EXHIBIT 33

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, *et al.*, *Plaintiffs*, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, *Defendants*.	Case No. 1:25-cv-10787-BEM

DECLARATION OF APHA MEMBER 9

I, Jesus Ramirez-Valles, pursuant to 28 U.S.C. § 1746, depose and say as follows:

1. I am the Division Chief of the Division of Prevention Science and Professor of Medicine in the Department of Medicine at the University of California San Francisco (UCSF). My work focuses on the challenges of health and healthcare for excluded communities including LGBTQ+ populations, people of color, women, and people living with HIV. My current work researches the extent to which structural racism and discrimination shapes older gay men's health.

2. I am offering this declaration in my individual capacity and not on behalf of my employer.

3. My interest in this area of research began during my work as a community organizer near El Paso, Texas during the HIV/AIDS epidemic in the 1980s, when I took care of countless LBGTQ+ individuals—including friends—as they died from HIV/AIDS. After that harrowing experience, I wanted to dedicate my career to learning how to prevent those harms in the future, and I discovered my passion for using research to advocate for the unmet health and healthcare

needs of excluded communities. Beginning early in my career, I began to study the particular harms of homophobia, racism, and stigma that Latine LGBTQ+ communities felt.

4. Prior to working at the University of California San Francisco, I served as the director of the Healthy Equity Institute at San Francisco State University. Before that, I chaired the department of Community Health Sciences at the University of Illinois-Chicago School of Public Health, where I was a professor of public health for 22 years.

5. I received my B.A. in Communications from the Monterrey Institute of Technology and Higher Education in 1988. I received my master's degree in 1993 and my PhD in 1997 in public health at the University of Michigan, where I studied the intersection of community organizing and public health issues such as reproductive maternal and child health and substance abuse prevention.

6. To date, I have published at least 46 peer-reviewed journal articles and 2 scholarly books made possible, in large part, through significant research funding by NIH.

7. I am a dues-paying member of the American Public Health Association (APHA).

8. I have applied for and received 17 grants from the NIH over the course of my career. The application process for each of those grants required months, if not years, of preparation to ensure that the proposal would yield impactful research according to high standards through the rigorous NIH review process. To prepare each application, I completed significant preparation work including pilot research to assess feasibility, literature review, assembling a team including community partners, development of the research plan, and creating a prospective budget. On average, it takes at least one year to prepare. In my experience, the NIH review process involves an iterative series of communications with NIH officials to ensure my grants align with the priorities of the agency and the goals of the funding announcement.

9. Prior to March 2025, I successfully renewed my grant funding every year without issue. To do so, I submitted a progress report, and our funding was disbursed without disruption.

10. But since March 2025, NIH has terminated at least two grants that supported my research. For each of these grants, NIH stated in a termination notice that the project "no longer effectuates agency priorities." The total amount awarded originally across those two grants is over $3.6 million.

11. One of those terminated grants is a project-based R01 grant awarded by the National Institute on Aging beginning on September 15, 2022. A true and correct copy of the notice of award (NOA) for that grant is attached hereto as Exhibit A. That grant—titled *Structural Racism and Discrimination in Older Men's Health Inequities* (Project Number 5R01AG077934)—originally had a total award value of approximately $3.25 million. *See* Ex. A.

12. The goal of this project was to shed light on the extent and the manner in which structural racism and discrimination shapes the health of older gay men (*i.e.*, over the age of 55). More specifically, our goal was to better understand how gay men's life experiences involving exodus from hostile environments (such as communities or work places) and the formation of support communities defined their long-term health prospects. This is important because older gay men's health (including HIV) fares worse than that of their heterosexual counterparts, as they experience higher structural discrimination and have less access to supportive resources on average. The grant aimed to assess the relationships among health, stigma, structural racism and discrimination, resources, and biomarkers of health and aging in older gay men to better understand the reasons for the disparity in health outcomes relative to similarly situated heterosexual men. This population has been historically understudied in aging research because, prior to this cohort, we did not have many older LGTBQ+ people, and because the HIV/AIDS

epidemic claimed the lives of so many gay men before they reached older adulthood, limiting the opportunity for study until now.

13. This project took the form of a study in the San Francisco Bay Area. The project originally aimed to recruit 600 older gay men from whom we would collect structural data (*i.e.*, about the community in which the subject lived), individual data (*i.e.*, about the social, economic and medical background of the subject), and biological data (*i.e.*, blood samples). We intended to use these data to test hypotheses about associations between structural discrimination, resources, and health (including mental health, HIV risk and treatment, and cognitive function) of older gay men. For example, we could study the biomarkers in blood samples to see the longterm effects of stress and trauma. Ultimately, the data and findings from this study were intended to constitute the baseline to demonstrate how different factors including HIV status, medications taken, race, and place of residence, could have long-term effects on the body as it aged. This data could be used for the basis of a longitudinal study tracking participants to continue to understand queer aging in more particular ways.

14. I designed the study in response to NIH's Request for Applications (RFA) titled "Understanding and Addressing the Impact of Structural Racism and Discrimination and Minority Health and Health Disparities." A true and correct copy of that RFA, last accessed April 23, 2025, is attached hereto as Exhibit B. The RFA states that the funding opportunity purpose is to "support (1) observational research to understand the role of structural racism and discrimination [] in causing and sustaining health disparities, and (2) intervention research that addresses [structural racism and discrimination] in order to improve minority health or reduce health disparities." Ex. B at 1. According to the RFA, "[p]rojects must address [structural racism and discrimination] in one or more NIH-designated populations with health disparities in

the US and should address documented disparities in health outcomes." *Id.* at 3. Among those NIH-designated populations with health disparities are "[r]acial and ethnic minorities" and "sexual and gender minorities in the U.S." *Id.* at 1. The study also attends to the NIH Office of AIDS Research Strategic Plan of addressing HIV comorbidities, complications, and health disparities.

15. I spent a significant amount of time curating and successfully explaining the project's relevance to structural discrimination in order to meet the funding program's stated objective. I began to develop the study over fifteen years ago as we began to witness and experience the first generation of HIV positive people living long enough to age. First, I conducted pilot research and a literature review, through which I published a book and a couple of articles about queer aging. After the publications, it took roughly one year for my team and I to develop our initial proposal. Over the following years, I submitted several versions of the application to NIH and refined the application in response to NIH reviews to highlight the public health significance of studying HIV and aging, incorporated the emerging biomarkers, and centered the project in San Francisco – a city with deep ties to the history of the HIV epidemic and a large population of individuals living with HIV. The NIH grant was awarded in 2022.

16. Prior to March 2025, NIH officials never raised any concerns to me about this grant during those renewal reviews, and the NIH Office of AIDS Research featured the project as an exemplar project. In fact, just last year, NIH approved a supplemental grant for the project.

17. This grant was originally supposed to end in 2026. However, on March 21, 2025, NIH issued a termination notice stating that the grant had been terminated. A true and correct copy of this termination notice is attached hereto as Exhibit C. Prior to this notice, there was never any indication that this grant was in jeopardy. Three days later, on March 24, 2025, I also received a

revised NOA reflecting the termination of the grant and echoing the language of the termination notice. A true and correct copy of the revised NOA is attached hereto as Exhibit D.

18. Neither the revised NOA nor the termination notice includes any individualized explanation for why the grant was cancelled, and both fail to discuss any of the data or analysis from our application, annual progress reports, or other related material. Instead, the termination notice includes the following language about its decision:

> This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Ex. C at 2; *see also* Ex. D at 5-6.

19. The termination notice also states that, although "'NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,' no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities." Ex. C. at 2.

20. I do not understand what the notice means by "amorphous equity objectives" or "diversity, equity, and inclusion" or "DEI." I also do not understand why NIH believes that this project is based on "artificial and non-scientific categories" or that it does "not enhance health, lengthen life, or reduce illness." I also am uncertain why NIH believes this project does not effectuate agency priorities.

21. This termination will severely hinder our ability to complete our study and develop recommendations based on any findings. The study had recruited only approximately three hundred (300) of the six hundred (600) intended participants. Of those participants, several selected for a qualitative data collective interview had not completed the full study at the time of termination. This sample size is not large enough to offer scientifically valid hypotheses (*e.g.*, such that an analysis could determine any associations between biomarkers and other variables in the study, such as racial or HIV status). The supplement to the project to study transgender women had recruited only fifteen (15) of the one hundred fifty (150) intended participants. For those participants mid-study or yet to be recruited, the time to collect data is of the essence, as participants by their nature are of older age. In addition, rebuilding the recruitment process will take significant start up time and effort.

22. The termination also harms our relationships with community members and partners. Recruiting participants for the study required building relationships and contacts within the community. The abrupt termination of the project harmed the trust we built with community partner organizations and members of the community who participated in the study.

23. The project had a staff of seven UCSF members including myself, one at San Francisco State University, one at Tulane University, and one at the University of Alabama. Because of the termination of this grant and the other grant terminated by NIH, I will likely have to lay off at least two staff members. These lost grants also accounted for approximately 20% of my salary, and although I am currently relying on reserve funding to make up the difference, I do not believe that will be a long-term solution for that loss. Several other co-investigators, including the three team members at our partner institutions and one at UCSF, will also be at risk of losing a portion of their salaries.

24. As we are witnessing the first generation of people with HIV living to reach old age, we also have our first opportunity to study how aging is affected by HIV, related medications, and other factors like discrimination. If studies like mine are unable to continue, we will lose a cohort of aging people and their experiences, as well as the opportunity to learn from them. Investigating how social and medical factors affect aging people from communities not often studied can directly lead us to answers about how those people can live longer. Such studies also help inform the body of science generally around how people age.

25. I have suffered substantial emotional distress about the termination of this project. This work was the culmination of a career-long effort to use public health research to help LGBTQ+ populations, especially those affected by the HIV/AIDS epidemic that I myself witnessed firsthand.

26. On April 7, 2025, we filed an appeal for the grant termination. I submitted an appeal for the grant because I do not anticipate being able to find replacement funding for the projects. But I also do not understand why the grant was terminated, and I had no idea how to address any agency concerns or recharacterize or revise my project for the purposes of appeal, especially in light of the lack of information provided by NIH. I also do not know how to submit new proposals in light of the vagueness of this language and in light of my current research portfolio and goals.

27. I received a substantially similar termination notice for another grant that supports my work (Project Number 1R01MD020284—Measures of Structural Stigmatization and Discrimination for HIV Research with Latine Sexual and Gender Minorities). NIH issued that termination on March 12, 2025. A true and correct copy of that termination notice is attached hereto as Exhibit E. Among other identical language, this notice uses the exact same paragraph

to explain the agency's decision to cut this grant, including that the "award no longer effectuates agency priorities." Ex. E at 1. An appeal for this grant was submitted, but I have the same concerns with this appeal as I do with the appeal described above.

28. I do not know whether any appeal has any chance of success, given the following language across the termination notices I received: "The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities."

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 24 day of April, 2025.

Jesus Ramirez-Valles

EXHIBIT A

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG077934
Federal Award Date
09-09-2022

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, THE
1855 FOLSOM ST STE 425

SAN FRANCISCO, 94143

2. Congressional District of Recipient
12

3. Payment System Identifier (ID)
1946036493A6

4. Employer Identification Number (EIN)
946036493

5. Data Universal Numbering System (DUNS)
094878337

6. Recipient's Unique Entity Identifier
KMH5K9V7S518

7. Project Director or Principal Investigator
Jesus Ramirez-Valles, PHD
Professor And Director
jesus.ramirez-valles@ucsf.edu
415-405-4350

8. Authorized Official
Estrella Garcia
estrella.garcia@ucsf.edu
415-260-5128

Federal Agency Information

9. Awarding Agency Contact Information
Lesa McQueen

NATIONAL INSTITUTE ON AGING
lesa_mcqueen@nih.gov
301-496-1472

10. Program Official Contact Information
Melissa S Gerald
Health Science Administrator
NATIONAL INSTITUTE ON AGING
geraldmel@nia.nih.gov
301-402-4156

Federal Award Information

11. Award Number
1R01AG077934-01

12. Unique Federal Award Identification Number (FAIN)
R01AG077934

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Structural Racism and Discrimination in Older Men's Health Inequities

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 09-15-2022 **– End Date** 05-31-2023	
20. Total Amount of Federal Funds Obligated by this Action	$844,201
20 a. Direct Cost Amount	$526,667
20 b. Indirect Cost Amount	$317,534
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$844,201
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$844,201
26. Project Period Start Date 09-15-2022 **– End Date** 05-31-2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$844,201

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Ryan Blakeney

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 ON AGING

SECTION I – AWARD DATA – 1R01AG077934-01

Principal Investigator(s):
Jesus Ramirez-Valles, PHD

Award e-mailed to: cgrasteam@ucsf.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $844,201 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to The Regents of the UCSF 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 On Aging of the National Institutes of Health under Award Number R01AG077934. 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,

Ryan Blakeney
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

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

Salaries and Wages	$279,042
Fringe Benefits	$108,812
Personnel Costs (Subtotal)	$387,854
Materials & Supplies	$11,310
Travel	$14,442
Other	$33,149
Subawards/Consortium/Contractual Costs	$77,912
Publication Costs	$2,000
Federal Direct Costs	$526,667
Federal F&A Costs	$317,534
Approved Budget	$844,201
Total Amount of Federal Funds Authorized (Federal Share)	$844,201
TOTAL FEDERAL AWARD AMOUNT	$844,201
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$844,201

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$844,201	$844,201
2	$807,774	$807,774
3	$800,878	$800,878
4	$798,781	$798,781

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

Fiscal Information:

Payment System Identifier: 1946036493A6
Document Number: RAG077934A
PMS Account Type: P (Subaccount)
Fiscal Year: 2022

IC	CAN	2022	2023	2024	2025
AG	8470694	$844,201	$807,774	$800,878	$798,781

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

NIH Administrative Data:
PCC: 2BPDIGE / **OC**: 41021 / **Released**: Blakeney, Ryan 08-31-2022
Award Processed: 09/09/2022 12:06:07 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01AG077934-01

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 – 1R01AG077934-01

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) R01AG077934. 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 – AG SPECIFIC AWARD CONDITIONS – 1R01AG077934-01

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.

RESTRICTION: The present award is being made without a currently valid certification of IRB approval for this project with the following restriction: Only activities that are clearly severable and independent from activities that involve human subjects, including recruitment, may be conducted pending the National Institute on Aging's acceptance of the certification of IRB approval.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for any research involving human subjects prior to the National Institute on Aging's notification to the grantee that the identified issues have been resolved and this restriction removed.

Failure to respond within the 60-day period and/or to otherwise comply with the above requirements may result in suspension and/or termination of this award, audit/or disallowances, and/or other appropriate action.

See the NIH Grants Policy Statement, Chapter 4.1.15 Human Subjects Protections (http://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements__objectives_and_other_appropriation_mandates.htm), for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

_____

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

This award includes funds awarded for consortium activity with SAN FRANCISCO STATE UNIVERSITY in the amount of $21,179 ($13,664 direct costs + $7,515 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:
http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15_consortium_agreements.htm

This award includes funds awarded for consortium activity with University of Alabama at Birmingham in the amount of $21,381 ($14,398 direct costs + $6,983 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at:

http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

This award includes funds awarded for consortium activity with University of Tulane Univ. School of Public Health and Tropical Medicine in the amount of $35,352 ($23,258 direct costs + $12,094 facilities and administrative costs). Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

This award includes funds for twelve months of support. The competing budget period is awarded for less than 12 months. Continuation awards will cycle each year on 06/01. The Research Performance Progress Report (RPPR) is due 45 days prior to this date for SNAP awards or 60 days prior for non-SNAP awards.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01AG077934-01

INSTITUTION: The Regents of the UCSF

Budget	Year 1	Year 2	Year 3	Year 4
Salaries and Wages	$279,042	$260,538	$273,776	$299,238
Fringe Benefits	$108,812	$100,489	$105,332	$113,354
Personnel Costs (Subtotal)	$387,854	$361,027	$379,108	$412,592
Materials & Supplies	$11,310	$480	$480	$480
Travel	$14,442	$25,760	$20,558	$13,194
Other	$33,149	$71,155	$50,150	$11,052
Subawards/Consortium/Contractual Costs	$77,912	$59,197	$69,146	$86,859
Publication Costs	$2,000	$2,260	$2,789	$3,500
TOTAL FEDERAL DC	$526,667	$519,879	$522,231	$527,677
TOTAL FEDERAL F&A	$317,534	$287,895	$278,647	$271,104
TOTAL COST	$844,201	$807,774	$800,878	$798,781

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4
F&A Cost Rate 1	61.5%	61.5%	61.5%	61.5%
F&A Cost Base 1	$516,315	$468,122	$453,085	$440,819
F&A Costs 1	$317,534	$287,895	$278,647	$271,104

EXHIBIT B

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov))

Components of Participating Organizations

National Institute on Minority Health and Health Disparities (NIMHD (https://www.nimhd.nih.gov/))

National Eye Institute (NEI (https://www.nei.nih.gov/))

National Heart, Lung, and Blood Institute (NHLBI (https://www.nhlbi.nih.gov/))

National Human Genome Research Institute (NHGRI (https://www.genome.gov/))

National Institute on Aging (NIA (https://www.nia.nih.gov/))

National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://www.niaaa.nih.gov/))

National Institute of Allergy and Infectious Diseases (NIAID (https://www.niaid.nih.gov/))

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS (https://www.niams.nih.gov/))

National Institute of Biomedical Imaging and Bioengineering (NIBIB (https://www.nibib.nih.gov/))

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (https://www.nichd.nih.gov/))

National Institute on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))

National Institute of Dental and Craniofacial Research (NIDCR (https://www.nidcr.nih.gov/))

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/))

National Institute on Drug Abuse (NIDA (https://www.drugabuse.gov/))

National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))

National Institute of General Medical Sciences (NIGMS (https://www.nigms.nih.gov/))

National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/index.shtml))

National Institute of Neurological Disorders and Stroke (NINDS (https://www.ninds.nih.gov/))

National Institute of Nursing Research (NINR (https://www.ninr.nih.gov/))

National Center for Complementary and Integrative Health (NCCIH (https://nccih.nih.gov/))

National Cancer Institute (NCI (https://www.cancer.gov/))

Office of The Director, National Institutes of Health (OD (https://www.nih.gov/institutes-nih/nih-office-director))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Division of Program Coordination, Planning and Strategic Initiatives, Office of Disease Prevention (ODP (https://prevention.nih.gov/))

Office of Behavioral and Social Sciences Research (OBSSR (https://obssr.od.nih.gov/))

Sexual and Gender Minority Research Office (SGMRO (https://dpcpsi.nih.gov/sgmro))

Office of Research on Women's Health (ORWH (https://orwh.od.nih.gov/))

Funding Opportunity Title

Understanding and Addressing the Impact of Structural Racism and Discrimination on Minority Health and Health Disparities (R01 Clinical Trial Optional)

Activity Code

R01 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r01&Search.x=0&Search.y=0&Search_Type=Activity) Research Project Grant

Announcement Type

New

Related Notices

- **April 23, 2021** - Notice of Pre-Application Technical Assistance Webinar for RFA-MD-21-004. See Notice NOT-MD-21-018 (https://grants.nih.gov/grants/guide/notice-files/NOT-MD-21-018.html).

Funding Opportunity Announcement (FOA) Number

RFA-MD-21-004

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.307, 93.855, 93.172, 93.273, 93.399, 93.867, 93.866, 93.846, 93.242, 93.113, 93.865, 93.286, 93.310, 93.121, 93.279, 93.213, 93.853, 93.173, 93.859, 93.361, 93.313, 93.837, 93.838, 93.839, 93.840, 93.233, 93.847

Funding Opportunity Purpose

This initiative will support (1) observational research to understand the role of structural racism and discrimination (SRD) in causing and sustaining health disparities, and (2) intervention research that addresses SRD in order to improve minority health or reduce health disparities.

Key Dates

Posted Date

March 23, 2021

Open Date (Earliest Submission Date)

July 20, 2021

Letter of Intent Due Date(s)

July 20, 2021

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
August 24, 2021	Not Applicable	August 24, 2021	November 2021	January 2022	April 2022

All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date

August 25, 2021

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000),except where instructed to do otherwise (in this FOA or in a Notice from NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/)).

Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Key Definitions for the FOA:

Discrimination: A socially structured action that is unfair or unjustified and harms individuals and groups. Discrimination can be attributed to social interactions that occur to protect more powerful and privileged groups or institutions at the detriment of other groups. Racism refers to discrimination based on race or ethnicity.

Structural discrimination refers to macro-level conditions (e.g., residential segregation) that limit opportunities, resources, and well-being of less privileged groups (Healthy People 2020, https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/discrimination (https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/discrimination)).

Structural racism and discrimination (SRD): For the purposes of this FOA, SRD refers to structural discrimination on the basis of race/ethnicity and/or other statuses, including but not limited to gender, sexual orientation, gender identity, disability status, social class or socioeconomic status, religion, national origin, immigration status, limited English proficiency, or physical characteristics or health conditions.

NIH-designated Populations with Health Disparities: Racial and ethnic minorities, socioeconomically disadvantaged populations, underserved rural populations, and sexual and gender minorities in the U.S. (see https://www.nimhd.nih.gov/about/overview/ (https://www.nimhd.nih.gov/about/overview/)).

Background

There is increasing recognition that racism and discrimination contribute to poorer health outcomes for racial/ethnic minorities and other populations that experience health disparities. In fact, all populations with health disparities experience increased exposure to racism and/or other forms of discrimination over the life course. There is also a growing societal recognition that racism and discrimination extend beyond the behavior of individuals to include SRD, which is embedded in historical societal, institutional, organizational and governmental structures through formal and informal processes, procedures, and practices that limit both opportunities and resources to segments of the population. SRD is supported by the power structures that exist in society and in the institutions that are most likely to influence health outcomes.

Despite this enhanced awareness, racism and discrimination are not routinely included as determinants of health in biomedical research. Health research on racism and discrimination to date has largely focused on interpersonal interactions, and to a lesser extent, one specific form of SRD, residential segregation. Typically, such research focuses on the adverse health consequences of SRD exposures. Less research has explored the resilience among populations exposed to SRD or community strategies to resist or mitigate historic or contemporary SRD exposures. Additionally, intervention research has rarely emphasized reduction of SRD as a strategy to improve health and reduce disparities. Research on mitigation of SRD is needed to inform health care and social policies at all levels.

Health research and interventions need to routinely incorporate constructs and measurement of SRD across multiple socioecological domains and levels of influence in order to improve minority health, promote health equity, and eliminate health disparities (see the NIMHD Research Framework for more information: https://www.nimhd.nih.gov/about/overview/research-framework.html (https://www.nimhd.nih.gov/about/overview/research-framework.html)). Examples of domains in which SRD may occur include, but are not limited to, the following:

- Organizational/Institutional: Organizational-level climate; workplace hiring, promotion, or disciplinary practices; academic tracking, stigmatization, school disciplinary and admission practices; tolerance of abuse/harassment; health care system practices.
- Neighborhood/Community: Housing or lending practices and property value assessments; zoning laws; neighborhood distribution of public transportation, green spaces, grocery stores, hospitals and emergency departments, ambulatory health clinics, resource allocation for schools through local tax base, location of cellular towers, highways and major thoroughfares, and industrial or waste sites; criminal justice profiling; targeted social marketing of harmful or ineffective products; hate crimes.
- Societal: Criminal justice policies and sentencing practices, land/water use rights, self-governance or political representation for tribal communities and US territories, immigration and asylum policies and procedures, gerrymandering, voter suppression laws or practices, religious and cultural discrimination, depiction or representation in national media and social media.

Research Objectives

This initiative will support observational or intervention research to understand and address the impact of SRD on minority health and health disparities.

Projects must address SRD in one or more NIH-designated populations with health disparities in the US and should address documented disparities in health outcomes. Applications are expected to provide a justification for why the specific types of SRD included constitute SRD, such as how the racism or discrimination is structural rather than reflecting individual-level behavior and how the SRD results in differential treatment or outcomes for less advantaged individuals, groups or populations. For example, with a project examining discriminatory school disciplinary practices, documentation of different overall rates of student suspensions or expulsions by race/ethnicity would not be sufficient to label this pattern as SRD. However, different rates of student suspensions or expulsions by race/ethnicity for the same type of student behavior or violation could be evidence of SRD. Applications are also expected to **provide a conceptual model** identifying hypothesized pathways between the SRD and health outcomes. Potential health outcomes may reflect health status; health condition-specific or all-cause disability, quality of life, mortality and morbidity; biological measures that reflect cumulative exposures to and effects of SRD; health behaviors; or access to, utilization of, or quality of health care.

It is also expected that projects will collect data on SRD beyond individual self-reported perceptions and experiences to include data at organizational, community or societal levels. Potential data sources for SRD may include but are not limited to U.S. Census data, birth and mortality records; health surveillance data; crime statistics; traditional and social media data, school-based or educational data; labor statistics; voting records; local, state, and Federal law and policies; home ownership covenants; and organizational/institutional mission statements, policy guidance, operating procedures, or other relevant documents.

Projects are expected to involve collaborations with relevant organizations or groups or stakeholders, such as academic institutions, health service providers and systems, state and local public health agencies or other governmental agencies such as housing and transportation, criminal justice systems, school systems, patient or consumer advocacy groups, community-based organizations, and faith-based organizations. Multidisciplinary research teams, including researchers from areas outside of the health sciences, such as economics, education, history, criminology, law, and political science, are encouraged.

Observational Studies: Projects may (1) examine the impact of SRD on health, and/or (2) evaluate the impact that existing efforts to address SRD (e.g., laws, policies, programs, organizational practices and procedures) have on the health of individuals, families, and communities. Projects may involve collection of primary data/and or analysis of existing data and may involve quantitative or mixed methods approaches. Projects must be exclusively domestic, including U.S. territories. Projects using longitudinal designs or multiple sites are strongly encouraged, as are projects examining resilience in the face of exposure to SRD.

Intervention Studies: Projects may focus on health promotion, treatment, and/or prevention. Interventions may focus primarily on addressing SRD to improve health outcomes, or SRD may be included as one of several determinants of health addressed to improve health outcomes. For both types of intervention approaches, interventions must directly address the cause or source of SRD, not just help individuals or populations to cope with SRD. To this end, it is expected that investigators will collaborate with leadership from organizations, agencies, or programs where the SRD is originating from or being sustained (e.g., a project addressing SRD in the workplace should involve organizational leaders, human resource managers, or other relevant personnel involved in establishing, maintaining, or enforcing workplace policies and practices rather than only involving employees within a workplace). It is also expected that interventions will involve other relevant personnel or individuals within the setting (e.g., teachers, clinicians, co-workers, bystanders) as appropriate to enact changes to SRD, not just those who are directly experiencing SRD.

Research designs should allow for the assessment of mechanisms through which the intervention modifies SRD and how these changes result in improvement in the targeted health outcomes. Mechanisms of interest related to SRD include changes to behaviors, environments, or policies at the interpersonal, organizational, neighborhood/community, or societal level.

Cluster randomized designs for all types of intervention studies are strongly encouraged, as are research designs comparing interventions with and without SRD components. It is expected that the interventions will have potential for sustainability in the intervention setting after the project is over as well as scalability to be implemented in other settings.

Design, Analysis, and Sample Size for Studies to Evaluate Group-Based Interventions: Investigators who wish to evaluate the effect of an intervention on a health-related biomedical or behavioral outcome may propose a study in which (1) groups or clusters are assigned to study arms and individual observations are analyzed to evaluate the effect of the intervention, or (2) participants are assigned individually to study arms but receive at least some of their intervention in a real or virtual group or through a shared facilitator. Such studies may propose a parallel group- or cluster-randomized trial, an individually randomized group-treatment trial, a stepped-wedge design, or a quasi-experimental version of one of these designs. In these studies, special methods may be warranted for analysis and sample size estimation. Applicants should show that their methods are appropriate given their plans for assignment of participants and delivery of interventions. Additional information is available at https://researchmethodsresources.nih.gov/ (https://researchmethodsresources.nih.gov/).

Applicants are strongly encouraged to assess social determinants of health using measures available in the Social Determinants of Health Collection of the PhenX Toolkit (www.phenxtoolkit.org (http://www.phenxtoolkit.org)), as appropriate..

Applications Not Responsive to the FOA

- Projects without a focus on addressing SRD toward one or more NIH-designated populations with health disparities.
- Projects that are exclusively qualitative or that only use individual-level data.
- Projects that do not examine the impact of SRD on health-related outcomes.
- Projects that propose data collection or testing of interventions outside of the U.S.
- Projects that include prohibited policy lobbying or advocacy activities (see https://grants.nih.gov/grants/lobbying_guidance.htm (https://grants.nih.gov/grants/lobbying_guidance.htm) for more information).

Non-responsive applications will not be reviewed. Applicants are strongly encouraged to reach out to the relevant scientific contacts to discuss whether their applications are responsive.

Specific Areas of Research Interest

NIMHD encourages projects that use approaches that encompass multiple domains (e.g., biological, behavioral, socio-cultural, environmental, physical environment, health system) and multiple levels (e.g., individual, interpersonal, community, societal) to understand and address the impact of SRD on minority health and health disparities (see the NIMHD Research Framework, https://www.nimhd.nih.gov/about/overview/research-framework.html (https://www.nimhd.nih.gov/about/overview/research-framework.html), for examples of health determinants of interest).

Areas of specific interest to **NIMHD** include but are not limited to the following:

- Examination of the impact of structural racial/ethnic or socioeconomic status-based discrimination in the criminal justice system (e.g., police stops, arrests, bail and pre-trial detainment and diversion, sentencing, and probation and parole practices) on the health and well-being of individuals, families, and communities.
- Examination of the impact of SRD in health care settings on access to and quality of care and health outcomes.
- Identification of family, organizational, neighborhood, cultural and community protective factors that moderate the relationship between SRD exposures and health.
- Examination of how cumulative and chronic experiences of SRD impact biological processes (e.g., epigenome, allostatic load, inflammation, microbiome, neurological signatures) that contribute to poor health outcomes.
- Examination of the impact of SRD related to social and mass media practices and policies, such as stereotyping, targeted marketing, cyberbullying and hate speech, on community/population-level health.
- Interventions to improve mental and physical health by fostering positive interactions and more inclusive social climates in schools, workplaces, and other organizations/institutions.
- Interventions that address SRD in healthcare settings across multiple domains (clinicians and staff interacting with patients, physical space, service delivery structure, financing, access, and others) in order to improve health care outcomes.
- Place-based interventions to address SRD in multiple sectors (criminal justice, education, labor, transportation, parks and recreation, housing, and others) based on community priorities and strategies.
- Multi-level, multi-component interventions that address SRD as well as other determinants of health to prevent chronic disease, unintentional injury, or violence victimization and perpetration.

NCCIH promotes research on the use of complementary and integrative health approaches for improving minority health and eliminating disparities in health conditions such as mental health, emotional well-being, behavioral health, or pain. Complementary approaches include those with physical and/or psychological therapeutic inputs, often called mind and body approaches (e.g., acupuncture, yoga, tai chi, qi gong, meditation, hypnosis, music therapy, art therapy, spinal or chiropractic manipulation, and massage) as well as approaches with dietary or nutritional therapeutic inputs, or considered natural products (e.g., botanicals, probiotics/microbials, naturally derived peptides, dietary supplements, and special diets). Integrative approaches include therapies that combine complementary approaches with conventional medical interventions such as pharmacologic, surgery, or device-based treatments.

Areas of interest to **NCCIH** include but are not limited to:

- Studies to examine the impact of SRD on access to, implementation, adherence, dissemination, and adoption of evidence-based complementary and integrative health approaches for prevention and treatment of mental health, emotional well-being, behavioral health, or pain among health disparity populations.
- Multilevel interventions (e.g., interpersonal, community, societal) that address SRD in order to improve access to evidence-based complementary and integrative health approaches to address mental health, emotional well-being, behavioral health, or pain in diverse settings (e.g., schools, criminal justice, health care).

NCI is committed to eliminating cancer related disparities and promoting equity in cancer prevention, diagnosis, treatment, and survivorship. For this FOA, NCI will accept intervention projects focused on addressing structural/institutional racism/discrimination (SRD) that influence cancer-related outcomes -- from early detection through end of life. Projects submitted to NCI may focus on cancer prevention, diagnosis, treatment, and/or survivorship based and provide a conceptual model identifying hypothesized pathways or mechanisms between the SRD and cancer-related outcomes. Areas of specific interest to NCI include multilevel interventions focused on addressing SRD to improve cancer outcomes, or interventions that address several determinants of health in addition to SRD.

NCI areas of interest in intervention research include, but are not limited to:

- Multi-level, multi-component interventions that address SRD as well as other determinants of health to prevent cancer, improve cancer care for patients, and/or improve cancer outcomes.
- Intervention research examining family, organization, neighborhood, cultural and community factors that may moderate SRD exposure and cancer prevention and care.
- Intervention research focusing on the prevention of cancer that incorporates risk and resilience factors in response to structural racism such as historical trauma, immigration policies, school and language-based discrimination, housing and criminal justice practices, etc.
- Research on development of cancer treatment interventions and service delivery approaches that address systemic racism and structural barriers health services such as staff training, service delivery settings and schedules, use of digital platforms, language and health literacy barriers, costs, etc.
- Mechanistic studies of the effects of discrimination-based trauma and/or chronic experiences on biological processes (e.g., epigenome, inflammation, microbiome, or other molecular/cellular processes) that contribute to poorer cancer and overall health outcomes.

NEI will consider applications within our mission areas of preventing, treating, or reversing vision loss and addressing the special health problems and requirements of the visually impaired, with special emphasis on structural racism influences on the delivery of eye health care in underserved populations.

NHGRI is interested in supporting both observational and interventional research that 1) will advance understanding of how SRD intersects with and impacts the field of human genomics, the practice of genomic medicine, and other uses of genomic information that impact health outcomes; or 2) will identify effective strategies for addressing SRD at various levels of influence within and across organizations, institutions, or groups that directly and indirectly contribute to health disparities in genomic medicine. NHGRI defines genomic medicine as use of genomic information in clinical care and the health outcomes associated with that clinical use at an individual, group, and population levels. Areas of specific interest include but are not limited to the following:

1. Examination of the impact of SRD on views, behaviors or experiences of patients and/or providers about the risks and benefits of utilizing genomic information in healthcare to mitigate health disparities.
2. Examination of the role of SRD in whether and how genomic information is used within health care settings (e.g., hospital, health center, private practice) and outside of health care settings (e.g., insurance, labor, criminal justice, direct to consumer genetic testing) and the differential impact of that use on the health and well-being of individuals, families, and communities who experience health disparities.
3. Examination of laws, regulations, policies, guidelines, or interventions that prevent, discourage, or exacerbate racist and discriminatory practices in the use of genomic data, knowledge, and technologies within healthcare settings; and their effectiveness in achieving equity in health outcomes or health service delivery.
4. Interventions that address SRD within healthcare organizations, laboratories, and public health systems to ensure equity in the availability, accessibility, comprehensiveness, and quality of genomic medicine in one or more NIH-designated populations with health disparities in the US.
5. Examination of how SRD biases the design, implementation, and dissemination of genomic research and directly contributes to health disparities in genomic medicine across patient populations (e.g., scientifically valid health-related information, effectiveness of treatment options, evidence-informed care or advice, individual health status), especially for populations whose genetic ancestry is underrepresented in genomic research.

Applicants are encouraged to incorporate the measures from PhenX Toolkit (https://www.phenxtoolkit.org/ (https://www.phenxtoolkit.org/)), whenever possible.

In general, **NHGRI** supports studies that provide generalizable methods and knowledge that can be applied across genomics. Approaches that use a particular disease or organ system as a proof of principle, but can show that methods, outcomes and/or knowledge gained are generalizable, may be in scope for NHGRI. Approaches that are comprehensive across the genome or are generalizable across variants, tissues, diseases, or function also may be in scope for NHGRI.

Applications whose primary scientific objective is to understand a single biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention, will not be in scope for NHGRI. Applications relevant only to a particular disease or organ system should be directed to the appropriate Institute or Center.

Applicants are strongly encouraged to contact the **NHGRI** program directors listed below to discuss the relevance of their proposed topic(s) to the research mission of NHGRI.

The **NHLBI** is interested in the following research topics:

- Observational studies to describe ways in which structural racism and discrimination is associated with disparities in heart, lung, and blood diseases and sleep disorders
- Investigations to uncover the mechanisms by which the multiple domains of structural racism (interpersonal, structural, cultural) impact heart, lung, and blood diseases and sleep disorders
- Hybrid implementation studies to address structural racism to improve heart, lung, and blood diseases and sleep disorders
- Investigations of implementation strategies to increase the uptake of evidence-based strategies to address structural racism
- Community-based research focused on existing practices that support strengths and resilience factors
- Studies to evaluate the impact of structural racism and discrimination in the context of health care settings on heart, lung, and blood diseases and sleep disorders

NIA promotes research related to aging and life course health and well-being, including research on Alzheimer's Disease and related dementias (AD/ADRD). A strategic priority of NIA is understanding the environmental, sociocultural, behavioral and biological drivers of health inequities and disparities related to aging and AD/ADRD. NIA also supports research to develop strategies for the improvement of health among midlife and older adults in racial minority and other populations that experience health inequities/disparities. These priorities are outlined in NIA's strategic directions for health disparities research (https://www.nia.nih.gov/about/aging-strategic-directions-research/goal-health-disparities-adults) and the NAPA Health Disparities milestones (https://www.nia.nih.gov/research/milestones/population-studies-precision-medicine-health-disparities) and reflected within NIA's Health Disparities framework (https://www.nia.nih.gov/research/osp/framework).

NIA encourages investigations of the impacts of the multiple pathways of Structural Racism and Discrimination (SRD) and subsequent health consequences on individuals across the adult lifespan. NIA also encourages research that will investigate how SRD works synergistically with other mechanisms (or forms) of racism (e.g. individual or cultural racism) to influence health outcomes.

Applicants proposing to develop interventions are expected to proactively identify a theory or model that applies to the intervention proposed and the critical variables expected to result in change. Applications are required to use an appropriate experimental design to test the proposed theory, to identify the essential components of complex interventions, or to elucidate the mechanism(s) by which an intervention exerts its effects. For the development of behavioral interventions, applicants are encouraged to articulate their research aims and the stage of intervention development proposed using the NIH Stage Model (https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development) framework.

NIA interests include, but are not limited to, the following:

- Research that examines the mechanisms that produce disparate health and well-being outcomes at older ages due to structural racism including incarceration, segregation, and inequity.
- Investigation of how cumulative and chronic experiences of SRD impact mechanisms related to premature aging or increased risk for AD/ADRD.
- Studies of structural or institutional factors that mitigate or exacerbate disparities in access to healthcare services in midlife and older age adults or healthcare services for AD/ADRD patients and their caregivers.
- Studies to elucidate whether and how mechanisms connecting structural racism to aging- relevant health outcomes, including well-being, independent function, cognition and AD/ADRD, operate on multiple levels (e.g., individual, interpersonal, societal).
- Multi-level, multi-component interventions that address SRD in healthcare settings to improve aging outcomes, prevent premature aging or AD/ADRD, and/or improve care for older adults, including those with AD/ADR.

NIAAA is interested in prevention, health services and treatment interventions that address the impact of structural racism and discrimination on the development, course and recovery from alcohol misuse and alcohol use disorders. While observational research might be part of formative work necessary to develop effective interventions, the focus of the proposed research ***must*** be on interventions to address alcohol problem. Areas of interest to NIAAA include but are not limited to:

- Research on prevention of early initiation of and/or continued alcohol use across the lifespan that incorporates risk and resilience factors in response to structural racism such as historical trauma, immigration policies, school and language-based discrimination, housing and criminal justice practices, etc.
- Research on development of treatment interventions and service delivery approaches that address systemic racism and structural barriers to alcohol use services such as staff training, service delivery settings and schedules, use of digital platforms, language and health literacy barriers, costs, etc.
- Integration of culturally-grounded, culturally competent and/or bilingual alcohol prevention and treatment services that address effects of structural racism in general health and specialty services settings (including aftercare), school based settings, criminal justice settings, etc.

NIAID supports basic and applied research to better understand, treat, and prevent infectious, immunologic, and allergic diseases, with the goal of developing new therapies, vaccines, diagnostic tests, and other technologies. Research areas include microbiology and infectious diseases, HIV/AIDS and HIV/AIDS-related research, immunology, allergy, transplantation, and biodefense. NIAID is interested in intervention research within the scope of NIAID's mission that will develop and evaluate strategies that mitigate the impact of structural racism and discrimination (SRD).

Specific areas of interest to **NIAID** include, but are not limited to:

HIV/AIDS Research

- Strategies to identify and end structural racism in health care settings of relevance to persons with HIV (PWH) including structural racism that may impact the type of care that is offered to PWH, the way the care is delivered, and racism existent in care adjacent settings that may impact PWH.
- Strategies to identify and end structural racism in non-care settings that may impact the ability of PWH to engage in appropriate medical care and/or fully benefit from medical care.
- Research to address SRD at the health policy, organization and provider levels that fosters medical mistrust and impedes uptake and retention in HIV prevention and treatment programs.
- Research to identify and counter SRD and related intersectional stigma resulting from the impact of HIV, sexual/gender affiliation and/or common co-occurring medical and social conditions (e.g., mental health and substance abuse disorders, poverty).
- Characterization of targeted interventions that can be deployed as public health policies to mitigate the impact of SRD that exists in health systems and health care delivery strategies to improve engagement and retention in care among populations affected by SRD.
- Research to elucidate effective patterns of communications that enable healthcare providers of all races and ethnicities to overcome barriers of medical mistrust in healthcare and improve participation of racial minorities in research.
- Research to evaluate structural interventions that address disparities in access to research by both participants and researchers from racial and ethnic minorities; and, the role of racism and health disparities in terms of access to both accurate HIV prevention information and pre-exposure prophylaxis (PrEP) products, including the continued and consistent use of HIV PrEP.

Allergy, Immunology and Transplantation

- Role of SRD in sustaining disparities in the development, prevalence, and management of asthma, food allergies, allergic rhinitis, allocation of organs for transplantations, allograft function and survival in children from low-income families and racial and ethnic minorities.
- Examine the contribution of SRD to 1) the morbidity and mortality and 2) the hesitancy to participate in clinical research and methods to overcome the hesitancy, seen in some autoimmune diseases (e.g. Systemic lupus erythematosus (SLE) that are more common and potentially more severe in racial and ethnic minorities.
- Interventions to evaluate the impact of SRD on access to kidney transplantation among persons on renal dialysis.

Infectious Diseases

- Research that studies the impact of SRD on infectious disease (ID) prevalence and health outcomes, access to ID vaccines, diagnosis, prevention technologies and products, and treatment along with service delivery models to expand access and utilization in racial, ethnic, and sexual minorities.
- Effects of SRD on health outcome following respiratory and sexually transmitted diseases (e.g. COVID-19, gonorrhea, syphilis), vaccine uptake (e.g. COVID-19, HPV) and access to diagnosis and treatment especially Sexually Transmitted Infections (STIs).
- Innovative treatment options to address antimicrobial resistance (especially STIs and Tuberculosis (TB), supply chain limitations, and other barriers to effective treatment.

NIAMS encourages research designed to understand and address the impact of SRD on minority health and health disparities, among underserved and minority populations who are also at risk for or who are patients with NIAMS diseases of interest (arthritis, musculoskeletal, skin). NIAMS has interest in research understanding and addressing macro-level factors that underlie SRD and subsequent health consequences.

Areas of specific interest to **NIAMS** under this RFA include but are not limited to:

Observational research with focus on:

- Examination of the impact of SRD on access to and quality of care, including delays in diagnoses, treatment and rehabilitation.
- Identifying protective factors at multiple upstream levels (family, organizational, neighborhood, cultural and community) that are associated with less impact of SRD on health outcomes.
- Utilization of innovative design and analysis methods to evaluate natural experiments of existing efforts to mitigate SRD at a macro-level.

Intervention research with focus on:

- Projects that focus on prevention interventions that can reduce SRD and improve health-outcomes in NIAMS mission-relevant diseases.
- Projects that use multi-level and multi-component interventions that address SRD to improve health-outcomes in arthritis, musculoskeletal, and skin diseases.

NIBIB supports the development and integration of advanced bioengineering, sensing, imaging, and computational technologies for the improvement of human health and medical care.

Areas of specific interest to **NIBIB** under this FOA include. but are not limited to the following:

- Observational research to understand the role of structural racism and discrimination in causing and sustaining health disparities mediated through biomedical technologies (e.g., biomedical imaging, bioinformatics and bioengineering), such as
    a. the exclusion or inappropriate consideration of racial differences in needs finding, specification, design and testing of these technologies.
    b. the lack of availability, access, or insufficient/inappropriate application of such technologies in the prevention, diagnosis, and treatment of disease for certain groups or in certain settings, and
- Intervention research that addresses

    a. the eradication of implicit bias and racism in approaches and assumptions in needs finding, specification, design and testing of biomedical technologies,
    b. improving minority health, promoting health equity, and eliminating health disparities through the innovation of novel technologies or enhancement of existing technologies in biomedical imaging, bioinformatics and bioengineering.

NIBIB funding of clinical trials will be in accordance with NOT-EB-21-005 "NIBIB Guidance for Support of Clinical Trial Applications." Briefly, NIBIB will only support mission-focused (see NIBIB's program areas) early-stage clinical trial applications, i.e., feasibility, Phase I, first-in-human, safety, or other small clinical trials, that inform early-stage technology development. NIBIB will not support applications proposing pivotal, Phase II, III, IV, or trials in which the primary outcome is efficacy, effectiveness, or a post-market concern. Also, mechanistic trials are not supported unless the primary focus of the project is on technology development.

NICHD seeks applications that will address questions relevant to the NICHD mission and should align with the NICHD Strategic Plan (https://www.nichd.nih.gov/about/org/strategicplan).

NICHD is interested in the following **populations**: Infants, children, adolescents, and individuals in the transition from adolescence to adulthood; pregnant and lactating women; men and women of reproductive age with regards to reproductive health; girls and women from pre-puberty through perimenopause with regards to research on gynecological and/or reproductive health; individuals of any age with intellectual delays and/or disabilities. NICHD is also interested in research on how parents and other caretakers and/or family members exposure to SRD affects health outcomes for the NICHD populations of interest. In addition, NICHD is interested in research on how prospectively measured exposures to SRD in childhood affects adult health outcomes. NICHD is interested in both observational and intervention research, and, among observational research projects using longitudinal designs, is particularly interested in use of population-representative data.

NICHD is interested in the following **health and health-related outcomes**: Maternal and infant mortality and morbidity, adolescent and young adult mortality and morbidity; contraceptive use and non-use; reproductive health, gynecological health, and fertility; and, for NICHD populations of interest, access to health care and diagnosis and treatment of health problems. NICHD is interested in research on all the **domains** in which SRD may occur that are listed in this RFA, with particular interest in educational settings; the criminal justice system, including the juvenile justice system; and gynecological/reproductive health settings. NICHD is also interested in research on SRD that affects exposure to violence among NICHD populations of interest.

The **National Center for Medical Rehabilitation Research** within **NICHD** seeks applications for intervention research on individuals with physical disabilities. Areas of interest include but are not limited to referrals for and access to health care and inpatient and outpatient rehabilitation services for both primary and secondary conditions, and outcomes related to improving functional outcomes.

NIDA is interested in supporting observational/etiologic, prevention, treatment, and health services research to address the impact of structural racism and discrimination on substance use, substance use disorders, substance use consequences, and comorbid conditions including HIV. Topics of interest include but are not limited to:

- Research on the extent to which racial discrimination, systematic inequities, and segregation in housing, education, employment opportunities, and health resources contribute to and perpetuate disparities in access to substance use and HIV prevention, addiction treatment, and recovery services.
- Research on the effects of systematic racism and discrimination on behavioral, cognitive, and neurobiological markers known to increase vulnerability to substance use, substance use disorders, and HIV across the lifecourse.
- Studies of how bias in the criminal justice system, including arrest, incarceration, probation and post-sentencing practices, affect substance use trajectories, HIV/HCV risk, addiction-related health outcomes, and health disparities experienced by communities of color.
- Targeted efficacious, effective and scalable, culturally specific interventions to address social determinants of health by promoting resiliency and confronting structural racism, with a focus on stigma, discrimination, and prejudice in the context of SUD and HIV prevention and treatment services.
- Research partnerships with state and local officials to determine the impact of administrative and legislative measures to improve equity within housing, education, employment, and other areas of public policy on substance use outcomes in youth and adolescents.
- Research partnerships with state/local agencies and private or public health systems to develop models to eliminate systemic barriers to addiction care or addiction and HIV care, particularly those rooted in racism or structural discrimination.

NIDCD encourages either observational or interventional projects that aim to better understand and address the impact of SRD on minority health and health disparities as they relate to the mission areas of hearing, balance, taste, smell, voice, speech, and language across the lifespan. Areas of interest include but are not limited to applications that address the influence and mitigation of SRD on:

- the diagnosis, treatment, and re/habilitation of childhood hearing, voice, speech, and language disorders.
- the diagnosis, treatment, and rehabilitation of adults with communication disorders including but not limited to hearing loss and acquired neurologic communication disorders.
- the development and interpretation of tests/assessment approaches for voice, speech and language disorders and differences, including measures of dialectal code switching.

NIDCR is interested in observational research aimed at understanding the role of structural racism and discrimination (SRD) in contributing to oral health disparities. Additionally, interventional research that addresses SRD, with the goal of improving minority oral health and reduce oral health disparities, is of interest through this FOA.

Areas of specific interest to **NIDCR** include, but are not limited to, the following:

- Examination of racial/ethnic differences in management and treatment approaches for dental, oral, and craniofacial diseases/conditions, and the role of multi-level SRD factors (e.g. policies, organization characteristics, provider unconscious/implicit bias, etc.) in contributing to these differences.
- Examination of the impact of SRD on access to and quality of care and oral health outcomes, including the role residential segregation may play.
- Examination of the role of language barriers, cultural differences between patients and dental providers, or other impacts of multi-level SRD that may prevent minority groups from seeking oral health care.
- Identification of family, organizational, neighborhood, cultural, and community protective factors that moderate the relationship between SRD exposures and oral health.
- Interventions that address SRD in settings where oral health care is delivered across multiple domains (e.g. provider-patient interactions, service delivery, access to care, etc.) to improve oral health outcomes in minority groups that experience a higher prevalence of oral disease than their counterparts.

NIDDK is committed to promoting health equity and reducing and eliminating health disparities relevant to diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases. For this FOA, NIDDK is interested in intervention projects focused on understanding and addressing the impact of structural racism and discrimination (SRD) on patients and populations disproportionately affected by conditions that fall within the mission of NIDDK. Meaningful stakeholder engaged approaches are encouraged to improve feasibility and maximum potential for sustainability of successful interventions beyond the funded project period. NIDDK is also interested in observational studies, such as deep characterization of SRD that will inform interventional studies and evaluation of natural experiments that employ appropriate designs and methodologies necessary to strengthen causal inferences.

NIDDK will not support studies that focus solely on training health care providers or testing communication and dissemination strategies to facilitate the use of health information.

The mission of **NIEHS** is to discover how the environment affects people to promote healthier lives. The NIEHS 2018-2023 Strategic Plan (https://www.niehs.nih.gov/about/strategicplan/index.cfm) emphasizes our ongoing commitment to the study of environmental health disparities and need for environmental justice among communities affected by toxic levels of exposure. Importantly, structural factors contribute to disproportionate exposure burdens affecting the health of racial, ethnic, immigrant, socioeconomically disadvantaged, and rural communities. Structural factors that intersect with environmental health include, for example, reversal of environmental protections that regulate harmful pollutants, and redlining practices or residential segregation that result in the location of racial/ethnic communities near industrial and/or heavily polluted areas.

NIEHS is interested in observational research examining the role of structural racism and discrimination (SRD) as a significant determinant in environmental health disparities, or evidence-based intervention research that mitigates or prevents the negative health outcomes attributable to environmental SRD. Applicants are ***strongly encouraged*** to utilize community engaged research approaches and include letters of support from community partners. Applications that demonstrate collaborative (i.e., community-academic partnerships) approaches to understand and/or address the negative health effects of environmental SRD across ***multiple*** health disparity communities will be prioritized. Areas of specific interest to NIEHS in environmental SRD include, but are not limited to: single or combined environmental exposures (i.e., mixtures) affecting the health of communities; health impacts of climate change, extreme weather and natural or human caused disasters; the built environment and greenspace, including green gentrification; studies grounded in community identified concerns around the intersection of environmental SRD and health outcomes; the impact of environmental SRD on health outcomes across the lifespan; and the role of environmental SRD in occupational exposures.

NIGMS supports basic research that increases our understanding of biological processes and lays the foundation for advances in disease diagnosis, treatment, and prevention. NIGMS' research mission (https://www.nigms.nih.gov/about/overview/) is aimed at understanding the principles, mechanisms, and processes that underlie living organisms, often using research models. NIGMS does not support research that is relevant to the diseases, organ systems, stages of life, or populations within the mission areas of other NIH Institutes and Centers. Areas of interest to NIGMS include but are not limited to studies that address:

- The impact of structural racism and discrimination (SRD) on health disparities that affect conditions related to clinical areas that NIGMS supports: sepsis (see NOT-GM-19-054 (NOT-GM-19-054)), injury and critical illness, anesthesiology, clinical pharmacology, wound healing, and innate immunity and inflammation.
- The sources of bias in computational research using electronic health records and other health-related data (e.g., artificial intelligence, machine learning, and development of improved algorithms and other methodologies), and/or the development of effective strategies to reduce these disparities.
- Computational modeling to understand the sources of SRD on health disparities in infectious disease spread, and/or to develop effective strategies to reduce these disparities.
- Mechanistic studies of the effects of discrimination-based social trauma on epigenetic and other molecular or cellular processes.

NIMH is interested in receiving applications that address research priority areas in translational, services and interventions research focused on mental health outcomes; and applications that address NIMH priority areas in HIV/AIDS research. Areas of interest include, but are not limited to, those below.

Translational Research:

- Elucidate mechanisms at the individual, community, and organizational levels by which structural racism and discrimination result in specific adverse mental health outcomes across the lifespan, especially those that can point towards therapeutic targets.
- Identify how structural racism and discrimination impact trajectories of mental health disorders across the lifespan, particularly focusing on sequential and integrative relationships across neural, behavioral, and environmental factors that lead to disparities in mental health outcomes.
- Studies that use or develop methods to systematically and reliably quantify individual exposure to structural racism and discrimination, including development of rigorous measures of environmental and sociocultural factors like neighborhood effects, access to and quality of healthcare, food and resource security, intersectionality, and cultural beliefs.

Interventions Research:

NIMH is interested in applications that focus on mental health as the primary outcome. Intervention research may include mental health promotion, prevention and/or treatment Interventions. Interventions may focus primarily on addressing structural racism and discrimination to improve mental health outcomes. Consistent with NIMH's experimental therapeutics approach, research designs should allow for the assessment of mechanisms through which the intervention modifies structural racism and discrimination and how these changes result in improvement in the targeted mental health outcomes. See the Support for Clinical Trials at NIMH (https://www.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml)web page for additional information regarding dedicated FOAs for NIMH clinical trials research support.

Areas of interest include, but are not limited to:

- Interventions to address structural racism and discrimination by cultivating positive interactions and inclusive climates in schools, workplaces and other institutions, with the goal of improving mental health.
- Interventions to improve mental health and associated comorbidities by addressing structural racism and discrimination that takes place in different institutional settings (e.g., child welfare, juvenile and criminal justice, education, housing, etc.).
- Interventions to address structural racism and discrimination at the community level, with the goal of reducing risk for mental health and associated difficulties.

Services Research:

- Non-intervention studies to identify specific, mutable factors indicative of structural racism and discrimination that may serve as targets of interventions to reduce structural racism as it impacts mental health outcomes.
- Non-intervention studies designed to examine structural factors that might be used to identify and/or measure systematic health disparities (e.g., use E.H.R. to examine patient, provider, and system level factors that represent systematic differences in identification, referral, quality of care).
- Studies testing the effectiveness of provider-, organization-, or systems-level interventions in reducing or eliminating structural racism and testing whether such reductions mediate improved mental health outcomes.
- Studies identifying structural aspects of provider, clinic, organization or systems processes in specific systems (e.g.: school or school systems, health care systems, justice systems, etc.) that may be associated with mental health outcomes and may serve as indicators of and measures of changes in structural racism.

HIV/AIDS Research:

- Studies to identify and address the mechanisms, pathways and negative impact of structural racism, discrimination, and intersectional stigma on HIV outcomes across the prevention, care and treatment continuum.
- Studies that examine the impact of bias and discrimination on patient-provider communication, informed decision-making, and HIV care outcomes in service delivery settings.
- Research to understand the role of structural racism and discrimination on uptake of HIV testing, PrEP and other biomedical prevention strategies on individuals from high-incidence populations.
- Research to explore strengths-based approaches, mechanisms for change and opportunities for trust-building and engagement in communities that have been historically impacted by racism and discrimination and are also disproportionately impacted by HIV.
- Studies to identify societal factors that contribute to persistent discrimination, polices or laws associated with HIV vulnerabilities or resiliencies (positive outcomes) over time.
- Studies to identify ways to combat HIV misinformation and poorly delivered communication that contributes to racism, xenophobia and other discriminatory practices that negatively impact HIV outcomes.

NINDS commits to reducing the disproportionate burden of neurological diseases experienced by underserved groups of society, including racial and ethnic minoritized, rural, and socioeconomically disadvantaged populations, by funding a spectrum of research from basic science through clinical studies and training the next generation of health equity investigators (https://www.ninds.nih.gov/Current-Research/Focus-Tools-Topics/Health-Disparities). NINDS supports research activities focused on understanding how structural racism and discrimination (SRD) contribute to inequalities in neurologic health, healthcare, and health outcomes in disparate populations, including racial and ethnic minorities, the geographically disadvantaged, sexual and gender minoritized individuals and others who have been historically underserved, marginalized, and adversely affected by persistent inequality and socioeconomic disadvantage.

NINDS is particularly interested in:

- Research on the impact of SRD on mechanisms related to increased risk of cognitive impairment and Alzheimer's Disease Related Dementias (Frontotemporal degeneration, Lewy Body dementia, mixed etiology dementias and vascular contributions to cognitive impairment and dementia).
- Research on structural or institutional factors that mitigate or exacerbate neurological inequalities in access to healthcare services for midlife and older age adults and/or ADRD patients and their caregivers/families.
- Studies to elucidate whether and how mechanisms connecting structural racism to neurological health outcomes, including well-being, independent function, cognition and ADRD, operate on multiple levels (e.g., individual, interpersonal, or societal).

A letter of intent and communication with **NINDS** program staff prior to submission of an application is strongly encouraged. Observational studies should be theory-based to enable the future development of actionable items and evidence-based interventions. Applicants proposing to develop interventions are expected to proactively identify a theory or model that applies to the intervention proposed and the critical variables expected to result in change. Applications are required to use an appropriate experimental design to test the proposed theory, identify the essential components of complex interventions, and/or elucidate the mechanism(s) by which an intervention exerts its effects. For the development of behavioral interventions, applicants are encouraged to articulate their research aims and a proposed framework.

NINR supports research that uses nursing's holistic perspective to improve individual and population health outcomes and eliminate health inequities by bridging biomedical science and provision of healthcare services with the realities of people's lives and living conditions (i.e., social determinants) across the clinical and community settings where nurses practice. These settings include hospitals, clinics, people's homes, long-term care facilities, schools, workplaces, criminal justice facilities, and the community at large. NINR recognizes the importance of engaging with and responding to the experiences of individuals, households, and populations.

Areas of specific interest to **NINR** include but are not limited to the following topics:

- Developmental, evaluation, and implementation research concerning interventions, programs, and policies aimed at addressing structural discrimination across clinical and community settings for their health effects. Studies adopting natural experiment, and clinical trial designs are all of interest, especially those adopting a holistic perspective on individual and population health.
- Studies aimed at better understanding factors moderating negative health effects of SRD. Studies of innovative models of care including social care and trauma-informed care are encouraged.
- Research on system level interventions to reduce negative effects of implicit bias in healthcare providers on health outcomes for NIH-designated populations with health disparities.

NINR will not support studies that focus solely on training nurses or other healthcare providers to reduce SRD.

The **OBSSR** is part of the Office of the Director of NIH and works in partnership with the 27 NIH Institutes and Centers to ensure that behavioral and social sciences research is well integrated into the NIH research enterprise. In alignment with its strategic priorities (https://obssr.od.nih.gov/about/strategic-plan/), **OBSSR** is interested in providing co-funding support for project(s) funded under this RFA that do one or more of the following: incorporate novel ways of assessing SRD; focus on the mechanisms through which SRD influence health outcomes; incorporate implementation science approaches; utilize innovative methods to evaluate natural experiments of existing efforts; identify protective factors and resiliency-based approaches. Note that OBSSR does not accept assignment of applications or manage awards that are funded. Please contact one of the ICs for inquiries regarding the suitability of the proposed project for the RFA and the IC's research portfolio.

The **ODP** is the lead office at the NIH responsible for assessing, facilitating, and stimulating research in disease prevention, and disseminating the results of this research to improve public health. In partnership with the 27 NIH Institutes and Centers, ODP strives to increase the scope, quality, dissemination, and impact of NIH-supported prevention research. The ODP is interested in providing co-funding support for projects that have strong implications for disease prevention, promise for wide uptake, and that include innovative and appropriate design, measurement, and analysis methods. ODP has specific interests in projects seeking to do one or more of the following: develop analytic methods for rigorously measuring the structures and systems that sustain racial inequities; develop or adopt data sources and methods that accurately and appropriately represent minority and vulnerable communities; capitalize on community-based participatory research approaches for developing and testing interventions; assess for race/ethnic differences; incorporate implementation science approaches and strategies that will be responsive to community and health/service system needs; utilize innovative methods to evaluate natural experiments in healthcare and services delivery and health promotion interventions; and, increase uptake and long-term sustainability of evidence-based interventions and approaches. For additional information about ODP's research priorities and interests, please refer to the **ODP Strategic Plan for Fiscal Years 2019 2023** (https://prevention.nih.gov/about-odp/strategic-plan-2019-2023).

Applications must be relevant to the objectives of at least one of the participating NIH Institutes and Centers (IC) listed above. ODP does not award grants. Please contact the relevant IC Scientific/Research Contact(s) listed below for questions regarding IC research priorities and funding.

The **ORWH** is part of the Office of the Director of NIH and works in partnership with the 27 NIH Institutes and Centers to ensure that women's health research is part of the scientific framework at the NIH and is supported in the larger scientific community. Research in recent decades has adopted an intersectionality framework to study and explain the complex nature of inequality. Integrating the purposeful accounting of sex as a biological variable (SABV) and gender as a social variable, alongside race and social class considerations in biomedical research, will enhance understanding of the effects of discrimination and its magnitude on mental and physical health (i.e. impacts on maternal morbidity and mortality or multimorbidities among groups of women). **ORWH** is interested in providing support for interdisciplinary, behavioral, clinical, and/or translational studies incorporating intersectional analyses into studies of racism and discrimination exposure among populations experiencing health disparities, including groups of women who are understudied, underrepresented, and underreported in research. For additional guidance, please refer to the 2019-2023 Trans-NIH Strategic Plan for the Health of Women on the ORWH website (https://www.nih.gov/women/strategicplan (https://www.nih.gov/women/strategicplan)).

The **SGMRO** resides in the NIH Office of the Director and coordinates research and activities related to the health of sexual and gender minorities (SGMs; see NOT-OD-19-139 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-139.html) for more information) by working directly with the agency's Institutes, Centers, and Offices. A robust and growing body of evidence demonstrates that SGMs often face institutional discrimination and poorer health outcomes than their non-SGM peers. SGM people with intersecting identities, including those based on race, ethnicity, and/or other statuses highlighted in this FOA, may face distinct and exacerbated health issues and disparities, and structural racism and discrimination may act as key drivers, modifiers, and intensifiers of the health-related concerns and challenges of these individuals. **SGMRO** is interested in social, behavioral, clinical, translational, and health services research to investigate how structural racism and discrimination adversely affect the lives and well-being of the most vulnerable SGM populations and to develop sustainable long-term strategies to attend to these pressing issues.
See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s).

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

NIMHD intends to commit $5,000,000 in FY2022 to fund 6-7 awards.

NCI intends to commit $1,000,000 in FY2022 to fund one award.

NCCIH intends to commit $850,000 in FY2022 to fund one award.

NEI intends to commit $1,000,000 in FY2022 to support one award.

NHGRI intends to commit $1,700,000 in FY2022 to fund 2 awards.

NHLBI intends to commit $1.5M to support up to 2 awards.

NIA intends to commit $4,500,000 in FY2022 to fund 6 awards, including $3,000,000 to fund 4 awards on Alzheimer's disease and related dementias and $1,500,000 to fund 2 awards on other topics.

NIAAA intends to commit $850,000 in FY2022 to fund one award.

NIDDK intends to commit $850,000 in FY 2022 to fund one award.

NIAID intends to commit $850,000 in FY2022 to fund one award.

NIAMS intends to commit $500,000 in FY2022 to fund one award.

NIBIB intends to commit $800,000 in FY2022 to fund one award.

NICHD intends to commit $850,000 in FY2022 to fund one award.

NIDA intends to commit $2,000,000 in FY2022 to fund 2 awards.

NIDCD intends to commit $700,000 in FY2022 to fund one award.

NIDCR intends to commit $750,000 in FY2022 to fund one award.

NIEHS intends to commit $850,000 in FY2022 to fund one award.

NIGMS intends to commit $2,000,000 in FY2022 to fund 4-6 awards.

NIMH intends to commit $850,000 in FY2022 to fund one award.

NINDS intends to commit $850,000 in FY2022 to fund one award.

NINR intends to commit $2,550,000 in FY2022 to fund 3 awards.

The OD, OBSSR, ODP, ORWH, and SGMRO have committed funds in FY2022 towards co-funding.

Award Budget

Application budgets are limited to $500,000 direct costs annually, not including consortia F&A.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

NIH grants policies as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments

- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments

- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are not** allowed.

Required Registrations

Applicant organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) Applicants must complete and maintain an active registration, which requires renewal at least annually. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html))

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000) except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Yujing Liu, MD, PhD
National Institute on Minority Health and Health Disparities (NIMHD)
Telephone: 301-827-7815
Email: liuyujin@mail.nih.gov

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy: Identify the health disparity populations that will be the focus of the project and describe the documented health disparity that will be studied. Provide a justification for how the specific types of SRD to be studied constitute SRD. Provide a conceptual model that describes hypothesized causal pathways between SRD and health outcomes. Describe data sources that will be used to document SRD. Provide a data analytic plan that specifies how multi-level factors, intervention effects and interactions, or outcomes will be handled, as appropriate. Describe and specify the roles of collaborators. For intervention projects, describe how the intervention will directly address the cause or source of SRD. Specify how organizations, agencies, or programs where the SRD is originating from or being sustained will be involved in the project, including involvement of leadership from these organizations as well as other individuals or groups. Describe the potential of the intervention to be sustainable in the intervention settings after the project is over and scalable to other settings.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered Yes to the question Are Human Subjects Involved? on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday (https://grants.nih.gov/grants/guide/url_redirect.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues (https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy (//grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Specific to this FOA: Does this project identify clearly and provide justification for study of the targeted health disparity populations? Does the project address a documented health disparity that is clearly specified and justified? Is an appropriate justification provided for how the types of SRD to be studied constitute SRD? Is an appropriate conceptual model provided that describes hypothesized causal pathways between SRD and health outcomes? For intervention projects, is a clear and compelling rationale provided for how the intervention will directly address the cause or source of SRD? Does the intervention have potential to be sustainable in the intervention settings after the project is over and scalable to other settings?

In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Specific to this FOA: Are the roles of collaborators clearly described and appropriate? For intervention studies, is the involvement of personnel from the organizations, agencies, or programs where the SRD is originating from or being sustained specified and appropriate?

In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

In addition, for applications involving clinical trials

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Specific to this FOA: Are the data sources used to document SRD identified and appropriate? Is an appropriate data analytic plan provided that specifies how multi-level factors, intervention effects and interactions, or outcomes will be handled, as applicable?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of

procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition, for applications involving clinical trials

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Study Timeline

Specific to applications involving clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (//grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (//grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (//grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable

Renewals

Not Applicable

Revisions

Not Applicable

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Not Applicable.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: (1) Data Sharing Plan (//grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) Sharing Model Organisms (//grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) Genomic Data Sharing Plan (GDS) (//grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by NIMHD, in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria (file:///C:/Users/mckenziene/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/13V4QPZR/Research%20Draft.doc#_1._Criteria). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Appeals (//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Representation of health disparity populations and/or types of SRD addressed.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.
Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11156).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain applicable clinical trials on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov (https://register.clinicaltrials.gov/)). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see https://grants.nih.gov/policy/clinical-trials/reporting/index.htm (https://grants.nih.gov/policy/clinical-trials/reporting/index.htm)

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (//grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html) and http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (https://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html).

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov). For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (https://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. Please see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html); https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html; and https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf (https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf). 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 (https://grants.nih.gov/grants/policy/harassment.htm).
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the NIH Grants Policy Statement. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161)
A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

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 from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported 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 FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 Award Term and Conditions for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Scientific/Research Contact(s)

Jennifer Alvidrez, PhD
National Institute on Minority Health and Health Disparities (NIMHD)
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Section VIII. Other Information

Recently issued trans-NIH policy notices (//grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts (//grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?03-26-21)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

EXHIBIT C

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Friday, March 21, 2025 9:28 AM
To: Takade, Tiffany <Tiffany.Takade@ucsf.edu>
Subject: Grant Termination Notification

National Institutes of Health
Office of Extramural Research

3/21/2025

Takade, Tiffany
University Of California, San Francisco
tiffany.takade@ucsf.edu

Dear Takade, Tiffany:

Effective with the date of this letter, funding for Project Number 5R01AG077934-03 is hereby terminated pursuant to the Fiscal Year 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on 6/1/2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards.[4]" According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340.[5]" At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of this award is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S Digitally signed by Michelle G. Bulls -S

Michelle G. Bulls, on behalf of Jeni Militano (Acting), Chief Grants Management Officer, NIA
Director, Office of Policy for Extramural Research Administration
Office of Extramural Research

[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.

[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373

[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

[4] NIH Grants Policy Statement at IIA-1.

[5] *Id.* at IIA-155.

[6] NIH Grants Policy Statement at IIA-156.

[7] *See* 2 C.F.R. § 200.343 (2024).

[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)

[9] *See* 45 C.F.R. § 75.374.

[10] See 42 C.F.R. Part 50, Subpart D

[11] 11 *Id.* § 50.406(a)

[12] 12 *Id.* § 50.406(b)

EXHIBIT D

Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE ON AGING

Notice of Award
FAIN# R01AG077934
Federal Award Date
03/24/2025

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, THE
1855 FOLSOM ST STE 425
SAN FRANCISCO, CA 94103

2. Congressional District of Recipient
11

3. Payment System Identifier (ID)
1946036493A6

4. Employer Identification Number (EIN)
946036493

5. Data Universal Numbering System (DUNS)
094878337

6. Recipient's Unique Entity Identifier
KMH5K9V7S518

7. Project Director or Principal Investigator
Jesus Ramirez-Valles, PHD
Professor And Director
jesus.ramirez-valles@ucsf.edu
3129721409

8. Authorized Official
Tiffany Takade
tiffany.takade@ucsf.edu
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Federal Agency Information

9. Awarding Agency Contact Information
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10. Program Official Contact Information
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Health Science Administrator
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301-402-4156

Federal Award Information

11. Award Number
5R01AG077934-03

12. Unique Federal Award Identification Number (FAIN)
R01AG077934

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Structural Racism and Discrimination in Older Men's Health Inequities

15. Assistance Listing Number
93.866

16. Assistance Listing Program Title
Aging 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 06/01/2024 **– End Date** 03/21/2025	
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	$800,878
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$800,878
26. Project Period Start Date 09/15/2022 **– End Date** 03/21/2025	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$2,554,402

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Philip E. 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.

Notice of Award

RESEARCH
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE ON AGING

SECTION I – AWARD DATA – 5R01AG077934-03 REVISED

Principal Investigator(s):
Jesus Ramirez-Valles, PHD

Award e-mailed to: cgrasteam@ucsf.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 The Regents of the UCSF 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 On Aging of the National Institutes of Health under Award Number R01AG077934. 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,

Philip E. Smith
Grants Management Officer
NATIONAL INSTITUTE ON AGING

Additional information follows

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

Salaries and Wages	$273,776
Fringe Benefits	$105,332

Personnel Costs (Subtotal)	$379,108
Materials & Supplies	$480
Travel	$20,558
Other	$50,150
Subawards/Consortium/Contractual Costs	$69,146
Publication Costs	$2,789
Federal Direct Costs	$522,231
Federal F&A Costs	$278,647
Approved Budget	$800,878
Total Amount of Federal Funds Authorized (Federal Share)	$800,878
TOTAL FEDERAL AWARD AMOUNT	$800,878
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$0

SUMMARY TOTAL FEDERAL AWARD AMOUNT YEAR (3) (for this Document Number)	
AWARD NUMBER	**TOTAL FEDERAL AWARD AMOUNT**
5R01AG077934-03	$800,878
3R01AG077934-03S1	$101,549
TOTAL	**$902,427**

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
3	$800,878	$902,427

Fiscal Information:
Payment System Identifier: 1946036493A6
Document Number: RAG077934A
PMS Account Type: P (Subaccount)
Fiscal Year: 2024

IC	CAN	2024
AG	8470694	$800,878

NIH Administrative Data:
PCC: 2BPDIGE / **OC**: 41025 / **Released**: 03/21/2025
Award Processed: 03/24/2025 12:04:40 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01AG077934-03 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 – 5R01AG077934-03 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) R01AG077934. 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 – AG SPECIFIC AWARD CONDITIONS – 5R01AG077934-03 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.

It is the policy of NIH not to prioritize DEI: Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to

expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.. Therefore, this project is terminated. UNIVERSITY OF CALIFORNIA-SAN FRANCISCO may request funds to support patient safety and orderly closeout of the project. Funds used to support any other research activities will be disallowed and recovered. Please be advised that your organization, as part of the orderly closeout process will need to submit the necessary closeout documents (i.e., Final Research Performance Progress Report, Final Invention Statement, and the Final Federal Financial Report (FFR), as applicable) within 120 days of the end of this grant.

NIH is taking this enforcement action in accordance with 2 C.F.R. § 200.340 as implemented in NIH GPS Section 8.5.2. This revised award represents the final decision of the NIH. It shall be the final decision of the Department of Health and Human Services (HHS) unless within 30 days after receiving this decision you mail or email a written notice of appeal to Dr. Matthew Memoli. Please include a copy of this decision, your appeal justification, total amount in dispute, and any material or documentation that will support your position. Finally, the appeal must be signed by the institutional official authorized to sign award applications and must be dated no later than 30 days after the date of this notice.

Supersedes Notice of Award issued 06/12/2024. Previous terms and conditions apply:

Funding for this award has been provided by Alzheimer's Disease Initiative funds.

This award includes funds awarded for consortium activity with SAN FRANCISCO STATE UNIVERSITY. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

This award includes funds awarded for consortium activity with University of Alabama at Birmingham. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement Page 6 of 6 Version: 13 - 8/3/2022 12:59 PM | Generated on: 5/12/2023 12:19 AM is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

This award includes funds awarded for consortium activity with University of Tulane Univ. School of Public Health and Tropical Medicine. Consortiums are to be established and administered as described in the NIH Grants Policy Statement (NIH GPS). The referenced section of the NIH Grants Policy Statement is available at: http://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15 consortium_agreements.htm

SPREADSHEET SUMMARY
AWARD NUMBER: 5R01AG077934-03 REVISED

INSTITUTION: The Regents of the UCSF

Budget	Year 3
Salaries and Wages	$273,776
Fringe Benefits	$105,332
Personnel Costs (Subtotal)	$379,108
Materials & Supplies	$480
Travel	$20,558
Other	$50,150
Subawards/Consortium/Contractual Costs	$69,146
Publication Costs	$2,789
TOTAL FEDERAL DC	$522,231
TOTAL FEDERAL F&A	$278,647
TOTAL COST	$800,878

Facilities and Administrative Costs	Year 3
F&A Cost Rate 1	61.5%
F&A Cost Base 1	$453,085
F&A Costs 1	$278,647

EXHIBIT E

National Institutes of Health
Office of Extramural Research

March 12, 2025

Drexel University
Susan Elkins
DUResearch@drexel.edu

Dear Susan Elkins:

Funding for Project Number 1R01MD020284-01 is hereby terminated pursuant to the 2024 National Institutes of Health ("NIH") Grants Policy Statement,[1] and 2 C.F.R. § 200.340(a)(2). This letter constitutes a notice of termination.[2]

The 2024 Policy Statement applies to your project because NIH approved your grant on August 22, 2024, and "obligations generally should be determined by reference to the law in effect when the grants were made."[3]

The 2024 Policy Statement "includes the terms and conditions of NIH grants and cooperative agreements and is incorporated by reference in all NIH grant and cooperative agreement awards."[4] According to the Policy Statement, "NIH may … terminate the grant in whole or in part as outlined in 2 CFR Part 200.340."[5] At the time your grant was issued, 2 C.F.R. § 200.340(a)(2) permitted termination "[b]y the Federal awarding agency or pass-through entity, to the greatest extent authorized by law, if an award no longer effectuates the program goals or agency priorities."

This award no longer effectuates agency priorities. Research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry, do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately do not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination on the basis of race and other protected characteristics, which harms the health of Americans. Therefore, it is the policy of NIH not to prioritize such research programs.

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[1] https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf.
[2] 2 C.F.R. § 200.341(a); 45 C.F.R. § 75.373
[3] *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).
[4] 2024 Policy Statement at IIA-1.
[5] *Id.* at IIA-155.

Although "NIH generally will suspend (rather than immediately terminate) a grant and allow the recipient an opportunity to take appropriate corrective action before NIH makes a termination decision,"[6] no corrective action is possible here. The premise of Project Number 5 1R01MD020284-01is incompatible with agency priorities, and no modification of the project could align the project with agency priorities.

Costs resulting from financial obligations incurred after termination are not allowable.[7] Nothing in this notice excuses either NIH or you from complying with the closeout obligations imposed by 2 C.F.R. §§ 75.381-75.390. NIH will provide any information required by the Federal Funding Accountability and Transparency Act or the Office of Management and Budget's regulations to *USAspending.gov*.[8]

Administrative Appeal

You may object and provide information and documentation challenging this termination.[9] NIH has established a first-level grant appeal procedure that must be exhausted before you may file an appeal with the Departmental Appeals Board.[10]

You must submit a request for such review to Dr. Matt Memoli no later than 30 days after the written notification of the determination is received, except that if you show good cause why an extension of time should be granted, Dr. Memoli may grant an extension of time.[11]

The request for review must include a copy of the adverse determination, must identify the issue(s) in dispute, and must contain a full statement of your position with respect to such issue(s) and the pertinent facts and reasons in support of your position. In addition to the required written statement, you shall provide copies of any documents supporting your claim.[12]

Sincerely,

Michelle G. Bulls -S

Digitally signed by Michelle G. Bulls -S
Date: 2025.03.12 16:59:58 -04'00'

Michelle G. Bulls, ***on behalf*** of Priscilla Grant, Chief Grants Management Officer, NIMHD
Director, Office of Policy for Extramural Administration
Office of Extramural Research

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[6] 2024 Policy Statement at IIA-156.
[7] *See* 2 C.F.R. § 200.343 (2024).
[8] 2 C.F.R. § 200.341(c); 45 C.F.R. § 75.373(c)
[9] *See* 45 C.F.R. § 75.374.
[10] See 42 C.F.R. Part 50, Subpart D.
[11] *Id.* § 50.406(a).
[12] *Id.* § 50.406(b).