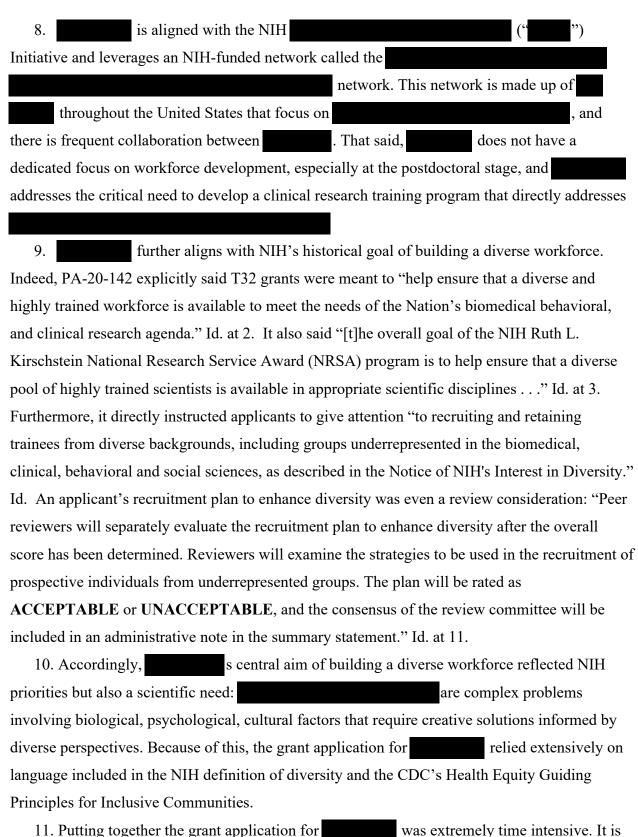
EXHIBIT 32

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN PUBLIC HEALTH ASSOCIATION, et al.,						
v. NATIONAL INSTITUTES OF HEALTH, et al.,	Case No. 1:25-cv-10787-BEM Leave to File Under Seal Granted April 24, 2025 (ECF No. 36)"					
Defendants.						
I, pur follows:	APHA MEMBER 7 suant to 28 U.S.C. § 1746, depose and say as					
1. My name is and I am a t	enured Professor at a public university in the					
Northeast. I am a physician-scientist and specialis	ze in research that focuses on					
and I also practice medicine in this are	a.					
2. I am offering this Declaration in my indiv	idual capacity and not on behalf of my					
employer.						
3. I have been a doctor since 2005. I did my residency in						
fellowships and remain board certified in	and and am board					
and Callin	My PhD is in					

from a school of Public Health. I have published 150 peer-

also more vulnerable to developing
, among other means. Additionally, diagnoses like
, and are associated with
Therefore,
highly complex.
Historically, the scientific research and clinical medicine have been
, but in practice if you don't , including how
these , you are unlikely to . I became
passionate about these issues because I saw them so often clinically.
is so common in the United States that almost every American has experience
these challenges personally or in someone they love. I have dedicated my career to addressing
the critical problem of treating
5. I am a member of APHA and pay \$230 in annual dues.
6. I am the Principal Investigator for a T32 grant awarded by the National Institute of
Health ("NIH"). As described in NIH PA-20-142, T32 grants are Ruth L. Kirschstein National
Research Service Awards (Kirschstein-NRSA) and are issued by NIH to enhance pre- and post-
doctoral research training to ensure that a diverse pool of scientists are available in various
scientific disciplines to address biomedical, behavioral, and clinical research needs. The grant
award number is . A true and correct copy of the expired PA-20-142 is
attached hereto as Exhibit A.
7. The grant I was awarded funds a training program called
. This program provides
personalized and rigorous training to postdoctoral fellows who plan careers at
Fellows are mentored on a longitudinal research project by
experts in the field, participate in a rigorous, comprehensive curriculum based on core clinical
and translational science competencies, attend annual retreats and in-person conferences, and
participate in short-term research experiences.
allowing the program to reduce barriers that would normally be presented by requiring fellows to
research hub. prioritizes recruitment of fellows who will contribute to the
diversification of the workforce.



to developing the program plan, several partnerships with scientists who would serve as mentors were needed to lay the foundation for a successful program. This involved hours of networking, outreach, and conversations to explain the purpose and design of . The application also required letters of recommendations, which required identifying appropriate people, making the request, and tracking the status of the letters to ensure they were submitted on time. I spent about a 6-month period intensively writing the application, and in the end the application package was over 550 pages. Despite enthusiasm for key features of the proposal, the first application I submitted was not funded because the study section wanted further clarification on would occur and proffered constructive criticism on the program plan. Thankfully, I was given the opportunity to resubmit, and I was encouraged to do so by my NIH program officer. Reworking the application was an added lift, and I spent hundreds of hours revising for resubmission.

- 12. On June 14, 2024, NIH issued a Notice of Award ("NOA") for a five-year project period with a cumulative total award amount of running Funding for this whole five-year period was contingent upon submission of annual noncompetitive renewals to ensure program goals were being met. A true and correct copy of that NOA is attached hereto as Exhibit B.
- 13. I launched immediately upon receiving the NOA and have been working on operationalizing the training program ever since. Most of the activities in our first year have been geared towards start-up. For example, we made a website, created an online application system for interested fellows, designed an evaluation process for reviewing applicants, and advertised among professional societies. Initially, we recruited two fellows, however one decided not to become a researcher because of concerns about the federal funding climate in the current administration. Since then, we've recruited two additional fellows who were to begin the training program in July, bringing the total number of fellows to three. Despite the stated goal of diversifying the number of researchers studying , race was not a criteria for selection and of the four fellows recruited, all have been white.
- 14. The one fellow who is in their first year of the program has had a fantastic start. The training they have received has been extensive and includes a three-day writing retreat, a conference where they had the opportunity to interact with several high-level NIH staff and

scientists from around the United States, and coursework. The training program is structured so that the fellows can participate in ongoing research projects, as well as launch their own new research projects with close mentorship. So far, the current fellow has supported ongoing research that is being conducted at my university, and they have just started thinking about their focused research project. They have had several brainstorming sessions with various mentors and are actively thinking about what direction they want to take their research scientifically. When the grant was terminated, they were in the process of writing their "Aims" page, which describes a project's rationale, objectives, hypotheses, and important elements of the research approach.

15. However, on March 21, 2025, I received a termination letter from the NIH notifying me that my award was terminated. The letter said:

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.

A true and correct copy of the termination letter is attached hereto as Exhibit C.

16. On March 22, 2025, a revised NOA was posted online with a revised project period end date of March 21, 2025. The revised NOA said,

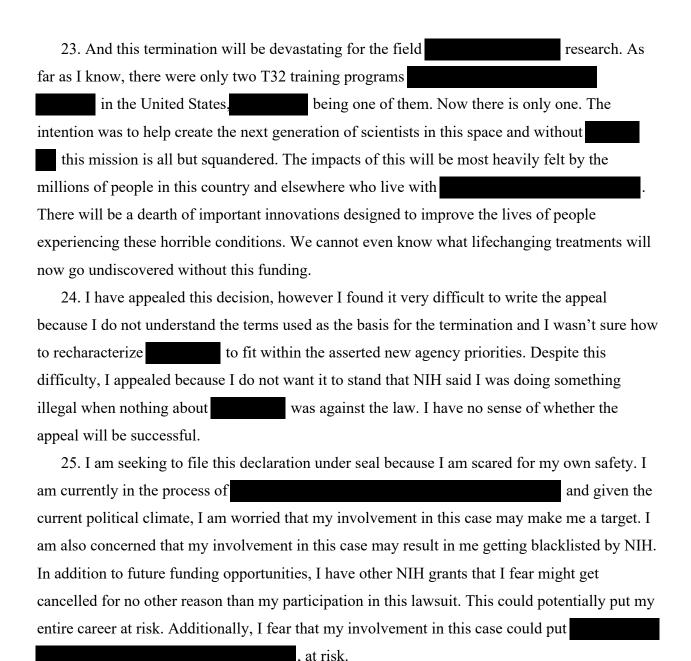
It is the policy of NIH not to further prioritize research programs based primarily on artificial and non-scientific categories, including amorphous equity objectives, are antithetical to the scientific inquiry [sic], do nothing to expand our knowledge of living systems, provide low returns on investment, and ultimately to not enhance health, lengthen life, or reduce illness. Worse, so-called diversity, equity, and inclusion ("DEI") studies are often used to support unlawful discrimination since race and other protected characteristics, which harms the health of Americans [sic]. Therefore, this project is terminated.

A true and correct copy of the revised NOA is attached hereto as Exhibit D.

- 17. Nothing in the termination letter or the revised NOA was specific to and I was not provided with an individualized explanation as to why the grant was cancelled.
- 18. Also, neither the termination letter nor the revised NOA defined the terms within it, and I don't understand what is meant by "DEI" in this context. On the face of my grant application, I

did talk about diversifying the workforce, but I am left to guess as to what aspect of diversifying the workforce does not fit NIH's new priorities. The program does not preferentially admit people based on any demographic criteria. As mentioned before, all four fellows who have been selected happened to have been white; they were selected because they were the strongest candidates within the pool of applicants. Furthermore, some of the applicants who were not selected met the definition of diversity that NIH has historically used. They were not selected because they were either underqualified or their application materials did not demonstrate that their skillset was strong enough to be successful in the program.

- 19. The termination letter and the NOA also say is "unscientific" which is program is grounded in research on curriculum design and several untrue. The experts in fields such as and clinical research were engaged in developing the is pedagogically sound. Likewise, the research projects that fellows program. support and design as part of the mentorship aspect of the program are developed with key scientific principles at the forefront. The purpose of the program is to ensure early career researchers have the tools necessary to build strong careers in the biomedical field; it would be counterintuitive and counterproductive to train them to practice science in an "unscientific" manner. As such, it is unclear to me what "unscientific" means in the context of
- 20. This termination is shocking because over the course of the 10 years I have been applying for NIH funding, I have been awarded seven grants. Before January 20, 2025, I have never had an NIH grant terminated, nor am I aware of any other NIH grants among colleagues that had been terminated. A grant termination was something I had never even given much thought to as a possibility.
- 21. The termination of the grant has profound consequences. Most immediately, the one fellow that is in the middle of the program has had all their funding terminated. Beyond the financial hardship they are suddenly thrust into, in a field where NIH funding is critical to longer term career growth and finding institutions to support your research, this is devastating.
- 22. The personal consequences to this termination are also difficult to swallow. I have spent years designing this program, and bringing it to life was a career highlight for me. I also have no idea what the longer-term consequences will be to having had a grant terminated; I don't know if it will make future funding opportunities with NIH more difficult to compete for, or if being marked as having done something "unlawful" will be a scarlet letter I'm forced to carry.



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

Executed this 22day of April, 2025.



EXHIBIT A

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This notice has expired. Check the NIH Guide (https://grants.nih.gov/funding/searchquide/) for active opportunities and notices.

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 Cancer Institute (NCI_(http://www.nci.nih.gov/))

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

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

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

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

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

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

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

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

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

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

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

National Institute on Drug Abuse (NIDA (http://www.nida.nih.gov/))

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

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

National Institute of Mental Health (NIMH (http://www.nimh.nih.gov/))

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

 $National\ Center\ for\ Complementary\ and\ Integrative\ Health\ (\underline{NCCIH\ (\underline{http://www.nccam.nih.gov/})})$

Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP (http://dpcpsi.nih.gov/orip/index.aspx))

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/nrsa-institutional-research-training-grant-parent-t32.html) website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

Funding Opportunity Title

Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32)

Activity Code

T32 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=t32&Search.x=0&Search_Type=Activity). Institutional National Research Service Award (NRSA)

Announcement Type

Reissue of PA-18-403 (https://grants.nih.gov/grants/guide/pa-files/pa-18-403.html) for due dates on or after May 25, 2020

Related Notices

See Notices of Special Interest (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=32974), associated with this funding opportunity

- January 26, 2023 This PA has been reissued as PA-23-048 (//grants.nih.gov/grants/guide/pa-files/PA-23-048.html)
- NOT-OD-23-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-012.html) Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 New Grant Application Instructions Now Available
- NOT-OD-22-190 (/grants/guide/notice-files/NOT-OD-22-190.html) Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022
- February 04, 2022 Notice of Change in Interest Areas Relevant to the NIDDK for PA-20-142 Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32). See Notice NOT-DK-22-012 (https://grants.nih.gov/grants/guide/notice-files/NOT-DK-22-012.html).
- December 7, 2021 Notice of Additional Receipt Cycle for T32 Grant Applications. See Notice NOT-DA-21-088 (//grants.nih.gov/grants/guide/notice-files/NOT-DA-21-088.html)
- October 28, 2021 Reminder: FORMS-G Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2022 New Grant Application Instructions Now Available. See Notice NOT-OD-22-018 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-018.html).
- September 13, 2021 Updates to the Non-Discrimination Legal Requirements for NIH Recipients. See Notice NOT-OD-21-181 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-181.html).
- August 5, 2021 New NIH "FORMS-G" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2022. See Notice NOT-OD-21-169 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-169.html)
- August 5, 2021 Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements. See Notice NOT-OD-21-170 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-170.html)
- April 20, 2021 Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel. See Notice NOT-OD-21-109 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-109.html)
- October 21, 2021 Notice of High Priority Research Areas for NIDA T32 Training Grants. See Notice NOT-DA-21-087 (//grants.nih.gov/grants/guide/notice-files/NOT-DA-21-087.html)
- May 11, 2020 NIH Late Application Policy for Institutional Training Grants to PA-20-142 and PA-20-162 Due to Public Health Emergency for United States Coronavirus Disease 2019 (COVID-19). See Notice NOT-OD-20-105 (//grants.nih.gov/grants/guide/notice-files/NOT-OD-20-105.html).
- April 16, 2020 Notice of Change in Interest Areas Relevant to the NIDDK Division of Kidney, Urologic and Hematologic Disorders for PA-20-142, Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32). See Notice NOT-DK-20-023 (/grants/guide/notice-files/NOT-DK-20-023.html).

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PA-20-142

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.398; 93.867; 93.172; 93.837; 93.840; 93.838; 93.839; 93.866; 93.273; 93.855; 93.846; 93.286; 93.286; 93.279; 93.173; 93.113; 93.859; 93.242; 93.361; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.879; 93.213; 93.2

Funding Opportunity Purpose

The National Institutes of Health (NIH) will award Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants (T32) to eligible, domestic institutions to enhance predoctoral and postdoctoral research training, including short-term research training, and help ensure that a diverse and highly trained workforce is available to meet the needs of the Nation's biomedical, behavioral, and clinical research agenda. Research training programs are expected to incorporate didactic, research, and career development elements to prepare trainees for careers that will have a significant impact on the health-related research needs of the Nation. Programs proposing only short-term predoctoral research training should not apply to this announcement, but rather to the Kirschstein-NRSA Short-Term Institutional Research Training Grant Program (T35) exclusively reserved for predoctoral, short-term research training.

This Funding Opportunity Announcement (FOA) does not allow appointed Trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor.

Key Dates

Posted Date

March 20, 2020

Open Date (Earliest Submission Date)

April 25, 2020

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

 $\underline{Standard\ dates\ (//grants.nih.gov/grants/guide/url_redirect.htm?id=11111)}\ apply$

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.

AIDS Application Due Date(s)

 $\underline{Standard\ AIDS\ dates\ (\textit{//grants.nih.gov/grants/guide/url_redirect.htm?id=11112})\ apply}$

All applications are due by 5:00 PM local time of applicant organization. All <u>types of AIDS and AIDS-related applications</u> 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.

Scientific Merit Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) apply

Advisory Council Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) apply

Earliest Start Date

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) apply

Expiration Date

May 8, 2023

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Training (T) 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 the 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.

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Section V. Application Review Information

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Section VII. Agency Contacts

Section VIII. Other Information

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. In order to accomplish this goal, NRSA training programs are designed to train individuals to conduct research and to prepare for research careers. More information about NRSA programs may be found at the Ruth L. Kirschstein National Research Service Award (NRSA) ((((grants.nih.gov/grants/guide/url_redirect.htm?id=41125)) website.

Purpose and Background Information

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Research training activities can be in basic biomedical or clinical sciences, in behavioral or social sciences, in health services research, or in any other discipline relevant to the NIH mission. Each program should provide high-quality research training, mentored research experiences, including training in appropriate methods, technologies, relevant quantitative/computational approaches, rigorous experimental design, and interpretation of data, and professional development skills such as communication, management, leadership, and teamwork.

Institutional NRSA programs allow the Training Program Director/Principal Investigator (Training PD/PI) to select the trainees and develop a program of coursework, mentored research experiences, and technical and professional skills development appropriate for the selected trainees.

The grant offsets the cost of stipends, tuition and fees, and training related expenses, including health insurance, for the appointed trainees in accordance with the approved NIH support levels.

Program Objective

The objective of the Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (T32) program is to develop and/or enhance research training opportunities for individuals interested in careers in biomedical, behavioral and clinical research that are relevant to the NIH mission. As the scientific enterprise has expanded, there is greater variation in the backgrounds of people participating, approaches taken to investigate research questions, and the range of the careers in the biomedical research workforce that doctoral recipients are pursuing. There is also increasing recognition of the need to enhance reproducibility of biomedical research results through scientific rigor and transparency.

Proposed training programs are expected to help trainees develop the following:

- The skills to independently acquire the knowledge needed to advance their chosen field;
- The ability to think critically, independently, and to identify important research questions and approaches that push forward the boundaries of their areas of study;
- An understanding of the health-related sciences and the relationship of their research training to health and disease.
- A strong foundation in scientific reasoning, rigorous and reproducible research design, experimental methods, quantitative/computational approaches, and data analysis and interpretation;
- $\bullet \ \ \mbox{A commitment to approaching and conducting research responsibly and with integrity;}$
- Experience initiating and conducting research, and interpreting research findings with increasing self-direction, as well as presenting and publishing their research findings;
- · Opportunities to interact with members of the broader scientific community at appropriate scientific meetings and workshops;
- The ability to work effectively with colleagues from a variety of backgrounds and scientific disciplines to contribute to inclusive and supportive scientific research environments;
- The knowledge, professional skills, and experiences required to identify and transition into careers that sustain biomedical research in areas that are relevant to the NIH mission.

The proposed institutional research training program may complement other ongoing research training and career development programs at the applicant institution, but must be clearly distinct from related programs currently receiving Federal support.

Program Considerations

The duration of training, the transition of trainees to individual support mechanisms, and their transition to the next career stage are important considerations in institutional training programs. Training PDs/Pls should limit appointments to individuals who are committed to a research career and who plan to remain in training for no less than two years, whether that support comes from a training grant or some combination of NRSA and non-NRSA programs. Training PDs/Pls should encourage and make available appropriate skills training so that trainees are prepared to apply for subsequent independent support for their training, career development or research program (e.g., an individual fellowship award, mentored career development award, or research project grant), as appropriate for their career stage. In addition, past studies have shown that health professional trainees who train in programs with postdoctoral researchers who have intensive research backgrounds are more likely to apply for and receive subsequent research grant support. Programs that emphasize research training for individuals with the MD or other health-professional degrees are therefore encouraged to develop interactions with basic science departments and include trainees with research doctorates when this approach is consistent with the goals of the proposed training program.

Biomedical research and the resulting scientific knowledge are increasingly complex and multidisciplinary in nature. Training PDs/Pls are encouraged to develop institutional training programs that will provide trainees with education and experience in a diversity of rigorous and reproducible scientific approaches, systems for study, tools and technologies. Consideration of team-based research approaches may also be warranted depending upon the goals of the proposed training program. Funded training programs must ensure that trainees have a solid foundation in methods to enhance data reproducibility through rigor and transparency.

Within the framework of the NRSA program's longstanding commitment to excellence, attention should be given to recruiting and retaining trainees from diverse backgrounds, including groups underrepresented in the biomedical, clinical, behavioral and social sciences, as described in the Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

Institutional commitment and support for the proposed training program are important elements of the application. The research training program may complement and synergize with other ongoing federally-supported research training programs at the applicant institution (e.g., in the development of skills needed for careers in the research workforce that are not discipline-specific).

The career outcomes of individuals supported by NRSA training programs include both research-intensive careers in academia and industry and research-related careers in various sectors, e.g., academic institutions, government agencies, for-profit businesses, and private foundations. Training programs should make available structured, career development advising and learning

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opportunities (e.g., workshops, discussions, Individual Development Plans). Through such opportunities, trainees are expected to obtain a working knowledge of various potential career paths that would make strong use of the knowledge and skills gained during research training and the steps required to transition successfully to the next stage of their chosen career.

Institutional research training grants must be used to support a program of full-time research training. Within the full-time training period, research trainines who are also training as clinicians must devote their time to the proposed research training and confine clinical duties to those that are an integral part of the research training experience or can be conducted in the allowable additional 25% of their time (e.g., 10 hours per week) that may be devoted to clinical employment. The program may not be used to support studies leading to the MD, DDS, or other clinical, health-professional degrees except when those studies are part of a formal combined research degree program, such as the MD/PhD. Similarly, trainees may not accept NRSA support for clinical training that is part of residency training leading to clinical certification in a medical or dental specialty or subspecialty. It is permissible and encouraged, however, for clinicians to engage in NRSA-supported, full-time postdoctoral research training even when that experience is creditable toward certification by a clinical specialty or subspecialty board.

Short-term training is not intended, and may not be used, to support activities that would ordinarily be part of a research degree program, nor for any undergraduate-level training. Short-term positions should be requested at the time of application, as described in the NIH Grants Policy Statement (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_11/11_1_general.htm).

Research training programs solely for short-term research training should not apply to this announcement, but rather the T35 NRSA FOA, which can be found in the NIH Training Kiosk. (https://researchtraining.nih.gov/programs/training-grants)

This Funding Opportunity Announcement (FOA) does not allow appointed Trainees to lead an independent clinical trial but does allow them to obtain research experience in a clinical trial led by a mentor or co-mentor. NIH strongly supports training towards a career in clinically relevant research and so gaining experience in clinical trials under the guidance of a mentor or co-mentor is encouraged.

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this FOA, prospective applicants MUST consult the <u>Table of IC-Specific Information</u>, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/nrsa-institutional-research-training-grant-parent-t32.html), to make sure that their application is appropriate for the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

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

Renewal

Resubmission

Revision

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?

Not Allowed: Only accepting applications that do not propose clinical trials

Note: Appointed Trainees are permitted to obtain research experience in a clinical trial led by a mentor or co-mentor.

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

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets are not limited, but need to reflect the actual needs of the proposed project.

Grantees are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (NIH Grants Policy Statement - Institutional Research Training Grants (///grants.nih.gov/grants/guide/url_redirect.htm?id=41126)). Funds may be used only for those expenses that are directly related to and necessary for the research training and must be expended in conformance with OMB Cost Principles, the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.

Award Project Period

Awards for T32 institutional NRSA research training grants may be for project periods up to five years in duration and are renewable.

Other Award Budget Information

Stipends, Tuition, and Fees

Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.

NIH will contribute to the combined cost of tuition and fees at the rate in place at the time of award.

Stipend levels, as well as funding amounts for tuition and fees and the institutional allowance are announced annually in the NIH Guide for Grants and Contracts, and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Trainee Travel

Trainee travel to attend scientific meetings and workshops that the institution determines to be necessary for the individual's research training experience is an allowable trainee expense for predoctoral and postdoctoral trainees.

The amount of funds provided for trainee travel may vary by NIH Institute or Center; applicants are encouraged to consult the <u>Table of IC-Specific Information</u>, <u>Requirements and Staff Contacts</u> (https://grants.nih.gov/grants/guide/contacts/parent-T32-institutional-research.html) for further information.

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For short-term trainees, the NIH awarding component may provide grant funds to cover the costs of trainee travel, including attendance at scientific meetings, which the organization determines is necessary to the individual's training. Trainees must be appointed to the training grant at the time of the actual travel for this to be an allowable cost.

Training Related Expenses

NIH will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, equipment, research supplies, and faculty/staff travel directly related to the research training program. The most recent levels of training related expenses are announced annually in the NIH Guide for Grants and Contracts, and are also posted on the Ruth L. Kirschstein National Research Service Award (NRSA) webpage (https://researchtraining.nih.gov/resources/policy-notices).

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees, consortium costs in excess of \$25,000, and expenditures for equipment), rather than on the basis of a negotiated rate agreement.

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

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)

Governments

- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations

The sponsoring institution must assure support for the proposed program. Appropriate institutional commitment to the program includes the provision of adequate staff, facilities, and educational resources that can contribute to the planned program.

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.

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.

- <u>Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform)</u>. 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.
- <u>eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u> 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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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 training program as the Training Program Director/Principal Investigator (Training PD/PI) 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.

The PD/PI should be an established investigator in the scientific area in which the application is focused and capable of providing both administrative and scientific leadership to the development and implementation of the proposed program. The PD/PI will be responsible for the selection and appointment of trainees to the approved research training program, and for the overall direction, management, administration, and evaluation of the program. The PD/PI will be expected to monitor and assess the program and submit all documents and reports as required. The PD/PI has responsibility for the day to day administration of the program and is responsible for appointing members of the Advisory Committee (when applicable), using their recommendations to determine the appropriate allotment of funds.

The participation of multiple PDs/Pls is encouraged, particularly when each brings a unique perspective and skill set that will enhance training. For institutions/organizations proposing multiple PDs/Pls, visit the Multiple Program Director/Principal Investigator Policy (//grants.nih.gov/grants/multi_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the SF 424 (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 programmatically 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)).

Preceptors/Mentors

Program faculty should have strong records as researchers, including recent publications and successful competition for research support in the area of the proposed research training program. Program faculty should also have a record of research training and mentoring, including successful, former trainees who have established productive careers relevant to the NIH mission. Programs are encouraged to build a diverse team of preceptors/mentors that includes, for example, faculty from underrepresented groups, women, and faculty at different career stages (i.e., junior as well as senior faculty). (See the Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).)

Trainees

The individuals to be trained must be citizens or noncitizen nationals of the United States or have been lawfully admitted for permanent residence at the time of appointment. Additional details on citizenship, training period, and aggregate duration of support are available in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=61131).

All trainees are required to pursue their research training full time, normally defined as 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Appointments are normally made in 12-month increments, and no trainee may be appointed for less than 9 months during the initial period of appointment, except with prior approval of the awarding unit, or when trainees are appointed to approved, short-term training positions.

Predoctoral Trainees

Predoctoral trainees must be enrolled in a program leading to a PhD or in an equivalent research doctoral degree program. Health-professional students who wish to interrupt their studies for a year or more to engage in full-time research training before completing their formal training programs, are also eligible.

Postdoctoral Trainees

Postdoctoral trainees must have received, as of the beginning date of the NRSA appointment, a PhD, MD, DDS, or comparable doctoral degree from an accredited domestic or foreign institution. Comparable doctoral degrees include, but are not limited to, the following: DMD, DC, DO, DVM., OD, DPM, ScD, EngD, DrPH, DNSc, DPT, PharmD, ND (Doctor of Naturopathy), DSW, PsyD, as well as a doctoral degree in nursing research. Documentation by an authorized official of the degree-granting institution certifying all degree requirements have been met prior to the beginning date of the training appointment is acceptable. Individuals in postgraduate clinical training, who wish to interrupt their studies for a year or more to engage in full-time research training before completing their formal training programs, are also eligible.

Short-Term Trainees

If requested, short-term trainees must be medical students, dental students, students in other health-professional programs, or graduate students in the physical or quantitative sciences. To be eligible for short-term, predoctoral research training positions students must be enrolled, in good standing, and must have completed at least one quarter or semester in a program leading to a clinical doctorate or a doctorate in a physical or quantitative science such as physics, mathematics, or engineering before participating in the training program. Individuals already matriculated in a formal research degree program in the health sciences, or those holding a research doctorate, a master's degree, or a combined health-professional/research doctorate normally are not eligible for short-term training positions. Within schools of pharmacy, only individuals who are candidates for the PharmD degree are eligible for short-term, research training positions.

Trainees selected for short-term training are required to pursue research training for 2-3 months on a full-time basis devoting at least 40 hours per week, or as specified by the sponsoring institution in accordance with its own policies. Within the full-time training period, trainees must devote their time to the proposed research training and must confine clinical duties to those that are an integral part of the research training experience. Successful trainees may be appointed for additional periods of short-term training or, if appropriate to their career level, they should be encouraged to apply for an extended period of full-time training supported by an NRSA training grant or fellowship, or an NIH career development award.

Short-term training is not intended, and may not be used, to support activities that would ordinarily be part of a research degree program, nor for any undergraduate-level training.

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 Training (T) Instructions in the <u>SF424_(R&R)Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000)</u> 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.

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Page Limitations

All page limitations described in the SF424 (R&R) Application Guide and the <u>Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=61134)</u> 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

Follow all instructions provided in the SF424 (R&R) Application Guide.

SF424(R&R) Project/Performance Site Locations

Follow all instructions provided in the SF424 (R&R) Application.

SF424 (R&R) Other Project Information

Follow all instructions provided in the SF424 (R&R) Application, with the following additional modifications:

Project Summary/Abstract: In the abstract, provide an overview of the program. Include the objectives, rationale, and design of the research training program. Highlight key activities in the training plan that promote skills development and successful transitions into careers in the biomedical research workforce. Indicate the planned duration of appointments, the projected number of trainees, including their levels (i.e., predoctoral, postdoctoral, short-term), and intended trainee outcomes.

Other Attachments. An Advisory Committee is not a required component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of such a committee to monitor progress of the training program. The composition, roles, responsibilities, and desired expertise of committee members, frequency of committee meetings, and other relevant information should be included. Describe how the Advisory Committee will evaluate the overall effectiveness of the program. Proposed Advisory Committee members should be named in the application if they have been invited to participate at the time the application is submitted. Renewal applications with Advisory Committees should include the names of all committee members during the past project period. Name your file Advisory_Committee.pdf.

The filename provided for each Other Attachment will be the name used for the bookmark in the electronic application in eRA Commons.

SF424(R&R) Senior/Key Person Profile Expanded

Follow all instructions provided in the SF424 (R&R) Application. In addition:

Where applicable, personal statements should highlight prior experience with training and mentoring, promoting an inclusive and supportive scientific environment, and providing instruction in scientific rigor.

PHS 398 Cover Page Supplement

Follow all instructions provided in the SF424 (R&R) Application.

PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the SF424 (R&R) Application Guide.

Training Budget

Follow all instructions provided in the SF424 (R&R) Application Guide, with the following additional modifications:

• Include all personnel other than the Training PD(s)/PI(s) in the Other Personnel section, including clerical and administrative staff.

PHS 398 Research Training Program Plan

The PHS 398 Research Training Program Plan Form is comprised of the following sections:

- Training Program Section
- Faculty, Trainees, and Training Record
- · Other Training Program Sections
- Appendix Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the FOA specifically instructs applicants to do so.

Follow all instructions provided in the SF424 (R&R) Application Guide with the following additional modifications:

Particular attention must be given to the required <u>Training Data Tables</u> (//grants.nih.gov/grants/guide/url_redirect.htm?id=61169). Applicants should summarize, in the body of the application, key data from the tables that highlight the characteristics of the applicant pool, faculty mentors, the educational and career outcomes of participants, and other factors that contribute to the overall environment of the program.

Training Program

Program Plan

Program Administration

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PDs/PIs) will promote the success of the trainees and training program. Multiple PDs/PIs are encouraged, particularly when each brings a unique perspective and skill set that will enhance training, as described in the <u>Eligible Individuals (https://grants.nih.gov/grants/guide/pa-files/par-17-341.html#_Eligible_Individuals_(Program)</u> section. The application should expand on the information in the biosketch(es) to address how the PD/PI or PD/PI team has:

- The scientific expertise, including a record of rigorous research, as well as the administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program.
- The time to commit sufficient effort to ensure the program's success, given other professional obligations (applicants should indicate the program director's percent effort in the proposed program).
- . The planned strategy and administrative structure to oversee and monitor the program and ensure appropriate and timely trainee progress.

Program Faculty

In addition to the information specified in the Application Guide, describe:

- · How the program faculty are trained to ensure the use of training and mentoring practices that promote the development of trainees from all backgrounds.
- How the program has a diverse team of program faculty, including faculty at a range of career stages and from a variety of scientific backgrounds.
- How the program faculty will provide supportive mentoring.
- · In programs where trainees will have multiple mentors, how the faculty will effectively coordinate training and mentorship responsibilities.

Proposed Training

In addition to the information specified in the Application Guide, describe:

How trainees will be instructed on data science principles that are relevant to their areas of research. Examples include statistics, computational science, bioinformatics, data sharing and access, data management, data security, and data privacy in human subjects research.

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- Program activities intended to develop the working knowledge needed for trainees to select among and prepare for the next step in the varied research career options available in the biomedical workforce. For example, programs should provide all trainees with instruction and training in oral and written presentations and in skills needed to apply for individual fellowship or other grant support. All postdoctoral trainees should also be provided with instruction in laboratory and project management.
- For programs that propose short-term training, any didactic training must be well structured and appropriately justified for the duration of the training experience. Short-term trainees must have the opportunity to carry out supervised biomedical, behavioral, or clinical research with the primary objective of developing or enhancing their research skills and knowledge in preparation for a health-related research career.
- · For renewal applications, highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge or educational practices.

Training Program Evaluation

In addition to the information specified in the Application Guide, describe:

- · How the proposed evaluation will assess the extent to which trainees find the training program to be inclusive and supportive of trainee development.
- · The program's procedures for responding to program evaluation findings.

Trainee Candidates

Through the narrative and summaries of the information presented in the <u>Training Data Tables (https://grants.nih.gov/grants/forms/data-tables.htm</u>) and the attachments, the application should::

- Provide a strong justification for the number of requested trainee positions.
- Expand upon the recruitment plan to enhance diversity and explain how it will identify and recruit a diverse group of candidates from a wide variety of institution types and backgrounds as described in NIH's Notice of Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

Institutional Environment and Commitment to Training

The application should describe how the level of institutional and departmental commitment to research and training excellence will promote the success of the trainees and training program. For institutions that have multiple NIH-funded training grants, the letter should also explain what distinguishes the proposed program from existing ones at the same training level, how the programs will synergize and share resources when appropriate, and how the training faculty, pool of potential trainees, and resources are sufficiently robust to support the proposed program in addition to existing ones. A letter providing assurances of the institutional commitment should be provided in the Letters of Support section of the application. Detailed instructions on the types of support are found below in the Letters of Support section of the FOA.

Recruitment Plan to Enhance Diversity

The applicant must provide a recruitment plan to enhance diversity. Include outreach strategies and activities designed to recruit prospective trainees from diverse backgrounds, e.g. those from groups described in the Notice of NIH's Interest in Diversity (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html). Describe the specific efforts to be undertaken by the training program and how these might coordinate with trainee recruitment efforts of the medical school(s), graduate school(s), and/or the institution(s). Training grant program faculty are expected to be actively involved in recruitment efforts.

Plan for Instruction in the Responsible Conduct of Research

Individuals are required to comply with the instructions for Plan for Instruction in the Responsible Conduct of Research as provided in the SF424 (R&R) Application Guide. This includes the following: Describe how the Responsible Conduct of Research (RCR) components are well integrated into the overall training plan, including instruction at multiple stages of trainee careers and in a variety of formats and contexts. Where applicable, explain how instruction in RCR synergizes with elements of the curriculum designed to enhance trainees abilities to conduct rigorous and reproducible research. Describe how all participating faculty will reiterate and augment key elements of responsible conduct when trainees are performing mentored research projects.

Plan for Instruction in Methods for Enhancing Reproducibility

Individuals are required to comply with the instructions for the Plan for Instruction in Methods for Enhancing Reproducibility as provided in the SF424 (R&R) Application Guide, which include a description of how the program will provide training in scientific reasoning, rigorous research design, relevant experimental methods, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, quantitative approaches, and data analysis and interpretation, as appropriate to the field of study and the level and prior preparation of the trainees

Progress Report for Renewal Applications

For renewal applications, highlight how the training program has evolved in response to changes in relevant scientific and technical knowledge, educational practices, and evaluation of the training program.

Faculty, Trainees, And Training Record Section

Participating Faculty Biosketches

Program faculty are encouraged to provide a personal statement that describes their prior experience with:

- Training, mentoring, and promoting an inclusive and supportive scientific environment.
- · Providing training in rigorous and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.
- · Aiding and supporting trainees in identifying and transitioning into careers in the biomedical research workforce that are consistent with trainees' skills, interests, and values.

Letters of Support

Institutional Support Letter. The application must include a signed letter on institutional letterhead from a President, Provost, Dean or key institutional leader that describes the activities and resources provided by the institution that will ensure the success of the planned training program and its trainees (not to exceed 10 pages). Institutional commitment to the following areas should be described in the letter:

- · Developing and promoting a culture in which the highest standards of scientific rigor, reproducibility and responsible conduct are advanced.
- Ensuring sufficient resources and support will be available to the training faculty and trainees, for example, to permit early stage faculty to participate in training and trainees to continue in training if their mentors experience a hiatus in research funding.
- · Supporting core facilities and technology resources and describing how they can be used to enhance training
- Providing adequate staff, facilities, and educational resources to the planned program.
- Supporting the PDs/PIs and other key staff associated with the planned training program; ensuring faculty have protected time available to devote to mentoring, training and research; considering activities integral to excellent training (such as teaching and mentorship) in tenure and promotion decisions.
- Promoting diversity and inclusion at all levels of the research training environment (trainees, staff, faculty, and leadership); ensuring the research facilities and laboratory practices promote the safety of trainees; ensuring the research facilities are accessible to trainees with disabilities; ensuring a positive, supportive and inclusive research and training environment for individuals from all backgrounds.
- Ensuring that proper policies, procedures, and oversight are in place to prevent discriminatory harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH (NOT-OD-19-056 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-056.html)) or OCR (e.g., see NOT-OD-15-152 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-152.html)).

- · Providing the types and levels of support necessary for trainees to successfully complete the research training program.
- · Supporting evaluation of the training program and procedures for responding to evaluation findings.

All information related to institutional support, as defined above, must be included within the 10-page limit of this letter.

Appendix

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide; any instructions provided here are in addition to the SF424 (R&R) Application Guide instructions.

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.htm? id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to <u>Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128)</u> (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 <u>eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123)</u>, 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). The National Research Service Award (NRSA) policies (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171) apply to this program. An NRSA appointment may not be held concurrently with another Federally sponsored fellowship, traineeship, or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=11143). Note, however, that pre-award costs are not allowable charges for stipends or tuition/fees on institutional training grants because these costs may not be charged to the grant until a trainee has actually been appointed and the appropriate paperwork submitted to the NIH awarding component. Any additional costs associated with the decision to allow research elective credit for short-term research training are not allowable charges on an institutional training grant.

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)/Pl(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/Pl Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

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 (SAM). 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, NIH. Applications that are incomplete or non-compliant will not be reviewed.

Requests of \$500,000 or more for direct costs in any year

Applicants requesting \$500,000 or more in direct costs in any year (excluding consortium F&A) must contact a <u>Scientific/ Research Contact</u> at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request \$500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide. Applicants are advised to refer to <u>Agency Contacts</u> for exceptions.

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

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.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will produce a diverse pool of well-trained scientists with the skills necessary to conduct rigorous and reproducible research. The overall impact score should reflect reviewers assessment of the likelihood that the proposed training program will prepare individuals for successful, productive scientific research careers and thereby exert a sustained 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 the merit of the training program, and give a separate score for each. When applicable, the reviewers will consider relevant questions in the context of proposed short-term training. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Training Program and Environment

- · Are the research facilities and research environment conducive to preparing trainees for successful careers as biomedical research scientists?
- · Are the objectives, design and direction of the proposed research training program likely to ensure effective training?
- Does the application describe an effective strategy and administrative structure to oversee and monitor the program to ensure appropriate and timely trainee progress?
- Do the courses, where relevant, and research experiences provide opportunities for trainees to acquire skill and expertise in transparent, rigorous and reproducible research methodologies and tools applicable to the goals of the training program, including relevant areas of data science?
- Does the program provide appropriate inter- or multidisciplinary research training opportunities?
- Is the proposed training program likely to ensure trainees will be well prepared for research-intensive and research-related careers?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to ensure the success of the program?
- Is it clear how the proposed training program is distinguished from other externally funded training programs at the institution?

Training Program Director(s)/Principal Investigator(s) (PD(s)/PI(s))

- Does the PD/PI, and where relevant, multiple PDs/PIs, have the scientific expertise, including a record of rigorous research, administrative, and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Does the PD/PI, and where relevant, multiple PD/PIs, plan to commit sufficient effort to ensure the program's success?
- · For applications designating multiple PDs/PIs:
 - Is a strong justification provided that the multiple PD/PI leadership approach will benefit the training program and the trainees?
 - Is a strong and compelling leadership approach evident, including the designated roles and responsibilities, governance, and organizational structure consistent with and justified by the aims of the training program and the complementary expertise of the PDs/PIs?

Preceptors Mentors

- Are sufficient numbers of experienced preceptors/mentors with appropriate expertise and funding available to support the number and level of trainees (including short-term trainees, if applicable) proposed in the application?
- Do the preceptors/mentors have strong records as researchers, including recent publications and successful competition for research support in areas directly related to the proposed research training program?
- Do the preceptors/mentors have strong records of training and effective and supportive mentoring of individuals at the level of trainees proposed in the program (including short-term trainees, if applicable)? Are appropriate plans in place to ensure that preceptors with less former research training experience will be provided with guidance on how to provide strong and successful mentoring?
- Is there a diverse team of program faculty, including faculty at a range of career stages and from a variety of scientific backgrounds?
- If the program will support clinical trial research experience for the trainees, do the mentor(s) who will supervise the trainee(s) have the expertise, experience, resources, and ability to provide appropriate guidance and help the trainee(s) to meet the timelines?

Trainees

- Is a recruitment plan proposed with strategies likely to attract well-qualified trainees for the training program?
- Is there a competitive applicant pool of sufficient size and quality, at each of the proposed levels (predoctoral, postdoctoral and/or short-term), to ensure a successful training program?
- Does the application provide a strong justification for the number of trainee positions requested?
- Are there well-defined and justified selection and re-appointment criteria as well as retention strategies?

Training Record

- How successful are the trainees (or, for new applications, other past students/postdoctorates in similar training) in completing the program?
- Has the training program ensured that trainees are productive (or, for new applications, other past students/postdoctorates in similar training) in terms of research accomplishments, publication of research conducted during the training period, and subsequent training appointments and fellowship or career development awards?
- How successful are the trainees (or, for new applications, other past students/postdoctorates in similar training) in achieving productive scientific careers as evidenced by successful
 competition for research science positions in industry, academia, government, or other research venues; grants; receipt of honors, awards, or patents; high-impact publications; promotion
 to scientific leadership positions; and/or other such measures of success?
- To what extent do trainees subsequent positions in industrial, academic, government, non-profit, or other sectors benefit from their NRSA-supported research training and directly benefit the broader biomedical research enterprise?
- Does the program propose a rigorous evaluation plan to assess the quality and effectiveness of the training? Are effective mechanisms in place for obtaining the views of current and former trainees, including feedback about the training environment?
 - For applications that propose to train health professionals, is there a record of retaining health professional trainees in research training or other research activities for at least two years?

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.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Vertebrate Animals

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Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of the Scientific Review Officer.

Training in Methods for Enhancing Reproducibility

Does the plan for Instruction in Methods for Enhancing Reproducibility describe how trainees will receive training in scientific reasoning, rigorous research design, relevant experimental methods, consideration of relevant biological variables such as sex, authentication of key biological and/or chemical resources, quantitative approaches, and data analysis and interpretation, appropriate to field of study and the level and prior preparation of the trainees?

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

For Renewals, the committee will consider the progress made in the last funding period, including on the Recruitment Plan to Enhance Diversity, and Training in the Responsible Conduct of Research. Does the application describe the program's accomplishments over the past funding period(s)? Is the program achieving its training objectives? Has the program evaluated the quality and effectiveness of the training experience (and when applicable, short-term training experience), and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon? Are changes proposed that are likely to improve or strengthen the research training experience during the next project period (may not be applicable to short-term training)? Does the program continue to evolve and reflect changes in the research area in which the training occurs?

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific aspect of the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

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.

Recruitment Plan to Enhance Diversity

Peer reviewers will separately evaluate the recruitment plan to enhance diversity after the overall score has been determined. Reviewers will examine the strategies to be used in the recruitment of prospective individuals from underrepresented groups. The plan will be rated as **ACCEPTABLE** or **UNACCEPTABLE**, and the consensus of the review committee will be included in an administrative note in the summary statement.

Training in the Responsible Conduct of Research

All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the specific characteristics of the training program, the level of trainee experience, and the particular circumstances of the trainees, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) Format - Does the plan satisfactorily address the format of instruction, e.g., lectures, coursework and/or real-time discussion groups, including face-to-face interaction? (A plan involving only on-line instruction is not acceptable.); 2) Subject Matter Does the plan include a sufficiently broad selection of subject matter, such as conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics? 3) Faculty Participation - Does the plan adequately describe how faculty will participate in the instruction? For renewal applications, are all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period named in the application? 4) Duration of Instruction - Does the plan meet the minimum requirements for RCR, i.e., at least eight contact hours of instruction? 5) Frequency of Instruction Does the plan meet the minimum requirements for RCR, i.e., at least once during each career stage (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels) and at a frequency of no less than once every four years?

For renewal applications, does the progress report document acceptable RCR instruction in the five components described above? Does the plan describe how participation in RCR instruction is being monitored? Are appropriate changes in the plan for RCR instruction proposed in response to feedback and in response to evolving issues related to responsible conduct of research?

Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE, and the summary statement will provide the consensus of the review committee.

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).

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.

Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by the sponsoring Institute or Center in accordance with NIH peer review policy and procedures (//grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all 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.
- Will receive a written critique.

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.

3. Anticipated Announcement and Award Dates

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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 <u>eRA Commons</u> (<u>///grants.nih.gov/grants/guide/url_redirect.htm?id=11123</u>). 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 <u>NIH Grants Policy Statement</u> (<u>//grants.nih.gov/grants/guide/url_redirect.htm?id=11157</u>).

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 grantee's business official.

Awardees must comply with any funding restrictions described in <u>Section IV.5. Funding Restrictions</u>. 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 <u>Award Conditions and Information for NIH Grants</u> (<u>///grants.nih.gov/grants/guide/url_redirect.htm?id=11158</u>) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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, Grantees, 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-provider-obligations/index.html and https://www.hhs.gov/ccr/civilrights/understanding/section1557/index.html (https://www.hhs.gov/ccr/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.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).
- 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.eoc.gov/about/offices/list/ocr/docs/shguide.html; and https://www.eoc.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/con

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.

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the <u>NIH Grants Policy Statement - Institutional Research Training Grants</u> (//grants.nih.goy/grants/quide/url_redirect.htm?id=61170).

The taxability of stipends is described in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171). Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171).

As specified in the NIH Revitalization Act of 1993, Kirschstein-NRSA recipients incur a service payback obligation for the first 12 months of postdoctoral support. Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the NIH Grants Policy Statement (//grants.nih.gov/grants/guide/url_redirect.htm?id=41171); and more details are in the Frequently Asked Questions (//grants.nih.gov/grants/guide/url_redirect.htm?id=61174). Officials at the grantee institution have the responsibility of explaining the terms of the payback requirements to all prospective trainees before appointment to the training grant. Additionally, all trainees recruited into the training program should be provided with information related to the career options that might be available when they complete the program. The suitability of such career options as methods to satisfy the NRSA service payback obligation should be discussed.

Inventions and Copyrights

Awards made primarily for educational purposes are exempted from the PHS invention requirements and thus invention reporting is not required, as described in the <u>NIH Grants Policy Statement</u> (<u>//grants.nih.gov/grants/guide/url_redirect.htm?id=61131</u>).

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. Continuation support will not be provided until the required forms are submitted and accepted.

Failure by the grantee institution to submit required forms in a timely, complete, and accurate manner may result in an expenditure disallowance or a delay in any continuation funding for the

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//lgrants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over \$25,000. See the www.fsrs.gov/(lgrants.nih.gov/grants/guide/url_redirect.htm?id=11171)) for additional information on this reporting requirement.

Other Reporting Requirements

- The institution must submit a completed Statement of Appointment (PHS Form 2271 (//grants.nih.gov/grants/guide/url_redirect.htm?id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Grantees must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//grants.nih.gov/grants/guide/url_redirect.htm?id=41183). An appointment or reappointment may begin any time during the budget period, but not before the budget period start date of the grant year.
- Additionally, a completed Payback Agreement Form (<u>PHS Form 6031 (//grants.nih.gov/grants/guide/url_redirect.htm?id=41181</u>)) must be submitted for each postdoctoral trainee in his or her first 12 months of support.
- A notarized statement verifying possession of permanent residency documentation must be submitted with the Statement of Appointment (PHS Form 2271
 (//grants.nih.gov/grants/guide/url_redirect.htm?id=61189)). Individuals with a Conditional Permanent Resident status must first meet full (non-conditional) Permanent Residency requirements before receiving support.
- Termination Notice: Within 30 days of the end of the total support period, the institution must submit a Termination Notice (PHS Form 416-7 (//grants.nih.gov/grants/guide/url_redirect.htm? id=41179)) via xTrain (//grants.nih.gov/grants/guide/url_redirect.htm?id=41183) for each trainee appointed for eight weeks or more. Trainees with service payback requirements must notify the NIH of any change in address and submit Annual Payback Activities Certification Forms (PHS Form 6031-1 (//grants.nih.gov/grants/guide/url_redirect.htm?id=41180)) until the payback service obliqation is satisfied.

A final RPPR, the expenditure data portion of the Federal Financial Report, and Termination Notices for all Trainees, 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).

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.

4. Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Section VII. Agency Contacts

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

Because of the difference in individual Institute and Center (IC) program requirements for this FOA, prospective applications **MUST** consult the <u>Table of IC-Specific Information</u>, <u>Requirements</u>, <u>and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/nrsa-institutional-research-training-grant-parent-t32.html)</u>, to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

Application Submission Contacts

eRA Commons Help 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)

 $Email: \underline{GrantsInfo@nih.gov\ (mailto:GrantsInfo@nih.gov)}\ (preferred\ method\ of\ contact)$

Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)

Contact Center Telephone: 800-518-4726

Email: support@grants.gov)

Scientific/Research Contact(s)

See: Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/nrsa-institutional-research-training-grant-parent-t32.html)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

See: Table of IC-Specific Information, Requirements and Staff Contacts (https://grants.nih.gov/grants/guide/contacts/nrsa-institutional-research-training-grant-parent-t32.html)

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

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Awards are made under the authorization of Section 487 of the Public Health Service Act as amended (42 USC 288) and under Federal Regulations 42 CFR 66.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?03-20-20) NIH Funding Opportunities and Notices (/grants/guide/index.html)



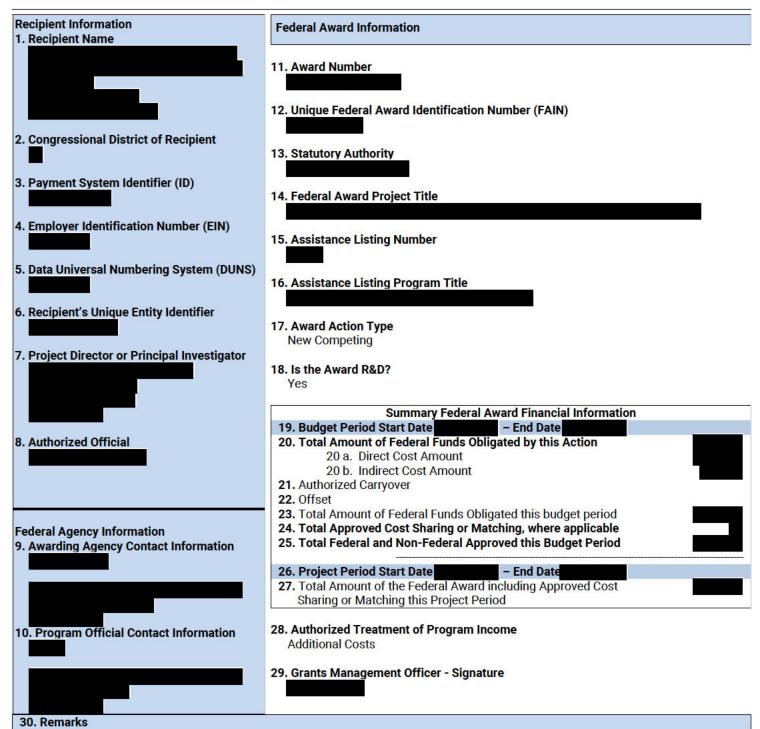




NIH... Turning Discovery Into Health®

EXHIBIT B

Federal Award Date 06/14/2024



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



NATIONAL RESEARCH SERVICE AWARD

Department of Health and Human Services
National Institutes of Health



SECTION I – AWARD DATA –
Principal Investigator(s):
Award e-mailed to:
Dear Authorized Official:
The National Institutes of Health hereby awards a grant in the amount of in Section I and "Terms and Conditions" in Section III) to in support of the above referenced project. This award is pursuant to the authority of 42 USC 288 42 CFR 66 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 Drug Abuse of the National Institutes of Health under Award Number 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,
Grants Management Officer
Additional information follows

<u>Cumulative Award Calculations for this Budget Period (U.S. Dollars)</u>
Childcare Costs
Stipends
Tuition & Fees



Trainee Travel
Training related Expenses

Federal Direct Costs
Federal F&A Costs
Approved Budget
Total Amount of Federal Funds Authorized (Federal Share)
TOTAL FEDERAL AWARD AMOUNT



AMOUNT OF THIS ACTION (FEDERAL SHARE)

	THIS AWARD			CUMU	MULATIVE TOTALS			
YR	Total	Pre	Post	Short Term	Cumulative Total	Pre	Post	Short Term
1			2				2	
2			4				4	
3			6				6	
4			6	- 1			6	
5			6				6	

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

Fiscal Information:

Payment System Identifier:
Document Number:
PMS Account Type:
Fiscal Year:
2024

IC	CAN	2024	2025	2026	2027	2028

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

NIH Administrative Data:

PCC: / OC: / Released: 06/05/2024 Award Processed: 06/14/2024 12:19:46 AM

SECTION II - PAYMENT/HOTLINE INFORMATION -

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 -

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.
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- 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).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

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). Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

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

- 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.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 antidiscrimination laws, see 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 Page 4 of 7

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.

Childcare Costs:

This award includes childcare costs of per full-time predoctoral or postdoctoral trainee. These funds are restricted and may not be used for any other purpose.

Treatment of Program Income:

Additional Costs

SECTION IV - SPECIFIC AWARD CONDITIONS -

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.

CHANGE OF PI APPROVED

This revised award reflects 's approval of as the Principal Investigator, replacing , per the request submitted on from .

MULTIPLE PI

The following principal investigators (PIs) are associated with this project:

is the contact PI for correspondence purposes. As this grant has multiple PIs, all NIH Grant policies regarding multiple PIs, including, but not limited to, all prior approval requirements, must be followed accordingly, see NIH Grants Policy Statement, section on Multiple Program Director/Principal Investigators, found at http://grants.nih.gov/policy/nihgps/index.htm.

FY 2024 FUNDING

The award amount for the current year is based upon IRG/Council recommendations, cost analysis, program priorities and availability of funds.

This award contains grant-specific restrictions. These restrictions may only be lifted by a revised Notice of Award (NoA).

CHILDCARE COSTS RESTRICTED

This award includes funds of predoctoral NRSA appointed trainees, as announced in NOT-OD-21-177. These funds are restricted for the stated purpose and may not be rebudgeted or used for any other purpose, without prior approval from a service of service and cannot be rebudgeted for any other purpose without prior approval from a service of service of

NRSA STIPENDS FY 2024

This award reflects the stipend amount, tuition and fees, and institutional allowance amount for Fiscal Year 2024 which are published in the NIH Guide for Grants and Contracts at NOT-OD-24-104.

APPOINTMENT/TERMINATION FORM REQUIREMENTS

Recipients must submit an electronic Statement of Appointment Form (PHS 2271) by the start of each trainee's appointment or reappointment. No stipend or other allowance may be paid until the appointment form has been submitted.

Trainees are generally appointed for full-time 12-month continuous periods and may begin at any time during the budget period. When an appointment starts in the budget period, the entire stipend & tuition and fees for that appointment must be charged to that same budget period. Trainee appointments may extend beyond the end date of the budget period to accommodate a normal 12-month appointment. That is, such appointment need not coincide with the end of the budget period. If an appointment does extend beyond the end date of the budget period, the Federal Financial Report (FFR) should reflect the portion of the stipend commitment and tuition remaining unpaid as of the end of the budget period as an unliquidated obligation.

Recipients must submit an electronic Termination Notice Form (PHS 416-7) for each trainee within 30 days of the end of the total period of support even if the trainee is not available for signature. Failure to submit ALL required forms in a timely manner may result in an expenditure disallowance or a delay in any continuation of funding.

SUBMISSION OF FORMS - PAYBACK AGREEMENT REQUIREMENTS

A Payback Agreement (Form PHS 6031) is required for all postdoctoral trainees in their first 12 months of Kirschstein-NRSA support. Electronic submission of the Payback Agreement will be permitted until further notice. Please DO NOT include the trainees Personally Identifiable Information (PII) on the digital copy of the Payback Agreement. Recipients must maintain the hard copy of the form with original signatures.

SUBMISSION OF FORMS - TRAINEE CITIZENSHIP REQUIREMENTS

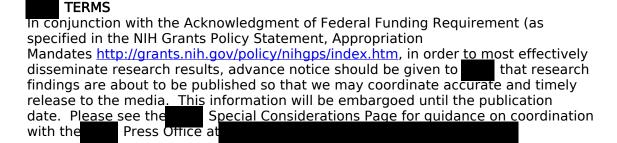
All trainees must be a citizen, a noncitizen national of the United States, or have been lawfully admitted for permanent residence at the time of appointment. Electronic submission of a notarized statement verifying possession of permanent residency documentation must be submitted at the time the State of Appointment (PHS Form 2271) is submitted in X-train. However, do not send the actual residency documentation as this is considered Personally Identifiable Information (PII).

T32 PROGRAM REMINDER

Recipients should ensure that a contingency plan is in place for any new trainees added within the last year of funding to ensure the successful career progression of the trainee should the competing application not be awarded. Recipients should have no expectation that will continue to support trainees through the T32 program once the program's funding has ended.

HUMAN SUBJECTS/VERTEBRATE ANIMAL INVOLVEMENT REMINDERS

No trainee will be permitted to work on projects involving live vertebrate animals or human subjects that have not been approved by the recipient's Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), as appropriate.



at	or contact the	Press Office
Please see Special Considerationat	ns for Funding	Opportunities and Awards
SPREADSHEET SUMMARY	٥	

INSTITUTION:

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Childcare Costs	100				A Section 1
Stipends					
Tuition & Fees			100		280
Trainee Travel					
Training related Expenses					
TOTAL FEDERAL DC					
TOTAL FEDERAL F&A	30 30		100	12 S	3
TOTAL COST					

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	8%	8%	8%	8%	8%
F&A Cost Base 1					
F&A Costs 1					

EXHIBIT C





March 21, 2025

Dear

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

The 2024 Policy Statement applies to your project because NIH approved your grant on July 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, socalled 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.

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," 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. 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,

Digitally signed Michelle G. Bulls -S Bulls -S

Michelle G. Bulls, on behalf of

Chief Grants Management Officer, National

Director, Office of Policy for Extramural Research Administration Office of Extramural Research

2

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)

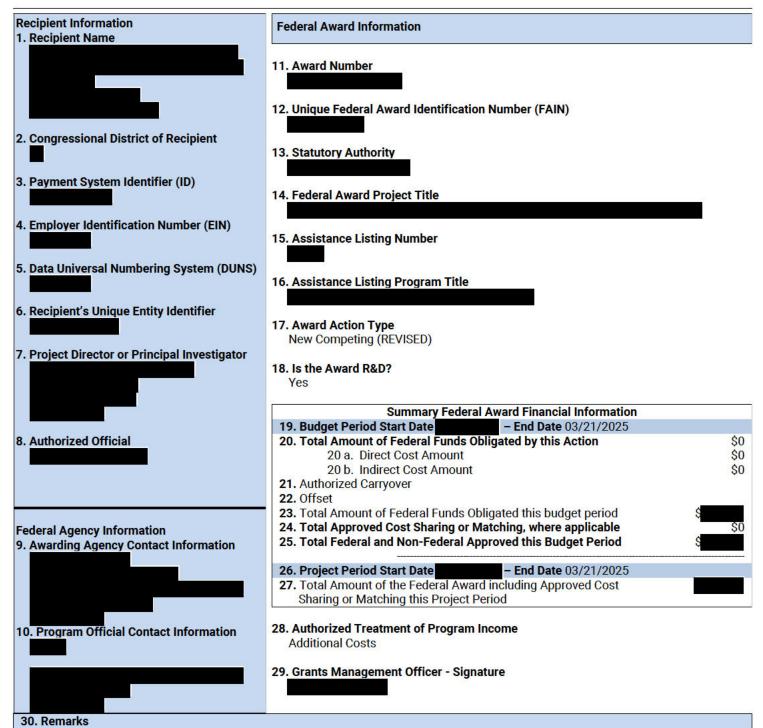
⁹ See 45 C.F.R. § 75.374.

¹⁰ See 42 C.F.R. Part 50, Subpart D

¹¹ 11 *Id.* § 50.406(a)

¹² 12 *Id.* § 50.406(b)

EXHIBIT D



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



NATIONAL RESEARCH SERVICE AWARD

Department of Health and Human Services
National Institutes of Health



SECTION I – AWARD DATA –
Principal Investigator(s):
Award e-mailed to:
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 in support of the above referenced project. This award is pursuant to the authority of 42 USC 288 42 CFR 66 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 Drug Abuse of the National Institutes of Health under Award Number. 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,
Grants Management Officer
Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)
Childcare Costs
Stipends
Tuition & Fees



Trainee Travel
Training related Expenses

Federal Direct Costs
Federal F&A Costs
Approved Budget
Total Amount of Federal Funds Authorized (Federal Share)
TOTAL FEDERAL AWARD AMOUNT



AMOUNT OF THIS ACTION (FEDERAL SHARE)

	SUMMARY TOTALS FOR ALL YEARS (for this Document Number)							
	THIS AWARD			CU	MULATIVE	TOTALS		
YR	Total	Pre	Post	Short Term	Cumulative Total	Pre	Post	Short Term
1			2				2	

Fiscal Information:

Payment System Identifier: Document Number: PMS Account Type: Fiscal Year:



IC	CAN	2024

NIH Administrative Data:

PCC: / OC: / Released: 03/21/2025 Award Processed: 03/22/2025 12:01:56 AM

SECTION II - PAYMENT/HOTLINE INFORMATION -

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 -

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.
- 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.
- 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).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

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This award has been assigned the Federal Award Identification Number (FAIN). 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#qps.

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-provider-obligations/index.html and https://www.hhs.gov/.

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- 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.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/religious-freedom/index.html.

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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.

Childcare Costs:

This award includes childcare costs of per full-time predoctoral or postdoctoral trainee. These funds are restricted and may not be used for any other purpose.

Treatment of Program Income:

Additional Costs

SECTION IV - SPECIFIC AWARD CONDITIONS - 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.

REVISION #1 - TERMINATION

It is the policy of NIH not to further prioritize 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 since race and other protected characteristics, which harms the health of Americans.

Therefore, this project is terminated.

The 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 Program Report (F-RPPR), Final Invention Statement (FIS), and the Final Federal Financial Report (FFR)) within 120 days of the end date of this grant to avoid unilateral closeout.

NIH is taking this enforcement action in accordance with <u>2 C.F.R. § 200.340</u> as implemented in <u>NIH GPS Section 8.5.2</u>. 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.

This revision supersedes Notice of Award (NoA) issued 6/14/2024.

CHANGE OF PI APPROVED This revised award reflects 's approval of as the Principal Investigator, replacing from from

MULTIPLE PI

The following principal investigators (PIs) are associated with this project:

Investigators, found at http://grants.nih.gov/policy/nihgps/index.htm.

is the contact PI for correspondence purposes. As this grant has multiple PIs, all NIH Grant policies regarding multiple PIs, including, but not limited to, all prior approval requirements, must be followed accordingly, see NIH Grants Policy Statement, section on Multiple Program Director/Principal

FY 2024 FUNDING

M

The award amount for the current year is based upon IRG/Council recommendations, cost analysis, program priorities and availability of funds.

This award contains grant-specific restrictions. These restrictions may only be lifted by a revised Notice of Award (NoA).

CHILDCARE COSTS RESTRICTED

This award includes funds of _______ in Direct Costs for Childcare Costs for all full-time predoctoral or postdoctoral NRSA appointed trainees, as announced in NOT-OD-21-177. In These funds are restricted for the stated purpose and may not be rebudgeted or used for any other purpose, without prior approval from _______ 's Grants Management Branch. In Future year funds provided for childcare costs are also restricted and cannot be rebudgeted for any other purpose without prior approval from _______ s Grants Management Branch. In Section G.1 of the RPPR, recipients must upload a PDF named "Childcare_Costs.pdf" (without quotation marks). The attachment must specify the number of trainees who used childcare costs in the reporting period.

NRSA STIPENDS FY 2024

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All trainees must be a citizen, a noncitizen national of the United States, or have been lawfully admitted for permanent residence at the time of appointment. Electronic submission of a notarized statement verifying possession of permanent residency documentation must be submitted at the time the State of Appointment (PHS Form 2271) is submitted in X-train. However, do not send the actual residency documentation as this is considered Personally Identifiable Information (PII).

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Recipients should ensure that a contingency plan is in place for any new trainees added within the last year of funding to ensure the successful career progression of the trainee should the competing application not be awarded. Recipients should have no expectation that will continue to support trainees through the T32 program once the program's funding has ended.

HUMAN SUBJECTS/VERTEBRATE ANIMAL INVOLVEMENT REMINDERS

No trainee will be permitted to work on projects involving live vertebrate animals or human subjects that have not been approved by the recipient's Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), as appropriate.

In conjunction with the Acknowledgment of Federal Funding Requirement (as specified in the NIH Grants Policy Statement, Appropriation Mandates http://grants.nih.gov/policy/nihgps/index.htm, in order to most effectively disseminate research results, advance notice should be given to about to be published so that we may coordinate accurate and timely release to the media. This information will be embargoed until the publication date. Please see the accurate and timely release to the media. This information will be embargoed until the publication date. Please see the accurate and timely release to the media. The press Office at a p

Please see Special Considerations for Funding Opportunities and Awards at

SPREADSHEET SUMMARY	
AWARD NUMBER:	REVISED
INSTITUTION:	

Budget	Year 1
Childcare Costs	
Stipends	
Tuition & Fees	
Trainee Travel	
Training related Expenses	210
TOTAL FEDERAL DC	
TOTAL FEDERAL F&A	
TOTAL COST	

Facilities and Administrative Costs	Year 1
F&A Cost Rate 1	8%
F&A Cost Base 1	

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F&A Costs 1	\$	