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Attorneys for Plaintiffs and the Certified Classes

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 MARCUS A. HORWITZ

DECLARATION OF MARCUS A. HORWITZ

I, Marcus A. Horwitz, 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 Distinguished Professor of Medicine and of Microbiology, Immunology, and Molecular Genetics in the Department of Medicine at the University of California Los Angeles School of Medicine. A true and correct copy of my curriculum vitae is attached as **Exhibit A**.

3. I earned my A.B in Physics from Cornell University in 1968, and my M.D. from Columbia University College of Physicians and Surgeons in 1972. I subsequently trained in Internal Medicine and Infectious Diseases at the Albert Einstein College of Medicine. I served for two years as an Epidemic Intelligence Officer at the CDC and then trained in cellular physiology and immunology at The Rockefeller University. From 1980 to 1985, I was on the faculty of The Rockefeller University as an Assistant Professor and Associate Physician. In 1985, I joined the faculty of UCLA as a Professor of Medicine and of Microbiology, Immunology and Molecular Genetics, a position I held until 2011. I also served as Chief of the Division of Infectious Diseases at UCLA School of Medicine from 1985-92. I have held the position of Distinguished Professor of Medicine and of Microbiology, Immunology, and Molecular Genetics since 2011.

4. I am a fellow in the Infectious Diseases Society of America and a member of the American Society for Clinical Investigation. My awards include the Oswald Avery (formerly Squibb) Award from the Infectious Diseases Society of America and election to Fellowship in the American Association for the Advancement of Science.

5. My research has focused on intracellular parasitism, especially the immunobiology of the etiologic agents of Legionnaires' disease, leprosy, tuberculosis, and tularemia. In addition, in translational work, I have developed vaccines against Legionnaires' disease, tuberculosis, leprosy; the Tier 1 Select Agent Diseases tularemia, anthrax, plague and melioidosis; and a universal vaccine against COVID-19. Finally, in additional translational work, I have developed an ultra-short drug treatment regimen for treating tuberculosis that is currently in clinical trials. I

have authored more than 320 papers and abstracts including more than 150 peer-reviewed publications in scientific journals, and edited a book titled "Bacteria – Host Cell Interaction." I have 26 issued U.S. patents and numerous foreign patents on technologies developed in my laboratory. I have been a co-investigator or principal investigator on numerous projects funded through research grants from governmental and private sources, including 34 research grants from the National Institutes of Health ("NIH") since 1985.

6. Most of these research grants have been multi-year awards providing funds for 2, 3, 4 or 5 years. In my over 40 years of continuous NIH funding, I have never before received notice that NIH suspended grant funding for projects that I had been working on, until I received notice that NIH had suspended four of my projects' grants, including three which still had funds remaining. The three still-active grants and the impacts of their suspension are discussed in turn below.

Suspended Grant 1 – The TB Vaccine Project (Grant Number 1R01AI135631)

7. On November 29, 2017, NIH, through the National Institute of Allergy and Infectious Diseases, issued a Notice of Award for Grant Number 1R01AI135631-01, authorizing grant funding for the project for which I am Principal Investigator, titled "Optimization and Advanced Proof-of-Concept Studies of a Listeria-vectored Multi-Antigenic Vaccine against Tuberculosis" (hereafter, the "TB Vaccine Project"). The goal of the TB Vaccine Project was to identify a more effective vaccination against Tuberculosis. The Project Narrative for the TB Vaccine Project explained:

> Tuberculosis (TB) is one of the world's most important diseases, and a safe and effective vaccine against the causative agent *Mycobacterium tuberculosis (Mtb)* that is more potent than the currently available only partially effective *M. bovis* strain *Bacille Calmette-Guerin* (BCG) vaccine is sorely needed. It is generally acknowledged that both an improved replacement vaccine for BCG and a potent heterologous booster vaccine are needed in the fight against TB. The purpose of this project is to optimize and conduct advanced proof-of-concept studies in small animals and non-human primates (NHP) of a second-generation heterologous multiantigenic recombinant attenuated *Listeria monocytogenes*-vectored vaccine against TB.

8. A true and correct copy of the TB Vaccine Project Narrative is attached as **Exhibit B**. A true and correct copy of NIH's November 2017 Notice of Award for the TB Vaccine Project

is attached as **Exhibit C**. That Notice of Award authorized funding for five years of work on the TB Vaccine Project, from December of 2017 through November of 2022, for a total award of $5,424,173.

9. NIH issued further Notices of Award for the TB Vaccine Project, authorizing continued funding in November 2018, December 2019, and November 2020. True and correct copies of each of these Notices of Award are attached as **Exhibits D**, **E**, and **F** respectively. The TB Vaccine Project's work with primates was delayed during COVID-19, and as a result, the TB Vaccine Project obtained three No-Cost Time Extensions. True and correct copies of each of these No-Cost Time Extensions are attached as **Exhibits G**, **H**, and **I**. These No-Cost Time Extensions increased the TB Vaccine Project from five years to eight years, with the TB Vaccine Project's end date revised to November 30, 2025.

10. On August 1, 2025, I received an email from UCLA's Office of Contract & Grant Administration with the subject line "Grant Suspension Notice – Stop Work Order [PATS 20173817]". This email informed me that "UCLA has received a suspension notice from NIH-NIAID" for the TB Vaccine Project, and notified me that I must "***immediately stop incurring costs/expenditures on the grant(s) referenced above effective July 31, 2025***." (emphasis in original). A true and correct copy of this Stop Work Order is attached as **Exhibit J**. NIH's suspension of TB Vaccine Project suspended approximately $143,594 in unfunded award still outstanding to complete TB Vaccine Project's work.

11. I, my team, and the public interest have all suffered harm as a result of the TB Vaccine Project's grant funding suspension. First, while the live-animal component of the final definitive proof-of-concept vaccine study in non-human primates at the Texas Biomedical Research Institute (TBRI) was completed, we are unable to proceed further with analyzing bacterial read-outs, or study lung pathology and radiology (PET/CT), or analyze these data as a correlate of vaccine function. Therefore, despite completing the live-animal component of the final definitive vaccine efficacy study, we cannot uncover the extent to which the vaccine worked. Were that information available and the vaccine shown to be highly protective, as preliminary data suggests, we would have immediately begun plans to take the vaccine into

clinical trials. Our inability to do so potentially substantially delays development of a potent TB vaccine for which the primary purpose is to boost the immunity of the ~5 billion people in the world previously vaccinated with BCG and in whom most TB cases in the world develop. Second, our inability to complete the work and publish it hinders the career of the Project Scientist in my laboratory who developed this vaccine and the careers of our collaborators at TBRI. Third, the suspension of this study before the final results could be determined, at a cost to taxpayers of over $5.3 million dollars, constitutes a major waste of taxpayer funds.

Suspended Grant 2 – The Latent TB Treatment Project (Grant Number 1R01AI183978)

12. On February 27, 2024, NIH, through the National Institute of Allergy and Infectious Diseases, issued a Notice of Award for Grant Number 1R01AI183978-01 authorizing grant funding for the project for which I am Principal Investigator, titled "Efficacy and Safety of AI-enabled PRS Regimen VI (Clofazimine, Bedaquiline and Pyrazinamide) as Ultra-Short Course Therapy of LTBI in Non-Human Primates in a Setting Mimicking HIV co-infection" (hereafter, the "Latent TB Treatment Project"). The goal of the Latent TB Treatment Project was to examine a short-term three-drug treatment regimen for latent tuberculosis infection ("LTBI"), leveraging the artificial intelligence-enabled parabolic response surface platform (AI-PRS) to determine whether this treatment prevents reactivation of tuberculosis. As explained in the Project Summary for the Latent TB Treatment Project:

> The great majority of people who are infected with *Mycobacterium tuberculosis* (Mtb) do not develop active disease but contain the bacterium in a dormant state [known as LTBI]… Many of these people reactivate tuberculosis (TB) later in life, often in association with an immunocompromised status, such as co-infection with HIV, immunotherapy for cancer or other diseases, aging, etc. An estimated 2 billion people on earth have LTBI and constitute a huge reservoir of people at risk of reactivation TB unless treated and the persistent Mtb state eliminated. Current treatment regimens for LTBI are long and burdensome, negatively impacting treatment completion. The study proposed herein seeks to examine a potentially much shorter regimen requiring as little as one or two weeks. If successful, and then replicated in humans, such a short term regimen could change clinical practice… If short term Clofazimine, Bedaquiline and Pyrazinamide treatment prevents reactivation TB, this study will pave the way for a definitive treatment-shortening trial of Clofazimine, Bedaquiline and Pyrazinamide in LTBI and potentially revolutionize the treatment of LTBI, hastening the elimination of the TB reservoir and subsequently TB.

13. A true and correct copy of the Project Summary for the Latent TB Treatment

Project is attached as **Exhibit K**. A true and correct copy of the NIH's February 2024 Notice of Award for the Latent TB Treatment Project is attached as **Exhibit L**. That Notice of Award authorized funding for nearly three years of work on the Latent TB Treatment Project, from March 2024 through January 2027. NIH's initial Notice of Award was superseded by a revised Notice of Award sent on May 30, 2024, which provided for total funding of $2,798,273 between March 2024 and January 2027. A true and correct copy of NIH's May 2024 Revised Notice of Award for the Latent TB Treatment Project is attached as **Exhibit M**.

14. NIH issued a further Notice of Award for the Latent TB Treatment Project, authorizing continued funding in February 2025. A true and correct copy of this Notice of Award is attached as **Exhibit N**.

15. On August 1, 2025, I received an email from UCLA's Office of Contract & Grant Administration with the subject line "Grant Suspension Notice – Stop Work Order [PATS 20240819]". This email informed me that "UCLA has received a suspension notice from NIH-NIAID" for the Latent TB Treatment Project, and notified me that I must "***immediately stop incurring costs/expenditures on the grant(s) referenced above effective July 31, 2025***." (emphasis in original). A true and correct copy of this Stop Work Order is attached as **Exhibit O**. NIH's suspension of Latent TB Treatment Project suspended approximately $2,333,898 in unfunded award still outstanding to complete Latent TB Treatment Project's work.

16. I, my team, and the public interest have all suffered harm as a result of the Latent TB Treatment Project's grant funding suspension. First, we are unable to continue to support the salary component of collaborating individuals at the Subaward site Texas Biomedical Research Institute (TBRI) including the two leading collaborating co-investigators, a Staff Scientist, a Post-doctoral fellow, and two technicians. Second, this significantly damages the career of the collaborating co-investigators, staff scientist, and especially the post-doctoral fellow as they are unable to complete and publish the work. Third, while we made impressive headway in performing initial work on pharmacodynamics and pharmacokinetics of these drugs, we are unable to complete this work in collaboration with another collaborating co-investigator and specialist in this area at another collaborating institution. Fourth, while we were close to

beginning the animal component of the studies using non-human primates (NHPs), and TBRI had identified and assigned primates for this purpose, we are now unable to begin this critical study which would have uncovered if this drug regimen has efficacy against LTBI. Such a result has the potential to revolutionize treatment of people with LTBI worldwide, of which there are approximately 2 billion, and in whom TB can reactivate at any point in their lives if not appropriately treated.

Suspended Grant 3 – The T7SS Drug Project (Grant Number 1R21AI185484)

17. On July 17, 2025, NIH, through the National Institute of Allergy and Infectious Diseases, issued a Notice of Award for Grant Number 1R21AI185484-01A1 authorizing grant funding for the project for which I am Principal Investigator, titled "Identification by High Throughput Screening of Inhibitors of the Mycobacterium tuberculosis ESX-1 and ESX-5 Type VII Secretion Systems – critical virulence determinants and novel drug targets" (hereafter, the "T7SS Drug Project"). The goal of the T7SS Drug Project was to identify promising lead compounds with the highest therapeutic ratio and study them to potentially develop a new class of antibiotics to treat tuberculosis. As explained in the Project Summary for T7SS Drug Project:

> Tuberculosis (TB) is a serious global health problem, causing ~10.6 million active cases and 1.3 million deaths/year. Better drugs are urgently needed to shorten the burdensomely long treatment course and to combat the global emergence of drug resistant strains of *Mycobacterium tuberculosis* (Mtb), the causative agent. Attractive and novel targets not previously exploited for new drug development are the newly identified Type 7 Secretion Systems (T7SSs), designated ESX-1 to ESX-5, that transport factors through the Mtb hydrophobic cell wall that are essential to Mtb viability…These studies will identify the most promising lead compounds with the highest therapeutic ratio for further development. Such compounds will serve as vital tools for additional studies of the role of T7SS in Mtb pathogenesis as well as lead compounds for development of a new class of antibiotics to treat TB.

18. A true and correct copy of the Project Summary for T7SS Drug Project is attached as **Exhibit P**. A true and correct copy of the NIH's July 2025 Notice of Award for T7SS Drug Project is attached as **Exhibit Q**. That Notice of Award authorized funding for two years of work on the T7SS Drug Project, from July 2025 through June 2027, for a total award of $433,125.

19. On August 1, 2025, I received an email from UCLA's Office of Contract & Grant Administration with the subject line "Grant Suspension Notice – Stop Work Order [PATS 20255646]". This email informed me that "UCLA has received a suspension notice from NIH-

NIAID" for the T7SS Drug Project, and notified me that I must "***immediately stop incurring costs/expenditures on the grant(s) referenced above effective July 31, 2025***." (emphasis in original). A true and correct copy of this Stop Work Order is attached as **Exhibit R**. NIH's suspension of T7SS Drug Project suspended approximately $429,518 in unfunded award still outstanding to complete T7SS Drug Project's work.

20. I, my team, and the public interest have all suffered harm as a result of the T7SS Drug Project's grant funding suspension. First, we are unable to continue to support the salary component of several people in my laboratory including myself, a co-investigator Professor, and a co-investigator Project Scientist. Additionally, we are unable to support the salary component of a collaborating co-investigator Professor in the high throughput screening facility and his Research Associate. Importantly, we are unable to carry out the high throughput screens of tens of thousands of molecules for their capacity to inhibit the T7SS of *Mycobacterium tuberculosis*, the causative agent of tuberculosis, thereby preventing us from discovering new drugs to treat this very important infectious disease. *M. tuberculosis* kills more people than any other infectious agent and is rapidly developing resistance to currently available drugs. Hence, suspension of this award potentially delays the development of life saving drugs.

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 20th day of August, 2025, in Los Angeles, California.

Signed by:
Marcus A. Horwitz
C80918610...

Marcus A. Horwitz

EXHIBIT A

CURRICULUM VITAE

MARCUS A. HORWITZ, M.D.

Current Position
Distinguished Professor of Medicine and Microbiology, Immunology & Molecular Genetics
University of California–Los Angeles, Los Angeles, CA

Employment and Experience

Intern and Resident in Internal Medicine Albert Einstein College of Medicine, Bronx, NY	1972-1974
Epidemic Intelligence Service Officer Center for Disease Control and Prevention, Atlanta, GA	1974-1976
Fellow in Infectious Diseases Albert Einstein College of Medicine, Bronx, NY	1976-1977
Postdoctoral fellow, Lab. of Cellular Physiology & Immunology The Rockefeller University, New York	1977-1980
Assistant Professor and Associate Physician The Rockefeller University, New York, NY	1980-1984
Chief, Division of Infectious Diseases University of California–Los Angeles School of Medicine	1985-1992
Professor of Medicine and Microbiology, Immunology & Molecular Genetics University of California–Los Angeles School of Medicine	1985-2010
Distinguished Professor of Medicine and Microbiology, Immunology & Molecular Genetics University of California–Los Angeles School of Medicine	2011 - Present

Education

Cornell University, College of Arts & Sciences: A.B. (Physics) Ithaca, New York	1964-1968
Columbia University, College of Physicians & Surgeons: M.D. New York, New York	1968-1972

Certifications

Diplomate, National Board of Medical Examiners 1973
Diplomate in Internal Medicine, American Board of Internal Medicine 1977
Diplomate, Subspecialty of Infectious Diseases, American Board of Internal Medicine 1978

Affiliations

American Association for the Advancement of Science (Fellow)
American Society for Clinical Investigation
American Society for Microbiology
Infectious Diseases Society of America (Fellow)

Honors and Awards

Phi Beta Kappa, Cornell University, 1968.
cum laude in Physics and Distinction in All Subjects, Cornell University, 1968.
National Science Foundation Fellowship, Lawrence Radiation Laboratory, Berkeley, CA 1968.
Certificate of Appreciation for services in the medical support of Operation New Life (the evacuation of refugees from Vietnam), First Medical Group, U.S. Army, 1975.
Certificate of Appreciation, Interagency Task Force for Indochina Refugees, Department of Health, Education and Welfare, 1975.
Alexander D. Langmuir Award, Center for Disease Control, 1976.
National Institutes of Health National Research Service Award, 1977.
American Cancer Society Junior Faculty Research Award, 1980.
Hartford Foundation Fellowship, 1981.
Election to Member, American Society for Clinical Investigation, 1985
American Cancer Society Faculty Research Award, 1985.
American Society for Microbiology Divisional Lecture, Division B (Microbial Pathogenesis), 89th General Meeting, 1989.
James C. Feeley Award for Legionella Research (1st Annual Award), 1991.
Oswald Avery (formerly Squibb) Award for Outstanding Research in Infectious Diseases, Infectious Diseases Society of America, 1991.
James C. Feeley Award for Legionella Research, 1993.
Election to Fellow, American Association for the Advancement of Science, 1999
American Society for Microbiology Divisional Lecture, Division U (Mycobacteriology), 101st Annual Meeting, 2001.
Distinguished Professor of Medicine and Microbiology, Immunology & Molecular Genetics University of California–Los Angeles, 2011
Presidential Lecture, Elmira College, 2014
Farness Lecturer, U. of Arizona, 2017

Advisory Committees

Centers for Disease Control, Vessel Sanitation Program (Passenger Cruise Ships) Operations Manual Review Group, 1989.
WHO Global Forum on TB Vaccines Research & Development, 2001
Valley Fever Vaccine Project Review, California State University, 2014

Boards

American Leprosy Foundation (Leonard Wood Memorial) Scientific Advisory Board, 1985-2003; Chairman, 1990-2003.
U.S.-Japan Cooperative Medical Sciences Program, Tuberculosis Panel, 1991-1995.
Trudeau Institute Board of Trustees, 1994-98.
Cornell University Life Sciences Advisory Board 2004-2009.

Editorial Boards

Editorial Board, Infection and Immunity, 1984-87, 2002-04.
Editorial Board, The Journal of Clinical Investigation, 1989-93.
Guest Editor, The Journal of Clinical Investigation, 1992-96.
Invited Editor, mBio, 2019

Study Sections/Grant Reviewer

National Institutes of Health, Tropical Med. & Parasitology Special Study Section, 1984.
National Institutes of Health, NIAID Special Review Committee, 1989.
National Institutes of Health, NIAID Bacteriol. & Mycol. Special Study Section, 1990, 1992
National Institutes of Health, NIAID, Special Emphasis Panel, 1995
National Institutes of Health, Special Emphasis Panel (Microbial Vaccines), 2005
National Institutes of Health, Special Emphasis Panel (Infectious Dis/Microbiology), 2005
National Institutes of Health, HIV/AIDS Vaccines Study Section, 2006
National Institutes of Health, AIDS Research Review Committee, 2009
National Institutes of Health, Director's Opportunity for Research Grant Reviewer, 2010
National Institutes of Health, NIA, Special Emphasis Panel, 2012
National Institutes of Health, NIA, Special Emphasis Panel, 2014
National Institutes of Health, Vaccines Against Microbial Diseases Study Section, 2014
National Institutes of Health, NIA, Special Emphasis Panel, 2015
National Institutes of Health, NIA, Special Emphasis Panel, 2021
National Science Foundation, 1985-1987
University of California, University-wide Task Force on AIDS Study Section, 1985, 1986.
The Welcome Trust 1989-1992, 1996-1998
March of Dimes, 1989
Medical Research Council of Canada, 1994
World Health Organization, Tuberculosis Programme, 1995, 1997
Netherlands Organization for Scientific Research, 1997
Sequella Global Tuberculosis Foundation, 2002
U.S. Civilian Research & Development Foundation for Science Centers Program of the U.S. Dept. of State, Grant Reviewer, 2005
Institute Merieux, Grant reviewer, 2011
Defense Threat Reduction Agency, Basic Research Program, Grant Reviewer, 2011
DOD CDMRP Grant Reviewer/Programmatic Review, 2017

Issued U.S. Patents (Corresponding Foreign Patents Omitted for Brevity)

1. Patent No.: U.S. 5,108,745
Date of Patent: April 28, 1992
Title: Tuberculosis and Legionellosis Vaccines and Methods for their Production
Inventor: Marcus A. Horwitz

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/5108745?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJmMTQ5YzRlNS0wNjVhLTRiZTYtYjU3OC0yMzA0MjAxZjJhOWIiLCJleHAiOjB9

2. Patent No.: U.S. 5,721,209
Date of Patent: Feb. 24, 1998
Title: Iron Chelator and Inhibitor of Iron-Mediated Oxidant Injury
Inventors: Marcus A. Horwitz, Lawrence D. Horwitz, Bradford W. Gibson, and Joseph Reeve

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/5721209?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJmMTQ5YzRlNS0wNjVhLTRiZTYtYjU3OC0yMzA0MjAxZjJhOWIiLCJleHAiOjB9

3. Patent No.: U.S. 5,994,346
Date of Patent: Nov. 30, 1999
Title: Use of Exochelins in the Preservation of Organs for Transplant
Inventors: Marcus A. Horwitz and Lawrence D. Horwitz

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/5994346?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJmMTQ5YzRlNS0wNjVhLTRiZTYtYjU3OC0yMzA0MjAxZjJhOWIiLCJleHAiOjB9

4. Patent No.: U.S. 6,013,660
Date of Patent: Jan. 11, 2000
Title: Externally Targeted Prophylactic and Chemotherapeutic Method and Agents
Inventors: Marcus A. Horwitz and Günter Harth

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/6013660?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJmMTQ5YzRlNS0wNjVhLTRiZTYtYjU3OC0yMzA0MjAxZjJhOWIiLCJleHAiOjB9

5. Patent No.: U.S. 6,054,133
Date of Patent: April 25, 2000
Title: Antimicrobial Targeting for Intracellular Pathogens
Inventors: Marcus A. Horwitz and Daniel L. Clemens

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/6054133?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJmMTQ5YzRlNS0wNjVhLTRiZTYtYjU3OC0yMzA0MjAxZjJhOWIiLCJleHAiOjB9

6. Patent No.: U.S. 6,471,967
Date of Patent: Oct. 29, 2002
Title: Recombinant Intracellular Pathogen Vaccines and Methods for Use
Inventors: Marcus A. Horwitz and Günter Harth

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/6471967?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

7. Patent No.: U.S. 6,599,510
Date of Patent: July 29, 2003
Title: Abundant Extracellular Products and Methods for their Production and Use
Inventors: Marcus A. Horwitz and Günter Harth

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/6599510?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

8. Patent No.: U.S. 6,752,993
Date of Patent: June 22, 2004
Title: Abundant Extracellular Product Vaccines and Methods for their Production and Use
Inventor: Marcus A. Horwitz
https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/6752993?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

9. Patent No.: U.S. 6,761,894
Date of Patent: July 13, 2004
Title: Abundant Extracellular Products and Methods for their Production and Use
Inventor: Marcus A. Horwitz

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/6761894?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

10. Patent No.: U.S. 6,818,223
Date of Patent: Nov. 16, 2004
Title: Abundant Extracellular Products and Methods for their Production and Use
Inventors: Marcus A. Horwitz and Günter Harth

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/6818223?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

11. Patent No.: U.S. 6,924,118
Date of Patent: Aug. 2, 2005
Title: Recombinant Intracellular Pathogen Immunogenic Compositions and Methods for Use
Inventors: Marcus A. Horwitz, Günter Harth, and Michael V. Tullius

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/6924118?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

12. Patent No.: U.S. 7,002,002
Date of Patent: Feb. 21, 2006
Title: Abundant Extracellular Products and Methods for their Production and Use
Inventors: Marcus A. Horwitz and Günter Harth

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/7002002?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

13. Patent No.: U.S. 7,300,660
Date of Patent: Nov. 27, 2007
Title: Abundant Extracellular Products and Methods for their Production and Use
Inventors: Marcus A. Horwitz, Günter Harth and Bai-Yu Lee

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/7300660?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

14. Patent No.: U.S. 7,622,107
Date of Patent: Nov. 24, 2009
Title: Recombinant Intracellular Pathogen Immunogenic Compositions and Method of Use
Inventors: Marcus A. Horwitz and Günter Harth

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/7622107?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

15. Patent No.: U.S. 8,124,068
Date of Patent: Feb. 28, 2012
Title: Recombinant Intracellular Pathogen Immunogenic Compositions and Methods of Use
Inventors: Marcus A. Horwitz, Günter Harth, and Michael Tullius

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/8124068?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

16. Patent No.: U.S. 8,163,294
Date of Patent: April 24, 2012
Title: Growth Regulatable Recombinant BCG Compositions
Inventors: Marcus A. Horwitz and Michael Tullius

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/8163294?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

17. Patent No.: U.S. 8,206,700
Date of Patent: June 26, 2012
Title: Methods and Compositions for Treating Tularemia
Inventors: Marcus A. Horwitz, Qingmei Jia, Bai-Yu Lee Clemens, and Daniel Clemens
https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/8206700?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

18. Patent No.: U.S. 8,287,879
Date of Patent: Oct. 16, 2012
Title: Immunostimulatory Recombinant Intracellular Pathogen Immunogenic Compositions and Methods of Use
Inventors: Marcus A. Horwitz and Gunter Harth

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/8287879?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

19. Patent No.: U.S. 8,383,132 B2
Date of Patent: Feb. 26, 2013
Title: Immunostimulatory Recombinant Intracellular Pathogen Immunogenic Compositions and Methods of Use II
Inventors: Marcus A. Horwitz and Michael Tullius

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/8383132?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

20. Patent No.: U.S. 8,481,024
Date of Patent: July 9, 2013
Title: Vaccines Against Tularemia
Inventors: Marcus A. Horwitz, Qingmei Jia, and Bai-Yu Lee-Clemens

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/8481024?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

21. Patent No.: U.S. 8,932,846
Date of Patent: January 13, 2015
Title: Unmarked Recombinant Intracellular Pathogen Immunogenic Compositions Expressing High Levels of Recombinant Proteins
Inventors: Marcus A. Horwitz and Michael Tullius

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/8932846?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

22. Patent No.: U.S. 10,010,595
Date of Patent: July 3, 2018
Title: Live Recombinant Booster Vaccine Against Tuberculosis
Inventors: Marcus A. Horwitz and Qingmei Jia

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/10010595?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

23. Patent No.: U.S. 10,080,749
Date of Patent: Sept. 25, 2018
Title: Multi-Drug Therapies for Tuberculosis Treatment
Inventors: Chih-Ming Ho, Daniel L. Clemens, Bai-Yu Lee Clemens, Marcus A. Horwitz, Aleidy Silva Vite, Theodore Kee, Xianting Ding
https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/10080749?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

24. Patent No. US 10,576,079
Date of Patent: March 3, 2020
Title: Multi-Drug Therapies for Tuberculosis Treatment II
Inventors: Chih-Ming Ho, Daniel L. Clemens, Bai-Yu Lee Clemens, Marcus A. Horwitz, Aleidy Silva Vite, Theodore Kee, Xianting Ding
https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/10576079?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

25. Patent No. US 11,045,555
Date of Patent: June 29, 2021
Title: Pathogen-specific cargo delivery and diagnostic platform based on Mesoporous Silica Nanoparticles
Inventors: Jeffrey I. Zink, Bastian Ruehle, Marcus A. Horwitz, Daniel L. Clemens, Bai-Yu Lee Clemens

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/11045555?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

26. Patent No.: U.S. 11,224,647 B2
Date of Patent: Jan. 18, 2022
Title: Safe potent single platform vaccine against Tier 1 Select Agents and other pathogens
Inventors: Marcus A. Horwitz and Qingmei Jia

https://ppubs.uspto.gov/dirsearch-public/print/downloadBasicPdf/11224647?requestToken=eyJzdWIiOiJiOWE0MGEzNS02NmMxLTQ3MTgtYjUyMy1mM2ZlMDVmNzcwMTAiLCJ2ZXIiOiJjMGIxMzg0NC04ZDUzLTQ3NGMtODAyOC04YzMxNjViNmMyZjAiLCJleHAiOjB9

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123. Bozue, J., K. Mlynek, S. Biryukov, C. Cline, B. Bachert, R. Toothman, C. Klimko, J. Dankmeyer, Z. Hedrick, M. Hunter, J. Shoe, Q. Jia, C. Cote, and M. Horwitz. 2023. The rLVS Δ*capB*/*iglABC* vaccine provides potent protection to Fisher rats against aerosol challenge with multiple virulent *Francisella tularensis* strains. Abstracts of ASM Microbe, Houston, Texas, June 17, 2023.

124. Mlynek, K., C. Cline, S. Biryukov, B. Bachert, R. Toothman, C. Klimko, J. Dankmeyer, Z. Hedrick, S. Mou, M. Hunter, Q. Jia, C. Cote, M. A. Horwitz, and J. A. Bozue. 2023. The rLVS Δ*capB*/*iglABC* vaccine provides potent protection to Fisher rats against aerosol challenge with multiple virulent *Francisella tularensis* strains. Abstracts of the 10th International Conference on Tularemia, Grenoble, France Sept. 25-28, 2023.

Presentations at National and International Meetings

1. Horwitz, M.A., and V.R. Dowell. 1974. Clinical, epidemiologic, and laboratory aspects of foodborne botulism outbreaks reported to the Center for Disease Control, October 1, 1973 - October 1, 1974. Presented at the 1974 Technical Meeting, Interagency Botulism Research Coordinating Committee, Food and Drug Administration, Parklawn Bldg., Washington D.C., October 3, 1974.

2. Horwitz, M.A., and V.R. Dowell. 1975. Association of botulism with acid foods. Presented at Meeting of the Ad Hoc Work Group on Botulism, U.S. Department of Agriculture, Federal Center Bldg., Hyattsville, MD, February 14, 1975.

3. Horwitz, M.A., and C.L. Hatheway. 1975. Clinical, epidemiologic, and laboratory aspects of foodborne botulism outbreaks reported to the Center for Disease Control October 1, 1974 - October 1, 1975. Presented at the 1975 Technical Meeting, Interagency Botulism Research Coordinating Committee, U.S. Army Natick Development Center, Natick, MA, October 9, 1975.

4. Horwitz, M.A. 1976. Nursery outbreak of peritonitis with pneumo-peritoneum probably caused by thermometer-induced rectal perforation. Presented at the 25th Annual Epidemic Intelligence Service Conference, Center for Disease Control, Atlanta, GA, April 7, 1976.

5. Horwitz, M.A. 1976. The role of poultry in foodborne illness. Presented at the 1976 Annual Meeting for Representatives of Supporting Organizations of the Food Research Institute, The Wisconsin Center, University of Wisconsin, Madison, WI, May 12, 1976.

6. Horwitz, M.A., and S.C. Silverstein. 1979. Influence of the Escherichia coli capsule on complement fixation and phagocytosis. Presented at the Seventy-First Annual Meeting of the American Society for Clinical Investigation, Washington, D.C., May 7, 1979.

7. Horwitz, M.A. 1979. The roles of the Fc and C3 receptors in phagocytosis and killing of bacteria by human phagocytes. Presented at the Sixteenth National Meeting of the Reticuloendothelial Society, San Antonio, TX, December 6, 1979.

8. Horwitz, M.A., and S.C. Silverstein. 1980. The Legionnaires' disease bacterium (*Legionella pneumophila*) grows intracellularly in human monocytes. Presented at the Plenary Session of the Seventy-Second Annual Meeting of the American Society for Clinical Investigation, Washington, D.C., May 11, 1980.

9. Horwitz, M.A., and S.C. Silverstein. 1980. The Legionnaires' disease bacterium resists killing by human phagocytes, antibody, and complement. Presented at the Twentieth Interscience Conference on Antimicrobial Agents and Chemotherapy, Sponsored by the American Society for Microbiology, New Orleans, LA, September 23, 1980.

10. Horwitz, M.A. 1980. Interaction of human phagocytes with extracellular and intracellular bacteria. Presented at the 1980 National Meeting of the German Society of Hygiene and Microbiology, Mainz, Germany, September 26, 1980.

11. Horwitz, M.A., and S.C. Silverstein. 1981. Activated human monocytes inhibit the intracellular multiplication of Legionnaires' disease bacteria. Presented at the Seventy-Third Annual Meeting of the American Society for Clinical Investigation, San Francisco, CA, April 27, 1981.

12. Horwitz, M.A. 1981. Antibacterial defense by macrophages. Presented at the symposium entitled The Macrophage in Host Defense at the Twenty-first Interscience Conference on Antimicrobial Agents and Chemotherapy, Sponsored by the American Society for Microbiology, Chicago, IL, November 4, 1981.

13. Horwitz, M.A., and S.C. Silverstein. 1981. The intracellular multiplication of Legionnaires' disease bacteria is reversibly inhibited by erythromycin and rifampin. Presented at the Twenty-first Interscience Conference on Antimicrobial Agents and Chemotherapy, Sponsored by the American Society for Microbiology, Chicago, IL, November 5, 1981.

14. Horwitz, M.A. 1982. Roles of antibody and complement in phagocytosis and killing of extracellular and intracellular bacteria by human phagocytes. Presented at the 13th Round Table Symposium on Applied Immunology, Axams, Tirol, Austria, January 26, 1982.

15. Horwitz, M.A. 1982. Demonstration of cell-mediated immunity in Legionnaires' disease. Presented at the 1982 National Meeting of the Association of American Physicians/ American Society for Clinical Investigation/American Federation for Clinical Research, Washington, D.C., May 10, 1982.

16. Horwitz, M.A. 1982. The intracellular site of replication of Legionnaires' disease bacteria. Presented at the 1982 Gordon Research Conference on Lysosomes, Andover, NH, June 30, 1982.

17. Horwitz, M.A. 1982. Immunobiology of *Legionella pneumophila*. Presented at the 1982 Gordon Research Conference on Microbial Toxins and Pathogenicity, Plymouth, NH, August 6, 1982.

18. Nash, T.W., D.M. Libby, and M.A. Horwitz. 1982. Legionnaires' disease bacteria multiply in human alveolar macrophages and activated alveolar macrophages inhibit multiplication. Presented at the Twenty-second Interscience Conference on Antimicrobial Agents and Chemotherapy, Sponsored by the American Society for Microbiology, Miami Beach, FL, October 4, 1982.

19. Horwitz, M.A. 1982. Interaction between Legionnaires' disease bacteria and human monocytes: Formation of a unique intracellular vacuole and inhibition of phagosome - lysosome fusion. Presented at the Twenty-second Interscience Conference on Antimicrobial Agents and Chemotherapy, Sponsored by the American Society for Microbiology, Miami Beach, FL, October 4, 1982.

20. Horwitz, M.A. 1983. Legionnaires' disease bacteria and mononuclear phagocytes: an intriguing relationship. Presented at the Symposium entitled Cell Biology of Infectious Non-viral Intracellular Agents at the Sixty-seventh annual meeting of the Federation of American Societies for Experimental Biology, Chicago, IL, April 14, 1983.

21. Horwitz, M.A. 1983. Interaction between *Legionella pneumophila* and human mononuclear phagocytes. Presented at the Second International Symposium on *Legionella*, Atlanta, GA, June 20, 1983.

22. Gabay, J.E., M.S. Blake, and M.A. Horwitz. 1984. Isolation and characterization of the cytoplasmic and outer membranes of *Legionella pneumophila* and purification of the major outer membrane protein. Presented at the 1984 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation for Clinical Research, Washington, D.C., May 7, 1984.

23. Horwitz, M.A. 1984. Interactions between *Legionella pneumophila* and human mononuclear phagocytes. Presented at the Fourth Leiden Conference on Mononuclear Phagocytes, Noordwijk aan Zee, The Netherlands, May 14, 1984.

24. Horwitz, M.A. 1984. Features of *Legionella pneumophila* - mononuclear phagocyte interactions. Presented at the 1984 Gordon Research Conference on Lysosomes, Plymouth, NH, June 25, 1984.

25. Horwitz, M.A. 1985. Intracellular wars: Invasion of Legionnaires' Disease bacteria. Presented at the 7th Annual Infectious Diseases Symposium entitled "Studies of New Disease Agents." Zurich, Switzerland, April 18, 1985

26. Horwitz, M.A. 1985. Interaction between human mononuclear phagocytes and *Legionella pneumophila*. Presented at the conference entitled "Mechanisms of Host Resistance to Infectious Agents, Tumors, and Allografts", Trudeau Institute, Inc., Saranac Lake, NY, July 27-30, 1985.

27. Breiman, R.F., and M.A. Horwitz. 1986. Sublethal infection of guinea pigs with aerosolized *Legionella pneumophila* induces humoral and cell-mediated immune responses and protects against lethal aerosol challenge. Presented at the Twenty-sixth Interscience Conference on Antimicrobial Agents and Chemotherapy. Sponsored by the American Society for Microbiology, New Orleans, LA, September 29 - October 1, 1986.

28. Horwitz, M.A. 1986. Inhibition of phagosome acidification by *Legionella pneumophila*. Presented at Symposium entitled "The Roles of Acid Intracellular Vesicles" at the 1986 Joint Meeting of the American Society of Tropical Medicine and Hygiene and the American Society of Parasitologists", Denver, CO, December 7-1, 1986.

29. Payne, N.R., and M.A. Horwitz. 1987. Phagocytosis of *Legionella pneumophila* by human monocytes is mediated by membrane receptors for the third component of complement and monoclonal antibodies against these receptors inhibit intracellular multiplication. Presented at the 1987 Annual Meeting of the American Society of Microbiology, Atlanta, GA, March 1-6, 1987.

30. Bellinger-Kawahara, C.G., and M.A. Horwitz. 1987. *Legionella pneumophila* fixes complement component C3 to its surface -- demonstration by ELISA. Presented at the 1987 Annual Meeting of the American Society for Microbiology, Atlanta, GA, March 1-6, 1987.

31. Horwitz, M.A., N.R. Payne, and C.G. Bellinger-Kawahara. 1987. Intracellular biology of *Legionella pneumophila*. Presented at UCLA Symposium on Bacteria-Host Cell Interaction, Park City, UT, February 13-19, 1987.

32. Horwitz, M.A. 1987. Phagocytosis of *Legionella pneumophila*. Presented at the NATO Advanced Research Workshop entitled "Bacteria, Complement, and the Phagocytic Cell", Maratea, Italy, April 6-9, 1987.

33. Byrd, T.F., and M.A. Horwitz. 1987. Intracellular multiplication of *Legionella pneumophila* in human monocytes is iron-dependent and the capacity of activated monocytes to inhibit intracellular multiplication is reversed by iron-transferrin. Presented at the 1987 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation for Clinical Research, San Diego, CA, May 1-4, 1987.

34. Breiman, R.F., and M.A. Horwitz. 1987. The major secretory protein of *Legionella pneumophila* stimulates proliferation of splenic lymphocytes from immunized guinea pigs. Presented at the 1987 National Meeting of the Association of American Physicians/ American Society for Clinical Investigation/American Federation for Clinical Research, San Diego, CA, May 1-4, 1987.

35. Bellinger-Kawahara, C.G., and M.A. Horwitz. 1987. The major outer membrane protein is a prominent acceptor molecule for complement component C3 on *Legionella pneumophila*. Presented at the 1987 National Meeting of the Association of American Physicians/ American Society for Clinical Investigation/American Federation for Clinical Research, San Diego, CA, May 1-4, 1987.

36. Horwitz, M.A. 1987. Role of complement receptors in phagocytosis of *Legionella pneumophila*. Presented at the Cytokines and Parasites Workshop, Eleventh International RES Congress and Twenty-fourth National Meeting of the Reticuloendothelial Society, Kauai, Hawaii, October 17-21, 1987.

37. Horwitz, M.A. 1988. Complement receptors and bacteria. Presented at the World Health Organization meeting entitled "Molecular Aspects of Parasite Recognition, Penetration, and Survival", Cotswolds, England, February 15-18, 1988.

38. Schlesinger, L.S., and M.A. Horwitz. 1988. Phagocytosis of leprosy bacilli by human monocytes is mediated by complement receptors CR1 and CR3. Presented at the 1988 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation for Clinical Research, Washington, D.C., April 29 - May 2, 1988.

39. Blander, S.J., R.F. Breiman, and M.A. Horwitz. 1988. A live avirulent mutant *Legionella pneumophila* vaccine induces protective immunity against lethal aerosol challenge. Presented at the 1988 National Meeting of the Association of American Physicians/ American Society for Clinical Investigation/American Federation for Clinical Research, Washington, D.C., April 29 - May 2, 1988.

40. Horwitz, M.A. 1988. Host defense against *Legionella pneumophila*. Presented at the Symposium entitled "Nosocomial Legionellosis: New Insights" at the 1988 Annual Meeting of the American Society for Microbiology. Miami Beach, FL, May 8-13, 1988.

41. Horwitz, M.A. 1988. Immunobiology of *Legionella pneumophila*. Presented at the Symposium entitled "Mechanisms of Intracellular Infection" at the 1988 Annual Meeting of the American Society for Microbiology, Miami Beach, FL, May 8-13, 1988.

42. Horwitz, M.A. 1988. Role of cell surface structures in phagocytosis and intracellular biology of *Legionella pneumophila* and other intracellular bacteria. Presented at the Annual National Meeting of the Finnish Society for Biochemistry, Biophysics, and Microbiology, Helsinki, Finland, May 17-18, 1988.

43. Horwitz, M.A. 1988. Role of iron in the intracellular biology of *Legionella pneumophila* and in host defense against this bacterium. Presented at the 1988 Gordon Research Conference on Microbial Toxins and Pathogenesis, Plymouth, NH, August 1-5, 1988.

44. Horwitz, M.A. 1988. Molecular mechanisms in *Legionella pneumophila* - mononuclear phagocyte interaction. Presented at the symposium entitled "Molecular Mechanisms in the Pathogenesis of Infectious Diseases" at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, Los Angeles, CA, October 23-26, 1988.

45. Horwitz, M.A. 1988. The *Legionella pneumophila* model of intracellular parasitism. Presented at National Institutes of Health Meeting entitled "The Molecular Basis of the Interaction between Parasites and the Complement System", Bethesda, MD, December 1-3, 1988.

46. Horwitz, M.A. 1989. Divisional Lecture, Division B. The *Legionella pneumophila* model of intracellular parasitism. Presented at the 89th Annual Meeting of the American Society for Microbiology, New Orleans, LA, May 14-18, 1989.

47. Schlesinger, L.S., and M.A. Horwitz. 1989. Complement receptors and complement component C3 mediate phagocytosis of *Mycobacterium tuberculosis* and *Mycobacterium leprae*. Presented at the 24th U.S.- Japan Leprosy and Tuberculosis Symposium, San Diego, CA, August 24, 1989.

48. Horwitz, M.A. 1989. Prototypic vaccines against Legionnaires' disease. Presented at symposium entitled "*Legionella*: New Insights" at the 29th Interscience Conference on Antimicrobial Agents and Chemotherapy, Houston, TX, September 17-20, 1989.

49. Horwitz, M.A. 1989. Bacterial and host cell molecules mediating *Legionella pneumophila* - mononuclear phagocyte interaction. Presented at the Laudet Conference entitled "Bacterial Pathogenesis, from Molecular Genetics to Cell Biology", Alsace, France, Oct. 22-26, 1989.

50. Byrd, T.F., and M.A. Horwitz. 1990. Iron-lactoferrin and non-physiologic iron-chelates reverse the capacity of activated monocytes to inhibit *Legionella pneumophila* intracellular multiplication. Presented at the 1990 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/ American Federation for Clinical Research, Washington, D.C., May 4-7, 1990.

51. Byrd, T.F., and M.A. Horwitz. 1990. Interferon gamma-activated human monocytes downregulate the intracellular concentration of ferritin: a potential new mechanism for limiting iron availability to *Legionella pneumophila* and subsequently inhibiting intracellular multiplication. Presented at the 1990 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation for Clinical Research, Washington, D.C., May 4-7, 1990.

52. Byrd, T.F., and M.A. Horwitz. 1990. An individual's monocytes which are uniquely non-permissive to *Legionella pneumophila* intracellular multiplication have low numbers of transferrin receptors, and iron reverses the non-permissive state. Presented at the 1990 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation for Clinical Research, Washington, D.C., May 4-7, 1990.

53. Blander, S.J., and M.A. Horwitz. 1990. Vaccination of guinea pigs with *Legionella pneumophila* membranes induces protective immunity against lethal aerosol challenge. Presented at the 1990 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation for Clinical Research, Washington, D.C., May 4-7, 1990.

54. Blander, S.J., and M.A. Horwitz. 1990. Cross-protective immunity to Legionnaires' disease induced by vaccination with the major secretory protein of *Legionella*. Presented at the 1990 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation for Clinical Research, Washington, D.C., May 4-7, 1990.

55. Clemens, D.L., and M.A. Horwitz. 1990. Demonstration that *Legionella pneumophila* produces its major secretory protein in infected human monocytes and localization of the protein by immunocytochemistry and immunoelectron microscopy. Presented at the 1990 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation for Clinical Research, Washington, D.C., May 4-7, 1990.

56. Schlesinger, L.S., and M.A. Horwitz. 1990. Phenolic Glycolipid-I of *Mycobacterium leprae* is an acceptor molecule for complement component C3 and may mediate complement receptor - dependent phagocytosis. Presented at the 1990 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/ American Federation for Clinical Research, Washington, D.C., May 4-7,1990.

57. Schlesinger, L.S., and M.A. Horwitz. 1990. Phagocytosis of leprosy bacilli by human monocyte-derived macrophages is complement-receptor dependent, and interferon gamma activation downregulates complement receptor activity and phagocytosis of these bacteria. Presented at the 1990 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation for Clinical Research, Washington, D.C. May 4-7, 1990.

58. Horwitz, M.A. 1990. New concepts in intracellular parasitism. Presented at the Symposium entitled "Host Responses to Pathogens" at the 90th Annual Meeting of the American Society for Microbiology, Anaheim, CA, May 13-17, 1990.

59. Horwitz, M.A. 1990. *Legionella pneumophila* interactions with monocytes and alveolar macrophages. Presented at the Symposium entitled "Determinants of Bacterial Infection on Respiratory Mucosal Surfaces" at the 90th Annual Meeting of the American Society for Microbiology, Anaheim, CA, May 13-17, 1990.

60. Horwitz, M.A. 1990. State-of-the-Art Lecture: Interactions of *Mycobacterium tuberculosis* with Mononuclear Phagocytes. Presented at the Workshop on Future Directions in Tuberculosis Research at the National Institutes of Health, Bethesda, MD, December 12-14, 1990.

61. Schlesinger, L.S., and M.A. Horwitz. 1991. Natural antibody mediates C3 fixation to the leprosy bacillus and C1q binding to phenolic glycolipid-1, the C3 acceptor molecule on the bacterial surface. Presented at the 1991 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation for Clinical Research, Seattle, WA, May 3-6, 1991.

62. Pal, P.G., and M.A. Horwitz. 1991. Immunization with extracellular proteins of *Mycobacterium tuberculosis* induces cell-mediated and protective immunity in a guinea pig model of pulmonary tuberculosis. Presented at the 1991 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation Clinical Research, Seattle, WA, May 3-6, 1991.

63. Clemens, D.L., and M.A. Horwitz. 1991. Membrane sorting during phagocytosis: Selective concentration of complement receptors and exclusion of MHC molecules during complement-mediated coiling and conventional phagocytosis. Presented at the 1991 National Meeting of the Association of American Physicians/American Society for Clinical Investigation/American Federation for Clinical Research, Seattle, WA, May 3-6, 1991.

64. Horwitz, M.A. 1991. Host and Bacterial Molecules Important to *Legionella pneumophila* Pathogenesis. Presented at the Fifth Leiden Conference on Mononuclear Phagocytes, Noordwijk, The Netherlands, May 13-17, 1991.

65. Schlesinger, L.S., and M.A. Horwitz. 1991. Host and bacterial molecules mediating phagocytosis of *Mycobacterium leprae* by human mononuclear phagocytes. Presented at the 26th U.S.-Japan Leprosy Research Conference, U.S.-Japan Cooperative Medical Science Program, Seattle, WA, August 6-9, 1991.

66. Pal, P.G., and M.A. Horwitz. 1991. Guinea pigs immunized with extracellular proteins of *Mycobacterium tuberculosis* develop cell-mediated immune responses and protective immunity against aerosol infection with tuberculosis bacilli. Presented at the 26th Tuberculosis Research Conference, U.S.-Japan cooperative Medical Science Program, Seattle, WA, August 6-9, 1991.

67. Horwitz, M.A. 1992. State-of-the-Art Address. Towards an understanding of the molecular basis for *Legionella pneumophila* pathogenesis. Presented at the 1992 International Symposium on *Legionella*. Orlando, FL, January 26-29, 1992.

68. Mengaud, J., and M.A. Horwitz. 1992. Major iron-proteins of *Legionella pneumophila*. Presented at the 1992 International Symposium on *Legionella*. Orlando, FL, January 26-29, 1992.

69. Horwitz, M.A. 1992. Approaches to pathogenesis and protection. Presented at the National Institutes of Health NIAID Tuberculosis Research Workshop, Bethesda, MD. February 10, 1992.

70. Horwitz, M.A. 1992. Mechanisms of cell entry by *Legionella* and Mycobacteria. Presented at Symposium entitled "What Mycobacteriologists can Learn from Studies of Other Pathogens" at the 92nd Annual Meeting of the American Society for Microbiology, New Orleans, LA, May 26-30, 1992.

71. Lee, B-W.E., P.G. Pal, and M.A. Horwitz. 1992. Cell-mediated immune responses to the native 71 KD protein of *Mycobacterium tuberculosis* in guinea pigs and humans. Presented at the 27th U.S.-Japan Tuberculosis Research Conference, U.S.-Japan Cooperative Medical Science Program, Matsue, Japan, August 4-8, 1992.

72. Horwitz, M.A. 1993. Protective immunity against *Legionella pneumophila*. Presented at symposium entitled "Mechanisms of Protective Immunity: Mononuclear Cells and their Products" at the 93rd Annual Meeting of the American Society for Microbiology, Atlanta, GA, May 16-20, 1993.

73. Clemens, D.L., and M.A. Horwitz. 1993. Characterization of the *Mycobacterium tuberculosis* phagosome and evidence that phagosomal maturation is inhibited. Presented at the 28th U.S.-Japan Tuberculosis Research Conference, U.S.-Japan Cooperative Medical Science Program, Washington, D.C., July 17-19, 1993.

74. Hanberg, F.B., J. Gobin, J.R. Reeve, Jr., B.W. Gibson, D. Tang, and M.A. Horwitz. 1993. Exochelins of *Mycobacterium tuberculosis*. Presented at the 28th U.S.-Japan Cooperative Medical Science Program, Washington, D.C., July 17-19, 1993.

75. Horwitz, M.A. 1993. *Legionella pneumophila* and *Mycobacterium tuberculosis* - A tale of two pathogens. Presented at the SFB Symposium entitled "Cross-Talk between Host Cells and Pathogenic Microorganisms", Würzburg, Germany, October 28-30, 1993.

76. Horwitz, M.A. 1994. Tuberculosis and human macrophages: The inside story. Presented at the State-of-the-Art Plenary Session entitled "Molecular Mechanisms of Infection" at the joint 1994 annual meeting of The American Pediatric Society, The Society for Pediatric Research, and The Ambulatory Pediatric Association, Seattle, WA, May 3, 1994.

77. Horwitz, M.A. 1994. Identification of immunoprotective determinants of *Mycobacterium tuberculosis* using the guinea pig model of pulmonary tuberculosis. Presented at symposium entitled "Animal Models of Mycobacterial Diseases" at the 94th General Meeting of the American Society for Microbiology, Las Vegas, NV, May 23-27, 1994.

78. Horwitz, M.A. 1994. *Mycobacterium tuberculosis* and human macrophages: The inside story. Presented at the University of Alberta - University of Calgary International Conference on Infectious Diseases, Kananaskis Village, Alberta, Canada, May 28 - June 1, 1994.

79. Horwitz, M.A. 1994. New insights into the pathogenesis of *Mycobacterium tuberculosis*. Presented at the Second Annual Campbell River Conference Intracellular Pathogens in Infectious Disease, Campbell River, British Columbia, Canada, June 24-26, 1994.

80. Horwitz, M.A. 1994. Progress in the development of a subunit vaccine against tuberculosis. Presented at the 29th Joint Research Conference on Tuberculosis and Leprosy of the U.S. - Japan Cooperative Medical Science Program, Kyoto, Japan, August 19-22, 1994.

81. Horwitz, M.A. 1994. *Mycobacterium tuberculosis* - human macrophage interaction. Presented at the 30th National meeting of the Society for Leukocyte Biology, Tucson, AZ, September 21-24, 1994.

82. Horwitz, M.A. 1994. New concepts in vaccine development. Presented at the 10th World Congress of Gastroenterology, Los Angeles, CA, October 2-7, 1994.

83. Horwitz, M.A., B-W.E. Lee, B.J. Dillon, G. Harth, E.V. Tan, E.L. dela Cruz, R.M. Abalos, J.B. Nazareno, L.J. Young, L.G. Villahermosa, and G.P. Walsh. 1995. Progress in the development of a subunit vaccine against tuberculosis and a new nonhuman primate model of pulmonary tuberculosis. Presented at the symposium entitled "Molecular Mechanisms in Tuberculosis" of the Keystone Symposia on Molecular and Cellular Biology, Tamarron, Colorado, February 19-25, 1995.

84. Clemens, D.L. and M.A. Horwitz. 1995. Characterization of the *Mycobacterium tuberculosis* phagosome. Presented at the symposium entitled "Molecular Mechanisms in Tuberculosis" of the Keystone Symposia on Molecular and Cellular Biology, Tamarron, CO, February 19-25, 1995.

85. Gobin, J., C. Moore, J.R. Reeve, Jr., D. Wong, B.W. Gibson, and M.A. Horwitz. 1995. Exochelins of *Mycobacterium tuberculosis*: Characterization and demonstration of their capacity to remove iron from host iron-binding proteins. Presented at the symposium entitled "Molecular Mechanisms in Tuberculosis" of the Keystone Symposia on Molecular and Cellular Biology, Tamarron, CO, February 19-25, 1995.

86. Calder, K.M., and M.A. Horwitz. 1995. Iron limited growth and iron regulated proteins of *Mycobacterium tuberculosis*. Presented at the symposium entitled "Molecular Mechanisms in Tuberculosis" of the Keystone Symposia on Molecular and Cellular Biology, Tamarron, CO, February 19-25, 1995.

87. Harth, G., D.L. Clemens, and M.A. Horwitz. 1995. Characterization of *Mycobacterium tuberculosis* glutamine synthetase. Presented at the symposium entitled "Molecular Mechanisms in Tuberculosis" of the Keystone Symposia on Molecular and Cellular Biology, Tamarron, CO, February 19-25, 1995.

88. Lee, B-Y. and M.A. Horwitz. 1995. Macrophage-induced proteins of *Mycobacterium tuberculosis.* Presented at the symposium entitled "Molecular Mechanisms in Tuberculosis" of the Keystone Symposia on Molecular and Cellular Biology, Tamarron, CO, February 19-25, 1995.

89. Horwitz, M.A. 1995. Development of a Subunit Vaccine Against Tuberculosis. Presented at a meeting of the World Health Organization entitled "Definition of a Coordinated Strategy for a New Tuberculosis Vaccine", Madrid, Spain, March 3, 1995.

90. Horwitz, M.A. 1995. Macrophage - *M. tuberculosis* Interactions. Presented at the Gordon Research Conference on Phagocytes, Plymouth, NH, June 11-16, 1995.

91. Horwitz, M.A. 1995. Principles of Intracellular Parasitism. Presented at the Sixth Annual Meeting of the Japanese Society for Biodefense Research, Niigata City, Japan, July 11, 1995.

92. Horwitz, M.A. 1995. Subunit Vaccines Against TB. Presented at the NIAID TB Vaccine Workshop, Fort Collins, CO, July 18, 1995.

93. Horwitz, M.A., and J. Gobin. 1995. Exochelins of *Mycobacterium tuberculosis* have the Capacity to Remove Iron from Human Iron-Binding Proteins and to Donate Iron to Mycobactins in the *M. tuberculosis* Cell Wall. Presented at the 30th Joint Research Conference on Tuberculosis and Leprosy of the U.S.-Japan Cooperative Medical Science Program, Fort Collins, CO, July 17-21, 1995.

94. Lee, B-Y., D.L. Clemens, and M.A. Horwitz. 1995. Purification and Characterization of *Mycobacterium tuberculosis* Urease, a Potentially Critical Determinant of Host-Pathogen Interaction. Presented at the 30th Joint Research Conference on Tuberculosis and Leprosy of the U.S.-Japan Cooperative Medical Science Program, Fort Collins, CO, July 17-21, 1995.

95. Clemens, D.L., and M.A. Horwitz. 1995. The *Mycobacterium tuberculosis* Phagosome Exhibits Maturational Arrest, Interacts with Early Endosomes, and Acquires Transferrin. Presented at the 30th Joint Research Conference on Tuberculosis and Leprosy of the U.S.-Japan Cooperative Medical Science Program, Fort Collins, CO, July 17-21, 1995.

96. Horwitz, M.A. 1995. Vaccination Challenges. Presented at Symposium entitled "Tuberculosis in the Past and in Your Future" commemorating the 75th Anniversary of Olive View-UCLA Medical Center, Granada Hills, CA, October 11, 1995.

97. Horwitz, M.A. 1997. Progress in the development of a subunit vaccine against tuberculosis. Presented at Symposium entitled "Future Prospects: Tuberculosis Vaccine Development" at the 97th General Meeting of the American Society for Microbiology, Miami Beach, FL, May 4-8, 1997.

98. Horwitz, M.A. 1997. TB Vaccines - 1997. Presented at the American Society for Microbiology Conference on "Tuberculosis: Past, Present, and Future", Copper Mountain, CO, July 8-12, 1997.

99. Clemens, D.L., B-Y. Lee, and M.A. Horwitz. 1998. Intracellular biology of *Mycobacterium tuberculosis*. Presented at the Keystone Symposium entitled "TB: Molecular Mechanisms and Immunologic Aspects", Keystone, CO, April 2-8, 1998.

100. Horwitz, M.A., and G. Harth. 1998. Extracellular proteins of mycobacteria and other pathogens as novel drug targets. An inhibitor of exported *Mycobacterium tuberculosis* glutamine synthetase blocks bacterial growth in axenic culture and in human monocytes. Presented at the Inventor's Showcase, 1998 UCSD Connect Conference, Biotechnology/ Biomedical Corporate Partnership Forum, La Jolla, CA, November 17, 1998.

101. Harth, G., and M.A. Horwitz. 2000. The role of exported glutamine synthetase in the growth and survival of mycobacteria. Presented at Symposium entitled "The Host Response and Pathogenesis of Mycobacterial Infections", 100th General Meeting of the American Society for Microbiology, Los Angeles, CA, May 21-25, 2000.

102. Horwitz, M.A. 2000. Exported Molecules of *M. tuberculosis*. Presented at Symposium entitled "Mycobacterial Physiology, Genetics, and Molecular Biology", 100th General Meeting of the American Society for Microbiology, Los Angeles, CA, May 21-25, 2000.

103. Horwitz, M.A. 2000. An effective TB vaccine. Are we there yet? Presented at the 38th Annual Meeting of the Infectious Diseases Society of America, New Orleans, LA, September 7-10, 2000.

104. Horwitz, M.A. 2000. New recombinant vaccines against tuberculosis more potent than BCG vaccine. Presented at the International Meeting: Novel Approaches for Immunization Against Infectious Agents, Sponsored by the Israel Science Foundation, Jerusalem, Israel, September 17-19, 2000.

105. Horwitz, M.A. 2001. Recombinant BCG vaccines expressing the *Mycobacterium tuberculosis* 30 kDa major secretory protein (Antigen 85B) induce greater protective immunity against tuberculosis than conventional BCG vaccines in the guinea pig model. Presented at the Keystone Symposium: Molecular and Cellular Aspects of Tuberculosis Research in the Post Genome Era, Taos, NM, January 25-30, 2001.

106. Horwitz, M.A. 2001. The extracellular protein hypothesis for vaccines against intracellular parasites. Presented at the 7th National Symposium entitled "Basic Aspects of Vaccines", Sponsored by the Walter Reed Army Institute of Research, Washington, D.C. at the Uniformed Services University of the Health Sciences, Bethesda, MD, May 2-4, 2001.

107. Horwitz, M.A. 2001. Division U Lecture: Cell wars in tuberculosis: Fighting the Enemy within from without. Presented at the symposium entitled "How Molecular Approaches Contribute to our Understanding of Tuberculosis" at the 101st General Meeting of the American Society for Microbiology, Orlando, FL, May 20-24, 2001.

108. Horwitz, M.A. 2001. Exported Proteins as Novel Drug Targets of Mycobacteria. Presented at the Symposium entitled "Antibiotic Resistance: Mechanisms, Dissemination and New Trends to Overcome the Problem". American Association for the Advancement of Science, Pacific Division, Annual Meeting, University of California, Irvine, CA, June 17-20, 2001

109. Horwitz, M.A. 2001. New vaccines against tuberculosis more potent than BCG. Presented at the Symposium entitled "Microbial Pathogenesis and Vaccine Development" at the 39th Annual Meeting of the Infectious Diseases Society of America, San Francisco, CA, October 25-28, 2001.

110. Horwitz, M.A. 2001. The recombinant rBCG30 vaccine against tuberculosis. Presented at the Sequella Foundation Vaccine 2001 Conference, Montreal, Canada, November 7-9, 2001.

111. Horwitz, M.A. 2002. Intracellular parasitism: Molecular mechanisms and vaccine strategies. Presented at the Albert Einstein College of Medicine Infectious Diseases Division 30th Anniversary Celebration, The New York Academy of Sciences, New York, NY, January 9, 2002.

112. Horwitz, M.A. 2002. rBCG30, a new TB vaccine. Presented at the Tuberculosis Vaccine Symposium, hosted by the Pediatric Infectious Diseases Unit, School of Childhood and Adolescent Health, University of Cape Town, Cape Town, South Africa, February 20, 2002.

113. Horwitz, M.A. 2002. Tuberculosis: Progress in the Development of a New Vaccine Against the Captain of All the Men of Death. The Mary Lou Clements-Mann Memorial Lecture in Vaccine Sciences. Presented at the Fifth Annual Conference on Vaccine Research, Baltimore, MD, May 6, 2002.

114. Horwitz, M.A. 2002. rBCG30. Presented at the Sequella Global Tuberculosis Foundation Third Annual Meeting, Washington, D.C., December 12, 2002.

115. Horwitz, M.A. 2004. Novel strategies in vaccine development. State-of-the-Art Lecture. Western Regional Meetings, Carmel, CA, January 31, 2004.

116. Horwitz, M.A. 2004. *Francisella tularensis*: Intracellular biology and vaccine development. Presented at the Congressionally Directed Medical Research Programs' Military Health Research Forum, San Juan, Puerto Rico, April 25-28, 2004.

117. Horwitz, M.A. 2004. rBCG30. Presented at the World Health Organization Meeting entitled "New Live Mycobacterial Vaccines: Defining Essential Steps Towards Clinical Development", Geneva, Switzerland, November 3-4, 2004.

118. Horwitz, M.A. 2007. New more potent and safer recombinant BCG vaccines against tuberculosis. Presented at the Keystone Symposium entitled "Tuberculosis: From Lab Research to Field Trials". Vancouver, British Columbia, Canada, March 20-25, 2007.

119. Horwitz, M.A. 2007. New more potent and safer recombinant BCG vaccines against tuberculosis. Presented at the 107th General Meeting of the American Society for Microbiology, Toronto, Canada, May 21-25.

120. Gillis, T., Harth, G., and M.A. Horwitz. 2008. Recombinant BCG Expressing *Mycobacterium leprae* or *Mycobacterium tuberculosis* Ag85B Induce Protection Against *M. leprae* Challenge Comparable or Superior to BCG. Presented at the 17th International Leprosy Congress, Hyderabad (Andhra Pradesh), India, January 30 - February 4, 2008.

121. Horwitz, M.A. 2008. Live recombinant vaccines against tuberculosis that are safer and more potent than BCG. Presented at the First International Congress: Mycobacteria, A challenge for the 21st century. Bogota, Columbia, September 24-27, 2008.

122. Horwitz, M.A. 2009. Strategies in Vaccine Development. Presented at the meeting: Valley Fever Vaccine Project – A Retrospective. California State University Bakersfield, Bakersfield, CA, April 3, 2009.

123. Horwitz, M.A. 2009. Comparative biology of intracellular growth of *Francisella tularensis*. Chair and Discussant. Presented at the 6th International Conference on Tularemia, Berlin, Germany, September 13-16, 2009.

124. Horwitz, M.A. 2011. New strategies for the development of vaccines against tularemia. Presented at the 7th Annual Meeting of the Pacific Southwest Regional Center of Excellence for Biodefense & Emerging Infectious Diseases Research. Honolulu, Hawaii, July 31-August 2, 2011.

125. Horwitz, M.A. 2011. New strategies in the development of vaccines against tuberculosis. Presented at the 7th Sino-U.S. Symposium on Medicine in the 21st Century. The Salk Institute, La Jolla, CA, September 21-23, 2011

126. Horwitz, M.A. 2013. FSC Optimization of Drug Treatment of Tuberculosis. Presented at meeting entitled "Feedback System Control (FSC) TB Drug Development Meeting", Bill and Melinda Gates Foundation, Seattle, WA, January17, 2013.

127. Horwitz, M.A. 2013. Cell Line and Animal Studies for FSC Optimization of Drug Treatment of Tuberculosis. Presented at the meeting entitled "FSC.X Based Clinical Tests of Combinatorial Drugs for TB and HIV". Shanghai Jiao Tong University, Xuhui, Shanghai, China. January 31, 2013.

128. Horwitz, M.A. 2013. Intracellular Biology of *Francisella tularensis*. Presented at the 9th Annual Meeting of the Pacific Southwest Regional Center of Excellence for Biodefense & Emerging Infectious Diseases Research. Huntington Beach, CA, November 17-19, 2013.

129. Horwitz, M.A. 2015. *In Vitro* and *In Vivo* Efficacy of Functionalized Nanotherapeutics Against Francisella tularensis. Presented at the Nanostructured Active Therapeutic Vehicles meeting, Defense Threat Reduction Agency. Springfield, VA, January 19-21, 2015.

130. Clemens, D.L., P. Ge, B-Y. Lee, H. Zhou, and M.A. Horwitz. 2015. Atomic structure and functional analysis of Francisella Type VI Secretion System. Presented at the 8th International Conference on Tularemia, Opatija, Croatia, September 28 - October 1, 2015.

131. Horwitz, M.A., B-Y. Lee, Z. Li, D.L. Clemens, B.J. Dillon, A. Hwang, and J.I. Zink. 2015. Stimulus responsive mesoporous silica nanoparticles provide controlled release of moxifloxacin and enhanced efficacy against pneumonic tularemia in mice. Presented at the 8th International Conference on Tularemia, Opatija, Croatia, September 28 – October 1, 2015.

132. Horwitz, M.A. 2015. Functionalized Nanotherapeutics Against *Francisella tularensis.* Presented at the Nanostructured Active Therapeutic Vehicles (NATV) Meeting, Defense Threat Reduction Agency, Springfield, VA, December 10, 2015

133. Horwitz, M.A. 2016. Immunobiology of *Francisella tularensis.* Presented at the Symposium in Honor of Samuel Silverstein: Deciphering the Language of the Leukocyte. New York, NY, April 8, 2016.

134. Horwitz, M.A. 2018. Identification by parabolic response surface methodology of a universal TB drug treatment regimen that compared with the Standard Regimen reduces the time to achieve relapse-free cure in mice from 20 weeks to only 4 weeks. Presented at the Keystone Symposium entitled “Tuberculosis: Translating Scientific Findings for Clinical and Public Health Impact” Fairmont Chateau Whistler, Whistler, British Columbia, Canada, April 15-19, 2018.

135. Horwitz, M.A. 2018. Functionalized nanotherapeutics targeting intracellular pathogens and biowarfare agents. Presented at the Kyoto University-UCLA International Symposium entitled “Harnessing Physical Forces for Medical Application: Convergence of Physics, Nanomaterials, Cell Biology and Cancer Research” organized by iCeMS of Kyoto University and California NanoSystems Institute, University of California – Los Angeles, Los Angeles, CA, Nov. 15-16, 2018.

136. Horwitz, M.A. 2021. Novel COVID-19 Vaccine Utilizing a Replicating Intracellular Bacterium Vector Platform for Vaccines against Select Agents and Emerging Pathogens. Presented virtually at the 6th International Conference on Vaccines Research and Development – 2021, Baltimore, MD, Nov.1-3, 2021.

137. Horwitz, M.A. 2022. Listeria-vectored vaccine expressing multiple *Mycobacterium tuberculosis* immunoprotective antigens provides potent protective immunity against aerosol challenge with virulent *Mycobacterium tuberculosis* in mouse and guinea pig models. Presented virtually at the 6th Global Forum on TB Vaccines, Toulouse, France, Feb. 22-25, 2022.

EXHIBIT B

PROJECT SUMMARY

Tuberculosis (TB) is one of the world's most important diseases, and a safe and effective vaccine against the causative agent *Mycobacterium tuberculosis* (*Mtb*) that is more potent than the currently available only partially effective *M. bovis* strain *Bacille Calmette-Guérin* (BCG) vaccine is sorely needed. It is generally acknowledged that both an improved replacement vaccine for BCG and a potent heterologous booster vaccine are needed in the fight against TB. The purpose of this project is to optimize and conduct advanced proof-of-concept studies in small animals and non-human primates (NHP) of a second-generation heterologous multiantigenic recombinant attenuated *Listeria monocytogenes*-vectored vaccine against TB.

Live attenuated recombinant *Listeria monocytogenes* (rLm) vaccines offer major advantages over other approaches to booster vaccines, including protein in adjuvant and virus-vectored vaccines, in terms of cost, ease of manufacture, immunogenicity and efficacy. In preliminary studies, we have identified an improved multi-deletional Listeria vector (Lm Δ*actA* Δ*inlB prfA**) and demonstrated that rLm vaccines expressing four key immunoprotective Mtb proteins (rLmMtb4Ag) substantially augment protective immunity when used as a heterologous booster vaccine in a prime-boost vaccination strategy against Mtb aerosol challenge in mice and guinea pigs. Moreover, delivering the immunoprotective *Mtb* protein via a first generation rLm vector was more efficacious than delivering it via a recombinant viral vector or administering it with a potent adjuvant.

The goal of this application is to optimize expression of an Lm-vectored vaccine expressing the 4 Mtb antigens; expand its antigen repertoire to six antigens to increase its potency; and to evaluate the optimized final lead rLm vaccine candidate for safety, immunogenicity and efficacy as a standalone vaccine and as a heterologous booster vaccine to BCG-primed animals in mouse, guinea pig, and non-human primate (NHP) models of pulmonary TB. We shall accomplish this goal by: a) Optimizing the protein expression cassette of rLmMtb4Ag vaccine; systematically evaluating additional novel Mtb antigens for immunogenicity and efficacy in mice, selecting the top two antigens, and subsequently constructing a rLmMtb6Ag lead vaccine candidate; b) Conducting comprehensive proof-of-concept studies of the optimized rLmMtb6Ag lead vaccine candidate for safety, immunogenicity, and efficacy as standalone and heterologous booster vaccine in the mouse model of pulmonary TB; c) Conducting selected proof-of-concept studies of the lead rLmMtb6Ag vaccine as a standalone and heterologous booster vaccine for safety, immunogenicity and efficacy in a guinea pig model of pulmonary TB; and d) as Aeras requires proof-of-concept in NHP for a vaccine to enter preclinical development, evaluating the lead rLmMtb6Ag candidate as a standalone vaccine for safety, immunogenicity and efficacy in a NHP model of pulmonary TB in collaboration with Aeras, Bioqual, and Tulane National Primate Research Centre.

EXHIBIT C

University of California, Los Angeles
Award Snapshot

Section I: Award Summary

Principal Investigator:	HORWITZ, MARCUS	**Fund Number:**	31370
Sponsor:	NIH-NIAID National Institute of Allergy and Infectious Diseases [000064]	**Sponsor Award Number:**	1R01AI135631-01
Administering Unit:	MEDICINE-INFECTIOUS DISEASE [1560]	**Prime Sponsor:**	N/A
Project Title:	Optimization and Advanced Proof-of-Concept Studies of a Listeria-vectored Multi-Antigenic Vaccine against Tuberculosis		
		Current Action:	New
Current Budget Period:	12/1/2017 - 11/30/2018	**Funds Awarded this Action:**	$457,768
Project Period:	12/1/2017 - 11/30/2022	**Total Funds Awarded to Date:**	$968,076

- ***See Section VII for Other Investigators***
- ***For a History of Actions on this award, refer to the Award Snapshot Attachment***

Section II: Special Attention Needed

1. This award is subject to a sponsor salary cap limitation. Salary Cap Type: Health and Human Services
2. Review the Award Snapshot Attachment and the Award document for additional terms and conditions.

Section III: Award Demographics

Sponsor Award Number:	1R01AI135631-01	**UCLA PATS Number:**	20173817
Proposal Type:	New	**Award Type:**	Grant
Program Type:	Applied Org Research	**Special Program Type:**	Not applicable
Award Status:	Awarded/Fully Executed	**Location:**	On Site
Payment Basis:	Cost Reimbursable	**Special Payment Type:**	None

Transaction Budget Period	Direct Costs	F&A Costs	Total	F&A Rate	F&A Base	Award Status	Action Type
12/01/2017 - 11/30/2018	$348,915	$161,393	$510,308	55.0 %	MTDC	Awarded/Fully Executed	New
12/01/2017 - 11/30/2018	$293,441	$164,327	$457,768	56.0 %	MTDC	Awarded/Fully Executed	New
12/01/2018 - 11/30/2019	$622,143	$317,236	$939,379	56.0 %	MTDC	Anticipated/Committed	Continuation
12/01/2019 - 11/30/2020	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Anticipated/Committed	Continuation
12/01/2020 - 11/30/2021	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Anticipated/Committed	Continuation
12/01/2021 - 11/30/2022	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Anticipated/Committed	Continuation

Section IV: Training Grant Approved Slots/Subawards Approved in the Award

Budget Period	Undergraduate	Graduate	Post-Doc	Other	Subawardee
12/01/2017 - 11/30/2018	0	0	0	0	Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)
12/01/2018 - 11/30/2019	N/A	N/A	N/A	N/A	Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)
12/01/2019 - 11/30/2020	N/A	N/A	N/A	N/A	Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)
12/01/2020 - 11/30/2021	N/A	N/A	N/A	N/A	Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)
12/01/2021 - 11/30/2022	N/A	N/A	N/A	N/A	Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)

Section V: Program Income, Cost Sharing and Approvals

Anticipated Program Income

No

Cost Sharing?	Cost Sharing Type	Unfunded Effort (other than salary over the cap)	Cost Share Fund	Amount
No	None	No	N/A	$0

Special Review Type	Approval Status	Reference
Animal Subjects	Pending	N/A

Section VI: Deliverables

As you prepare the required reporting/deliverable to the Sponsor for this project keep in mind that it may contain patentable information. The TDG Technology Transfer Officers are ready to meet or speak with you to discuss your pending work and you are encouraged to report potential inventions at any and all stages of your research. Invention disclosures can be submitted to http://tdg.ucla.edu.submit-invention-report and upon receipt TDG will be in touch with you to discuss your work. **Note that filing a technical report without consulting TDG may jeopardize UCLA's ability to secure a patent to protect your work.**

Non-Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Tech/Scientific	Annual	Progress Report	10/15/2018	Not Started
Tech/Scientific	Annual	Progress Report	10/15/2019	Not Started
Tech/Scientific	Annual	Progress Report	10/15/2020	Not Started
Tech/Scientific	Annual	Progress Report	10/15/2021	Not Started

Invention/Patent	One Time	Final	03/30/2023	Not Started
Tech/Scientific	One Time	Final	03/30/2023	Not Started

Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Financial Report	Once	Final	02/28/2023	Deliverable Not Started

Section VII: Other Investigators

Role	Name
PD/PI	HORWITZ, MARCUS

Section VIII: Contacts

Contacts

OCGA	FRANK FALCON II (frank.falcon@research.ucla.edu)	3102069898
EFM	MARIA FRANCHESCA KIM (franchesca.kim@research.ucla.edu)	3107948359

University of California, Los Angeles
Award Snapshot Attachment

UCLA PATS NUMBER: 20173817

Alert(s)

1. Please review and adhere to the award terms and conditions.
2. Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA).

Reference Document(s)

1. Award(s) available via the ORA Award Status & Snapshot Report [http://portal.research.ucla.edu/index.aspx?Section=PostAward]
2. Federal-Wide Research Terms and Conditions November 2017 https://www.nsf.gov/awards/managing/rtc.jsp
3. RTC Prior Approval and Other Requirements Matrix [https://www.nsf.gov/bfa/dias/policy/fedrtc/appa_march17.pdf]
4. RTC NIH Agency-Specific https://www.nsf.gov/pubs/policydocs/rtc/agencyspecifics/nih_417.pdf
5. NIH Grants Policy Statement November 2016: https://grants.nih.gov/policy/nihgps/index.htm
6. 45 CFR Part 75: Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations.

Action(s)

1. *This Snapshot*: Sponsor award dated 11/29/2017 provides funding in the amount of $959,273. The sponsor has also issued a revised award dated 12/15/2017 increasing finding for Year 1 in the amount of $8,803 in accordance with the new F&A rate agreement.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 11/29/2017

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 1R01AI135631-01
FAIN: R01AI135631

Principal Investigator(s):
MARCUS AARON HORWITZ, MD

Project Title: Optimization and Advanced Proof-of-Concept Studies of a Listeria-vectored Multi-Antigenic Vaccine against Tuberculosis

Frank Falcon II
Grant Analyst
UCLA Office of Contract & Grant Adm
10889 Wilshire Blvd. Ste 700
Los Angeles, CA 900951406

Award e-mailed to: NIHAward@research.ucla.edu

Period Of Performance:
Budget Period: 12/01/2017 – 11/30/2018
Project Period: 12/01/2017 – 11/30/2022

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $959,273 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI135631. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Tamia Y. Powell
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I – AWARD DATA – 1R01AI135631-01

Award Calculation (U.S. Dollars)

Salaries and Wages	$253,870
Fringe Benefits	$136,130
Personnel Costs (Subtotal)	$390,000
Consultant Services	$1,350
Equipment	$55,473
Materials & Supplies	$65,128
Travel	$2,800
Other	$94,170
Subawards/Consortium/Contractual Costs	$31,865
Publication Costs	$1,570
Federal Direct Costs	$642,356
Federal F&A Costs	$316,917
Approved Budget	$959,273
Total Amount of Federal Funds Obligated (Federal Share)	$959,273
TOTAL FEDERAL AWARD AMOUNT	$959,273
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$959,273

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$959,273	$959,273
2	$928,049	$928,049
3	$1,144,241	$1,144,241
4	$1,198,652	$1,198,652
5	$1,193,958	$1,193,958

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Allergy and Infectious Diseases Research
CFDA Number:	93.855
EIN:	1956006143A1
Document Number:	RAI135631A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2018

IC	CAN	2018	2019	2020	2021	2022
AI	8472315	$959,273	$928,049	$1,144,241	$1,198,652	$1,193,958

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: M33A B / **OC**: 414A / **Released**: POWELLTY 11/21/2017
Award Processed: 11/29/2017 12:02:22 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AI135631-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 1R01AI135631-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VI Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI135631. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and

...in the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI Special Terms and Conditions – 1R01AI135631-01

This Notice of Award (NoA) includes funds for activity with:
AERAS in the amount of **$20,637** (**$18,429** direct costs + **$2,208** F&A costs)
Tulane National Primate Research Center in the amount of **$11,228** (**$11,228** direct costs + **$0** F&A costs)
*****
In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Committed future year (s) funding was adjusted accordingly. See: https://www.niaid.nih.gov/grants-contracts/financial-management-plan.
*****
Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;

of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Tamia Y. Powell
Email: powellty@niaid.nih.gov **Phone**: 240-669-2982 **Fax**: 301-493-0597

Program Official: Katrin Eichelberg
Email: keichelberg@niaid.nih.gov **Phone**: 240-669-2921

SPREADSHEET SUMMARY
GRANT NUMBER: 1R01AI135631-01

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$253,870	$253,870	$214,090	$122,689	$127,317
Fringe Benefits	$136,130	$136,130	$112,439	$60,760	$62,333
Personnel Costs (Subtotal)	$390,000	$390,000	$326,529	$183,449	$189,650
Consultant Services	$1,350	$1,350	$1,350	$1,350	$1,350
Equipment	$55,473				
Materials & Supplies	$65,128	$65,128	$42,340	$42,340	$39,750
Travel	$2,800	$2,800	$2,800	$2,800	$2,800
Other	$94,170	$101,282	$341,567	$102,497	$102,497
Subawards/Consortium/Contractual Costs	$31,865	$60,013	$41,361	$676,846	$674,028
Publication Costs	$1,570	$1,570	$1,570	$1,570	$1,570
TOTAL FEDERAL DC	$642,356	$622,143	$757,517	$1,010,852	$1,011,645
TOTAL FEDERAL F&A	$316,917	$305,906	$386,724	$187,800	$182,313
TOTAL COST	$959,273	$928,049	$1,144,241	$1,198,652	$1,193,958

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	54%	54%	54%	54%	54%
F&A Cost Base 1	$586,883	$566,493	$716,156	$347,778	$337,617
F&A Costs 1	$316,917	$305,906	$386,724	$187,800	$182,313

EXHIBIT D

University of California, Los Angeles
Award Snapshot

Section I: Award Summary

Principal Investigator:	Horwitz, Marcus	**Fund Number:**	31370
Sponsor:	NIH-NIAID National Institute of Allergy and Infectious Diseases [000064]	**Sponsor Award Number:**	5R01AI135631-02
Administering Unit:	MEDICINE-INFECTIOUS DISEASE [1560]	**Prime Sponsor:**	N/A
Project Title:	Optimization and Advanced Proof-of-Concept Studies of a Listeria-vectored Multi-Antigenic Vaccine against Tuberculosis		
		Current Action:	Continuation
Current Budget Period:	12/1/2018 - 11/30/2019	**Funds Awarded this Action:**	$939,379
Project Period:	12/1/2017 - 11/30/2022	**Total Funds Awarded to Date:**	$1,907,455

- ***See Section VII for Other Investigators***
- ***For a History of Actions on this award, refer to the Award Snapshot Attachment***

Section II: Special Attention Needed

1. This award is subject to a sponsor salary cap limitation. Salary Cap Type: Health and Human Services
2. Review the Award Snapshot Attachment and the Award document for additional terms and conditions.

Section III: Award Demographics

Sponsor Award Number:	5R01AI135631-02	**UCLA PATS Number:**	20173817
Proposal Type:	New	**Award Type:**	Grant
Program Type:	Applied Org Research	**Special Program Type:**	Not applicable
Award Status:	Awarded/Fully Executed	**Location:**	On Site
Payment Basis:	Cost Reimbursable	**Special Payment Type:**	None

Budget Period	Transaction Budget Period	Direct Costs	F&A Costs	Total	F&A Rate	F&A Base	Award Status	Action Type
1	12/01/2017 - 06/30/2018	$348,915	$161,393	$510,308	55.0 %	MTDC	Awarded/Fully Executed	New
1	07/01/2018 - 11/30/2018	$293,441	$164,327	$457,768	56.0 %	MTDC	Awarded/Fully Executed	New
2	12/01/2018 - 11/30/2019	$622,143	$317,236	$939,379	56.0 %	MTDC	Awarded/Fully Executed	Continuation
3	12/01/2019 - 11/30/2020	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Anticipated/Committed	Continuation
4	12/01/2020 - 11/30/2021	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Anticipated/Committed	Continuation
5	12/01/2021 - 11/30/2022	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Anticipated/Committed	Continuation

Section IV: Training Grant Approved Slots/Subawards Approved in the Award

Budget Period	Undergraduate	Graduate	Post-Doc	Other	Subawardee
12/01/2017 - 11/30/2018	0	0	0	0	Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)
12/01/2018 - 11/30/2019	0	0	0	0	Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)
12/01/2019 - 11/30/2020	0	0	0	0	Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)
12/01/2020 - 11/30/2021	0	0	0	0	Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)
12/01/2021 - 11/30/2022	0	0	0	0	Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)

Section V: Program Income, Cost Sharing and Approvals

Anticipated Program Income

No

Cost Sharing?	Cost Sharing Type	Unfunded Effort (other than salary over the cap)	Cost Share Fund	Amount
No	None	No	N/A	$0

Special Review Type	Approval Status	Reference
Animal Subjects	Approved	1995-130-73
Animal Subjects	Pending	N/A

Section VI: Deliverables

As you prepare the required reporting/deliverable to the Sponsor for this project keep in mind that it may contain patentable information. The TDG Technology Transfer Officers are ready to meet or speak with you to discuss your pending work and you are encouraged to report potential inventions at any and all stages of your research. Invention disclosures can be submitted to http://tdg.ucla.edu.submit-invention-report and upon receipt TDG will be in touch with you to discuss your work. **Note that filing a technical report without consulting TDG may jeopardize UCLA's ability to secure a patent to protect your work.**

Non-Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Tech/Scientific	Annual	Progress Report	10/15/2018	Submitted
Tech/Scientific	Annual	Progress Report	10/15/2019	Not Started

Tech/Scientific	Annual	Progress Report	10/15/2020	Not Started
Tech/Scientific	Annual	Progress Report	10/15/2021	Not Started
Invention/Patent	One Time	Final	03/30/2023	Not Started
Tech/Scientific	One Time	Final	03/30/2023	Not Started

Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Financial Report	Once	Final	02/28/2023	Not Started

Section VII: Other Investigators

Role	Name
PD/PI	Horwitz, Marcus

Section VIII: Contacts

Contacts

OCGA	Frank Falcon Ii (frank.falcon@research.ucla.edu)
EFM	Daniel Herrera (daniel.herrera@research.ucla.edu)

University of California, Los Angeles
Award Snapshot Attachment

UCLA PATS NUMBER: 20173817

Alert(s)

1. Please review and adhere to the award terms and conditions.
2. Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA).

Reference Document(s)

1. Award(s) available via the ORA Award Status & Snapshot Report [http://portal.research.ucla.edu/index.aspx?Section=PostAward]
2. NIH Grants Policy Statement October 2017 [http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf]
3. 45 CFR Part 75: Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations.
4. Federal-Wide Research Terms and Conditions October 2017 https://www.nsf.gov/awards/managing/rtc.jsp
5. RTC Prior Approval and Other Requirements Matrix [https://www.nsf.gov/bfa/dias/policy/fedrtc/appendix_a.pdf]
6. RTC Agency-Specific Requirements [https://www.nsf.gov/bfa/dias/policy/fedrtc/agencyspecifics/nsf_318.pdf]

Action(s)

1. Sponsor award dated 11/29/2017 provides funding in the amount of $959,273. The sponsor has also issued a revised award dated 12/15/2017 increasing finding for Year 1 in the amount of $8,803 in accordance with the new F&A rate agreement.
2. *This Snapshot*: Sponsor award dated 11/16/2018 provides continuation funding in the amount of $939,379 for Year 2.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 11/16/2018

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 5R01AI135631-02
FAIN: R01AI135631

Principal Investigator(s):
MARCUS AARON HORWITZ, MD

Project Title: Optimization and Advanced Proof-of-Concept Studies of a Listeria-vectored Multi-Antigenic Vaccine against Tuberculosis

Frank Falcon II
Grant Analyst
UCLA Office of Contract & Grant Adm
10889 Wilshire Blvd. Ste 700
Los Angeles, CA 900951406

Award e-mailed to: awards@research.ucla.edu

Period Of Performance:
Budget Period: 12/01/2018 – 11/30/2019
Project Period: 12/01/2017 – 11/30/2022

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $939,379 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI135631. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Adam Graham
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I – AWARD DATA – 5R01AI135631-02

Award Calculation (U.S. Dollars)

Federal Direct Costs	$622,143
Federal F&A Costs	$317,236
Approved Budget	$939,379
Total Amount of Federal Funds Obligated (Federal Share)	$939,379
TOTAL FEDERAL AWARD AMOUNT	$939,379

AMOUNT OF THIS ACTION (FEDERAL SHARE) $939,379

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$939,379	$939,379
3	$1,158,564	$1,158,564
4	$1,205,608	$1,205,608
5	$1,200,711	$1,200,711

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Allergy and Infectious Diseases Research
CFDA Number:	93.855
EIN:	1956006143A1
Document Number:	RAI135631A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2019

IC	CAN	2019	2020	2021	2022
AI	8472315	$939,379	$1,158,564	$1,205,608	$1,200,711

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: M33A B / **OC**: 414E / **Released**: INT_GRAHAMA_32 11/15/2018
Award Processed: 11/16/2018 05:19:24 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AI135631-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 5R01AI135631-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VI Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI135631. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This Notice of Award (NoA) includes funds for activity with **AERAS.**
This Notice of Award (NoA) includes funds for activity with **Tulane National Primate Research Center.**

*****
In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Committed future year (s) funding was adjusted accordingly. See: https://www.niaid.nih.gov/grants-contracts/financial-management-plan.
*****

Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Adam Graham
Email: adam.graham@nih.gov **Phone**: 301-761-6260 **Fax**: 301-493-0597

Program Official: Katrin Eichelberg
Email: keichelberg@niaid.nih.gov **Phone**: 240-669-2921

SPREADSHEET SUMMARY
GRANT NUMBER: 5R01AI135631-02

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	56%	56%	56%	56%
F&A Cost Base 1	$566,493	$716,156	$347,778	$337,617
F&A Costs 1	$317,236	$401,047	$194,756	$189,066

EXHIBIT E

University of California, Los Angeles
Award Snapshot

Section I: Award Summary

Principal Investigator:	Horwitz, Marcus	**Fund Number:**	31370
Sponsor:	NIH-NIAID National Institute of Allergy and Infectious Diseases [000064]	**Sponsor Award Number:**	5R01AI135631-03
Administering Unit:	MEDICINE-INFECTIOUS DISEASE [1560]	**Prime Sponsor:**	N/A
Project Title:	Optimization and Advanced Proof-of-Concept Studies of a Listeria-Vectored Multi-Antigenic Vaccine Against Tuberculosis		
		Current Action:	Continuation
Current Budget Period:	12/1/2019 - 11/30/2020	**Funds Awarded this Action:**	$1,158,564
Project Period:	12/1/2017 - 11/30/2022	**Total Funds Awarded to Date:**	$3,066,019

- ***See Section VII for Other Investigators***
- ***For a History of Actions on this award, refer to the Award Snapshot Attachment***

Section II: Special Attention Needed

1. This award is subject to a sponsor salary cap limitation. Salary Cap Type: Health and Human Services
2. Review the Award Snapshot Attachment and the Award document for additional terms and conditions.

Section III: Award Demographics

Sponsor Award Number:	5R01AI135631-03	**UCLA PATS Number:**	20173817
Proposal Type:	New	**Award Type:**	Grant
Program Type:	Applied Org Research	**Special Program Type:**	Not applicable
Award Status:	Awarded/Fully Executed	**Location:**	On Site
Special Payment Type:	None		

Budget Period	Transaction Budget Period	Direct Costs	F&A Costs	Total	F&A Rate	F&A Base	Payment Basis	Award Status	Action Type
1	12/01/2017 - 06/30/2018	$348,915	$161,393	$510,308	55.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	New
1	07/01/2018 - 11/30/2018	$293,441	$164,327	$457,768	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	New
2	12/01/2018 - 11/30/2019	$622,143	$317,236	$939,379	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	Continuation
3	12/01/2019 - 11/30/2020	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	Continuation
4	12/01/2020 - 11/30/2021	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Cost Reimb	Anticipated/Committed	Continuation
5	12/01/2021 - 11/30/2022	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Cost Reimb	Anticipated/Committed	Continuation

Section IV: Training Grant Approved Slots/Subawards Approved in the Award

Budget Period	Undergraduate	Graduate	Post-Doc	Other	Subawardee
12/01/2017 - 11/30/2018	0	0	0	0	Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)
12/01/2018 - 11/30/2019	0	0	0	0	Aeras Bioqual Inc. Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)
12/01/2019 - 11/30/2020	0	0	0	0	Aeras Bioqual Inc. Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)

Section V: Program Income, Cost Sharing and Approvals

Anticipated Program Income

No

Cost Sharing?	Cost Sharing Type	Unfunded Effort (other than salary over the cap)	Cost Share Fund	Amount
No	None	No	N/A	$0

Special Review Type	Approval Status	Reference
Animal Subjects	-	1995-130-81

Section VI: Deliverables

As you prepare the required reporting/deliverable to the Sponsor for this project keep in mind that it may contain patentable information. The TDG Technology Transfer Officers are ready to meet or speak with you to discuss your pending work and you are encouraged to report potential inventions at any and all stages of your research. Invention disclosures can be submitted to http://tdg.ucla.edu.submit-invention-report and upon receipt TDG will be in touch with you to discuss your work. **Note that filing a technical report without consulting TDG may jeopardize UCLA's ability to secure a patent to protect your work.**

Non-Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Tech/Scientific	Annual	Progress Report	10/15/2018	Submitted
Tech/Scientific	Annual	Progress Report	10/15/2019	Submitted
Tech/Scientific	Annual	Progress Report	10/15/2020	Not Started
Tech/Scientific	Annual	Progress Report	10/15/2021	Not Started
Invention/Patent	One Time	Final	03/30/2023	Not Started

Tech/Scientific	One Time	Final	03/30/2023	Not Started

Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Financial Report	Once	Final	02/28/2023	Not Started

Section VII: Other Investigators

Role	Name
PD/PI	Horwitz, Marcus

Section VIII: Contacts

Contacts

OCGA	Frank Falcon Ii (frank.falcon@research.ucla.edu)
EFM	Daniel Herrera (daniel.herrera@research.ucla.edu)

University of California, Los Angeles
Award Snapshot Attachment

UCLA PATS NUMBER: 20173817

Alert(s)

1. Please review and adhere to the award terms and conditions.
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Reference Document(s)

1. Award(s) available via the ORA Award Status & Snapshot Report [http://portal.research.ucla.edu/index.aspx?Section=PostAward]
2. NIH Grants Policy Statement October 2018 [http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf]
3. 45 CFR Part 75: Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations.
4. Federal-Wide Research Terms and Conditions October 2017 https://www.nsf.gov/awards/managing/rtc.jsp
5. RTC Prior Approval and Other Requirements Matrix [https://www.nsf.gov/bfa/dias/policy/fedrtc/appendix_a.pdf]
6. RTC Agency-Specific Requirements [https://www.nsf.gov/bfa/dias/policy/fedrtc/agencyspecifics/nih_417.pdf]

Action(s)

1. Sponsor award dated 11/29/2017 provides funding in the amount of $959,273. The sponsor has also issued a revised award dated 12/15/2017 increasing finding for Year 1 in the amount of $8,803 in accordance with the new F&A rate agreement.
2. Sponsor award dated 11/16/2018 provides continuation funding in the amount of $939,379 for Year 2.
3. *This Snapshot*: Sponsor award dated 12/03/2019 provides continuation funding in the amount of $1,158,564 for Year 3.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

Federal Award Date: 12/03/2019

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 5R01AI135631-03
FAIN: R01AI135631

Principal Investigator(s):
MARCUS AARON HORWITZ, MD

Project Title: Optimization and Advanced Proof-of-Concept Studies of a Listeria-vectored Multi-Antigenic Vaccine against Tuberculosis

Frank Falcon II
University of California Los Angeles
UCLA Office of Contract & Grant Adm
10889 Wilshire Blvd. Ste 700
Los Angeles, CA 900951406

Award e-mailed to: awards@research.ucla.edu

Period Of Performance:
Budget Period: 12/01/2019 – 11/30/2020
Project Period: 12/01/2017 – 11/30/2022

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $1,158,564 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI135631. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Tina M. Carlisle
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I – AWARD DATA – 5R01AI135631-03

Award Calculation (U.S. Dollars)

Salaries and Wages	$214,090
Fringe Benefits	$112,439
Personnel Costs (Subtotal)	$326,529
Consultant Services	$1,350
Materials & Supplies	$42,340
Travel	$2,800
Other	$341,567
Subawards/Consortium/Contractual Costs	$41,361
Publication Costs	$1,570
Federal Direct Costs	$757,517
Federal F&A Costs	$401,047
Approved Budget	$1,158,564
Total Amount of Federal Funds Obligated (Federal Share)	$1,158,564
TOTAL FEDERAL AWARD AMOUNT	$1,158,564
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$1,158,564

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$1,158,564	$1,158,564
4	$1,205,608	$1,205,608
5	$1,200,711	$1,200,711

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name:	Allergy and Infectious Diseases Research
CFDA Number:	93.855
EIN:	1956006143A1
Document Number:	RAI135631A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2020

IC	CAN	2020	2021	2022
AI	8472315	$1,158,564	$1,205,608	$1,200,711

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: M33A B / **OC**: 41025 / **Released**: CARLISLET 12/02/2019
Award Processed: 12/03/2019 12:03:19 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AI135631-03

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – TERMS AND CONDITIONS – 5R01AI135631-03

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VI Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI135631. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made

publicly available OMB designated government performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – AI Special Terms and Conditions – 5R01AI135631-03

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This Notice of Award (NoA) includes funds for activity with **AERAS.**

This Notice of Award (NoA) includes funds for activity with **Tulane National Primate Research Center.**

*****

Select Agents:

Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:

NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.

When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;

including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Mohan Aruldhas
Email: mohan.aruldhas@nih.gov **Phone**: 301.761.7240 **Fax**: 301-493-0597

Program Official: Katrin Eichelberg
Email: keichelberg@niaid.nih.gov **Phone**: 240-669-2921

SPREADSHEET SUMMARY
GRANT NUMBER: 5R01AI135631-03

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

Budget	Year 3	Year 4	Year 5
Salaries and Wages	$214,090	$122,689	$127,317
Fringe Benefits	$112,439	$60,760	$62,333
Personnel Costs (Subtotal)	$326,529	$183,449	$189,650
Consultant Services	$1,350	$1,350	$1,350
Materials & Supplies	$42,340	$42,340	$39,750
Travel	$2,800	$2,800	$2,800
Other	$341,567	$102,497	$102,497
Subawards/Consortium/Contractual Costs	$41,361	$676,846	$674,028
Publication Costs	$1,570	$1,570	$1,570
TOTAL FEDERAL DC	$757,517	$1,010,852	$1,011,645
TOTAL FEDERAL F&A	$401,047	$194,756	$189,066
TOTAL COST	$1,158,564	$1,205,608	$1,200,711

Facilities and Administrative Costs	Year 3	Year 4	Year 5
F&A Cost Rate 1	56%	56%	56%
F&A Cost Base 1	$716,156	$347,778	$337,617
F&A Costs 1	$401,047	$194,756	$189,066

EXHIBIT F

University of California, Los Angeles
Award Snapshot

Section I: Award Summary

Principal Investigator:	Horwitz, Marcus	**Fund Number:**	31370
Sponsor:	NIH-NIAID National Institute of Allergy and Infectious Diseases [000064]	**Sponsor Award Number:**	5R01AI135631-04
Administering Unit:	MEDICINE-INFECTIOUS DISEASE [1560]	**Prime Sponsor:**	N/A
Project Title:	Optimization and Advanced Proof-of-Concept Studies of a Listeria-Vectored Multi-Antigenic Vaccine Against Tuberculosis		
		Current Action:	Continuation
Current Budget Period:	12/1/2020 - 11/30/2021	**Funds Awarded this Action:**	$1,205,608
Project Period:	12/1/2017 - 11/30/2022	**Total Funds Awarded to Date:**	$4,271,627

- ***See Section VII for Other Investigators***
- ***For a History of Actions on this award, refer to the Award Snapshot Attachment***

Section II: Special Attention Needed

1. This award is subject to a sponsor salary cap limitation. Salary Cap Type: Health and Human Services
2. Review the Award Snapshot Attachment and the Award document for additional terms and conditions.

Section III: Award Demographics

Sponsor Award Number:	5R01AI135631-04	**UCLA PATS Number:**	20173817
Proposal Type:	New	**Award Type:**	Grant
Program Type:	Applied Org Research	**Special Program Type:**	Not applicable
Award Status:	Awarded/Fully Executed	**Location:**	On Site
Special Payment Type:	None		

Budget Period	Transaction Budget Period	Direct Costs	F&A Costs	Total	F&A Rate	F&A Base	Payment Basis	Award Status	Action Type
1	12/01/2017 - 06/30/2018	$348,915	$161,393	$510,308	55.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	New
1	07/01/2018 - 11/30/2018	$293,441	$164,327	$457,768	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	New
2	12/01/2018 - 11/30/2019	$622,143	$317,236	$939,379	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	Continuation
3	12/01/2019 - 11/30/2020	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	Continuation
4	12/01/2020 - 11/30/2021	$1,010,852	$194,756	$1,205,608	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	Continuation
5	12/01/2021 - 11/30/2022	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Cost Reimb	Anticipated/Committed	Continuation

Section IV: Subawards Approved in the Award

Subawardee	Budget Period
Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)	12/01/2017 - 11/30/2018
Aeras Bioqual Inc. Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)	12/01/2018 - 11/30/2019
Aeras Bioqual Inc. Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)	12/01/2019 - 11/30/2020
Aeras International AIDS Vaccine Initiative, Inc. (IAVI) Texas Biomedical Research Institute	12/01/2020 - 11/30/2021

Section V: Training Grant Approved Slots

Section VI: Program Income, Cost Sharing and Compliance Requirements

Anticipated Program Income	Anticipated Program Income Type
No	-

Mandatory Cost Sharing?	Unfunded Effort (other than salary over the cap)	Amount
No	No	$0

Special Review Type	Approval Status	Reference
Animal Subjects	See System of Record	1995-130-81
Animal Subjects	See System of Record	ARC-1995-130

Section VII: Deliverables

As you prepare the required reporting/deliverable to the Sponsor for this project keep in mind that it may contain patentable information. The TDG Technology Transfer Officers are ready to meet or speak with you to discuss your pending work and you are encouraged to report potential inventions at any and all stages of your research. Invention disclosures can be submitted to http://tdg.ucla.edu.submit-invention-report and upon receipt TDG will be in touch with you to discuss your work. **Note that filing a technical report without consulting TDG may jeopardize UCLA's ability to secure a patent to protect your work.**

Non-Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Tech/Scientific	Annual	Progress Report	10/15/2018	Submitted
Tech/Scientific	Annual	Progress Report	10/15/2019	Submitted
Tech/Scientific	Annual	Progress Report	10/15/2020	Submitted
Tech/Scientific	Annual	Progress Report	10/15/2021	Not Started
Invention/Patent	One Time	Final	03/30/2023	Not Started
Tech/Scientific	One Time	Final	03/30/2023	Not Started

Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Financial Report	Once	Final	03/30/2023	Not Started

Section VIII: Other Investigators

Role	Name
PD/PI	Horwitz, Marcus

Section IX: Contacts

Contacts	
OCGA	Frank Falcon Ii (frank.falcon@research.ucla.edu)
EFM	Maribel Gomez (maribel.gomez@research.ucla.edu)

University of California, Los Angeles
Award Snapshot Attachment

UCLA PATS NUMBER: 20173817

Alert(s)

1. Please review and adhere to the award terms and conditions.
2. Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA).

Reference Document(s)

1. Award(s) available via the ORA Award Status & Snapshot Report [http://portal.research.ucla.edu/index.aspx?Section=PostAward]
2. NIH Grants Policy Statement October 2019 [http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf]
3. 45 CFR Part 75: Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations.
4. Federal-Wide Research Terms and Conditions April 2017 https://www.nsf.gov/awards/managing/rtc.jsp
5. RTC Prior Approval and Other Requirements Matrix [https://www.nsf.gov/bfa/dias/policy/fedrtc/appendix_a.pdf]
6. RTC Agency-Specific Requirements [https://www.nsf.gov/bfa/dias/policy/fedrtc/agencyspecifics/nih_417.pdf]

Action(s)

1. Sponsor award dated 11/29/2017 provides funding in the amount of $959,273. The sponsor has also issued a revised award dated 12/15/2017 increasing finding for Year 1 in the amount of $8,803 in accordance with the new F&A rate agreement.
2. Sponsor award dated 11/16/2018 provides continuation funding in the amount of $939,379 for Year 2.
3. Sponsor award dated 12/03/2019 provides continuation funding in the amount of $1,158,564 for Year 3.
4. *This Snapshot*: Sponsor award dated 11/25/2020 provides continuation funding in the amount of $1,205,608 for Year 4.

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI135631
Federal Award Date
11/25/2020

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA, LOS ANGELES
10889 WILSHIRE BLVD STE 700

LOS ANGELES, CA 90095

2. Congressional District of Recipient
33

3. Payment System Identifier (ID)
1956006143A1

4. Employer Identification Number (EIN)
956006143

5. Data Universal Numbering System (DUNS)
092530369

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator
MARCUS AARON HORWITZ, MD
Professor
MHORWITZ@MEDNET.UCLA.EDU
(310) 206-0074

8. Authorized Official
Frank Falcon II
frank.falcon@research.ucla.edu
310-206-9898

Federal Agency Information

9. Awarding Agency Contact Information
JOSHUA SEWANU Elesinmogun

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

10. Program Official Contact Information
Katrin Eichelberg
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
keichelberg@niaid.nih.gov
240-669-2921

Federal Award Information

11. Award Number
5R01AI135631-04

12. Unique Federal Award Identification Number (FAIN)
R01AI135631

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Optimization and Advanced Proof-of-Concept Studies of a Listeria-vectored Multi-Antigenic Vaccine against Tuberculosis

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 12/01/2020 – **End Date** 11/30/2021	
20. Total Amount of Federal Funds Obligated by this Action	$1,205,608
20a. Direct Cost Amount	$1,010,852
20b. Indirect Cost Amount	$194,756
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$1,205,608
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,205,608
26. Project Period Start Date 12/01/2017 – **End Date** 11/30/2022	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$4,271,627

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Gregory P. Smith

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Version:200 - 11/17/2020 12:25 PM | Generated on: 11/25/2020 12:42 AM

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 5R01AI135631-04

Principal Investigator(s):
MARCUS AARON HORWITZ, MD

Award e-mailed to: awards@research.ucla.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $1,205,608 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA, LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI135631. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Gregory P. Smith
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Budget Period (U.S. Dollars)

Federal Direct Costs	$1,010,852
Federal F&A Costs	$194,756
Approved Budget	$1,205,608
Total Amount of Federal Funds Authorized (Federal Share)	$1,205,608
TOTAL FEDERAL AWARD AMOUNT	$1,205,608

AMOUNT OF THIS ACTION (FEDERAL SHARE) $1,205,608

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
4	$1,205,608	$1,205,608
5	$1,200,711	$1,200,711

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
Payment System Identifier: 1956006143A1
Document Number: RAI135631A
PMS Account Type: P (Subaccount)
Fiscal Year: 2021

IC	CAN	2021	2022
AI	8472315	$1,205,608	$1,200,711

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: M33A B / **OC**: 41025 / **Released**: Smith, Gregory 11/24/2020
Award Processed: 11/25/2020 12:42:13 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AI135631-04

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AI135631-04

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal

awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VI Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI135631. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 5R01AI135631-04

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This Notice of Award (NoA) includes funds for activity with **IAVI.**

*****

Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AI135631-04

INSTITUTION: UNIVERSITY OF CALIFORNIA, LOS ANGELES

Facilities and Administrative Costs	Year 4	Year 5

Project Costs 1	$552,534	$526,683
F&A Cost Base 1	$347,778	$337,617
F&A Costs 1	$194,756	$189,066

EXHIBIT G

University of California, Los Angeles
Award Snapshot

Section I: Award Summary

Principal Investigator:	Horwitz, Marcus	**Fund Number:**	31370
Sponsor:	NIH-NIAID National Institute of Allergy and Infectious Diseases [000064]	**Sponsor Award Number:**	R01AI135631-05
Administering Unit:	MEDICINE-INFECTIOUS DISEASE [1560]	**Prime Sponsor:**	N/A
Project Title:	Optimization and Advanced Proof-of-Concept Studies of a Listeria-Vectored Multi-Antigenic Vaccine Against Tuberculosis		
		Current Action:	No Cost Extension
Current Budget Period:	12/1/2021 - 11/30/2023	**Funds Awarded this Action:**	$0
Project Period:	12/1/2017 - 11/30/2023	**Total Funds Awarded to Date:**	$5,472,337

- ***See Section VIII for Other Investigators***
- ***For a History of Actions on this award, refer to the Award Snapshot Attachment***

Section II: Special Attention Needed

1. Changes in the status of the Principal Investigator or other key personnel on the award require prior approval from the Sponsor. Requests for prior approval must be processed through OCGA. Notify OCGA in advance or as soon as you become aware of any changes (or anything requiring prior approval).
2. This award is subject to a sponsor salary cap limitation. Salary Cap Type: Health and Human Services
3. Review the Award Snapshot Attachment and the Award document for additional terms and conditions.

Section III: Award Demographics

Sponsor Award Number:	R01AI135631-05	**UCLA PATS Number:**	20173817
Proposal Type:	New	**Award Type:**	Grant
Program Type:	Applied Org Research	**Special Program Type:**	Not applicable
Award Status:	Awarded/Fully Executed	**Location:**	On Site
Special Payment Type:	None		

‡ **COVID-19 Consequences**

Budget Period	Transaction Budget Period	Direct Costs	F&A Costs	Total	F&A Rate	F&A Base	Payment Basis	Award Status	Action Type
1	12/01/2017 - 06/30/2018	$348,915	$161,393	$510,308	55.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	New
1	07/01/2018 - 11/30/2018	$293,441	$164,327	$457,768	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	New
2	12/01/2018 - 11/30/2019	$622,143	$317,236	$939,379	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	Continuation
3	12/01/2019 - 11/30/2020	$757,517	$401,047	$1,158,564	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	Continuation
4	12/01/2020 - 11/30/2021	$1,010,852	$194,756	$1,205,608	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	Continuation
5	12/01/2021 - 11/30/2022	$1,011,645	$189,066	$1,200,711	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	Continuation
5 ‡	12/01/2022 - 11/30/2023	$0	$0	$0	56.0 %	MTDC	Cost Reimb	Awarded/Fully Executed	No Cost Extension

Section IV: Subawards Approved in the Award

Subawardee	Budget Period
Aeras Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)	12/01/2017 - 11/30/2018
Aeras Bioqual Inc. Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)	12/01/2018 - 11/30/2019
Aeras Bioqual Inc. Tulane University (Includes School of Medicine) - Health Sciences Campus (TUHSC)	12/01/2019 - 11/30/2020
Aeras International AIDS Vaccine Initiative, Inc. (IAVI) Texas Biomedical Research Institute	12/01/2020 - 11/30/2021
International AIDS Vaccine Initiative, Inc. (IAVI) Texas Biomedical Research Institute	12/01/2021 - 11/30/2023

Section V: Training Grant Approved Slots

Section VI: Program Income, Cost Sharing and Compliance Requirements

Anticipated Program Income	Anticipated Program Income Type
No	-

Mandatory Cost Sharing?	Unfunded Effort (other than salary over the cap)	Amount
No	No	

Special Review Type	Approval Status	Reference
Animal Subjects	See System of Record	1995-130-81
Animal Subjects	See System of Record	ARC-1995-130
No Cost Extension	Approved	11/30/2023

Section VII: Deliverables

As you prepare the required reporting/deliverable to the Sponsor for this project keep in mind that it may contain patentable information. The TDG Technology Transfer Officers are ready to meet or speak with you to discuss your pending work and you are encouraged to report potential inventions at any and all stages of your research. Invention disclosures can be submitted to http://tdg.ucla.edu.submit-invention-report and upon receipt TDG will be in touch with you to discuss your work. **Note that filing a technical report without consulting TDG may jeopardize UCLA's ability to secure a patent to protect your work.**

Non-Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Tech/Scientific	Annual	Progress Report	10/15/2018	Submitted

Tech/Scientific	Annual	Progress Report	10/15/2019	Submitted
Tech/Scientific	Annual	Progress Report	10/15/2020	Submitted
Tech/Scientific	Annual	Progress Report	10/15/2021	Submitted
Invention/Patent	One Time	Final	03/29/2024	Not Started
Tech/Scientific	One Time	Final	03/29/2024	Not Started

Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Financial Report	Once	Final	03/29/2024	Not Started

Section VIII: Other Investigators

Role	Name
PD/PI	Horwitz, Marcus

Section IX: Contacts

Contacts

OCGA	Pak, Jessica (jessica.pak@research.ucla.edu)
EFM	Fuentes, Veronica Elena (vfuentes@research.ucla.edu)

University of California, Los Angeles
Award Snapshot Attachment

UCLA PATS NUMBER: 20173817

Alert(s)

1. Please review and adhere to the award terms and conditions.
2. Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA).

Reference Document(s)

1. Award(s) available via the ORA Award Status & Snapshot Report [http://portal.research.ucla.edu/index.aspx?Section=PostAward]
2. NIH Grants Policy Statement, April 2021 [http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf]
3. 45 CFR Part 75: Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations.
4. Federal-Wide Research Terms and Conditions, November 2020 https://www.nsf.gov/awards/managing/rtc.jsp
5. RTC Prior Approval and Other Requirements Matrix [https://www.nsf.gov/bfa/dias/policy/fedrtc/appendix_a.pdf]
6. RTC Agency-Specific Requirements [https://www.nsf.gov/bfa/dias/policy/fedrtc/agencyspecifics/nih_1120.pdf]

Action(s)

1. Sponsor award dated 11/29/2017 provides funding in the amount of $959,273. The sponsor has also issued a revised award dated 12/15/2017 increasing finding for Year 1 in the amount of $8,803 in accordance with the new F&A rate agreement.
2. Sponsor award dated 11/16/2018 provides continuation funding in the amount of $939,379 for Year 2.
3. Sponsor award dated 12/03/2019 provides continuation funding in the amount of $1,158,564 for Year 3.
4. Sponsor award dated 11/25/2020 provides continuation funding in the amount of $1,205,608 for Year 4.
5. Sponsor award dated 11/23/2021 provides continuation funding in the amount of $1,200,711 for Year 5.
6. *This Snapshot*: Sponsor award dated 10/08/2022 approves a no-cost extension through 11/30/2023.

From: Pak, Jessica
To: Horwitz, Marcus A.; Sharoff, Saima M
Cc: ORA AWARDS
Subject: Re: Project Extension Submitted for Grant: R01AI135631-05 to the NIH.
Date: Monday, October 10, 2022 8:13:15 AM

From: era-notify@mail.nih.gov <era-notify@mail.nih.gov>
Sent: Saturday, October 8, 2022 7:29 AM
To: jessica.kim@research.ucla.edu <jessica.kim@research.ucla.edu>; Horwitz, Marcus, M.D. <MHorwitz@mednet.ucla.edu>
Subject: Project Extension Submitted for Grant: R01AI135631-05 to the NIH.

CAUTION - EXTERNAL EMAIL:Do not click links or open attachments unless you recognize the sender.

A Project Extension Request was completed by Signing Official: Kim, Jessica for grant application: R01AI135631-05 associated with Principal Investigator HORWITZ, MARCUS AARON using the NIH Commons. The new project end date for this grant is: 11/30/2023

This new date will now be reflected in the Application Detail section of Commons.
If you have any questions about this email, please contact Jessica Kim at jessica.kim@research.ucla.edu, who initiated this action.

For any further questions about this email, call the eRA Service Desk at 1-866-504-9552 or refer to http://grants.nih.gov/support for additional methods of contact. Please access Commons at http://public.era.nih.gov/commons/.
For more information please visit http://era.nih.gov/

EXHIBIT H

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI135631
Federal Award Date
12/08/2023

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA, LOS ANGELES
10889 WILSHIRE BLVD STE 700
LOS ANGELES, CA 90024

2. Congressional District of Recipient
36

3. Payment System Identifier (ID)
1956006143A1

4. Employer Identification Number (EIN)
956006143

5. Data Universal Numbering System (DUNS)
092530369

6. Recipient's Unique Entity Identifier
RN64EPNH8JC6

7. Project Director or Principal Investigator
MARCUS AARON HORWITZ, MD
Professor
MHORWITZ@MEDNET.UCLA.EDU
310-206-0074

8. Authorized Official
Frank Falcon II
frank.falcon@research.ucla.edu
310-206-9898

Federal Agency Information

9. Awarding Agency Contact Information
MEGAN JIN-A Lacy

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
megan.lacy@nih.gov
240-627-3358

10. Program Official Contact Information
Katrin Eichelberg
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
keichelberg@niaid.nih.gov
240-669-2921

Federal Award Information

11. Award Number
5R01AI135631-05

12. Unique Federal Award Identification Number (FAIN)
R01AI135631

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Optimization and Advanced Proof-of-Concept Studies of a Listeria-vectored Multi-Antigenic Vaccine against Tuberculosis

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 12/01/2021 **– End Date** 11/30/2024	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$1,200,711
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,200,711
26. Project Period Start Date 12/01/2017 **– End Date** 11/30/2024	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$5,472,338

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jordan A. Kindbom

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Version:13 - 8/3/2022 12:59 PM | Generated on: 12/8/2023 12:00 AM

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 5R01AI135631-05 REVISED

Principal Investigator(s):
MARCUS AARON HORWITZ, MD

Award e-mailed to: awards@research.ucla.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI135631. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jordan A. Kindbom
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$127,317
Fringe Benefits	$62,333
Personnel Costs (Subtotal)	$189,650
Consultant Services	$1,350
Materials & Supplies	$39,750
Travel	$2,800
Other	$102,497
Subawards/Consortium/Contractual Costs	$674,028
Publication Costs	$1,570
Federal Direct Costs	$1,011,645
Federal F&A Costs	$189,066
Approved Budget	$1,200,711
Total Amount of Federal Funds Authorized (Federal Share)	$1,200,711
TOTAL FEDERAL AWARD AMOUNT	$1,200,711
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$1,200,711	$1,200,711

Fiscal Information:

Payment System Identifier:	1956006143A1
Document Number:	RAI135631A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2022

IC	CAN	2022
AI	8472315	$1,200,711

NIH Administrative Data:
PCC: M33A B / **OC**: 41025 / **Released**: Kindbom, Jordan 12/07/2023
Award Processed: 12/08/2023 12:00:35 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AI135631-05 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AI135631-05 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.

c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI135631. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e.,

awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 5R01AI135631-05 REVISED

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: This revised Notice of Award (NoA) is issued to extend the project period end date in accordance with the letter dated 10/27/2023. The recipient is responsible for ensuring that all necessary human subjects and/or vertebrate animal requirements are fulfilled during the extension period. Failure to comply with this requirement can result in suspension and/or termination of this award, withholding of support, cost disallowances, and/or other appropriate action.

Supersedes previous Notice of Award dated 11/23/2021. All other terms and conditions still apply to this award.

******

This Notice of Award (NoA) includes funds for activity with **IAVI.**

******

Highly Pathogenic Agents:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If the Institutional Biosafety Committee (IBC) (or equivalent body) or designated institutional biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

> If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.
>
> If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.
>
> If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:
>
> > Any NIAID pre-approved changes in the use of the Select Agents and/or Highly Pathogenic Agents including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or official.
> >
> > If work with a new or additional Select Agents and/or Highly Pathogenic Agents is proposed in the upcoming project period, provide:
> >
> > - A list of the new and/or additional Agent(s) that will be studied;
> > - A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
> > - The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by the IBC or equivalent body or official. It is important to note if the work is being done in a new location;
> > - Any biosafety incidents that occurred and were reported to NIH/NIAID.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AI135631-05 REVISED

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

Budget	Year 5
Salaries and Wages	$127,317
Fringe Benefits	$62,333
Personnel Costs (Subtotal)	$189,650
Consultant Services	$1,350
Materials & Supplies	$39,750
Travel	$2,800

Other	$102,497
Subawards/Consortium/Contractual Costs	$674,028
Publication Costs	$1,570
TOTAL FEDERAL DC	$1,011,645
TOTAL FEDERAL F&A	$189,066
TOTAL COST	$1,200,711

Facilities and Administrative Costs	Year 5
F&A Cost Rate 1	56%
F&A Cost Base 1	$337,617
F&A Costs 1	$189,066

EXHIBIT I

National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI135631
Federal Award Date
03/07/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA, LOS ANGELES
10889 WILSHIRE BLVD STE 700
LOS ANGELES, CA 90024

2. Congressional District of Recipient
36

3. Payment System Identifier (ID)
1956006143A1

4. Employer Identification Number (EIN)
956006143

5. Data Universal Numbering System (DUNS)
092530369

6. Recipient's Unique Entity Identifier
RN64EPNH8JC6

7. Project Director or Principal Investigator
MARCUS AARON HORWITZ, MD
Professor
MHORWITZ@MEDNET.UCLA.EDU
310-206-0074

8. Authorized Official
Frank Falcon II
frank.falcon@research.ucla.edu
310-206-9898

Federal Agency Information

9. Awarding Agency Contact Information
MEGAN JIN-A Lacy

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
megan.lacy@nih.gov
240-627-3358

10. Program Official Contact Information
Katrin Eichelberg
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
keichelberg@niaid.nih.gov
240-669-2921

Federal Award Information

11. Award Number
5R01AI135631-05

12. Unique Federal Award Identification Number (FAIN)
R01AI135631

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Optimization and Advanced Proof-of-Concept Studies of a Listeria-vectored Multi-Antigenic Vaccine against Tuberculosis

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Non-Competing Continuation (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 12/01/2021 **– End Date** 11/30/2025	
20. Total Amount of Federal Funds Obligated by this Action	$0
20 a. Direct Cost Amount	$0
20 b. Indirect Cost Amount	$0
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$1,200,711
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$1,200,711
26. Project Period Start Date 12/01/2017 **– End Date** 11/30/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$5,472,338

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Tamia Y. Carter

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 5R01AI135631-05 REVISED

Principal Investigator(s):
MARCUS AARON HORWITZ, MD

Award e-mailed to: awards@research.ucla.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI135631. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Tamia Y. Carter
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$127,317
Fringe Benefits	$62,333
Personnel Costs (Subtotal)	$189,650
Consultant Services	$1,350
Materials & Supplies	$39,750
Travel	$2,800
Other	$102,497
Subawards/Consortium/Contractual Costs	$674,028
Publication Costs	$1,570
Federal Direct Costs	$1,011,645
Federal F&A Costs	$189,066
Approved Budget	$1,200,711
Total Amount of Federal Funds Authorized (Federal Share)	$1,200,711
TOTAL FEDERAL AWARD AMOUNT	$1,200,711
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
5	$1,200,711	$1,200,711

Fiscal Information:
Payment System Identifier: 1956006143A1
Document Number: RAI135631A
PMS Account Type: P (Subaccount)
Fiscal Year: 2022

IC	CAN	2022
AI	8472315	$1,200,711

NIH Administrative Data:
PCC: M33A B / **OC**: 41025 / **Released**: 03/06/2025
Award Processed: 03/07/2025 12:00:41 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AI135631-05 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AI135631-05 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor

should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI135631. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the Payment Management System (PMS) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the real-time cash drawdown data in PMS. NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH requires electronic submission of the final invention statement through the Closeout feature in the Commons.

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and must be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 5R01AI135631-05 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD: This revised Notice of Award (NoA) is issued to extend the project period end date in accordance with the request dated **10/25/2024.** The recipient is responsible for ensuring that all necessary human subjects and/or vertebrate animal requirements are fulfilled during the extension period**.** Failure to comply with this requirement can result in suspension and/or termination of this award, withholding of support, cost disallowances, and/or other appropriate action**.**

This is the final extension that will be allowed for this project.

Supersedes previous Notice of Award dated **12/08/2023**. All other terms and conditions still apply to this award.

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PREVIOUSLY REVISED AWARD**:** The previously revised Notice of Award (NoA) was issued to extend the project period end date in accordance with the letter dated 10/27/2023. The recipient is responsible for ensuring that all necessary human subjects and/or vertebrate animal requirements are fulfilled during the extension period. Failure to comply with this requirement can result in suspension and/or termination of this award, withholding of support, cost disallowances, and/or other appropriate action.

Supersedes previous Notice of Award dated 11/23/2021. All other terms and conditions still apply to this award.

******

This Notice of Award (NoA) includes funds for activity with **IAVI.**

******

Highly Pathogenic Agents:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If the Institutional Biosafety Committee (IBC) (or equivalent body) or designated institutional biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

> If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.
>
> If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.
>
> If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:
>
> > Any NIAID pre-approved changes in the use of the Select Agents and/or Highly Pathogenic Agents including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or official.
> >
> > If work with a new or additional Select Agents and/or Highly Pathogenic Agents is proposed in the upcoming project period, provide:
>
> - A list of the new and/or additional Agent(s) that will be studied;
> - A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;

- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by the IBC or equivalent body or official. It is important to note if the work is being done in a new location;
- Any biosafety incidents that occurred and were reported to NIH/NIAID.

******

Commitment overlap is not permitted, and occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested. Therefore, no individual's time commitment may exceed 100 percent (i.e., 12 person months). Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AI135631-05 REVISED

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

Budget	Year 5
Salaries and Wages	$127,317
Fringe Benefits	$62,333
Personnel Costs (Subtotal)	$189,650
Consultant Services	$1,350
Materials & Supplies	$39,750
Travel	$2,800
Other	$102,497
Subawards/Consortium/Contractual Costs	$674,028
Publication Costs	$1,570
TOTAL FEDERAL DC	$1,011,645
TOTAL FEDERAL F&A	$189,066
TOTAL COST	$1,200,711

Facilities and Administrative Costs	Year 5
F&A Cost Rate 1	56%
F&A Cost Base 1	$337,617
F&A Costs 1	$189,066

EXHIBIT J

From: UCLA Research Admin
To: Horwitz, Marcus, M.D.
Cc: cindy.hong@research.ucla.edu; nallely.gonzalez@research.ucla.edu; PATSRecords@research.ucla.edu; Sharoff, Saima M
Subject: Grant Suspension Notice - Stop Work Order [PATS 20173817]
Date: Friday, August 1, 2025 6:24:53 PM

Stop Work Notice

Award #: R01AI135631
Title: Optimization and Advanced Proof-of-Concept Studies of a Listeria-Vectored Multi-Antigenic Vaccine Against Tuberculosis
PATS #: 20173817
Fund #(s): 31370

Professor Horwitz,

UCLA has received a suspension notice from NIH-NIAID National Institute of Allergy and Infectious Diseases for the above referenced project.

This email is to notify you to ***immediately stop incurring costs/expenditures on the grant(s) referenced above effective July 31, 2025***.

If your grant includes active subawards, OCGA will be writing to the subawardee's administrative contact with formal notice of the subaward suspension and the requirement to stop immediately all expenditures against the subaward. You may also want to separately reach out to your collaborator to provide additional context.

UCLA is required to submit to the sponsor, within 30 days of this suspension, a financial report of expenditures through July 31, 2025. OCGA will request that the subawardee submit to you, within 15 days of the notice, an invoice for expenses incurred to date so that we can include those expenses in our report to the sponsor. Extramural Fund Management (EFM) will seek the support of your fund manager to prepare a complete and accurate financial report of expenses incurred through July 31, 2025.

We are saddened that this has happened and echo the sentiments expressed in the recent communications from Chanceller Frenk and Vice Chancellor for Research Wakimoto. Campus leadership is actively engaged in working to resolve these issues. Updates will be shared as they become available. For questions regarding the suspension, please contact awards@research.ucla.edu or reach out to me directly. For financial or reimbursement-related inquiries, reach out to your EFM contact.

ACTION REQUIRED

Please:

1. Forward any communications you may receive from the federal sponsor related to this suspension to OCGA at awards@research.ucla.edu.
2. Work with your fund manager or financial staff to ensure all expenditures are reported and subaward invoices are approved.

We understand this is a stressful time, and we appreciate your dedication to research excellence at UCLA.

Tracey Fraser
Senior Director
UCLA Office of Contract & Grant Administration
10889 Wilshire Boulevard, Suite 700
Los Angeles, CA 90095-1406
T: (310) 825-0671 | **E:** tracey.fraser@research.ucla.edu
https://ocga.research.ucla.edu/

EXHIBIT K

PROJECT SUMMARY/ABSTRACT

The great majority of people who are infected with *Mycobacterium tuberculosis* (Mtb) do not develop active disease but contain the bacterium in a dormant state, a condition referred to as latent tuberculosis infection (LTBI). Many of these people reactivate tuberculosis (TB) later in life, often in association with an immunocompromised status, such as co-infection with HIV, immunotherapy for cancer or other diseases, aging, etc. An estimated 2 billion people on earth have LTBI and constitute a huge reservoir of people at risk of reactivation TB unless treated and the persistent Mtb state eliminated. Current treatment regimens for LTBI are long and burdensome, negatively impacting treatment completion. The study proposed herein seeks to examine a potentially much shorter regimen requiring as little as one or two weeks. If successful, and then replicated in humans, such a short-term regimen could change clinical practice.

Our group pioneered the use of an artificial intelligence-enabled parabolic response surface (AI-PRS) platform allowing rapid identification of the most effective drug-dose combinations for treating active TB by testing only a small fraction of the total drug-dose efficacy response surface. This approach determined that bedaquiline (BDQ), clofazimine (CFZ), and pyrazinamide (PZA) at optimal dose ratios were highly synergistic and either by themselves or with a fourth drug were much more effective than standard treatment, achieving relapse-free cure in mouse models of active pulmonary TB within 3 weeks - an ~85% reduction in time versus the standard regimen for treating drug-sensitive TB. Here we propose to evaluate this 3-drug core regimen (BCZ) in non-human primates (NHPs) for treatment of LTBI in a setting mimicking co-infection with HIV. As a fourth drug is not needed to prevent emergence of resistance as in active TB therapy, the three core BCZ drugs should be more than sufficient for treatment of LTBI; current approved regimens comprise 1 or 2 drugs.

To achieve our goals, we shall leverage the two MPIs' expertise with AI-PRS technology and the NHP LTBI model. We shall initially perform limited pharmacokinetic (PK) studies of BCZ to optimize drug doses in NHPs such that blood levels are equivalent to the optimal human doses determined in a PK evaluation of these 3 core drugs as part of a similar AI-PRS derived ultra-short 4-drug regimen for treating active TB in a just initiated human study. We shall then infect NHPs with a low dose of Mtb by aerosol to establish LTBI infection; then not treat (Negative control - all expected later to reactivate TB with SIV co-infection), treat with BCZ for 1, 2, or 4 weeks, or treat with the approved regimen of isoniazid and rifapentine for 3 months (Positive control – none expected later to reactivate with SIV co-infection); and finally co-infect with SIV and monitor for reactivation TB. If short-term BCZ treatment prevents reactivation TB, this study will pave the way for a definitive treatment-shortening trial of BCZ in LTBI and potentially revolutionize the treatment of LTBI, hastening the elimination of the TB reservoir and subsequently TB.

EXHIBIT L

University of California, Los Angeles
Award Snapshot

Section I: Award Summary

Principal Investigator:	Horwitz, Marcus	**Fund Number:**	30209
Sponsor:	NIH-NIAID National Institute of Allergy and Infectious Diseases [000064]	**Sponsor Award Number:**	1R01AI183978-01
Administering Unit:	MEDICINE-INFECTIOUS DISEASE [1560]	**Prime Sponsor:**	N/A
Project Title:	Efficacy and Safety of AI-enabled PRS Regimen VI (Clofazimine, Bedaquiline and Pyrazinamide) as Ultra-Short Course Therapy of LTBI in Non-Human Primates in a Setting Mimicking HIV co-infection		
Current Budget Period:	3/1/2024 - 1/31/2025	**Current Action:**	New
Project Period:	3/1/2024 - 1/31/2027	**Funds Awarded this Action:**	$842,802
		Total Funds Awarded to Date:	$842,802

- ***See Section VIII for Other Investigators***
- ***For a History of Actions on this award, refer to the Award Snapshot Attachment***

Section II: Special Attention Needed

1. Changes in the status of the Principal Investigator or other key personnel on the award require prior approval from the Sponsor. Requests for prior approval must be processed through OCGA. Notify OCGA in advance or as soon as you become aware of any changes (or anything requiring prior approval).
2. This award is subject to a sponsor salary cap limitation. Salary Cap Type: Health and Human Services
3. Review the Award Snapshot Attachment and the Award document for additional terms and conditions.

Section III: Award Demographics

Sponsor Award Number:	1R01AI183978-01	**UCLA PATS Number:**	20240819
Proposal Type:	New	**Award Type:**	Grant
Program Type:	Applied Org Research	**Special Program Type:**	Not Applicable
Award Status:	Awarded/Fully Executed	**Location:**	On Site
Special Payment Type:	None	**Pre-Award Spend:**	90 days 12/2/2023

Budget Period	Transaction Budget Period	Direct	F&A	Total	F&A Rate	F&A Base	Payment Basis	Award Status	Action Type	Carry Forward Restricted
1	3/1/2024 - 6/30/2024	$733,801	$22,390	$756,191	57.0%	MTDC	Cost Reimb	Awarded/Fully Executed	New	No
1	7/1/2024 - 1/31/2025	$54,991	$31,620	$86,611	57.5%	MTDC	Cost Reimb	Awarded/Fully Executed	New	No
2	2/1/2025 - 1/31/2026	$908,830	$22,999	$931,829	57.5%	MTDC	Cost Reimb	Anticipated/Committed	Continuation	No
3	2/1/2026 - 1/31/2027	$908,547	$22,999	$931,546	57.5%	MTDC	Cost Reimb	Anticipated/Committed	Continuation	No

Section IV: Subawards Approved in the Award

Subawardee	Budget Period
Texas Biomedical Research Institute	3/1/2024 - 1/31/2025

Section V: Training Grant Approved Slots

Section VI: Program Income, Cost Sharing and Compliance Requirements

Anticipated Program Income	Anticipated Program Income Type
No	-

Mandatory Cost Sharing?	Unfunded Effort (other than salary over the cap)	Amount
No	No	-

Special Review Type	Approval Status	Reference
Animal Subjects	See System of Record	ARC-2023-116

Section VII: Deliverables

As you prepare the required reporting/deliverable to the Sponsor for this project keep in mind that it may contain patentable information. The TDG Technology Transfer Officers are ready to meet or speak with you to discuss your pending work and you are encouraged to report potential inventions at any and all stages of your research. Invention disclosures can be submitted to http://tdg.ucla.edu.submit-invention-report and upon receipt TDG will be in touch with you to discuss your work. **Note that filing a technical report without consulting TDG may jeopardize UCLA's ability to secure a patent to protect your work.**

Non-Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Tech/Scientific	Annual	Progress Report	12/15/2024	Not Started
Tech/Scientific	Annual	Progress Report	12/15/2025	Not Started
Invention/Patent	One Time	Final	5/31/2027	Not Started
Tech/Scientific	One Time	Final	5/31/2027	Not Started

Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Financial Report	Once	Final	5/31/2027	Not Started

Section VIII: Other Investigators

Role	Name
PD/PI	Horwitz, Marcus

Section IX: Contacts

Contacts	
OCGA	Sayers, Ummi Adilah ummi.sayers@research.ucla.edu
EFM	Nallely Gonzalez Castaneda nallely.gonzalez@research.ucla.edu

University of California, Los Angeles
Award Snapshot Attachment

UCLA PATS NUMBER: 20240819

Alert(s)

1. Please review and adhere to the award terms and conditions.
2. Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA).

Reference Document(s)

1. Award(s) available via the ORA Award Status & Snapshot Report [http://portal.research.ucla.edu/index.aspx?Section=PostAward]
2. NIH Grants Policy Statement, December 2022 [http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf]
3. 45 CFR Part 75: Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations.
4. Federal-Wide Research Terms and Conditions, November 2020 https://www.nsf.gov/awards/managing/rtc.jsp
5. RTC Prior Approval and Other Requirements Matrix [https://www.nsf.gov/bfa/dias/policy/fedrtc/appendix_a.pdf]
6. RTC Agency-Specific Requirements [https://www.nsf.gov/bfa/dias/policy/fedrtc/agencyspecifics/nih_421.pdf]

Action(s)

1. *This Snapshot*: Sponsor award dated 02/27/2024 provides funding in the amount of $842,802 for Year 1.

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award

FAIN# R01AI183978
Federal Award Date
02/27/2024

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA, LOS ANGELES
10920 WILSHIRE BLVD STE 500
LOS ANGELES, CA 90024

2. Congressional District of Recipient
32

3. Payment System Identifier (ID)
1956006143A1

4. Employer Identification Number (EIN)
956006143

5. Data Universal Numbering System (DUNS)
092530369

6. Recipient's Unique Entity Identifier
RN64EPNH8JC6

7. Project Director or Principal Investigator
MARCUS AARON HORWITZ, MD (Contact)
Professor
mhorwitz@mednet.ucla.edu
310-206-0074

8. Authorized Official
Ms. Ummi Sayers

Federal Agency Information

9. Awarding Agency Contact Information
Jenna L. Briggs
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
jenna.briggs@nih.gov
301-761-5137

10. Program Official Contact Information
ANNE ELIZABETH MAYER Bridwell
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
annie.bridwell@nih.gov
(301) 980-9876

Federal Award Information

11. Award Number
1R01AI183978-01

12. Unique Federal Award Identification Number (FAIN)
R01AI183978

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Efficacy and Safety of AI-enabled PRS Regimen VI (Clofazimine, Bedaquiline and Pyrazinamide) as Ultra-Short Course Therapy of LTBI in Non-Human Primates in a setting mimicking HIV co-infection

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 03/01/2024 **– End Date** 01/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$842,802
20 a. Direct Cost Amount	$788,792
20 b. Indirect Cost Amount	$54,010
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$842,802
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$842,802
26. Project Period Start Date 03/01/2024 **– End Date** 01/31/2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$842,802

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jenna L. Briggs

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Version:13 - 8/3/2022 12:59 PM | Generated on: 2/27/2024 12:16 AM

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 1R01AI183978-01

Principal Investigator(s):
MARCUS AARON HORWITZ (contact), MD
Deepak Kaushal, PHD

Award e-mailed to: awards@research.ucla.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $842,802 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI183978. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jenna L. Briggs
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$23,861
Fringe Benefits	$7,851
Personnel Costs (Subtotal)	$31,712
Materials & Supplies	$32,845
Travel	$2,250
Other	$1,162
Subawards/Consortium/Contractual Costs	$719,521
Publication Costs	$1,302
Federal Direct Costs	$788,792
Federal F&A Costs	$54,010
Approved Budget	$842,802
Total Amount of Federal Funds Authorized (Federal Share)	$842,802
TOTAL FEDERAL AWARD AMOUNT	$842,802
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$842,802

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$842,802	$842,802
2	$931,829	$931,829
3	$931,546	$931,546

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1956006143A1
Document Number:	RAI183978A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024	2025	2026
AI	8472325	$842,802	$931,829	$931,546

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: A30A / **OC**: 41021 / **Released**: Briggs, Jenna 02/15/2024
Award Processed: 02/27/2024 12:16:29 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AI183978-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01AI183978-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI183978. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the

basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 1R01AI183978-01

Clinical Trial Indicator: No

This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REMINDER: This grant is funded for HIV/AIDS research. Per the NIH Revitalization Act of 1993, funds are restricted for HIV/AIDS research and cannot be re-budgeted for other purposes.

In accordance with the fiscal year 2024 NIAID Financial Management Plan, NIAID is funding this grant at 90% of the approved budget for the initial budget period. If the final appropriations permit, adjustments may be made to restore funds at or near the requested amount.

The initial budget period has been adjusted to 11 months. See https://www.niaid.nih.gov/grants-contracts/financial-management-plan.

The budget period anniversary start date for future year(s) will be **February** 1.

Commitment overlap is not permitted, and occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested. Therefore, no individual's time commitment may exceed 100 percent (i.e., 12 person months). Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

This Notice of Award (NoA) includes funds for Texas Biomedical Research Institute in the amount of **$719,521**.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AI183978-01

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

Budget	Year 1	Year 2	Year 3
Salaries and Wages	$23,861	$26,513	$26,513
Fringe Benefits	$7,851	$8,723	$8,723
Personnel Costs (Subtotal)	$31,712	$35,236	$35,236
Materials & Supplies	$32,845		
Travel	$2,250	$2,500	$2,500
Other	$1,162	$816	$816
Subawards/Consortium/Contractual Costs	$719,521	$868,831	$868,548
Publication Costs	$1,302	$1,447	$1,447
TOTAL FEDERAL DC	$788,792	$908,830	$908,547
TOTAL FEDERAL F&A	$54,010	$22,999	$22,999
TOTAL COST	$842,802	$931,829	$931,546

Facilities and Administrative Costs	Year 1	Year 2	Year 3
F&A Cost Rate 1	57%	57.5%	57.5%
F&A Cost Base 1	$39,280	$39,999	$39,999
F&A Costs 1	$22,390	$22,999	$22,999
F&A Cost Rate 2	57.5%		

F&A Cost Base 2	$54,991		
F&A Costs 2	$31,620		

EXHIBIT M

UCLA

University of California, Los Angeles
Award Snapshot

Section I: Award Summary

Principal Investigator:	Horwitz, Marcus	**Fund Number:**	30209
Sponsor:	NIH-NIAID National Institute of Allergy and Infectious Diseases [000064]	**Sponsor Award Number:**	1R01AI183978-01R
Administering Unit:	MEDICINE-INFECTIOUS DISEASE [1560]	**Prime Sponsor:**	N/A
Project Title:	Efficacy and Safety of AI-enabled PRS Regimen VI (Clofazimine, Bedaquiline and Pyrazinamide) as Ultra-Short Course Therapy of LTBI in Non-Human Primates in a Setting Mimicking HIV co-infection		
Current Budget Period:	3/1/2024 - 1/31/2025	**Current Action:**	Modification/Amendment
Project Period:	3/1/2024 - 1/31/2027	**Funds Awarded this Action:**	$92,096
		Total Funds Awarded to Date:	$934,897

- ***See Section VIII for Other Investigators***
- ***For a History of Actions on this award, refer to the Award Snapshot Attachment***

Section II: Special Attention Needed

1. Changes in the status of the Principal Investigator or other key personnel on the award require prior approval from the Sponsor. Requests for prior approval must be processed through OCGA. Notify OCGA in advance or as soon as you become aware of any changes (or anything requiring prior approval).
2. This award is subject to a sponsor salary cap limitation. Salary Cap Type: Health and Human Services
3. Review the Award Snapshot Attachment and the Award document for additional terms and conditions.

Section III: Award Demographics

Sponsor Award Number:	1R01AI183978-01R	**UCLA PATS Number:**	20240819
Proposal Type:	New	**Award Type:**	Grant
Program Type:	Applied Org Research	**Special Program Type:**	Not Applicable
Award Status:	Awarded/Fully Executed	**Location:**	On Site
Special Payment Type:	None	**Pre-Award Spend:**	90 days 12/2/2023

Budget Period	Transaction Budget Period	Direct	F&A	Total	F&A Rate	F&A Base	Payment Basis	Award Status	Action Type	Carry Forward Restricted
1	3/1/2024 - 6/30/2024	$733,801	$22,390	$756,191	57.0%	MTDC	Cost Reimb	Awarded/Fully Executed	New	No
1	7/1/2024 - 1/31/2025	$54,991	$31,620	$86,611	57.5%	MTDC	Cost Reimb	Awarded/Fully Executed	New	No
1	3/1/2024 - 6/30/2024	$81,825	$1,106	$82,931	57.0%	MTDC	Cost Reimb	Awarded/Fully Executed	Modification/Amendment	No
1	7/1/2024 - 1/31/2025	$5,819	$3,346	$9,165	57.5%	MTDC	Cost Reimb	Awarded/Fully Executed	Modification/Amendment	No
2	2/1/2025 - 1/31/2026	$908,830	$22,999	$931,829	57.5%	MTDC	Cost Reimb	Anticipated/Committed	Continuation	No
3	2/1/2026 - 1/31/2027	$908,547	$22,999	$931,546	57.5%	MTDC	Cost Reimb	Anticipated/Committed	Continuation	No

Section IV: Subawards Approved in the Award

Subawardee	Budget Period
Texas Biomedical Research Institute	3/1/2024 - 1/31/2025

Section V: Training Grant Approved Slots

Section VI: Program Income, Cost Sharing and Compliance Requirements

Anticipated Program Income	Anticipated Program Income Type
No	-

Mandatory Cost Sharing?	Unfunded Effort (other than salary over the cap)	Amount
No	No	-

Special Review Type	Approval Status	Reference
Animal Subjects	See System of Record	ARC-2023-116

Section VII: Deliverables

As you prepare the required reporting/deliverable to the Sponsor for this project keep in mind that it may contain patentable information. The TDG Technology Transfer Officers are ready to meet or speak with you to discuss your pending work and you are encouraged to report potential inventions at any and all stages of your research. Invention disclosures can be submitted to http://tdg.ucla.edu.submit-invention-report and upon receipt TDG will be in touch with you to discuss your work. **Note that filing a technical report without consulting TDG may jeopardize UCLA's ability to secure a patent to protect your work.**

Non-Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Tech/Scientific	Annual	Progress Report	12/15/2024	Not Started
Tech/Scientific	Annual	Progress Report	12/15/2025	Not Started
Invention/Patent	One Time	Final	5/31/2027	Not Started
Tech/Scientific	One Time	Final	5/31/2027	Not Started

Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Financial Report	Once	Final	5/31/2027	Not Started

Section VIII: Other Investigators

Role	Name
PD/PI	Horwitz, Marcus

Section IX: Contacts

Contacts

OCGA	Sayers, Ummi Adilah ummi.sayers@research.ucla.edu
EFM	Gonzalez Castaneda, Nallely nallely.gonzalez@research.ucla.edu

University of California, Los Angeles
Award Snapshot Attachment

UCLA PATS NUMBER: 20240819

Alert(s)

1. Please review and adhere to the award terms and conditions.
2. Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA).

Reference Document(s)

1. Award(s) available via the ORA Award Status & Snapshot Report [http://portal.research.ucla.edu/index.aspx?Section=PostAward]
2. NIH Grants Policy Statement April 2024 [https://grants.nih.gov/policy/nihgps/index.htm] Effective for all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2023.
3. Federal-Wide Research Terms and Conditions November 2020 https://www.nsf.gov/awards/managing/rtc.jsp
    a. RTC Prior Approval and Other Requirements Matrix November 2020
    b. RTC NIH Agency-Specific Requirements November 2020
4. 2 CFR 200: Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations, Revised November 2020

Action(s)

1. Sponsor award dated 02/27/2024 provides funding in the amount of $842,802 for Year 1.
2. *This Snapshot*: Sponsor award dated 05/30/2024 provides additional funding in the amount of $92,096 to restore the commitment level for Year 1.

National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI183978
Federal Award Date
05/30/2024

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA, LOS ANGELES
10889 WILSHIRE BLVD STE 700
LOS ANGELES, CA 90024

2. Congressional District of Recipient
36

3. Payment System Identifier (ID)
1956006143A1

4. Employer Identification Number (EIN)
956006143

5. Data Universal Numbering System (DUNS)
092530369

6. Recipient's Unique Entity Identifier
RN64EPNH8JC6

7. Project Director or Principal Investigator
MARCUS AARON HORWITZ, MD (Contact)
Professor
mhorwitz@mednet.ucla.edu
310-206-0074

8. Authorized Official
Ms. Ummi Sayers

Federal Agency Information

9. Awarding Agency Contact Information
Jenna L. Briggs
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
jenna.briggs@nih.gov
301-761-5137

10. Program Official Contact Information
ANNE ELIZABETH MAYER Bridwell
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
annie.bridwell@nih.gov
(301) 980-9876

Federal Award Information

11. Award Number
1R01AI183978-01

12. Unique Federal Award Identification Number (FAIN)
R01AI183978

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Efficacy and Safety of AI-enabled PRS Regimen VI (Clofazimine, Bedaquiline and Pyrazinamide) as Ultra-Short Course Therapy of LTBI in Non-Human Primates in a setting mimicking HIV co-infection

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing (REVISED)

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 03/01/2024 – **End Date** 01/31/2025	
20. Total Amount of Federal Funds Obligated by this Action	$92,096
20 a. Direct Cost Amount	$87,644
20 b. Indirect Cost Amount	$4,452
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$934,898
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$934,898
26. Project Period Start Date 03/01/2024 – **End Date** 01/31/2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$934,898

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jenna L. Briggs

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 1R01AI183978-01 REVISED

Principal Investigator(s):
MARCUS AARON HORWITZ (contact), MD
Deepak Kaushal, PHD

Award e-mailed to: awards@research.ucla.edu

Dear Authorized Official:

The National Institutes of Health hereby revises this award to reflect an increase in the amount of $92,096 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI183978. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jenna L. Briggs
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$26,513
Fringe Benefits	$8,723
Personnel Costs (Subtotal)	$35,236
Materials & Supplies	$36,494
Travel	$2,500
Other	$1,291
Subawards/Consortium/Contractual Costs	$799,468
Publication Costs	$1,447
Federal Direct Costs	$876,436
Federal F&A Costs	$58,462
Approved Budget	$934,898
Total Amount of Federal Funds Authorized (Federal Share)	$934,898
TOTAL FEDERAL AWARD AMOUNT	$934,898
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$92,096

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$934,898	$934,898
2	$931,829	$931,829
3	$931,546	$931,546

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1956006143A1
Document Number:	RAI183978A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2024

IC	CAN	2024	2025	2026
AI	8472325	$934,898	$931,829	$931,546

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: A30A / **OC**: 41021 / **Released**: 05/29/2024
Award Processed: 05/30/2024 12:11:52 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AI183978-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01AI183978-01 REVISED

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI183978. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.

- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.
Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 1R01AI183978-01 REVISED

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REVISED AWARD:

This award is revised to increase the funding level to 100% of the approved budget for the initial budget period. Out-year commitments for continuation awards remain unchanged.

Supersedes previous Notice of Award dated **02/27/2024**. All other terms and conditions still apply to this award.

REMINDER: This grant is funded for HIV/AIDS research. Per the NIH Revitalization Act of 1993, funds are restricted for HIV/AIDS research and cannot be re-budgeted for other purposes.

The initial budget period has been adjusted to 11 months. See https://www.niaid.nih.gov/grants-contracts/financial-management-plan.

The budget period anniversary start date for future year(s) will be **February** 1.

Commitment overlap is not permitted, and occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested. Therefore, no individual's time commitment may exceed 100 percent (i.e., 12 person months). Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

This Notice of Award (NoA) includes funds for Texas Biomedical Research Institute in the amount of **$799,468.**

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AI183978-01 REVISED

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

Budget	Year 1	Year 2	Year 3
Salaries and Wages	$26,513	$26,513	$26,513
Fringe Benefits	$8,723	$8,723	$8,723
Personnel Costs (Subtotal)	$35,236	$35,236	$35,236
Materials & Supplies	$36,494		
Travel	$2,500	$2,500	$2,500
Other	$1,291	$816	$816
Subawards/Consortium/Contractual Costs	$799,468	$868,831	$868,548
Publication Costs	$1,447	$1,447	$1,447
TOTAL FEDERAL DC	$876,436	$908,830	$908,547
TOTAL FEDERAL F&A	$58,462	$22,999	$22,999
TOTAL COST	$934,898	$931,829	$931,546

Facilities and Administrative Costs	Year 1	Year 2	Year 3
F&A Cost Rate 1	57%	57.5%	57.5%
F&A Cost Base 1	$33,989	$39,999	$39,999
F&A Costs 1	$19,374	$22,999	$22,999
F&A Cost Rate 2	57.5%		
F&A Cost Base 2	$67,979		
F&A Costs 2	$39,088		

EXHIBIT N

UCLA

University of California, Los Angeles
Award Snapshot

Section I: Award Summary

Principal Investigator:	Horwitz, Marcus	**Fund Number:**	30209
Sponsor:	NIH-NIAID National Institute of Allergy and Infectious Diseases [000064]	**Sponsor Award Number:**	5R01AI183978-02
Administering Unit:	MEDICINE-INFECTIOUS DISEASE [1560]	**Prime Sponsor:**	N/A
Project Title:	Efficacy and Safety of AI-enabled PRS Regimen VI (Clofazimine, Bedaquiline and Pyrazinamide) as Ultra-Short Course Therapy of LTBI in Non-Human Primates in a Setting Mimicking HIV co-infection		
Current Budget Period:	2/1/2025 - 1/31/2026	**Current Action:**	Continuation
Project Period:	3/1/2024 - 1/31/2027	**Funds Awarded this Action:**	$931,829
		Total Funds Awarded to Date:	$1,866,726

- ***See Section VIII for Other Investigators***
- ***For a History of Actions on this award, refer to the Award Snapshot Attachment***

Section II: Special Attention Needed

1. Changes in the status of the Principal Investigator or other key personnel on the award require prior approval from the Sponsor. Requests for prior approval must be processed through OCGA. Notify OCGA in advance or as soon as you become aware of any changes (or anything requiring prior approval).
2. This award is subject to a sponsor salary cap limitation. Salary Cap Type: Health and Human Services
3. Review the Award Snapshot Attachment and the Award document for additional terms and conditions.

Section III: Award Demographics

Sponsor Award Number:	5R01AI183978-02	**UCLA PATS Number:**	20240819
Proposal Type:	New	**Award Type:**	Grant
Program Type:	Applied Org Research	**Special Program Type:**	Not Applicable
Award Status:	Awarded/Fully Executed	**Location:**	On Site
Special Payment Type:	None	**Pre-Award Spend:**	90 days 12/2/2023

Budget Period	Transaction Budget Period	Direct	F&A	Total	F&A Rate	F&A Base	Payment Basis	Award Status	Action Type	Carry Forward Restricted
1	3/1/2024 - 6/30/2024	$733,801	$22,390	$756,191	57.0%	MTDC	Cost Reimb	Awarded/Fully Executed	New	No
1	7/1/2024 - 1/31/2025	$54,991	$31,620	$86,611	57.5%	MTDC	Cost Reimb	Awarded/Fully Executed	New	No
1	3/1/2024 - 6/30/2024	$81,825	$1,106	$82,931	57.0%	MTDC	Cost Reimb	Awarded/Fully Executed	Modification/Amendment	No
1	7/1/2024 - 1/31/2025	$5,819	$3,346	$9,165	57.5%	MTDC	Cost Reimb	Awarded/Fully Executed	Modification/Amendment	No
2	2/1/2025 - 1/31/2026	$908,830	$22,999	$931,829	57.5%	MTDC	Cost Reimb	Awarded/Fully Executed	Continuation	No
3	2/1/2026 - 1/31/2027	$908,547	$22,999	$931,546	57.5%	MTDC	Cost Reimb	Anticipated/Committed	Continuation	No

Section IV: Subawards Approved in the Award

Subawardee	Budget Period
Texas Biomedical Research Institute	3/1/2024 - 1/31/2025
Texas Biomedical Research Institute	2/1/2025 - 1/31/2026

Section V: Training Grant Approved Slots

Section VI: Program Income, Cost Sharing and Compliance Requirements

Anticipated Program Income	Anticipated Program Income Type
No	-

Mandatory Cost Sharing?	Unfunded Effort (other than salary over the cap)	Amount
No	No	-

Special Review Type	Approval Status	Reference
Animal Subjects	See System of Record	ARC-2023-116

Section VII: Deliverables

As you prepare the required reporting/deliverable to the Sponsor for this project keep in mind that it may contain patentable information. The TDG Technology Transfer Officers are ready to meet or speak with you to discuss your pending work and you are encouraged to report potential inventions at any and all stages of your research. Invention disclosures can be submitted to http://tdg.ucla.edu.submit-invention-report and upon receipt TDG will be in touch with you to discuss your work. **Note that filing a technical report without consulting TDG may jeopardize UCLA's ability to secure a patent to protect your work.**

Non-Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Tech/Scientific	Annual	Progress Report	12/15/2024	Submitted
Tech/Scientific	Annual	Progress Report	12/15/2025	Not Started
Invention/Patent	One Time	Final	5/31/2027	Not Started
Tech/Scientific	One Time	Final	5/31/2027	Not Started

Financial Deliverables:

Deliverable Category	Frequency	Type	Due Date	Status
Financial Report	Once	Final	5/31/2027	Not Started

Section VIII: Other Investigators

Role	Name
PD/PI	Horwitz, Marcus

Section IX: Contacts

Contacts	
OCGA	Ummi Sayers ummi.sayers@research.ucla.edu
EFM	Nallely Gonzalez Castaneda nallely.gonzalez@research.ucla.edu

University of California, Los Angeles
Award Snapshot Attachment

UCLA PATS NUMBER: 20240819

Alert(s)
1. Please review and adhere to the award terms and conditions.
2. Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA).

Reference Document(s)
1. Award(s) available via the ORA Award Status & Snapshot Report [http://portal.research.ucla.edu/index.aspx?Section=PostAward]
2. NIH Grants Policy Statement April 2024 [https://grants.nih.gov/policy/nihgps/index.htm] Effective for all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2023.
3. Federal-Wide Research Terms and Conditions November 2020 https://www.nsf.gov/awards/managing/rtc.jsp
    a. RTC Prior Approval and Other Requirements Matrix November 2020
    b. RTC NIH Agency-Specific Requirements November 2020
4. 2 CFR 200: Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations, Revised November 2020

Action(s)
1. Sponsor award dated 02/27/2024 provides funding in the amount of $842,802 for Year 1.
2. Sponsor award dated 05/30/2024 provides additional funding in the amount of $92,096 to restore the commitment level for Year 1.
3. *This Snapshot*: Sponsor award dated 02/12/2025 provides continuation funding in the amount of $931,829 for Year 2.

National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R01AI183978
Federal Award Date
02/12/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA, LOS ANGELES
10889 WILSHIRE BLVD STE 700
LOS ANGELES, CA 90024

2. Congressional District of Recipient
36

3. Payment System Identifier (ID)
1956006143A1

4. Employer Identification Number (EIN)
956006143

5. Data Universal Numbering System (DUNS)
092530369

6. Recipient's Unique Entity Identifier
RN64EPNH8JC6

7. Project Director or Principal Investigator
MARCUS AARON HORWITZ, MD (Contact)
Professor
MHORWITZ@MEDNET.UCLA.EDU
310-206-0074

8. Authorized Official
Cindy Yoonhi Hong
cindy.hong@research.ucla.edu
310-794-4130

Federal Agency Information

9. Awarding Agency Contact Information
Cheryl Talbert Sam
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
cheryl.sam@nih.gov

10. Program Official Contact Information
MARINA Protopopova
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
marina.protopopova@nih.gov
3017617653

Federal Award Information

11. Award Number
5R01AI183978-02

12. Unique Federal Award Identification Number (FAIN)
R01AI183978

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Efficacy and Safety of AI-enabled PRS Regimen VI (Clofazimine, Bedaquiline and Pyrazinamide) as Ultra-Short Course Therapy of LTBI in Non-Human Primates in a setting mimicking HIV co-infection

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Non-Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 02/01/2025 **– End Date** 01/31/2026	
20. Total Amount of Federal Funds Obligated by this Action	$931,829
20 a. Direct Cost Amount	$908,830
20 b. Indirect Cost Amount	$22,999
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$931,829
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$931,829
26. Project Period Start Date 03/01/2024 **– End Date** 01/31/2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$1,866,727

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Sufiyan Saeed

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 5R01AI183978-02

Principal Investigator(s):
MARCUS AARON HORWITZ (contact), MD
Deepak Kaushal, PHD

Award e-mailed to: awards@research.ucla.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $931,829 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R01AI183978. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Sufiyan Saeed
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Federal Direct Costs	$908,830
Federal F&A Costs	$22,999
Approved Budget	$931,829
Total Amount of Federal Funds Authorized (Federal Share)	$931,829
TOTAL FEDERAL AWARD AMOUNT	$931,829
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$931,829

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
2	$931,829	$931,829
3	$931,546	$931,546

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1956006143A1
Document Number:	RAI183978A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2025

IC	CAN	2025	2026
AI	8472325	$931,829	$931,546

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: A30D / **OC**: 41025 / **Released**: 02/12/2025
Award Processed: 02/13/2025 12:31:40 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AI183978-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 5R01AI183978-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than

the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01AI183978. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year

period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 5R01AI183978-02

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

REMINDER: This grant is funded for HIV/AIDS research. Per the NIH Revitalization Act of 1993, funds are restricted for HIV/AIDS research and cannot be re-budgeted for other purposes.

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This Notice of Award (NoA) includes funds for Texas Biomedical Research Institute in the amount of $868,831.

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Commitment overlap is not permitted, and occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested. Therefore, no individual's time commitment may exceed 100 percent (i.e., 12 person months). Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AI183978-02

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

Facilities and Administrative Costs	Year 2	Year 3
F&A Cost Rate 1	57.5%	57.5%
F&A Cost Base 1	$39,999	$39,999
F&A Costs 1	$22,999	$22,999

EXHIBIT O

From:	UCLA Research Admin
To:	Horwitz, Marcus, M.D.
Cc:	cindy.hong@research.ucla.edu; nallely.gonzalez@research.ucla.edu; PATSRecords@research.ucla.edu; Sharoff, Saima M
Subject:	Grant Suspension Notice - Stop Work Order [PATS 20240819]
Date:	Friday, August 1, 2025 6:28:53 PM

Stop Work Notice

Award #: R01AI183978
Title: Efficacy and Safety of AI-enabled PRS Regimen VI (Clofazimine, Bedaquiline and Pyrazinamide) as Ultra-Short Course Therapy of LTBI in Non-Human Primates in a Setting Mimicking HIV co-infection
PATS #: 20240819
Fund #(s): 30209

Professor Horwitz,

UCLA has received a suspension notice from NIH-NIAID National Institute of Allergy and Infectious Diseases for the above referenced project.

This email is to notify you to ***immediately stop incurring costs/expenditures on the grant(s) referenced above effective July 31, 2025***.

If your grant includes active subawards, OCGA will be writing to the subawardee's administrative contact with formal notice of the subaward suspension and the requirement to stop immediately all expenditures against the subaward. You may also want to separately reach out to your collaborator to provide additional context.

UCLA is required to submit to the sponsor, within 30 days of this suspension, a financial report of expenditures through July 31, 2025. OCGA will request that the subawardee submit to you, within 15 days of the notice, an invoice for expenses incurred to date so that we can include those expenses in our report to the sponsor. Extramural Fund Management (EFM) will seek the support of your fund manager to prepare a complete and accurate financial report of expenses incurred through July 31, 2025.

We are saddened that this has happened and echo the sentiments expressed in the recent communications from Chanceller Frenk and Vice Chancellor for Research Wakimoto. Campus leadership is actively engaged in working to resolve these issues. Updates will be shared as they become available. For questions regarding the suspension, please contact awards@research.ucla.edu or reach out to me directly. For financial or reimbursement-related inquiries, reach out to your EFM contact.

ACTION REQUIRED

Please:

1. Forward any communications you may receive from the federal sponsor related to this suspension to OCGA at awards@research.ucla.edu.
2. Work with your fund manager or financial staff to ensure all expenditures are reported and subaward invoices are approved.

We understand this is a stressful time, and we appreciate your dedication to research excellence at UCLA.

Tracey Fraser
Senior Director
UCLA Office of Contract & Grant Administration
10889 Wilshire Boulevard, Suite 700
Los Angeles, CA 90095-1406
T: (310) 825-0671 | **E:** tracey.fraser@research.ucla.edu
https://ocga.research.ucla.edu/

EXHIBIT P

PROJECT SUMMARY/ABSTRACT

Tuberculosis (TB) is a serious global health problem, causing ~10.6 million active cases and 1.3 million deaths/year. Better drugs are urgently needed to shorten the burdensomely long treatment course and to combat the global emergence of drug resistant strains of *Mycobacterium tuberculosis* (Mtb), the causative agent. Attractive and novel targets not previously exploited for new drug development are the newly identified Type 7 Secretion Systems (T7SSs), designated ESX-1 to ESX-5, that transport factors through the Mtb hydrophobic cell wall that are essential to Mtb viability and virulence. Here, in a collaborative study involving researchers in a laboratory with years of experience studying the cell biology and pathogenesis of Mtb and developing novel drug regimens to combat TB and the Director of the state-of-the-art Molecular Screening Shared Resources (MSSR) facility at UCLA, we propose to identify small molecule inhibitors of the Mtb T7SS. In preliminary work, we have developed split-luciferase based high-throughput assays targeting a critical step in the function of the ESX-1 and ESX-5 secretion systems. We now propose to use these assays to screen the extensive small compound molecule libraries (> 300,000 compounds) at the UCLA MSSR to identify small molecule inhibitors of Mtb ESX-1 and ESX-5. Hit compounds will be retested in orthogonal assays to confirm their capacity to block Mtb T7SS secretion and Mtb growth in human macrophages in cell culture; ESX-5 inhibitors will additionally be evaluated for capacity to block Mtb growth in broth culture. We anticipate that validated hit compounds will fall into several series of structurally related compounds. We shall choose 5 - 10 of our most potent structural series for analoging (at least 20 analogs per series). We shall test the potency of the analogs in dose response in our original and orthogonal assays and assess their performance in *in vitro* ADMET assays. These studies will identify the most promising lead compounds with the highest therapeutic ratio for further development. Such compounds will serve as vital tools for additional studies of the role of the T7SS in Mtb pathogenesis as well as lead compounds for development of a new class of antibiotics to treat TB.

EXHIBIT Q

National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Notice of Award
FAIN# R21AI185484
Federal Award Date
07/17/2025

Recipient Information

1. Recipient Name
UNIVERSITY OF CALIFORNIA, LOS ANGELES
10889 WILSHIRE BLVD STE 700
LOS ANGELES, CA 90024

2. Congressional District of Recipient
36

3. Payment System Identifier (ID)
1956006143A1

4. Employer Identification Number (EIN)
956006143

5. Data Universal Numbering System (DUNS)
092530369

6. Recipient's Unique Entity Identifier
RN64EPNH8JC6

7. Project Director or Principal Investigator
MARCUS AARON HORWITZ, MD
Professor
mhorwitz@mednet.ucla.edu
310-206-0074

8. Authorized Official
Cindy Hong

Federal Agency Information

9. Awarding Agency Contact Information
WINSTON MORGAN Downing
Grants Management Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
winston.downing@nih.gov
(406) 363-9242

10. Program Official Contact Information
Jim P. Boyce
Program Official
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
jim.boyce@nih.gov
240-292-4069

Federal Award Information

11. Award Number
1R21AI185484-01A1

12. Unique Federal Award Identification Number (FAIN)
R21AI185484

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Identification by High Throughput Screening of Inhibitors of the Mycobacterium tuberculosis ESX-1 and ESX-5 Type VII Secretion Systems – critical virulence determinants and novel drug targets

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 07/17/2025 **– End Date** 06/30/2026	
20. Total Amount of Federal Funds Obligated by this Action	$236,250
20 a. Direct Cost Amount	$150,000
20 b. Indirect Cost Amount	$86,250
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$236,250
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$236,250
26. Project Period Start Date 07/17/2025 **– End Date** 06/30/2027	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$236,250

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Jordan A. Kindbom

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award

EXPLORATORY/DEVELOPMENT GRANT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 1R21AI185484-01A1

Principal Investigator(s):
MARCUS AARON HORWITZ, MD

Award e-mailed to: awards@research.ucla.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $236,250 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF CALIFORNIA LOS ANGELES in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number R21AI185484. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Jordan A. Kindbom
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Federal Direct Costs	$150,000
Federal F&A Costs	$86,250
Approved Budget	$236,250
Total Amount of Federal Funds Authorized (Federal Share)	$236,250
TOTAL FEDERAL AWARD AMOUNT	$236,250
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$236,250

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$236,250	$236,250
2	$196,875	$196,875

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:
Payment System Identifier: 1956006143A1
Document Number: RAI185484A
PMS Account Type: P (Subaccount)
Fiscal Year: 2025

IC	CAN	2025	2026
AI	8472364	$236,250	$196,875

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: M33G BR / **OC**: 41021 / **Released**: 07/08/2025
Award Processed: 07/17/2025 01:17:15 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R21AI185484-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R21AI185484-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R21AI185484. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.
- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings

information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI SPECIFIC AWARD CONDITIONS – 1R21AI185484-01A1

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

The budget period anniversary start date for future year(s) will be July 1.

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This is a Modular Award without direct cost categorical breakdowns in accordance with the guidelines published in the NIH Grants Policy Statement,
see https://grants.nih.gov/grants/policy/nihgps/HTML5/section_13/13.5_post-award_administration.htm.
Recipients are required to allocate and account for costs related to this award by category within their institutional accounting system in accordance with applicable cost principles.

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Highly Pathogenic Agents:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (https://www.cdc.gov/labs/BMBL.html). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If the Institutional Biosafety Committee (IBC) (or equivalent body) or designated institutional biosafety official recommends a higher biocontainment level, the higher recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Select Agent (see 42 CFR 73 for the relevant human Select Agents and Toxins; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant Select Agents and Toxins at https://www.selectagents.gov/regulations/ and https://www.selectagents.gov/sat/list.htm) and/or has been performed or is planned to be performed under this grant.

If the IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any NIAID pre-approved changes in the use of the Select Agents and/or Highly Pathogenic Agents including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or official.

If work with a new or additional Select Agents and/or Highly Pathogenic Agents is proposed in the upcoming project period, provide:

- A list of the new and/or additional Agent(s) that will be studied;
- A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
- The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by the IBC or equivalent body or official. It is important to note if the work is being done in a new location;
- Any biosafety incidents that occurred and were reported to NIH/NIAID.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

Budget	Year 1	Year 2
DMS Costs	$0	$0

SPREADSHEET SUMMARY
AWARD NUMBER: 1R21AI185484-01A1

INSTITUTION: UNIVERSITY OF CALIFORNIA LOS ANGELES

Budget	Year 1	Year 2
TOTAL FEDERAL DC	$150,000	$125,000
TOTAL FEDERAL F&A	$86,250	$71,875
TOTAL COST	$236,250	$196,875

Facilities and Administrative Costs	Year 1	Year 2
F&A Cost Rate 1	57.5%	57.5%
F&A Cost Base 1	$150,000	$125,000
F&A Costs 1	$86,250	$71,875

EXHIBIT R

From: UCLA Research Admin
To: Horwitz, Marcus, M.D.
Cc: cindy.hong@research.ucla.edu; PATSRecords@research.ucla.edu
Subject: Grant Suspension Notice - Stop Work Order [PATS 20255646]
Date: Friday, August 1, 2025 6:28:24 PM

Stop Work Notice

Award #: R21AI185484
Title: Identification by High Throughput Screening of Inhibitors of the Mycobacterium Tuberculosis ESX-1 and ESX-5 Type VII Secretion Systems – Critical Virulence Determinants and Novel Drug Targets
PATS #: 20255646
Fund #(s):

Professor Horwitz,

UCLA has received a suspension notice from NIH-NIAID National Institute of Allergy and Infectious Diseases for the above referenced project.

This email is to notify you to ***immediately stop incurring costs/expenditures on the grant(s) referenced above effective July 31, 2025***.

If your grant includes active subawards, OCGA will be writing to the subawardee's administrative contact with formal notice of the subaward suspension and the requirement to stop immediately all expenditures against the subaward. You may also want to separately reach out to your collaborator to provide additional context.

UCLA is required to submit to the sponsor, within 30 days of this suspension, a financial report of expenditures through July 31, 2025. OCGA will request that the subawardee submit to you, within 15 days of the notice, an invoice for expenses incurred to date so that we can include those expenses in our report to the sponsor. Extramural Fund Management (EFM) will seek the support of your fund manager to prepare a complete and accurate financial report of expenses incurred through July 31, 2025.

We are saddened that this has happened and echo the sentiments expressed in the recent communications from Chanceller Frenk and Vice Chancellor for Research Wakimoto. Campus leadership is actively engaged in working to resolve these issues. Updates will be shared as they become available. For questions regarding the suspension, please contact awards@research.ucla.edu or reach out to me directly. For financial or reimbursement-related inquiries, reach out to your EFM contact.

ACTION REQUIRED

Please:

1. Forward any communications you may receive from the federal sponsor related to this suspension to OCGA at awards@research.ucla.edu.
2. Work with your fund manager or financial staff to ensure all expenditures are reported and subaward invoices are approved.

We understand this is a stressful time, and we appreciate your dedication to research excellence at UCLA.

Tracey Fraser
Senior Director
UCLA Office of Contract & Grant Administration
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