumr:		
<u> </u>	Submission Planned in Near Future		
-	y of Pediatrics (funded via cooperative agreement with ATSDR and US EPA)		
	vard Period Covered: 09/21/2020 to 08/31/2021		
Location of Project: UC San Francisco			
Person-Months Per Year Committed to the Project.	Cal: 3.60 Acad: Sumr:		
Support:	Submission Planned in Near Future		
Project/Proposal: Participatory design of effective risk communication about wildfire smoke for hard-to-reach populations			
Source of Support: Environmental Protection Agency, ST	TAR Grant TAR Grant		
Total Award Amount: 259,812.00 Total Aw	vard Period Covered: 09/01/2021 to 02/29/2024		
Location of Project: UC Berkeley			
Person-Months Per Year Committed to the Project.	Cal: 0.60 Acad: Sumr:		
Support: Current Pending	Submission Planned in Near Future		
Project/Proposal:			
Source of Support:			
Total Award Amount: Total Aw	vard Period Covered: to		
Location of Project:			
Person-Months Per Year Committed to the Project.	Cal: Acad: Sumr:		
*If this project has previously been funded by another age	ency, please list and furnish information for immediately preceding funding		
period.			

NCER FORM 5 (9/01) For Use with **EPA STAR Grant Applications**

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3:25-cv-04737-RFL Documental States Filed 06/03/25 Page 68 of 101 ENVIRONMENTAL PROTECTION AGENCY Washington, DC 20460

Current and Pending Support

This collection of information is approved by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. (OMB Control No. 2030-0020). Responses to this collection of information are required to obtain an assistance agreement (40 CFR Part 30, 40 CFR Part 31, and 40 CFR Part 33 for awards made prior to December 26, 2014, and 2 CFR 200, 2 CFR 1500, and 40 CFR Part 31, and 40 CFR Part 30, 40 CFR Part 31, and 33 for awards made after December 26, 2014). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The public reporting and recordkeeping burden for this collection of information is estimated to be 0.5 hours per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the Regulatory Support Division Director, U.S. Environmental Protection Agency (2821T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

The following information should be provided for each investigator and other senior personnel. Failure to provide this information may delay consideration of this proposal.			
may using constant and proposed.	Other agencies (including NSF) t	o which this pro	pposal has been/will be submitted.
Investigator: Rosemarie de la Rosa, PhD, MP	· · · _ · · _ ·	·	
Cupperty Coursest Dending	Cultination Planned in No.		T*Transfer of Current
Support:	Submission Planned in New		*Transfer of Support
Project/Proposal: The Collaborative approach to	examining Adversity and bu	illuling Resil	nence Program
Source of Support: California Governor's Office of	f Planning and Research: si	ibcontract f	rom LICSE
		_	6/30/2024
Location of Project: UC Berkeley School of Public	Award Period Covered: 07/02/20	21 10 0	0/30/2024
•		a d.	Cumari
Person-Months Per Year Committed to the Project.		ad:	Sumr:
Support:	Submission Planned in Nea	ar Future	
Project/Proposal:			
Source of Support:			
Total Award Amount: Total A	Award Period Covered:	to	
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Support: Current Pending	Submission Planned in Nea	ar Future	☐*Transfer of Support
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Support: Current Pending Project/Proposal: Source of Support: Total Award Amount: Total A	Award Period Covered: Cal: Ac	to ad:	□ *Transfer of Support Sumr:

PHS OTHER SUPPORT

*Name of Individual: Elizabeth Noth Commons ID: ELIZABETHNOTH

Other Support – Project/Proposal

*Title: CHAPS Cohort Maintenance

*Major Goals: The major goal of this project is to continue longitudinal follow-up of the participants in the Children's Health and Air Pollution Study (CHAPS), an epidemiological study that has focused on the effects of air pollution on children growing up in the San Joaquin Valley of California, one of the most polluted areas in the country.

*Status of Support: Active

Project Number: R24ES030888

Name of PD/PI: John Balmes, Nina Holland and Elizabeth Noth (multiple-PI project)

*Source of Support: NIH

*Primary Place of Performance: UC Berkeley, Berkeley, CA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 2/15/2020-11/30/2024

* Total Award Amount (including Indirect Costs):\$1,922,554

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 2/15/20 -11/30/20	1.20 Calendar
2. 12/1/20 -11/30/21	1.20 Calendar
3. 12/1/21-11/30/22	1.20 Calendar
4. 12/1/22-11/30/23	1.20 Calendar
5. 12/1/23-11/30/24	1.20 Calendar

Title: Total Exposures to Air Pollutants and Noise in Disadvantaged Communities

*Major Goals: This study will be the first in California to measure indoor and outdoor noise levels concurrent with air quality and develop cumulative exposure metrics characterizing exposures to mixtures of air pollutants and noise. The information collected will foster unique insight into how disparities in air quality and noise exposures affect the health of California residents in disadvantaged communities.

*Status of Support: Active Project Number: 20RD012

Name of PD/PI: Elizabeth Noth

*Source of Support: California Air Resources Board

*Primary Place of Performance: UC Berkeley, Berkeley, CA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 04/01/2021-03/31/2023

* Total Award Amount (including Indirect Costs):\$799,981

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months	
	(##.##)	
1. 04/01/21-03/31/22	2.4 Calendar	
2. 04/01/22-03/31/23	2.4 Calendar	
3.		
4.		
5.		

Title: Wildfires and Intentional Biomass Burning in California and Preterm Birth

*Status of Support: Active Project Number: 12153sc Name of PD/PI: Elizabeth Noth

*Source of Support: UC San Francisco/NIH

*Primary Place of Performance: UC Berkeley, Berkeley, CA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 6/17/2020 - 3/30/2022

* Total Award Amount (including Indirect Costs):\$149,025

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 6/17/20-3/30/21	1.5 Calendar
2. 6/17/21-3/30/22	1.5 Calendar
3.	
4.	
5.	

Title: Pilot Air Quality Study for an AB617 Community (PAQS-AB617)

*Major Goals: The goal of this Pilot Air Quality Study in an AB 617 community is to measure ambient concentrations of selected airborne polycyclic aromatic hydrocarbons (PAHs) at appropriate locations to complement the targeted biomonitoring study being carried out the Office of Environmental Health Hazard Assessment (OEHHA).

*Status of Support: Active

^{*}Major Goals: Our overall goal is to study how mothers' exposures to wildfire and intentional biomass burning(i.e. prescribed burns, agricultural fires and residential wood burning) during pregnancy may affect whether her baby is born prematurely. We will also evaluate the role of neighborhood deprivation and race/ethnicity may modify the relationship between fire exposures and preterm birth.

Project Number: 19-E0020 Name of PD/PI: Elizabeth Noth

*Source of Support: California Office of Environmental Health Hazard Assessment

*Primary Place of Performance: UC Berkeley, Berkeley, CA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 5/1/2020 - 4/30/2022

* Total Award Amount (including Indirect Costs):\$49,999

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 5/1/20-6/30/20	0.5 Calendar
2. 7/1/20-6/30/21	0.75 Calendar
3. 7/1/21-6/30/22	0.5 Calendar
4.	
5.	

Title: Intergovernmental Personnel Agreement: Wildland Firefighter Exposure to Smoke and COVID-19

*Major Goals: The goal of this project is to deploy the Wildland Firefighter Exposure to Smoke and COVID-19 research questionnaire to assess exposures to both smoke and covid-19 via self-report by wildland firefighters.

*Status of Support: Active

Project Number: 21IPA2116214 Name of PD/PI: Elizabeth Noth

*Source of Support: DHHS CDC Centers for Disease Control

*Primary Place of Performance: UC Berkeley, Berkeley, CA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 6/1/2021 – 5/31/2022

* Total Award Amount (including Indirect Costs):\$17,000

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 6/1/21-5/31/22	1.35 Calendar
2	
3.	
4.	
5.	

Title: Disease, Disability and Death in an Aging Workforce

*Major Goals: To assess the impact on health and function of ubiquitous physical hazards in the work environment as they relate to the preventable causes of the major chronic diseases of working age adults—ischemic heart disease, asthma, musculoskeletal disorders and COPD.

*Status of Support: Active

Project Number: 61624544-45510

Name of PD/PI: Ellen Eisen

*Source of Support: Stanford University/NIH

*Primary Place of Performance: UC Berkeley, Berkeley, CA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 8/1/2017 - 5/31/2022

* Total Award Amount (including Indirect Costs):\$844,050

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months
	(##.##)
1. 8/1/17 – 5/31/18	2.0 Calendar
2. 06/01/18-5/31/19	2.0 Calendar
3. 06/01/19-5/31/20	1.5 calendar months
4. 06/01/20-5/31/21	0.9 calendar
5. 05/31/21-5/31/22	0.6 calendar

Title: Occupational Safety and Health Educational and Research Centers

*Major Goals: The award supports a consortium of occupational health and safety training programs.

*Status of Support: Active

Project Number: 2 T42OH008429 Name of PD/PI: John Balmes

*Source of Support: DHHS CDC Center for Disease Control

*Primary Place of Performance: UC Berkeley, Berkeley, CA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 7/1/2020-6/30/2025

* Total Award Amount (including Indirect Costs):\$3,593,139

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months	
	(##.##)	
1. 7/1/20-6/30/21	2.4 Calendar	
2. 7/1/21-6/30/22	2.4 Calendar	
3. 7/1/22-6/30/23	2.4 Calendar	

Year (YYYY)	Person Months	
	(##.##)	
4. 7/1/23-6/30/24	2.4 Calendar	
5. 7/1/24-6/30/25	2.4 Calendar	

Title: Air Pollution Measurements, Exposure Assessment, and Evaluation of the Sources of Particulate Matter in Fresno, CA

*Major Goals: The objectives of this study are to a) understand the sources of particulate matter (PM) exposures to residents of Fresno and Clovis and b) estimate concentrations of polycyclic aromatic hydrocarbons (PAH), black carbon (BC), brown carbon (BrC), and PM from each of these sources at the neighborhood level. We will focus on disentangling the sources of PM exposures (PM originating from traffic-related sources from other combustion sources, e.g., residential wood burning, agricultural burning, prescribed burns, and wildfires.

*Status of Support: Active

Project Number: 19RD003

Name of PD/PI: S Katherine Hammond

*Source of Support: California Air Resources Board

*Primary Place of Performance: UC Berkeley, Berkeley, CA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 5/1/2020 - 4/20/2023

* Total Award Amount (including Indirect Costs):\$300,000

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 5/1/20-4/30/21	2.4 Calendar
2. 5/1/21-4/30/22	2.4 Calendar
3. 5/1/22-4/30/23	2.4 Calendar
3. 3/1/22-4/30/23	2.4 Caleffual
5	

Title: Sports Injury Epidemiology: Impact of Episodic Environmental Events on Acute Health in Student Athletes

*Major Goals: To enhance an understanding of adverse health outcomes among student athletes from increased ambient temperatures and episodic air pollution exposures, we propose to assess the impact of two types of environmental exposures – heat waves and unusually high air pollution episodes.

*Status of Support: Pending

Project Number: UCB 20220875 Name of PD/PI: Elizabeth Noth *Source of Support: PAC-12 Conference

*Primary Place of Performance: UC Berkeley, Berkeley, CA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 7/1/2022 - 6/30/2025

* Total Award Amount (including Indirect Costs):\$446,457

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months
	(##.##)
1. 7/1/22-6/30/23	2.7 Calendar
2. 7/1/23-6/30/24	3 Calendar
3. 7/1/24-6/30/25	3 Calendar
4.	
5.	

Title: Covid-19: Individual-level Air Pollution and SARS-CoV-2 Infection in Fresno, California

*Major Goals: The goal of the study is to understand the role that air pollution exposure plays in risk of SARS-CoV-2 infection.

*Status of Support: Pending

Project Number: UCB 20210781

Name of PD/PI: John R. Balmes and Elizabeth Noth (Multiple-PI project)

*Source of Support: NIH-NIEHS

*Primary Place of Performance: UC Berkeley, Berkeley, CA

Project/Proposal Start and End Date: (MM/YYYY) (if available): 11/1/2020 - 10/31/2022

* Total Award Amount (including Indirect Costs):\$428,337

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. 11/1/20-10/31/21	3.00 Calendar
2. 11/1/21-10/31/22	1.20 Calendar
3.	
4.	
5.	

IN-KIND

^{*}Summary of In-Kind Contribution: None

*Overlap (summarized for each individual):

Elypha M. Nott

There is no scientific or budgetary overlap, any commitment overlap will be addressed prior to the funding of this application.

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

*Signature:

Date: 11/2/2021



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Current and Pending Support

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The following information should be provided for each inv may delay consideration of this proposal.	estigator and other senior p	personnel. Failur	e to provide this information
Thay acidy consideration of this proposal.	Other agencies (including N	SF) to which this pr	oposal has been/will be submitted.
Investigator: Fotini Chow		,	
Support:	Submission Planned in	Near Future	*Transfer of Support
Project/Proposal: Collaborative Research: Perdiga	oThe Stable Bounda	ry Layer over (Complex Terrain
Source of Support: NSF National Science Foundation			0.100.100.00
,	ard Period Covered: 07/01	1/2 0 16 to 0	6/30/2022
Location of Project: UC Berkeley			
Person-Months Per Year Committed to the Project.	Cal:	Acad:	Sumr: 0.05
Support:	Submission Planned in	Near Future	
Project/Proposal:			
Source of Support:			
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	ard Period Covered:	to	
Location of Project: Person-Months Per Year Committed to the Project.	Cal:	Acad:	Sumr:
Support: Current Pending	Submission Planned in		*Transfer of Support
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Project/Proposal:			
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Source of Support:	and Devied Course do	40	
	ard Period Covered:	to	
Location of Project:	Cal:	Acad:	Cume
Person-Months Per Year Committed to the Project. Support: Current Pending	Submission Planned in		Sumr: *Transfer of Support
Project/Proposal:		Near Future	Transier or Support
Trojosti roposai.			
Source of Support:			
	ard Period Covered:	to	
Location of Project:			
Person-Months Per Year Committed to the Project.	Cal:	Acad:	Sumr:
*If this project has previously been funded by another age	ency, please list and furnish	information for in	mmediately preceding funding
period.			

Case 3:25-4249, 07/22/2025, DktEntry: 11.1, Page 418 of 475 Case 3:25-cv-04737-RFL Document 10-2 Filed 06/05/25 Page 77 of 101

OTHER SUPPORT

Chan, Wanyu

None



Washington, DC 20460

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Current and Pending Support

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The following information should be provided for each inverse may delay consideration of this proposal.	stigator and other senior personnel. Failure to provide this information
may deray constant due to the proposation	Other agencies (including NSF) to which this proposal has been/will be submitted.
Investigator: Thomas Kirchstetter	
Support:	Submission Planned in Near Future **Transfer of Support
·· — — — — —	nprovements in Air Quality at Community, Urban and Regional Scales
	,,, ,, ,, ,
Source of Support: California Air Resources Board	
Total Award Amount: 50,000.00 Total Awa	rd Period Covered: 03/20/2021 to 09/19/2022
Location of Project: University of California, Berkeley	
Person-Months Per Year Committed to the Project.	Cal: 0.00 Acad: Sumr:
Support:	Submission Planned in Near Future*Transfer of Support
Project/Proposal: Assessment of Regulatory Air Pollution	Dispersion Models to Quantify the Impacts of Transportation
Sector Emissions.	
Source of Support: ICF International, Inc.	
Total Award Amount: 150,000.00 Total Awa	rd Period Covered: 06/12/2020 to 12/31/2020
Location of Project: University of California, Berkeley	
Person-Months Per Year Committed to the Project.	Cal: 0.00 Acad: Sumr:
·· — — — — —	Submission Planned in Near Future
Project/Proposal: Richmond Air Monitoring Network Ph	nase II: Black Carbon and Particulate Matter Characterization
Course of Cupport: DOE Haaltha France	
Source of Support: PSE Healthy Energy	1B : 10
	ord Period Covered: 07/01/2020 to 06/30/2023
Location of Project: University of California, Berkeley	Cal: 0.00 Acad: Sumr:
Person-Months Per Year Committed to the Project. Support:	Submission Planned in Near Future
Project/Proposal: San Joaquin Valley Black Carbon Mon	
Trojecti Toposai. San Joaquin Valley Black Carbon Mon	itoring
Source of Support: Central California Asthma Collaborat	ive
	ard Period Covered: 08/01/2020 to 01/01/2022
Location of Project: University of California, Berkeley	0 1/0 1/2022
Person-Months Per Year Committed to the Project.	Cal: 0.00 Acad: Sumr:
Support:	Submission Planned in Near Future*Transfer of Support
-	icle Emissions at the Caldecott Tunnel for Heavy-Duty Emission
Program Development and Verification	
Trogram Bovolopinion and volinioation	
Source of Support: California Air Resources Board	
Total Award Amount: 449,571.00 Total Awa	rd Period Covered: 02/01/2021 to 01/31/2025
Location of Project: University of California, Berkeley	
Person-Months Per Year Committed to the Project.	Cal: 2.00 Acad: Sumr:
	ncy, please list and furnish information for immediately preceding funding
period.	70

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OTHER SUPPORT

Basu, Rupa

None

Dr. Rupa is a State of California employee and does not have Support from other entities.

Letters of Support

Co-Investigators

University of California, Berkeley

- Drs. de la Rosa, Chow, Noth

Lawrence Berkeley National Laboratory

- Drs. Chan and Kirchstetter

Office of Environmental Health Hazard Assessment

- Dr. Basu

Community Partners

Fresno, CA

• Central California Asthma Coalition

Richmond, CA

- Contra Costa Health System
- Dr. Omotoso

San Francisco, CA

- San Francisco Department of Public Health
- San Francisco Office of Resilience and Capital Planning
- Brightline

Scientific Consultant

Cooperative Institute for Research in Environmental Sciences

UNIVERSITY OF CALIFORNIA, BERKELEY

BERKELEY · DAVIS · IRVINE · LOS ANGELES · RIVERSIDE · SAN DIEGO · SAN FRANCISCO



Rosemarie de la Rosa, PhD MPH Assistant Professor of Environmental Health Sciences UC Berkeley, School of Public Health 2121 Berkeley Way, Office 5123 Berkeley, California 94720-7360 Tel: (510)-643-1627 Email: rmd1025@berkeley.edu

November 4, 2021

Dear Dr. Thakur,

Re: EPA STAR application 'Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Wildfire PM_{2.5} in Environmental Justice Communities'

This letter is to express my strong support for your important proposal, "Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Wildfire PM_{2.5} in Environmental Justice Communities". My research examines the role of social determinants in shaping susceptibility to the toxic effects of environmental exposures. I have specific expertise in toxicology and molecular epidemiology. I have also published on assessing the cumulative effect of chemical and non-chemical stressors on human health. As you know, we are long-standing collaborators on the Richmond Environment and Asthma Community Health (REACH) Study, which aims to determine the combined role of intrinsic factors and extrinsic factors (e.g. psychosocial stress and environmental chemical) on asthma burden in adolescents. I am also a Co-Investigator on your project "A Collaborative approach to examining Adversity and building Resilience (CARE) Program" funded by the California Governor's Office, where my role is to examine biomarkers of toxic stress and resilience. We also recently reviewed in the *Journal of Allergy and Clinical Immunology* how structural racism contributes to disparities in asthma and atopic disease burden. I look forward to extending our collaborations through this project investigating the cumulative health effects from climate change in high-burden communities across California.

Dr. Noth also has ongoing collaborations with both Drs. Thakur and Kirchstetter. Dr Noth has worked together on the REACH study with Dr. Thakur, in gathering time-location data from participants as well as an on-going exposure assessment for outdoor air pollutants. Dr. Noth is currently collaborating with Dr. Kirchstetter on the San Joaquin Valley Pollution and Health Environment (SPHERE) study, in which they will characterize indoor and outdoor air pollution and noise exposures to children and adults in San Joaquin Valley communities that have high burdens of environmental toxins and noise. Dr. Noth will extend this expertise in exposure assessment to the current project.

Dr. Chow has expertise in modeling high-resolution smoke forecasting and will provide technical and scientific assistance to this project.

Our collective expertise will help provide guidance in the implementation, analysis, and interpretation of our research findings to ensure the success of the proposed project.

Sincerely,

Rosemarie de la Rosa, PhD, MPH

dele Reson



Energy Technologies Area

November 16, 2021

Neeta Thakur, MD Assistant Professor School of Medicine University of California San Francisco

Subject: Support for your EPA-G2021-STAR-H1 proposal/project

Dear Dr. Thakur,

We are excited to support your proposal titled Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Climate Change in Environmental Justice Communities. The proposed objectives to understand how buildings mitigate exposures to wildfire smoke and to engage with community groups to identify mitigation strategies fall within our active areas of research expertise. Should EPA award you a grant to conduct this research, we will be willing participants. We understand that, as employees of Berkeley Lab (an FFRDC), we cannot receive salary from the grant. Nonetheless, we look forward to advising the research team throughout the project.

Sincerely,

Wanyu (Rengie) Chan

Deputy, Indoor Environment Group, Berkeley Lab

Thomas Kirchstetter

JR HM

Director, Energy Analysis & Environmental Impacts Division, Lawrence Berkeley National Laboratory Adjunct Professor, Civil & Environmental Engineering Department, UC Berkeley 510-908-1237; twkirchstetter@lbl.gov, twkirchstetter@berkeley.edu

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CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT



Lauren Zeise, Ph.D., Director Jared Blumenfeld, Secretary for Environmental Protection Gavin Newsom, Governor

November 4, 2021

Neeta Thakur, MD, MPH Assistant Professor UCSF Pulmonary and Critical Care Medicine

Dear Dr. Thakur,

As the Chief of the Air and Climate Epidemiology Section of the Office of Environmental Health Hazard Assessment (OEHHA) at the California Environmental Protection Agency, it is with great pleasure that I extend this letter of support for your application *Partnering for Resilient Comportunities to Eliminate Cumulative Toxic (PROTECT) Health Enfects from Climate Change* to the EPA.

OEHHA is the lead state agency for the assessment of health risks posed by environmental contaminants. OEHHA's mission is to protect and enhance the health of Californians and our state's environment through scientific evaluations that inform, support, and guide regulatory and other actions. Your proposal to the US EPA will further our understanding of the risk of exposure from wildfire smoke PM_{2.5}, in terms of intensity and duration, health effects across communities in California and possible effect modification by housing attributes (e.g., age of the building, date of retrofitting), building evidence for a promising mitigation strategy. Furthermore, this proposed study will provide important information regarding which mitigation strategies address community needs and are viewed as acceptable by residents that are affected by wildfire smoke PM_{2.5} and disproportionately burdened. This study aligns with our goals at OEHHA and will provide important learning opportunities and models to public health programs.

I am committed to my role as a Co-Investigator for this proposed study. I have over two decades of research experience in environmental epidemiology, and I have specifically focused on identifying vulnerable subgroups from climate change and adverse health outcomes. I will provide comments on the study design of the proposed health analyses so that your study results will help answer important gaps in our understanding of wildfire and health research. The findings will also be valuable for targeting high-risk communities and have direct practical applications by helping provide state guidelines for preventive and mitigation efforts.

I am delighted to be included in this innovative and impactful proposal. I am confident that, if funded, your proposed work will contribute to California's aim of achieving better health outcomes and to the state's health equity goals for wildfire research.

Sincerely,

Rupa Basu, PhD, MPH

Chief, Air and Climate Epidemiology Section

Cal EPA/OEHHA

1515 Clay Street, 16th floor

Oakland, CA 94612

Rupa.Basu@oehha.ca.gov; phone (510) 622-3156



November 15, 2021

Neeta Thakur, MD, MPH UCSF Assistant Professor UCSF PRISE Center

Re: EPA-G2021-STAR-H1: Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/ Lifestages: Community-Based Research for Solutions

Dear Dr. Thakur:

We at the Central California Asthma Collaborative (CCAC) are enthusiastic about your application entitled **Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Wildfire PM_{2.5} in Environmental Justice Communities. Your proposal will improve our understanding of the health risks associated with wildfire smoke PM_{2.5} – including much needed information on how building characteristics affect penetration of smoke indoors.**

At CCAC, we promote sustainability and empowerment of low-income, disadvantaged communities within the San Joaquin Valley of California, one of the most polluted regions in the country. For over 10 years CCAC has been recognized as a leading voice for social and environmental justice in Fresno and the San Joaquin Valley. CCAC has played a significant role in developing both community capacity to participate in local, regional, and state activities targeting climate change, but also both provided and facilitated development of health focused interventions to mitigate or eliminate climate related health exposures in low income and communities of color in the region. We have worked with low-income residents of Fresno to improve their understanding of impacts that air pollution and climate change, including increasing exposures to wildfire smoke, have on their health. As you know, this community has higher burden of chronic medical conditions and little access to indoor air filtration and personal protective equipment. We have worked with Dr. John Balmes on research projects in the Fresno community for many years and are pleased that he has connected us to you.

We are especially interested in the interested in the information that will be generated from your community engagement and hope to partner with you on carrying out these efforts in our local communities in Fresno. Developing formal partnerships with community stakeholders to improve our understanding of barriers while identifying acceptable community-level interventions is key in our ability to our plan to mitigate the effects of poor air quality. This study aligns with our goals at CCAC and will provide important learning opportunities regarding community preferences and barriers to existing mitigation efforts.

CCAC is pleased to support and endorse this proposal. We look forward to the potential to partner with you on this project. Please do not hesitate to contact me directly with any questions.

Sincerely,

Kevin D Hamilton, RRT, ACS

Case 3:25-cv-04737-RFL Document 10-2 Filed 06/03/25 Page 85 of 101

ANNA M. ROTH, RN, MS, MPH HEALTH SERVICES DIRECTOR

DAN PEDDYCORD, RN, MPA/HA
CHIEF CLIMATE & HEALTH POLICY OFFICER



CONTRA COSTA
PUBLIC HEALTH

597 CENTER AVENUE, SUITE 200
MARTINEZ, CALIFORNIA 94553
PH (925) 222-1472
FAX (925) 313-6721
DANIEL PEDDYCORD@CCHEALTH.ORG

Neeta Thakur, MD, MPH UCSF Assistant Professor UCSF PRISE Center Subspecialty Program Director

Re: Funding Opportunity: EPA-G2021-STAR-H1

Dear Dr. Neeta Thakur:

Contra Costa Health Services (CCHS) is pleased to support the application of The University of California, San Francisco (UCSF) entitled **Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Climate Change.**

We have recently launched a Climate and Health initiative at CCHS, which is focused on building public health capacity to effectively and equitably identify and mitigate the health impacts of climate change. This initiative will identify ways to reduce the carbon footprint of CCHS, implement programs and policies to enable CCHS to help our clients reduce their carbon footprint and adapt to the impacts of climate change, and advocate for policies and practices in the County and the region that address the disproportionate impacts that climate change will have on vulnerable populations. Specifically related to this grant application, we are in the second year of a Green and Healthy Homes program designed to assist MediCal patients with moderate to severe asthma. This program provides in-home asthma trigger and energy efficiency assessments and then deploys mitigation measures that will address the impacts of wildfire smoke.

We very much support the work proposed in this study as it will further our understanding of the extent of the health risks associated with wildfire smoke PM_{2.5} and provide much needed evaluation information on mitigation efforts. In addition to the health effect data that will come from this study, we are specifically interested in the information that will be generated from the community engagement and outreach efforts. Developing formal partnerships with community stakeholders to improve our understanding of barriers while identifying acceptable community-level interventions is key in our ability to our plan to mitigate the effects of poor air quality. This study aligns with our goals at CCHS and will provide important learning opportunities and models to public health programs such as ours.



CCHS is pleased to support and endorse this proposal. We look forward to working with UCSF on this project. Please do not hesitate to contact me directly with any questions.

Sincerely,

Daniel Peddycord

Daniel W. Peddycord RN MPA/HA

Chief Climate and Health Policy Officer

Contra Costa Health Services

Chris Farnitano, MD

County Health Officer

Contra Costa Health Services



November 15, 2021.

Neeta Thakur, MD, MPH UCSF Assistant Professor UCSF PRISE Center

Re: EPA-G2021-STAR-H1: Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/ Life Stages: Community-Based Research for Solutions

Dear Dr. Neeta Thakur,

I, Dr. Omoniyi Omotoso, am thrilled to build on ongoing collaborative work over the past five years and fully support your application entitled "Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Climate Change." Your proposal will improve our understanding not only of the health risks associated with wild fire smoke PM_{2.5} – but also much needed information on how to address barriers to the adoption of mitigation strategies here in our community in Richmond, California. As you know, this community has a higher burden of chronic medical conditions, little access to indoor air filtration, and is also disproportionately burdened by environmental pollution and social stress.

Over the past five years in Richmond, we have been partnering on community-based research. Most relevant to this proposal, is our joint support of the Youth Participatory Action Research (YPAR) Internship as part of the Richmond Environment Asthma Community Health (REACH) Study. For the past three years, we have hired four to six local high school students who are residents of the Richmond community and also patients at Lifelong Medical Care, where I serve as the Associate Medical Director of Pediatrics. Empowering youth with research skills has enriched the REACH study with community perspective and has identified important areas for further exploration. Recently, as you know, these students were successful in obtaining a mini-grant from the Air District to better understand the sources of environmental pollution in the community, complimenting their work during the YPAR Internship that identified barriers to safe, recreational spaces in Richmond. We have also partnered on related efforts to address social needs coupled with resource navigation and linkage in the primary care setting, with this work being currently being funded by a California State grant.

Recently as a means to further leverage our community partnerships and clinical expertise, I joined the Community Emissions Reduction Plan (CERP) Steering Committee. This CERP Steering Committee was formed under Assembly Bill 617 for the Richmond, North Richmond and San Pablo communities. Our CERP Steering Committee's is a community-led initiative for strategies to reduce harmful air pollution impacts on the quality of life of people who live, work, play and pray in Richmond. As you can see, these goals closely align with the proposed EPA application and I can connect other Richmond community stakeholders in partnership.

I am pleased to endorse and fully support this proposal. I look forward to partnering with you on this project. Please do not hesitate to contact me directly with any questions.

Sincerely

Omoniyi Omotoso, MD, MPH, FAAP

LifeLong Medical Care Associate Medical Director of Pediatrics

Vice Chair, Alta Bates Department of Pediatrics

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San Francisco Department of Public Health

Grant Colfax, MD Director of Health

City and County of San Francisco London N. Breed Mayor

November 16, 2021

Neeta Thakur, MD, MPH
UCSF Assistant Professor
UCSF PRISE Center Subspecialty Program Director

Re: Funding Opportunity: EPA-G2021-STAR-H1

Dear Dr. Thakur:

The San Francisco Department of Public Health (SFDPH) is pleased to support the application of The University of California, San Francisco (UCSF) entitled **Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Climate Change.**

Over the last several years, SFDPH has led efforts to build public health capacity to effectively and equitably identify the health impacts of climate change. SFDPH has spent considerable time identifying the populations most vulnerable to climate-related health impacts; this work has included the development of maps, data tools, and planning to identify the communities that carry the heaviest health burden due to extreme heat and poor air quality. Though these communities are the most exposed to climate-impacted health conditions, they are the least likely to have the economic, social, or political resources to prepare for and respond to them. In response to the critical need to implement community-level interventions to mitigate the negative health effects exacerbated by climate change, SFDPH launched the Heat and Air Quality Resilience Project (HAQR). HAQR includes all municipal departments involved in emergency preparedness and response services, housing, and infrastructure. The purpose of HAQR is to bring together key City departments to align objectives, share data and collaboratively strategize how to improve the citywide response to extreme heat and air quality issues, especially among vulnerable populations. SFDPH sits on the HAQR Project leadership team and plays an essential role by chairing the coordinating committee, serving as the point of contact for implementation teams and regularly drafting reports on project status.

In partnership with you, we recently received funding from PCORI to formally incorporate into HAQR voices from community residents and advocacy groups living in neighborhoods disproportionally impacted by extreme heat and poor air quality. With this community stakeholder group, we hope to assess for barriers and identify acceptable community-level interventions to mitigate extreme health and poor air quality. This proposal is a potential extension of this work. Specifically, this grant would accelerate this engagement work forward at an unprecedent pace and

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San Francisco Department of Public Health

Grant Colfax, MD
Director of Health

City and County of San Francisco London N. Breed Mayor

allow for the co-development of mitigation strategies that address both the immediate threats of Wildfire $PM_{2.5}$ and the chronic environmental pollution that also burdens vulnerable communities in San Francisco.

SFDPH is pleased to support and endorse this proposal. We look forward to collaborating with UCSF on this project if it is funded.

Sincerely,

Grant Colfax, MD Director of Health

City & County of San Francisco

London N. Breed, Mayor



Office of the City Administrator

Carmen Chu, City Administrator Brian Strong, Chief Resilience Officer & Director, Office of Resilience and Capital Planning

Neeta Thakur, MD, MPH UCSF Assistant Professor UCSF PRISE Center Subspecialty Program Director

Re: Funding Opportunity: EPA-G2021-STAR-H1, Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/ Lifestages: Community-Based Research for Solutions

Dear Dr. Thakur:

The San Francisco Office of Resilience and Capital Planning (ORCP) is pleased to support the application of The University of California, San Francisco (UCSF) entitled Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Wildfire PM_{2.5} in Environmental Justice Communities.

ORCP promotes the preservation and sustainability of San Francisco's public capital assets and the city's overall resilience to acute shocks and chronic stresses, including preparing for and responding to stressors exacerbated by climate change. OCRP developed San Francisco's Hazards and Climate Resilience Plan, a road map with over 90 strategies to reduce the risks and adapt to climate change impacts. As part of this work, ORCP works closely with the San Francisco Department of Public Health (SFDPH) to study the overlap between vulnerable populations and vulnerable buildings to identify community-approved, infrastructure-related solutions to mitigate the health impacts of climate change.

In response to the critical need to implement community-level interventions to mitigate the negative health effects exacerbated by climate change, ORCP is a key stakeholder in the Heat and Air Quality Resilience Project (HAQR). The HAQR includes all municipal departments involved in emergency preparedness and response services, housing, and infrastructure. The purpose of the HAQR is to bring together key City departments to align objectives, share data and collaboratively strategize how to improve the city-wide response to extreme heat and air quality issues, especially among vulnerable populations. ORCP sits on the HAQR project leadership team and plays an essential role by co-chairing the coordinating committee with SFDPH, serving as a point of contact for implementation teams and regularly drafting reports on project status.

As you know, in partnership with you, we recently received funding from PCORI to formally incorporate voices into HAQR from community residents and advocacy groups living in neighborhoods disproportionally impacted by extreme heat and poor air quality. With this community stakeholder group, we hope to assess for barriers and identify acceptable community-level interventions to mitigate extreme health and poor air quality. Through this proposal, we would be able to accelerate this engagement work forward at an unprecedent speed and start to co-develop mitigation strategies that address both the immediate threats of Wildfire PM_{2.5} and the chronic environmental pollution that also burden vulnerable communities in San Francisco.

if this proposal is funded, ORCP would participate as a key stakeholder in these efforts. Our staff are leaders in developing and overseeing policies, programs, interagency initiatives and financial strategies to support the resilience of communities and the city's infrastructure to prepare for and respond to the

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stressors of climate change. ORCP is pleased to support and endorse this proposal. We look forward to working with UCSF on this project. Please do not hesitate to contact me directly with any questions.

Sincerely,

Brian Strong

Chief Resilience Officer and Director Office of Resilience and Capital Planning City and County of San Francisco

Brian.Strong@sfgov.org



Neeta Thakur, MD, MPH UCSF Assistant Professor UCSF PRISE Center

Re: EPA-G2021-STAR-H1: Cumulative Health Impacts at the Intersection of Climate Change, Environmental Justice, and Vulnerable Populations/ Lifestages: Community-Based Research for Solutions

Dear Dr. Thakur:

We at Brightline are enthusiastic about your application entitled **Partnering for Resilient Opportunities To Eliminate Cumulative Toxic (PROTECT) Health Effects from Wildfire PM2.5 in Environmental Justice Communities.** Your proposal will improve our understanding of the health risks associated with wildfire smoke PM_{2.5} – including much needed information on how building characteristics affect penetration of smoke indoors.

Since 2006, our nonprofit organization has promoted sustainability and empowerment of low-income, frontline communities within and outside of California. In addition to establishing a localized air quality montoring program, we have deeply engaged dense urban environmental justice communities throughout the Bay Area. In this work, we recently highlighted the impacts that climate change, including wildfire smoke, on residents of high-density, low-income housing (i.e., single-room occupancy). As you know, this community has higher burden of chronic medical conditions and little access to indoor air filtration and personal protective equipment.

We are especially interested in the interested in the information that will be generated from your community engagement and hope to partner with you on carrying out these efforts in our local communities in San Francisco. Developing formal partnerships with community stakeholders to improve our understanding of barriers while identifying acceptable community-level interventions is key in our ability to our plan to mitigate the effects of poor air quality. This study aligns with our goals at Brightline and will provide important learning opportunities regarding community preferences and barriers to existing mitigation efforts.

Brightline is pleased to support and endorse this proposal. We look forward to the potential to partner with you on this project. Please do not hesitate to contact me directly with any questions.

Sincerely,

Eddie H. Ahn Executive Director

Case 3:25-cv-04737-RFL Document 10-2 Filed 06/03/25 Page 93 of 101

University of Colorado at Boulder

Cooperative Institute for Research in Environmental Sciences

Campus Box 216 Boulder, Colorado 80309-0216 (303) 492-1143 FAX: (303) 492-1149

Neeta Thakur, MD, MPH UCSF Assistant Professor UCSF PRISE Center Subspecialty Program Director

Re: Funding Opportunity: EPA-G2021-STAR-H1

Dear Dr. Neeta Thakur:

The HRRR-Smoke modeling team at NOAA Global Systems Laboratory and CIRES is pleased to support the application of The University of California, San Francisco (UCSF) entitled **Partnering for Resilient Opportunities to Eliminate Cumulative Toxic (PROTECT) Health Effects from Climate Change.**

The HRRR-Smoke model provides critical predictions for wildfire smoke exposures across the country, using satellite detection of fire "hot spots" to drive a 3D numerical weather prediction model which simulates smoke transport and its feedback on meteorology. HRRR-Smoke output has been archived since 2016 and provides a unique dataset for examining spatial and temporal variability in smoke exposure across the state of California. We have worked closely with Dr. Tina Chow at UC Berkeley and a co-Investigator for this award on analysis of HRRR-Smoke for recent wildfire events, and we are excited about continued collaboration opportunities.

The work proposed in this proposal will further our understanding of the extent of the health risks associated with wildfire smoke (PM_{2.5}) and provide much needed information on mitigation efforts. We are excited to support the development of a model-data fusion product for HRRR-Smoke. This merged dataset will lead the way to creating a smoke "analysis" product (data assimilation using smoke PM_{2.5} observations) which can be used in various applications in the future.

This study aligns with our goals at HRRR-Smoke to provide the most accurate smoke predictions for human health and public safety. The study will provide important learning opportunities on the role of smoke modeling and exposure studies.

The HRRR-Smoke team is pleased to support and endorse this proposal. We look forward to working with UCSF and UC Berkeley on this project and will provide support with HRRR-Smoke data analysis. Please do not hesitate to contact us with any questions.

Sincerely,
Dr. Ravan Ahmadov
Cooperative Institute for Research in Environmental Sciences
University of Colorado at Boulder
Boulder, CO 80303

OMB Number: 2030-0020 Expiration Date: 04/30/2021

Preaward Compliance Review Report for All Applicants and Recipients Requesting EPA Financial Assistance

Note: Read Instructions before completing form.

I. A.	Applican [*]	t/Recipient (Name,	Address, City, St	tate, Zip Cod	e)					
	Name:	The Regents of	f the Universi	ty of Cali	fornia San Fr	ancisco				
	Address:	Office of Spor	nsored Researc Fourth Floor	h						
	City:	San Francisco]					
	State:	CA: California	<u> </u>		J		Zip Code:	94143-0000		
				1			ı			
В.	DUNS No	o. 09487833700	30							
II.	Is the ap	plicant currently re	eceiving EPA Ass	sistance?	Yes] No				
III.		ivil rights lawsuits or, national origin								
NA					•					,
IV.	discrimi	ivil rights lawsuits nation based on ra e actions taken.(ce, color, nationa	ıl origin, sex,	, age, or disabilit	y and enclos	se a copy of	all decisions.		
NA		<u> </u>			ор.ш			, , , , , , , , , , , , , , , , , , ,		
V.	of the re	ivil rights complia view and any deci: t. § 7.80(c)(3))								close a copy
NA	•									
VI.	Is the an	plicant requesting	FPΔ assistance f	or new cons	truction? If no	proceed to V	/II: if ves an	swer (a) and/o	or (h) helow	
•••	io aic ap	phodin requesting	Yes	⊠ No	· •		, y co, a	ower (a) and	or (b) below:	
		nt is for new cons le to and usable by							nstructed to	be readily
			Yes	☐ No						
b.		int is for new cons						ot be readily a	accessible to	and usable
		applicant/recipier color, national orig							X Yes	☐ No
a.	Do the m	ethods of notice a	ccommodate tho	se with impa	ired vision or he	aring?			X Yes	No
		tice posted in a pr ities, in appropria	•			,	education p	orograms	X Yes	☐ No
c.	Does the	notice identify a	lesignated civil ri	ghts coordin	ator?				X Yes	☐ No
		applicant/recipier of the population			on the race, colo	or, national o	origin, sex, a	ige, or	X Yes	☐ No
		applicant/recipier nglish proficiency				s to services	s for person	s with	X Yes	☐ No

Case: 25-4249, 07/22/2025, DktEntry: 11.1 Page 436 of 475 Case 3:25-cv-04737-RFL Document 10-2 Filed 06/03/25 Page 95 of 101

X. If the applicant is an education program or activity, or has 15 or more employees, has it designated an employee to coordinate its compliance with 40 C.F.R. Parts 5 and 7? Provide the name, title, position, mailing address, e-mail address, fax number, and telephone number of the designated coordinator.

UCSF Office for the Prevention of Harassment and Discrimination; Nyoki Sacramento, Director, EEO/AA, ADA and Title IX, 415-502-3400; OPHD@ucsf.edu; 490 Illinois Street, Floor 11, San Francisco, CA; https://diversity.ucsf. edu/nyoki-sacramento-appointement Renee Navarro, PharmD, MD, Vice Chancellor for Diversity and Outreach is the head of this department

XI. If the applicant is an education program or activity, or has 15 or more employees, has it adopted grievance procedures that assure the prompt and fair resolution of complaints that allege a violation of 40 C.F.R. Parts 5 and 7? Provide a legal citation or Internet Address for, or a copy of, the procedures.

The Office of Prevention of Harassment and Discrimination lists various policies at this website: https://ophd.ucsf.edu/policies-guidelines. Complaints may be filed and the procedures are listed here: https://ophd.ucsf.edu/interim-procedures-august-2012

	For the Applicant/Recipient						
	rm and all attachments thereto are true, accurate and complete unishable by fine or imprisonment or both under applicable law. ulations.						
A. Signature of Authorized Official	B. Title of Authorized Official	C. Date					
Mae Moredo UCSF Contracts and Grants Officer 11/16/2021							
I have reviewed the information provided by the ap compliance information required by 40 C.F.R. Part	For the U.S. Environmental Protection Agency oplicant/recipient and hereby certify that the applicant/recipient has 5 and 7; that based on the information submitted, this applical applicant has given assurance that it will fully comply with all a	tion satisfies the preaward					
A. *Signature of Authorized EPA Official	B. Title of Authorized Official	C. Date					

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* See Instructions

Instructions for EPA FORM 4700-4 (Rev. 06/2014)

General. Recipients of Federal financial assistance from the U.S. Environmental Protection Agency must comply with the following statutes and regulations.

Title VI of the Civil Rights Acts of 1964 provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. The Act goes on to explain that the statute shall not be construed to authorize action with respect to any employment practice of any employer, employment agency, or labor organization (except where the primary objective of the Federal financial assistance is to provide employment). Section 13 of the 1972 Amendments to the Federal Water Pollution Control Act provides that no person in the United States shall on the ground of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under the Federal Water Pollution Control Act, as amended. Employment discrimination on the basis of sex is prohibited in all such programs or activities. Section 504 of the Rehabilitation Act of 1973 provides that no otherwise qualified individual with a disability in the United States shall solely by reason of disability be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. Employment discrimination on the basis of disability is prohibited in all such programs or activities. The Age Discrimination Act of 1975 provides that no person on the basis of age shall be excluded from participation under any program or activity receiving Federal financial assistance. Employment discrimination is not covered. Age discrimination in employment is prohibited by the Age Discrimination in Employment Act administered by the Equal Employment Opportunity Commission. Title IX of the Education Amendments of 1972 provides that no person in the United States on the basis of sex shall be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance. Employment discrimination on the basis of sex is prohibited in all such education programs or activities. Note: an education program or activity is not limited to only those conducted by a formal institution. 40 C.F.R. Part 5 implements Title IX of the Education Amendments of 1972. 40 C.F.R. Part 7 implements Title VI of the Civil Rights Act of 1964, Section 13 of the 1972 Amendments to the Federal Water Pollution Control Act, and Section 504 of The Rehabilitation Act of 1973. The Executive Order 13166 (E.O. 13166) entitled; "Improving Access to Services for Persons with Limited English Proficiency" requires Federal agencies work to ensure that recipients of Federal financial assistance provide meaningful access to their LEP applicants and beneficiaries.

Items "Applicant" means any entity that files an application or unsolicited proposal or otherwise requests EPA assistance. 40 C.F.R. §§ 5.105, 7.25. "Recipient" means any entity, other than applicant, which will actually receive EPA assistance. 40 C.F.R. §§ 5.105, 7.25. "Civil rights lawsuits and administrative complaints" means any lawsuit or administrative complaint alleging discrimination on the basis of race, color, national origin, sex, age, or disability pending or decided against the applicant and/or entity which actually benefits from the grant, but excluding employment complaints not covered by 40 C.F.R. Parts 5 and 7. For example, if a city is the named applicant but the grant will actually benefit the Department of Sewage, civil rights lawsuits involving both the city and the Department of Sewage should be listed. "Civil rights compliance review" means any review assessing the applicant's and/or recipient's compliance with laws prohibiting discrimination on the basis of race, color, national origin, sex, age, or disability. Submit this form with the original and required copies of applications, requests for extensions, requests for increase of funds, etc. Updates of information are all that are required after the initial application submission. If any item is not relevant to the project for which assistance is requested, write "NA" for "Not Applicable." In the event applicant is uncertain about how to answer any questions, EPA program officials should be contacted for clarification. * Note: Signature appears in the Approval Section of the EPA Comprehensive Administrative Review For Grants/Cooperative Agreements & Continuation/Supplemental Awards form.

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OMB Number: 4040-0006 Expiration Date: 02/28/2022

BUDGET INFORMATION - Non-Construction Programs

Document 10-2 Filed 06/05/25

Case 3:25-cv-04737-RFL

Provision of Federal Program P
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SECTION B - BUDGET CATEGORIES

6 Object Class Categories		GRANT PROGRAM. F	GRANT PROGRAM, FUNCTION OR ACTIVITY		Total
	(1)	(2)	(3)	(4)	(5)
	N/A	N/A	4/N		
a. Personnel	\$ 56,768.00	\$ 65,118.00	\$ 65,118.00	\$	\$ 187,004.00
b. Fringe Benefits	14,978.00	17,742.00	17,742.00		50,462.00
c. Travel	8,917.00	8,917.00	8,917.00		26,751.00
d. Equipment					
e. Supplies					
f. Contractual	4160.00	4160.00	4160.00		12,480.00
g. Construction					
h. Other	225,597.00	306,490.00	313,616.00		845,703.00
i. Total Direct Charges (sum of 6a-6h)	312,500.00	404,507.00	405,393.00		\$ 1,122,400.00
j. Indirect Charges	72,192.00	70,812.00	65,132.00		\$ 208,136.00
k. TOTALS (sum of 6i and 6j)	\$ 384,692.00	\$ 475,319.00	\$ 470,525.00	49	\$ 1,330,536.00
7. Program Income	49	S	49	49	49
	d	Authorized for Local Reproduction	roduction	Stan Prescribed by OM	Standard Form 424A (Rev. 7-97) Prescribed by OMB (Circular A -102) Page 1A

Prescribed by OMB (Circular A -102) Page 1A

Funding Opportunity Number: EPA-G2021-STAR-H1 Received Date: Nov 16, 2021 08:15:34 PM EST

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		SECTION	C-NON-	SECTION C - NON-FEDERAL RESOURCES	URCES				
(a) Grant Program			q)	(b) Applicant	(c) State	ate	(d) Other Sources		(e)TOTALS
8. N/A			₩	0.00	₩	00.00	· o	0 · 00 8	0.00
6									
10.									
1.									
12. TOTAL (sum of lines 8-11)			€9	00.00	\$	00.00		0.00	0.00
		SECTION	D - FORE	SECTION D - FORECASTED CASH NEEDS	NEEDS			l İ	
	Tota	Total for 1st Year		1st Quarter	2nd Quarter	arter	3rd Quarter		4th Quarter
13. Federal	€	384,692.00	₩	96,173.00	€\$	96,173.00	\$ 96,173.00	69	96,173.00
14. Non-Federal	\$								
15. TOTAL (sum of lines 13 and 14)	₩	384,692.00	\$	96,173.00	\$	96,173.00	\$ 96,173.00	9	96,173.00
SECTION E - BU	JDGET ES	TIMATES OF FE	DERAL F	SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT	FOR BALANC	E OF THE P	ROJECT	1	
(a) Grant Program					FUTURE	FUTURE FUNDING PERIODS	ERIODS (YEARS)		
				(b)First	(c) Second	puo	(d) Third		(e) Fourth
16. N/A			₩	475,319.00	S	470,525.00	\$	9	
17.									
18.									
19.									
20. TOTAL (sum of lines 16 - 19)			₩	475,319.00	\$	470,525.00	•	69	
		SECTION F	- OTHER	SECTION F - OTHER BUDGET INFORMATION	MATION				
21. Direct Charges: 1,122,400				22. Indirect (22. Indirect Charges: 208,136	,136			
23. Remarks: UCSF adheres to calculating the	budget us	ing the MTDC at	61.5%, ex	cluding UC Berkel	ey, as our six	ster campus,	ting the budget using the MIDC at 61.5%, excluding UC Berkeley, as our sister campus, in the first \$25,000 of their subcontract.	of thei	r subcontract.

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Funding Opportunity Number: EPA-G2021-STAR-H1 Received Date: Nov 16, 2021 08:15:34 PM EST

AREAS AFFECTED BY PROJECT

For the ecologic health analysis, all cities in the 58 counties in California will be studied.

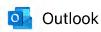
For Objective 4, the community engagement project, the cities of San Francisco, Fresno and Richmond, California will be included. The counties are San Francisco, Fresno and Contra Costa County.

Congressional Districts:

For the ecologic health analysis, all 53 Congressional Districts in California will be studied.

For Objective 4, the community engagement project, the California Congressional Districts include: CA-04, CA-11, CA-12, CA-13, CA-015, CA-16, CA-21, CA-22.

EXHIBIT C



Notice of EPA Award: Assistance Agreement RD-84048101

From Brooks, Jennifer <Brooks.Jennifer@epa.gov>

Date Tue 11/22/2022 5:52 AM

To Thakur, Neeta < Neeta. Thakur@ucsf.edu>

Cc HQgrantsnotification <HQgrantsnotification@epa.gov>; Hahn, Intaek <hahn.intaek@epa.gov>

🛭 1 attachment (221 KB)

Assistance Agreement 84048101-0.pdf;

This Message Is From an External Sender

This message came from outside your organization.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF MISSION SUPPORT

Re: Notice of EPA Assistance Award

Dear Authorized Representative:

Attached is your Notice of Award from the U.S. Environmental Protection Agency. Please carefully review the assistance agreement and <u>all</u> of the terms and conditions.

Please make a copy for your records and provide the appropriate copies within your organization (page three of the award package intentionally left blank). The recipient's signature is not required on the enclosed agreement in order to signify acceptance. Award recipients demonstrate acceptance of the award and commitment to carry out the award by either: 1) drawing down funds within 21 calendar days after the mailing date indicated on the face page of the award; or 2) not filing a notice of disagreement with the award terms and conditions within 21 calendar days after the mailing date indicated on the face page of the award. The terms and conditions of some awards require additional signed certifications or assurances. These should be scanned and emailed to the EPA Grants Specialist listed on the face page of the award document. To file a notice of disagreement with the terms and conditions, the authorized representative of the recipient may also contact the Grants Specialist via email. Alternatively, hard copies of documents or correspondence may be sent to one of the addresses below:

For regular postal delivery: Express delivery:

For courier or Federal

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Case: 25-4249_07/22/2025, Dkt=ntry: 11.1, Page 445 of 475
5/12/25, 10:08 AM Case 3:25-cv-04737 RucLof EPD Octub Nightin Logge mental legation by 5/12/25, Netrago 13:06

U.S. Environmental Protection Agency Agency Office of Grants and Debarment 1200 Pennsylvania Avenue, NW (3903R) Fifth Floor, Room 51234 Washington, DC 20460

Office of Grants and Debarment 1300 Pennsylvania Avenue, NW Fifth Floor, Room 51234 Washington, DC 20004

U.S. Environmental Protection

Payment will be made available after any required certifications and/or assurances are received, if applicable. The Research Triangle Park Finance Center (RTPFC) will provide information about how you will receive payment and report on your financial transactions during the period of performance.

Guidance, regulations and additional forms needed throughout the life of your award are located at https://www.epa.gov/grants/grant-regulations-and-forms-new-grantees. You may refer to the terms and conditions of your award for guidance on completing and submitting all forms requested or required.

Please pay particular attention to the following items that are procedural changes contained in EPA's <u>Online General Terms and Conditions</u> linked directly to within the Administrative Terms and Conditions of this award. Take note of the "Award Date," also listed on the award document face page, which corresponds to a set of online conditions unique to a specific period in time that apply to your individual award:

SF-425: FEDERAL FINANCIAL REPORTS (FFR) ANNUAL SUBMISSION:

Any monetary action (new, incremental and supplemental) issued on or after October 6, 2015 now requires EPA grant recipients to submit the SF-425: Federal Financial Report no later than 30 days after the end of each specified reporting period for quarterly and semi-annual reports, and 90 calendar days for annual reports. Final reports are due no later than 120 calendar days after the end date of the period of performance of the award. Extension of reporting due dates may be approved by EPA upon request of the recipient. The FFR form is available on the internet at: http://www2.epa.gov/financial/forms. All FFRs and manual payment requests (if not using ASAP) must be submitted to the RTPFC via email at rtpfc-grants@epa.gov or mail to:

US Environmental Protection Agency RTP-Finance Center (Mail Code AA216-01) 4930 Page Rd. Durham, NC 27703

Refer to the Online General Term and Condition titled: "Federal Financial Reporting" or "Final Federal Financial Report" as applicable.

SUBAWARDS:

As of March 29, 2016, the Office of Grants and Debarment issued the EPA Subaward Policy for EPA Assistance Agreements Recipients. Monetary actions (new, incremental and supplemental) issued after March 29 are subject to the subaward reporting requirements provisions of 2 CFR 200 and the EPA Subaward Policy. If your work plan and budget include subawards of financial assistance as defined in 2 CFR 200.1 and 2 CFR 200.331, EPA's National Term and Condition for Subawards titled: "Establishing and Managing Subawards" will apply.

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5/12/25, 10:08 AM

By accepting this assistance agreement your organization is certifying that it either has systems in place to comply with the regulatory or EPA policy requirements specified in the National Term and Condition for Subawards, or that it will refrain from making subawards with funding EPA provides under this agreement until the systems are designed and implemented. Should your organization decide to make a subaward(s) that was not described in the work plan and budgeted for under this agreement, you must obtain prior written approval from EPA's Award Official as provided at 2 CFR 200.308(c)(6).

If you have any questions, please contact your Grants Specialist identified on the award document. Please reference the EPA assistance number on all future correspondence regarding this assistance agreement.

Attachment (Official EPA Award Document)

Jennifer Brooks **Environmental Protection Agency** Grants & Interagency Agreement Management Division 1200 Pennsylvania Ave., NW Mail Code 3903R Washington, DC 20460 202-564-6374 Office Hours 6:30am - 3:00pm EST

https://intranet.epa.gov/ogd/contacts/ogdcontact/contact_grant_specialist.htm

3/3 about:blank

EXHIBIT D

STATES STATES TO NAMINORIVANIAN AGENCY

RECIPIENT TYPE:

State Institution of Higher Learning

U.S. ENVIRONMENTAL PROTECTION AGENCY

Grant Agreement

RD - 84048101 - 0 Page 1

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GRANT NUMBER (FAIN):	84048101	
MODIFICATION NUMBER:	0	DATE OF AWARD
PROGRAM CODE:	RD	11/17/2022
TYPE OF ACTION		MAILING DATE
New		11/22/2022
PAYMENT METHOD:		ACH#
ASAP		90202
4		

Send Payment Request to:

Contact EPA RTPFC at: rtpfc-grants@epa.gov

RECIPIENT: PAYER

The Regents of the University of CA - SF

The Regents of the University of CA - San Francisco

 1855 Folsom St. Suite 425 Box 0812
 1855 Folsom Street, Suite 425

 San Francisco, CA 94143-4249
 San Francisco, CA 94143-4249

EIN: 94-6036493

PROJECT MANAGER **EPA PROJECT OFFICER EPA GRANT SPECIALIST** Neeta Thakur Intaek Hahn Jennifer Brooks 1001 Potrero Avenue, 228 1200 Pennsylvania Ave, NW, 8725P 1200 Pennsylvania Ave, NW 3903R San Francisco, CA 94143-0841 Washington, DC 20460 Washington, DC 20460 Email: Hahn.Intaek@epa.gov Email: Brooks.Jennifer@epa.gov Email: Neeta.Thakur@ucsf.edu Phone: 415-476-0735 Phone: 202-564-4377 Phone: 202-564-6374

PROJECT TITLE AND DESCRIPTION

Partnering for Resilient Opportunities To Eliminate Cumulative Toxic Health Effects from Wildfire

See Attachment 1 for project description.

BUDGET PERIOD	PROJECT PERIOD	TOTAL BUDGET PERIOD COST	TOTAL PROJECT PERIOD COST
12/01/2022 - 11/30/2025	12/01/2022 - 11/30/2025	\$1,330,536.00	\$1,330,536.00

NOTICE OF AWARD

Based on your Application dated 11/16/2021 including all modifications and amendments, the United States acting by and through the US Environmental Protection Agency (EPA) hereby awards \$690,000.00. EPA agrees to cost-share 100.00% of all approved budget period costs incurred, up to and not exceeding total federal funding of \$690,000.00. Recipient's signature is not required on this agreement. The recipient demonstrates its commitment to carry out this award by either: 1) drawing down funds within 21 days after the EPA award or amendment mailing date; or 2) not filing a notice of disagreement with the award terms and conditions within 21 days after the EPA award or amendment mailing date. If the recipient disagrees with the terms and conditions specified in this award, the authorized representative of the recipient must furnish a notice of disagreement to the EPA Award Official within 21 days after the EPA award or amendment mailing date. In case of disagreement, and until the disagreement is resolved, the recipient should not draw down on the funds provided by this award/amendment, and any costs incurred by the recipient are at its own risk. This agreement is subject to applicable EPA regulatory and statutory provisions, all terms and conditions of this agreement and any attachments.

ISSUING OFFICE (GRANTS MANAGEMENT OFFICE)	AWARD APPROVAL OFFICE		
ORGANIZATION / ADDRESS	ORGANIZATION / ADDRESS		
Environmental Protection Agency , Grants and Interagency Agreement	Environmental Protection Agency, OSAPE		
1200 Pennsylvania Ave, NW Mail code 3903R	ORD - Office of Research and Development		
Washington, DC 20460	1200 Pennsylvania Ave, NW		
	Washington, DC 20460		
THE UNITED STATES OF AMERICA BY THE U	J.S. ENVIRONMENTAL PROTECTION AGENCY		

Dig Dag skal resignment unepskippl lie of 159 & PAW and a Doff Citif of all Jill Young - Chief - Grants Management Branch
LaShaun Phillips - Associate Award Official

11/17/2022

DATE

EPA Funding Information

FUNDS	FORMER AWARD	THIS ACTION	AMENDED TOTAL
EPA Amount This Action	\$0	\$690,000	\$690,000
EPA In-Kind Amount	\$0	\$0	\$0
Unexpended Prior Year Balance	\$0	\$0	\$0
Other Federal Funds	\$0	\$0	\$0
Recipient Contribution	\$0	\$0	\$0
State Contribution	\$0	\$0	\$0
Local Contribution	\$0	\$0	\$0
Other Contribution	\$0	\$0	\$0
Allowable Project Cost	\$0	\$690,000	\$690,000

Assistance Program (CFDA)	Statutory Authority	Regulatory Authority
66.509 - Science to Achieve Results (STAR) Program	Clean Air Act: Sec. 103	2 CFR 200, 2 CFR 1500, 40 CFR 33 and 40 CFR 40

				Fiscal					
Site Name	Req No	FY	Approp. Code	Budget Oganization	PRC	Object Class	Site/Project	Cost Organization	Obligation / Deobligation
-	232631M001	2223	С	2631000	000FK8XPV	4141	-	26A6A	\$690,000
									\$690,000

Case: 25-4249-07/22/2025, DktEntry: 11.1, Page 450 of 475 Case 3:25-cv-04737-RFL Document 10-4 Filed 06/05/25 Page 4 of 9

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Budget Summary Page

Table A - Object Class Category (Non-Construction)	Total Approved Allowable Budget Period Cost
1. Personnel	\$187,004
2. Fringe Benefits	\$50,462
3. Travel	\$26,751
4. Equipment	\$0
5. Supplies	\$0
6. Contractual	\$12,480
7. Construction	\$0
8. Other	\$845,703
9. Total Direct Charges	\$1,122,400
10. Indirect Costs: 61.50 % Base MTDC	\$208,136
11. Total (Share: Recipient0.00 % Federal100.00 %)	\$1,330,536
12. Total Approved Assistance Amount	\$1,330,536
13. Program Income	\$0
14. Total EPA Amount Awarded This Action	\$690,000
15. Total EPA Amount Awarded To Date	\$690,000

Attachment 1 - Project Description

The goal of the project is to understand the cascading impacts of recurrent and prolonged wildfire smoke exposure on health and well-being of the residents in underserved communities in conjunction with other relevant environmental factors such as social adversity in low-income, minority communities in California. The project will 1) estimate the health effects of sub-daily exposure to wildfire-specific PM2.5 in California, including across social vulnerability factors, with

particular focus on effects within EJ communities; 2) analyze community recovery from short-term health effects following exposure; 3) quantify indoor infiltration of wildfire

smoke and the mitigating effect of housing quality and behaviors; and 4) work with communities to develop mitigation interventions to fit the specific needs of the communities. Deliverables include annual and final research reports as well as scientific publications with more accurate estimates of wildfire-specific PM2.5 distributions across communities and smoke infiltration data for housing across California. Expected outcomes include the reduction of wildfire-related PM exposure. Intended beneficiaries include low-income, minority residents living in underserved communities across California, public health professionals, environmental managers, air quality specialists, and community planners. University of California - Berkeley (\$705,047) will (1) quantify wildfire specific fine particulate matter for fire seasons, (2) estimate magnitude of effect by wildfire PM on health outcomes, and (3) determine indoor penetration based on housing attributes data. Central California Asthma Collaboration (CCAC) (\$60,000) will coordinate engagement efforts, including recruiting stakeholders, administrating surveys, and conducting focus groups. \$23,100 to seven subawardees (TBD) to co-develop and implement pilot adaptation strategies.

Administrative Conditions

A. General Terms and Conditions

The recipient agrees to comply with the current EPA general terms and conditions available at: https://www.epa.gov/grants/epa-general-terms-and-conditions-effective-october-1-2022-or-later. These terms and conditions are in addition to the assurances and certifications made as a part of the award and the terms, conditions, or restrictions cited throughout the award.

The EPA repository for the general terms and conditions by year can be found at: https://www.epa.gov/grants/grant-terms-and-conditions#general.

B. Correspondence Condition

The terms and conditions of this agreement require the submittal of reports, specific requests for approval, or notifications to EPA. Unless otherwise noted, all such correspondence should be sent to the following email addresses:

- Federal Financial Reports (SF-425): rtpfc-grants@epa.gov and Brooks.Jennifer@EPA.gov
- MBE/WBE reports (EPA Form 5700-52A): DBE Coordinator, Dominick Washington; mbe.wbe@epa.gov
- All other forms/certifications/assurances, Indirect Cost Rate Agreements, Requests for Extensions of the Budget and Project Period, Amendment Requests, Requests for other Prior Approvals, updates to recipient information (including email addresses, changes in contact information or changes in authorized representatives) and other notifications: *Hahn.Intaek@EPA.gov*
- Payment requests (if applicable): <u>Hahn.Intaek@EPA.gov</u>
- Quality Assurance documents, workplan revisions, equipment lists, programmatic reports and deliverables: Hahn.Intaek@EPA.gov

C. Prompt Payment

In accordance with Section 2(d) of the Prompt Payment Act (P.L. 97-177), Federal funds may not be used by the recipient for the payment of interest penalties to contractors when bills are paid late nor may interest penalties be used to satisfy cost sharing requirements. Obligations to pay such interest penalties will not be obligations of the United States.

D. No Fed

The recipient understands that none of the funds for this project (including funds contributed by the recipient as cost sharing) may be used to pay for the travel of Federal employees or for other costs associated with Federal participation in this project. Except however, if a Federal agency is selected through the recipient's procurement process to carry out some of the work as a contractor to the recipient, funds may be used to allow necessary Federal travel and other costs associated with Federal participation in this project.

E. Partial Funding

EPA is funding this agreement incrementally. There is no guarantee of funding beyond the first year. The **Total Approved Assistance Amount** identified on Line 12 of the budget table of this award is contingent upon the availability of appropriated funds, EPA funding priorities, and satisfactory progress in carrying out the activities described in the scope of

work. If EPA informs the recipient that the amount on Line 12 will be reduced, the recipient agrees to provide an updated workplan and budget information, as needed, to amend the agreement.

F. Payment to Consultants

EPA participation in the salary rate (excluding overhead) paid to individual consultants retained by recipients or by a recipient's contractors or subcontractors shall be limited to the maximum daily rate for a Level IV of the Executive Schedule (formerly GS-18), to be adjusted annually. This limit applies to consultation services of designated individuals with specialized skills who are paid at a daily or hourly rate. As of January 1, 2022, the limit is \$675.84 per day and \$84.48 per hour. This rate does not include transportation and subsistence costs for travel performed (the recipient will pay these in accordance with their normal travel reimbursement practices). Contracts and subcontracts with firms for services which are awarded using the procurement requirements in Subpart D of 2 CFR 200, are not affected by this limitation unless the terms of the contract provide the recipient with responsibility for the selection, direction and control of the individuals who will be providing services under the contract at an hourly or daily rate of compensation. See 2 CFR 1500.10.

Programmatic Conditions

A. Standard Terms and Conditions for Research Awards

This award is subject to EPA's set of standard terms and conditions for research awards located at https://www.epa.gov/grants/grant-terms-and-conditions#office.

B. Quality Assurance

Authority: Quality Assurance applies to all assistance agreements involving environmental information as defined in <u>2</u> <u>C.F.R. § 1500.12</u> Quality Assurance.

The recipient shall ensure that subawards involving environmental information issued under this agreement include appropriate quality requirements for the work. The recipient shall ensure sub-award recipients develop and implement the Quality Assurance (QA) planning documents in accordance with this term and condition; and/or ensure sub-award recipients implement all applicable approved QA planning documents.

1. Quality Management Plan (QMP)

- a. Prior to beginning environmental information operations, the recipient must:
 - i. Develop a QMP,
 - ii. Prepare the QMP in accordance with the most current version of <u>EPA QA/R-2: EPA Requirements for Quality Management Plans</u>,
 - III. Submit the document to the EPA PO for EPA QA review, and
 - iv. Obtain EPA Director of Quality Assurance (DQA) approval prior to work start.
- b. The recipient must submit the QMP within 60 days after grant award.
- c. The recipient must review their approved QMP at least annually. The results of the QMP review and any revisions must be submitted to the PO and the DQA in the annual report and may also be submitted when changes

occur.

2. Quality Assurance Project Plan (QAPP)

- a. Prior to beginning environmental information operations, the recipient must:
 - i. Develop a QAPP,
 - ii. Prepare QAPP in accordance with the most current version of <u>EPA QA/R-5</u>: <u>EPA Requirements for Quality Assurance Project Plans</u>,
 - iii. Submit the document for EPA review, and

3. Obtain EPA DQA approval prior to work start.

- a. The recipient must submit the QAPP 90 days after grant award.
- b. The recipient shall notify the PO and DQA when substantive changes are needed to the QAPP. EPA may require the QAPP be updated and re-submitted for approval.
- c. The recipient must review their approved QAPP at least annually. The results of the QAPP review and any revisions must be submitted to the PO and the DQA in the annual report and may also be submitted when changes occur.

For Reference:

- EPA QA/R-2: EPA Requirements for Quality Management Plans and EPA QA/R-5: EPA Requirements for Quality
 Assurance Project Plans; contain quality specifications for EPA and non-EPA organizations and definitions applicable to these terms and conditions.
- EPA QA/G-5: Guidance for Quality Assurance Project Plans, Appendix C provides a QAPP Checklist.
- Quality Specifications for non-EPA Organizations to do business with EPA.
- The Office of Grants and Debarment Quality Assurance Requirements.

C. Geospatial Data Standards

All geospatial data created must be consistent with Federal Geographic Data Committee (FGDC) endorsed standards. Information on these standards may be found at www.fgdc.gov.

D. Sub-award Reporting

The recipient must report on its subaward monitoring activities under 2 CFR 200.332(d). Examples of items that must be reported if the pass-through entity has the information available are:

- 1. Summaries of results of reviews of financial and programmatic reports
- 2. Summaries of findings from site visits and/or desk reviews to ensure effective subrecipient performance
- 3. Environmental results the subrecipient achieved
- 4. Summaries of audit findings and related pass-through entity management decisions

5. Actions the pass-through entity has taken to correct deficiencies such as those specified at 2 CFR 200.332(e), 2 CFR 200.208 and 2 CFR 200.339

Note: EPA Project Officers may customize this reporting requirement based on programmatic information needs.

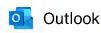
E. Cybersecurity Grant Condition for Other Recipients, Including Intertribal Consortia

- (a) The recipient agrees that when collecting and managing environmental data under this assistance agreement, it will protect the data by following all applicable State or Tribal law cybersecurity requirements.
- (b) (1) EPA must ensure that any connections between the recipient's network or information system and EPA networks used by the recipient to transfer data under this agreement, are secure. For purposes of this Section, a connection is defined as a dedicated persistent interface between an Agency IT system and an external IT system for the purpose of transferring information. Transitory, user-controlled connections such as website browsing are excluded from this definition.

If the recipient's connections as defined above do not go through the Environmental Information Exchange Network or EPA's Central Data Exchange, the recipient agrees to contact the EPA Project Officer (PO) no later than 90 days after the date of this award and work with the designated Regional/Headquarters Information Security Officer to ensure that the connections meet EPA security requirements, including entering into Interconnection Service Agreements as appropriate. This condition does not apply to manual entry of data by the recipient into systems operated and used by EPA's regulatory programs for the submission of reporting and/or compliance data.

(2) The recipient agrees that any subawards it makes under this agreement will require the subrecipient to comply with the requirements in (b)(1) if the subrecipient's network or information system is connected to EPA networks to transfer data to the Agency using systems other than the Environmental Information Exchange Network or EPA's Central Data Exchange. The recipient will be in compliance with this condition: by including this requirement in subaward agreements; and during subrecipient monitoring deemed necessary by the recipient under 2 CFR 200.332(d), by inquiring whether the subrecipient has contacted the EPA Project Officer. Nothing in this condition requires the recipient to contact the EPA Project Officer on behalf of a subrecipient or to be involved in the negotiation of an Interconnection Service Agreement between the subrecipient and EPA.

EXHIBIT E



Notice of EPA Award: 84048101-1

From Brooks, Jennifer <Brooks.Jennifer@epa.gov>

Date Wed 6/21/2023 12:09 PM

To Thakur, Neeta <Neeta.Thakur@ucsf.edu>

Cc HQgrantsnotification <HQgrantsnotification@epa.gov>; Hahn, Intaek <hahn.intaek@epa.gov>

🛭 1 attachment (215 KB)

Assistance Amendment 84048101-1.pdf;

This Message Is From an External Sender

This message came from outside your organization.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF MISSION SUPPORT

Re: Notice of EPA Assistance Award

Dear Authorized Representative:

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For regular postal delivery: Express delivery:

For courier or Federal

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Case: 25-4249_07/22/2025, DktEntry: 11.1, Page 458 of 475
5/12/25, 10:07 AM Case 3:25-cv-04737-RFL NGC Summerated 8594810File tile 01a 06 NUSA 25 sudool Page 3 of 4

U.S. Environmental Protection Agency Agency Office of Grants and Debarment 1200 Pennsylvania Avenue, NW (3903R) Fifth Floor, Room 51234 Washington, DC 20460

Office of Grants and Debarment 1300 Pennsylvania Avenue, NW Fifth Floor, Room 51234 Washington, DC 20004

U.S. Environmental Protection

Payment will be made available after any required certifications and/or assurances are received, if applicable. The Research Triangle Park Finance Center (RTPFC) will provide information about how you will receive payment and report on your financial transactions during the period of performance.

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Please pay particular attention to the following items that are procedural changes contained in EPA's <u>Online General Terms and Conditions</u> linked directly to within the Administrative Terms and Conditions of this award. Take note of the "Award Date," also listed on the award document face page, which corresponds to a set of online conditions unique to a specific period in time that apply to your individual award:

SF-425: FEDERAL FINANCIAL REPORTS (FFR) ANNUAL SUBMISSION:

Any monetary action (new, incremental and supplemental) issued on or after **October 6**, **2015** now requires EPA grant recipients to submit the SF-425: Federal Financial Report no later than 30 days after the end of each specified reporting period for quarterly and semi-annual reports, and 90 calendar days for <u>annual</u> reports. <u>Final</u> reports are due no later than 120 calendar days after the end date of the period of performance of the award. Extension of reporting due dates may be approved by EPA upon request of the recipient. The FFR form is available on the internet at: http://www2.epa.gov/financial/forms. All FFRs and manual payment requests (if not using ASAP) must be submitted to the RTPFC via email at rtpfc-grants@epa.gov or mail to:

US Environmental Protection Agency RTP-Finance Center (Mail Code AA216-01) 4930 Page Rd. Durham, NC 27703

Refer to the Online General Term and Condition titled: "Federal Financial Reporting" or "Final Federal Financial Report" as applicable.

SUBAWARDS:

As of March 29, 2016, the Office of Grants and Debarment issued the EPA Subaward Policy for EPA Assistance Agreements Recipients. Monetary actions (new, incremental and supplemental) issued after March 29 are subject to the subaward reporting requirements provisions of 2 CFR 200 and the EPA Subaward Policy. If your work plan and budget include subawards of financial assistance as defined in 2 CFR 200.1 and 2 CFR 200.331, EPA's National Term and Condition for Subawards titled: "Establishing and Managing Subawards" will apply.

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Case: 25-4249 07/22/2025, DktEntry: 11.1, Page 459 of 475
5/12/25, 10:07 AM Case 3:25-cv-04737-RFL 120cument at 08-504810Filed a 06/05/25 utlook Page 4 of 4

By accepting this assistance agreement your organization is certifying that it either has systems in place to comply with the regulatory or EPA policy requirements specified in the National Term and Condition for Subawards, or that it will refrain from making subawards with funding EPA provides under this agreement until the systems are designed and implemented. Should your organization decide to make a subaward(s) that was not described in the work plan and budgeted for under this agreement, you must obtain prior written approval from EPA's Award Official as provided at 2 CFR 200.308(c)(6).

If you have any questions, please contact your Grants Specialist identified on the award document. Please reference the EPA assistance number on all future correspondence regarding this assistance agreement.

Attachment (Official EPA Award Document)

Jennifer Brooks
Senior Grants Management Specialist
Environmental Protection Agency
Grants & Interagency Agreement Management Division
1200 Pennsylvania Ave., NW Mail Code 3903R
Washington, DC 20460
202-564-6374
Office Hours 6:30am – 3:00pm EST

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EXHIBIT F

PROGRAM CODE:

TYPE OF ACTION

ENVIRON	TO TALE PROTECTION
MK	WAL PROTECTION

State Institution of Higher Learning

U.S. ENVIRONMENTAL PROTECTION AGENCY

Assistance Amendment

RD - 84048101 - 1 Page 1 GRANT NUMBER (FAIN): 84048101 MODIFICATION NUMBER: DATE OF AWARD 1 RD 06/15/2023 MAILING DATE Augmentation: Increase 06/21/2023

PAYMENT METHOD: ACH# ASAP 90202

RECIPIENT TYPE: Send Payment Request to:

Contact EPA RTPFC at: rtpfc-grants@epa.gov

RECIPIENT:

The Regents of the University of CA - San Francisco The Regents of the University of CA - SF

1855 Folsom St. Suite 425 Box 0812 1855 Folsom Street, Suite 425 San Francisco, CA 94143-4249 San Francisco, CA 94143-4249

EIN: 94-6036493

PROJECT MANAGER **EPA PROJECT OFFICER EPA GRANT SPECIALIST** Intaek Hahn Neeta Thakur Jennifer Brooks 1001 Potrero Avenue, 228 1200 Pennsylvania Ave, NW, 8725P 1200 Pennsylvania Ave, NW 3903R San Francisco, CA 94143-0841 Washington, DC 20460 Washington, DC 20460 Email: Hahn.Intaek@epa.gov Email: Neeta.Thakur@ucsf.edu Email: Brooks.Jennifer@epa.gov Phone: 415-476-0735 Phone: 202-564-4377 Phone: 202-564-6374

PROJECT TITLE AND EXPLANATION OF CHANGES

Partnering for Resilient Opportunities To Eliminate Cumulative Toxic Health Effects from Wildfire

The goal of the project is to understand the cascading impacts of recurrent and prolonged wildfire smoke exposure on health and well-being of the residents in underserved communities in conjunction with other relevant environmental factors such as social adversity in low-income, minority communities in California.

Incremental Amendment: Completion of Partial Funding: This amendment provides incremental funding in the amount of \$640.536.

BUDGET PERIOD PROJECT PERIOD TOTAL BUDGET PERIOD COST TOTAL PROJECT PERIOD COST 12/01/2022 - 11/30/2025 12/01/2022 - 11/30/2025 \$1.330.536.00 \$1,330,536.00

NOTICE OF AWARD

Based on your Application dated 11/16/2021 including all modifications and amendments, the United States acting by and through the US Environmental Protection Agency (EPA) hereby awards \$640,536.00. EPA agrees to cost-share 100.00% of all approved budget period costs incurred, up to and not exceeding total federal funding of \$1,330,536.00. Recipient's signature is not required on this agreement. The recipient demonstrates its commitment to carry out this award by either: 1) drawing down funds within 21 days after the EPA award or amendment mailing date; or 2) not filing a notice of disagreement with the award terms and conditions within 21 days after the EPA award or amendment mailing date. If the recipient disagrees with the terms and conditions specified in this award, the authorized representative of the recipient must furnish a notice of disagreement to the EPA Award Official within 21 days after the EPA award or amendment mailing date. In case of disagreement, and until the disagreement is resolved, the recipient should not draw down on the funds provided by this award/amendment, and any costs incurred by the recipient are at its own risk. This agreement is subject to applicable EPA regulatory and statutory provisions, all terms and conditions of this agreement and any attachments.

ISSUING OFFICE (GRANTS MANAGEMENT OFFICE)	AWARD APPROVAL OFFICE			
ORGANIZATION / ADDRESS	ORGANIZATION / ADDRESS			
Environmental Protection Agency , Grants and Interagency Agreement	Environmental Protection Agency, OSAPE			
1200 Pennsylvania Ave, NW Mail code 3903R	ORD - Office of Research and Development			
Washington, DC 20460	1200 Pennsylvania Ave, NW			
	Washington, DC 20460			
THE UNITED STATES OF AMERICA BY THE U.S. ENVIRONMENTAL PROTECTION AGENCY				
Digital signature applied by EPA Award Official for Jill Young - Chief - Grants Management Branch DATE				

LaShaun Phillips - Award Official Delegate

06/15/2023

EPA Funding Information

FUNDS	FORMER AWARD	THIS ACTION	AMENDED TOTAL
EPA Amount This Action	\$690,000	\$640,536	\$1,330,536
EPA In-Kind Amount	\$0	\$0	\$0
Unexpended Prior Year Balance	\$0	\$0	\$0
Other Federal Funds	\$0	\$0	\$0
Recipient Contribution	\$0	\$0	\$0
State Contribution	\$0	\$0	\$0
Local Contribution	\$0	\$0	\$0
Other Contribution	\$0	\$0	\$0
Allowable Project Cost	\$690,000	\$640,536	\$1,330,536

Statutory Authority	Regulatory Authority
Clean Air Act: Sec. 103	2 CFR 200, 2 CFR 1500, 40 CFR 33 and 40 CFR 40
	i i

				Fiscal					
Site Name	Req No	FY	Approp. Code	Budget Oganization	PRC	Object Class	Site/Project	Cost Organization	Obligation / Deobligation
-	232631M057	2324	С	2631000	000FK8XPV	4141	-	26A6A	\$640,536
									\$640,536

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Budget Summary Page

Table A - Object Class Category (Non-Construction)	Total Approved Allowable Budget Period Cost
1. Personnel	\$187,004
2. Fringe Benefits	\$50,462
3. Travel	\$26,751
4. Equipment	\$0
5. Supplies	\$0
6. Contractual	\$12,480
7. Construction	\$0
8. Other	\$845,703
9. Total Direct Charges	\$1,122,400
10. Indirect Costs: 61.50 % Base MTDC	\$208,136
11. Total (Share: Recipient0.00 % Federal _100.00 %)	\$1,330,536
12. Total Approved Assistance Amount	\$1,330,536
13. Program Income	\$0
14. Total EPA Amount Awarded This Action	\$640,536
15. Total EPA Amount Awarded To Date	\$1,330,536

Administrative Conditions

A. General Terms and Conditions

The recipient agrees to comply with the current EPA general terms and conditions available at: https://www.epa.gov/grants/epa-general-terms-and-conditions-effective-october-1-2022-or-later. These terms and conditions are in addition to the assurances and certifications made as a part of the award and the terms, conditions, or restrictions cited throughout the award.

The EPA repository for the general terms and conditions by year can be found at: https://www.epa.gov/grants/grant-terms-and-conditions#general.

B. Correspondence Condition

The terms and conditions of this agreement require the submittal of reports, specific requests for approval, or notifications to EPA. Unless otherwise noted, all such correspondence should be sent to the following email addresses:

- Federal Financial Reports (SF-425): rtpfc-grants@epa.gov and brooks.jennifer@epa.gov
- MBE/WBE reports (EPA Form 5700-52A): DBE Coordinator, Dominick Washington; mbe.wbe@epa.gov
- All other forms/certifications/assurances, Indirect Cost Rate Agreements, Requests for Extensions of the Budget and Project Period, Amendment Requests, Requests for other Prior Approvals, updates to recipient information (including email addresses, changes in contact information or changes in authorized representatives) and other notifications: hahn.intaek@epa.gov
- Payment requests (if applicable): hahn.intaek@epa.gov
- Quality Assurance documents, workplan revisions, equipment lists, programmatic reports and deliverables: hahn.intaek@epa.gov

C. No Fed

The recipient understands that none of the funds for this project (including funds contributed by the recipient as cost sharing) may be used to pay for the travel of Federal employees or for other costs associated with Federal participation in this project. Except however, if a Federal agency is selected through the recipient's procurement process to carry out some of the work as a contractor to the recipient, funds may be used to allow necessary Federal travel and other costs associated with Federal participation in this project.

D. Payment to Consultants

EPA participation in the salary rate (excluding overhead) paid to individual consultants retained by recipients or by a recipient's contractors or subcontractors shall be limited to the maximum daily rate for a Level IV of the Executive Schedule (formerly GS-18), to be adjusted annually. This limit applies to consultation services of designated individuals with specialized skills who are paid at a daily or hourly rate. As of January 1, 2023, the limit is \$703.44 per day and \$87.93 per hour. This rate does not include transportation and subsistence costs for travel performed (the recipient will pay these in accordance with their normal travel reimbursement practices). Contracts and subcontracts with firms for services which are awarded using the procurement requirements in Subpart D of 2 CFR 200, are not affected by this limitation unless the terms of the contract provide the recipient with responsibility for the selection, direction and control of the individuals who will be providing services under the contract at an hourly or daily rate of compensation. See 2 CFR 1500.10.

All Other Administrative Conditions Remain the Same.

Programmatic Conditions

A. Cybersecurity Grant Condition for Other Recipients, Including Intertribal Consortia

- (a) The recipient agrees that when collecting and managing environmental data under this assistance agreement, it will protect the data by following all applicable State or Tribal law cybersecurity requirements.
- (b) (1) EPA must ensure that any connections between the recipient's network or information system and EPA networks used by the recipient to transfer data under this agreement, are secure. For purposes of this Section, a connection is defined as a dedicated persistent interface between an Agency IT system and an external IT system for the purpose of transferring information. Transitory, user-controlled connections such as website browsing are excluded from this definition.

If the recipient's connections as defined above do not go through the Environmental Information Exchange Network or EPA's Central Data Exchange, the recipient agrees to contact the EPA Project Officer (PO) no later than 90 days after the date of this award and work with the designated Regional/Headquarters Information Security Officer to ensure that the connections meet EPA security requirements, including entering into Interconnection Service Agreements as appropriate. This condition does not apply to manual entry of data by the recipient into systems operated and used by EPA's regulatory programs for the submission of reporting and/or compliance data.

(2) The recipient agrees that any subawards it makes under this agreement will require the subrecipient to comply with the requirements in (b)(1) if the subrecipient's network or information system is connected to EPA networks to transfer data to the Agency using systems other than the Environmental Information Exchange Network or EPA's Central Data Exchange. The recipient will be in compliance with this condition: by including this requirement in subaward agreements; and during subrecipient monitoring deemed necessary by the recipient under 2 CFR 200.332(d), by inquiring whether the subrecipient has contacted the EPA Project Officer. Nothing in this condition requires the recipient to contact the EPA Project Officer on behalf of a subrecipient or to be involved in the negotiation of an Interconnection Service Agreement between the subrecipient and EPA.

All Other Programmatic Conditions Remain the Same.

EXHIBIT G

	UNITED STATES	5
VIRONN	WAL PROTECTION	" AGENC
•	VIAL PROTECTION	

U.S. ENVIRONMENTAL PROTECTION AGENCY

Assistance Amendment

	112 01010101	
GRANT NUMBER (FAIN):	84048101	
MODIFICATION NUMBER:	2	DATE OF AWARD
PROGRAM CODE:	RD	04/28/2025
TYPE OF ACTION		MAILING DATE
No Cost Amendment		04/28/2025
PAYMENT METHOD:		ACH#
ASAP		90202

DECIDIENT	TVDE.	
RECIPIENT	TYPE:	

State Institution of Higher Learning

RECIPIENT:

REGENTS OF THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, THE

UCSF Controller's Office

1855 FOLSOM STREET, SUITE 425 Box 0812

SAN FRANCISCO, CA 94143

EIN: 94-6036493

Send Payment Request to:

Contact EPA RTPFC at: rtpfc-grants@epa.gov

PAYEE:

REGENTS OF THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, THE

1855 FOLSOM STREET, SUITE 425 SAN FRANCISCO, CA 94143-4249

PROJECT MANAGER	EPA PROJECT OFFICER	EPA GRANT SPECIALIST
Neeta Thakur	Intaek Hahn	Jennifer Brooks
1001 Potrero Avenue, 228	1200 Pennsylvania Ave, NW, 8725P	1200 Pennsylvania Ave, NW 3903R
San Francisco, CA 94143-0841	Washington, DC 20460	Washington, DC 20460
Email: Neeta.Thakur@ucsf.edu	Email: Hahn.Intaek@epa.gov	Email: Brooks.Jennifer@epa.gov
Phone: 415-476-0735	Phone: 202-564-4377	Phone: 202-564-6374

PROJECT TITLE AND EXPLANATION OF CHANGES

Partnering for Resilient Opportunities To Eliminate Cumulative Toxic Health Effects from Wildfire

This amendment is to stop work; terminate the agreement; reduce performance period duration; curtail scope of work; and waive certain reporting requirements. Administrative terms and conditions are added.

Per 2 CFR 200.340 and the Termination General Terms and Conditions of this agreement, EPA is terminating this award. Your organization shall immediately stop work and take all reasonable steps to minimize the incurrence of costs otherwise allocable to the assistance agreement. See terms and conditions.

BUDGET PERIOD	PROJECT PERIOD	TOTAL BUDGET PERIOD COST	TOTAL PROJECT PERIOD COST
12/01/2022 - 04/28/2025	12/01/2022 - 04/28/2025	\$ 1,330,536.00	\$ 1,330,536.00

NOTICE OF AWARD

Based on your Application dated 11/16/2021 including all modifications and amendments, the United States acting by and through the US Environmental Protection Agency (EPA) hereby awards \$ 0.00. EPA agrees to cost-share 100.00% of all approved budget period costs incurred, up to and not exceeding total federal funding of \$ 1,330,536.00. Recipient's signature is not required on this agreement. The recipient demonstrates its commitment to carry out this award by either: 1) drawing down funds within 21 days after the EPA award or amendment mailing date; or 2) not filing a notice of disagreement with the award terms and conditions within 21 days after the EPA award or amendment mailing date. If the recipient disagrees with the terms and conditions specified in this award, the authorized representative of the recipient must furnish a notice of disagreement to the EPA Award Official within 21 days after the EPA award or amendment mailing date. In case of disagreement, and until the disagreement is resolved, the recipient should not draw down on the funds provided by this award/amendment, and any costs incurred by the recipient are at its own risk. This agreement is subject to applicable EPA regulatory and statutory provisions, all terms and conditions of this agreement and any attachments.

ISSUING OFFICE (GRANTS MANAGEMENT OFFICE)	AWARD APPROVAL OFFICE		
ORGANIZATION / ADDRESS	ORGANIZATION / ADDRESS		
Environmental Protection Agency, Grants Management & Business Operations	Environmental Protection Agency, OSAPE		
Division	ORD - Office of Research and Development		
1200 Pennsylvania Ave, NW Mail code 3903R Washington, DC 20460	1200 Pennsylvania Ave, NW		
	Washington, DC 20460		
THE UNITED STATES OF AMERICA BY THE U.S. ENVIRONMENTAL PROTECTION AGENCY			

Digital signature applied by EPA Award Official LaShaun Phillips - Associate Award Official DATE 04/28/2025

EPA Funding Information

FUNDS	FORMER AWARD	THIS ACTION	AMENDED TOTAL
EPA Amount This Action	\$ 1,330,536	\$0	\$ 1,330,536
EPA In-Kind Amount	\$ 0	\$ 0	\$0
Unexpended Prior Year Balance	\$ 0	\$ 0	\$0
Other Federal Funds	\$ 0	\$ 0	\$0
Recipient Contribution	\$ 0	\$ 0	\$0
State Contribution	\$ 0	\$ 0	\$0
Local Contribution	\$ 0	\$ 0	\$0
Other Contribution	\$0	\$0	\$0
Allowable Project Cost	\$ 1,330,536	\$0	\$ 1,330,536

Assistance Program	Statutory Authority	Regulatory Authority
66.509 - Science to Achieve Results (STAR) Program	Clean Air Act: Sec. 103	2 CFR 200, 2 CFR 1500, 40 CFR 33 and 40 CFR 40

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Budget Summary Page

Table A - Object Class Category (Non-Construction)	Total Approved Allowable Budget Period Cost
1. Personnel	\$ 187,004
2. Fringe Benefits	\$ 50,462
3. Travel	\$ 26,751
4. Equipment	\$0
5. Supplies	\$0
6. Contractual	\$ 12,480
7. Construction	\$0
8. Other	\$ 845,703
9. Total Direct Charges	\$ 1,122,400
10. Indirect Costs: 61.50 % Base MTDC	\$ 208,136
11. Total (Share: Recipient0.00 % Federal100.00 %)	\$ 1,330,536
12. Total Approved Assistance Amount	\$ 1,330,536
13. Program Income	\$0
14. Total EPA Amount Awarded This Action	\$0
15. Total EPA Amount Awarded To Date	\$ 1,330,536

Administrative Conditions

UNILATERAL TERMINATION

- 1. The Agency is asserting its right under 2 CFR 200.340 and the Termination General Term and Condition of this agreement to unilaterally terminate this award. This amendment serves as required notice under 2 CFR 200.341.
- 2. Consistent with 2 CFR 200.343 Effect of suspension and termination, costs to the recipient or subrecipient resulting from financial obligations incurred by the recipient or subrecipient after the termination of a Federal award are not allowable. Costs after termination are allowable if:
 - a. The costs result from financial obligations which were properly incurred by the recipient or subrecipient before the effective date of suspension or termination, and not in anticipation of it; and
 - b. The costs would be allowable if the Federal award was not suspended or expired normally at the end of the period of performance in which the termination takes effect.
 - c. The costs are reasonable and necessary termination costs consistent with 2 CFR 200.472.
- 3. Federal Financial Reporting (FFR) General Terms and Conditions is still in full force and effect. EPA recipients must submit the SF-425 no later than 120 calendar days after the end date of the period of performance of the award.
- 4. Programmatic Terms and Conditions. Performance reporting is still in full force and effect. The recipient must submit the final report no later than 120 calendar days after the period of performance.

In accordance with 2 CFR 200.329, the recipient agrees to submit performance reports that include information on each of the following areas:

- a. A comparison of accomplishments to the outputs/outcomes established in the assistance agreement work plan for the reporting period;
- b. Explanations on why established outputs/outcomes were not met; and
- c. Additional information, analysis, and explanation of cost overruns or high-than-expected-unit costs.
- 5. Waiver of Reports

The following reports are waived:

- a. Utilization of Disadvantaged Business Enterprises General Terms and Conditions, EPA Form 5700-52A.
- b. Tangible Personal Property Report, SF-428, General Terms and Conditions.
- 6. Record Retention

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Access to Records, 2 CFR 200.337, is still in full force and effect. The termination of this award does not affect the right of EPA to disallow costs and recover funds on the basis of a later audit or other reviews. Information regarding record retention, property disposition in accordance with EPA regulations, and other frequently asked questions can be accessed at https://www.epa.gov/grants/frequent-questions-about-closeouts.

Programmatic Conditions

All Programmatic Conditions Remain the Same.

EXHIBIT H

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April 28, 2025

WASHINGTON, D.C. 20460

MEMORANDUM

SUBJECT: Termination of EPA Assistance Agreement RD 84048101 under 2 CFR 200.340

FROM: EPA Award Official

TO: Shelby Mayoral, Director, Contracts and Awards

The Regents of the University of California San Francisco

The purpose of this communication is to notify you that the U.S. Environmental Protection Agency (EPA) is hereby terminating Assistance Agreement No. RD 84048101 awarded to The Regents of the University of California San Francisco. This EPA Assistance Agreement is terminated in its entirety effective immediately on the grounds that the award no longer effectuates the program goals or agency priorities. The objectives of the award are no longer consistent with EPA funding priorities.

The EPA Administrator has determined that, per the Agency's obligations to the constitutional and statutory law of the United States, this priority includes ensuring that the Agency's grants do not conflict with the Agency's policy of prioritizing merit, fairness, and excellence in performing our statutory functions. In addition to complying with the law, it is vital that the Agency assess whether all grant payments are free from fraud, abuse, waste, and duplication, as well as to assess whether current grants are in the best interests of the United States.

The grant specified above provides funding for programs that promote initiatives that conflict with the Agency's policy of prioritizing merit, fairness, and excellence in performing our statutory functions; that are not free from fraud, abuse, waste, or duplication; or that otherwise fail to serve the best interests of the United States. The grant is inconsistent with, and no longer effectuates, Agency priorities.

The process for closeout is generally outlined in 2 CFR 200.344. EPA is clarifying what reports are required and what reports are waived below. Other requirements are still in effect if applicable to your grant.

EPA is requiring the following closeout reports due within 120 days of closeout (2 CFR 200.344a:)

- Final Federal Financial Report, SF-425
- Final Technical Report
- Other programmatic reports identified in your terms and conditions

As part of this termination, EPA is waiving the following closeout reports:

- Property Report, SF-428
- Final Minority Business Enterprise/Woman Business Enterprise Utilization Under Federal Grants and Cooperative Agreements, EPA Form 5700-52A

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The recipient may request payment from the Automated Standard Application Payments (ASAP) system for allowable costs incurred up to the date of this memo provided that such costs were contained in the approved workplan. Costs incurred by you after this termination are allowable only if (a) those costs were properly incurred by you before the effective date of this termination, and not in anticipation of it; and (b) those costs would be allowable if your federal award was not suspended or expired normally at the end of the period of performance in which the termination takes effect. See 2 C.F.R. § 200.343. You are encouraged to carefully review and discharge your closeout responsibilities set forth in 2 C.F.R. § 200.344-45 and your award agreement. Those responsibilities include, but are not limited to, your obligation to "promptly refund any unobligated funds" that have been paid out but "are not authorized to be retained." See 2 C.F.R. § 200.344(g).

Also, per 2 CFR 200.472, a recipient may use grant funds to properly closeout their grant including reasonable and necessary costs that might occur after the date of this memo. If the recipient drew down funds from ASAP for costs beyond the termination date or for costs that exceed the amount necessary to properly closeout their grant, the recipient must contact RTPFC at rtpfc-grants@epa.gov for instructions on how to return the excess funds.

The EPA Grants Management Office has issued an amendment to the agreement to document the termination.

If you wish to dispute this termination decision, the Disputes Decision Official (DDO), Schindel.Phillip@epa.gov, must receive the Dispute no later than 30 calendar days from the date this termination notice is electronically sent to you. Disputes must be sent electronically by email to the DDO, with a copy to the EPA Award Official, Phillips.LaShaun@epa.gov within the 30-day period stated above. The Dispute submitted to the DDO must include: (1) A copy of the disputed Agency Decision; (2) A detailed statement of the specific legal and factual grounds for the Dispute, including copies of any supporting documents; (3) The specific remedy or relief you seek under the Dispute; and (4) The name and contact information, including email address, of your designated point of contact for the Dispute. See 2 CFR 1500.15

The requirements on post-closeout adjustments and continuing responsibilities, including audit and record retention requirements, at 2 CFR 200.345 remain in effect.

ATTACHMENT Amendment Document

cc: Jennifer Brooks, EPA Grant Specialist Intaek Hahn, EPA Project Officer Neeta Thakur, Grantee Program Manager