# EXHIBIT 48

The Wayback Machine - https://web.archive.org/web/20250122W5054/https://grants.htm.gov/grants/guide/pa-files/pa-25-250-html/25 Page 2 of 17

# Department of Health and Human Services

### Part 1. Overview Information

**Number of Applications** 

Participating Organization(s) National Institutes of Health (NIH (https://web.archive.org/web/20250122105054/http://www.nih.gov/)) **Components of Participating Organizations** Office of The Director, National Institutes of Health (OD (https://web.archive.org/web/20250122105054/https://www.nih.gov/institutes-nih/nih-office-director)) National Eye Institute (NEI (https://web.archive.org/web/20250122105054/https://www.nei.nih.gov/) National Heart, Lung, and Blood Institute (NHLBI (https://web.archive.org/web/20250122105054/https://www.nhlbi.nih.gov/) National Institute on Aging (NIA (https://web.archive.org/web/20250122105054/https://www.nia.nih.gov/)) National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://web.archive.org/web/20250122105054/https://www.niaaa.nih.gov/) National Institute of Biomedical Imaging and Bioengineering (NIBIE (https://web.archive.org/web/20250122105054/https://www.nibib.nih.gov/)) National Institute on Deafness and Other Communication Disorders (NIDCD (https://web.archive.org/web/20250122105054/https://www.nidcd.nih.gov/) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK National Institute of Environmental Health Sciences (NIEHS (https://web.archive.org/web/20250122105054/https://www.niehs.nih.gov/) National Center for Complementary and Integrative Health (NCCIH (https://web.archive.org/web/20250122105054/https://nccih.nih.gov/) Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicant organizations should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/parent\_T32.html)https://grants.nih.gc specific-information-PA-25-280.html (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/quide/contacts/IC-specific-information-PA-25-280.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) Short-Term Institutional Research Training Grant (Parent T35) **Activity Code** T35 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/funding/ac\_search\_results.htm? text\_curr=t35&Search.x=0&Search.y=0&Search\_Type=Activity) National Research Service Award (NRSA) Short-Term Research Training Reissue of PA-23-080 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/pa-files/PA-23-Announcement Type 080.html) **Related Notices** See Notices of Special Interest (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/NOSIs\_targetingList.cfm? GuideDocID=42231) associated with this funding opportunity • April 4, 2024 - Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025. See Notice NOT-OD-24-084 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html). **Funding Opportunity Number (FON)** PA-25-280 **Companion Funding Opportunity** 

See Section III. 3. Additional Information on Eligibility.

# Assistance Listing Numbers e 1:25-cv-10787-WG3Y1, 93.000,05,477,95.263, 93.275 | ed.0,55,197,25.233, 93.139e 3 of 17

Funding Opportun	ity Purpose
------------------	-------------

The National Institutes of Health (NIH) will award Ruth L. Kirschstein National Research Service Award (NRSA) Short-Term Institutional Research Training Grants (T35) to eligible, domestic institutions to develop and/or enhance research training opportunities for predoctoral students interested in careers within biomedical, behavioral, or clinical research workforce. Many NIH Institutes and Centers (ICs) use this NRSA program exclusively to support intensive, short-term research training experiences for health professional students (medical students, veterinary students, and/or students in other health-professional programs) during the summer. This program is also intended to encourage training of graduate students in the physical or quantitative sciences to pursue interests in careers within the biomedical research workforce by providing short-term exposure to, and involvement in, the health-related sciences. The training should be of sufficient depth to enable the trainees, upon completion of the program, to have a thorough exposure to the principles underlying the conduct of biomedical research.

This Notice of Funding Opportunity (NOFO) does not allow 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.

Funding Opportunity Goal(s)

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability..

# **Key Dates**

Posted Date

January 03, 2025

Open Date (Earliest Submission Date)

December 25, 2024

Letter of Intent Due Date(s)

Not Applicable

The following table includes NIH <u>standard due dates (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm) marked with an asterisk.</u>

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
January 25, 2025 *	January 25, 2025 *	May 07, 2025 *	July 2025	August 2025	December 2025
May 25, 2025 *	May 25, 2025 *	September 07, 2025 *	November 2025	January 2026	April 2026
September 25, 2025 *	September 25, 2025 *	January 07, 2026 *	March 2026	May 2026	July 2026
January 25, 2026 *	January 25, 2026 *	May 07, 2026 *	July 2026	August 2026	December 2026
May 25, 2026 *	May 25, 2026 *	September 07, 2026 *	November 2026	January 2027	April 2027
September 25, 2026 *	September 25, 2026 *	January 07, 2027 *	March 2027	May 2027	July 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	August 2027	December 2027
January 25, 2027 *	January 25, 2027 *	May 07, 2027 *	July 2027	October 2027	December 2027
May 25, 2027 *	May 25, 2027 *	September 07, 2027 *	November 2027	January 2028	April 2028
September 25, 2027 *	September 25, 2027 *	January 07, 2028 *	March 2028	May 2028	July 2028
January 25, 2028 *	January 25, 2028 *	May 07, 2028 *	July 2028	August 2028	December 2028

All applications are due by 5:00 PM local time of applicant organization.

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

Expiration Date May 08, 2028

Due Dates for E.O. 12372 Not Applicable

### **Required Application Instructions**

It is critical that applicant organizations follow the Training (T) Instructions in the How to Apply Application Guide,

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) except where instructed to do otherwise (in this NOFO or in a Notice from the NIH Guide for Grants and Contracts (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11164)). Conformance to all requirements (both in the How to Apply Application Guide, (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) and the NOFO) is required and strictly enforced. Applicant organizations must read and follow all application instructions in the How to Apply Application Guide,

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply Application Guide. J//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400), follow the program-specific instructions. Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

Apply Online Using ASSIST

- 2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and <a href="mailto:eRA Commons">eRA Commons</a> (<a href="https://web.archive.org/web/20250122105054/https://public.era.nih.gov/commons/">https://web.archive.org/web/20250122105054/https://public.era.nih.gov/commons/</a>) to track your application. Check with your institutional officials regarding availability.
- 3. Use Grants.gov (/web/20250122105054/https://grants.nih.gov/grants/guide/ApplyButtonSplash.cfm?dest=https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-280) Workspace to prepare and submit your application and eRA Commons (https://web.archive.org/web/20250122105054/http://public.era.nih.gov/commons/) to track your application.

# **Table of Contents**

Part 1. Overview Information

Key Dates

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Section II. Award Information

**Other Award Budget Information** 

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts

Section VIII. Other Information

### Part 2. Full Text of Announcement

# **Section I. Funding Opportunity Description**

The overall purpose 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 <a href="https://grants.nih.gov/grants/guide/url\_redirect.php?id=41125">https://grants.nih.gov/grants.nih.gov/grants/guide/url\_redirect.php?id=41125</a>) website.

The NRSA program has been the primary means of supporting predoctoral and postdoctoral research training programs since enactment of the NRSA legislation in 1974. Institutional NRSA programs allow the Training Program Director/Principal Investigator (Training PD/PI) to select trainees and develop an enhanced program of coursework, mentored research experiences, and technical and professional skills development appropriate for the appointed trainees that provides added value to already existing programs.

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 goal of the Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grant (T35) program is to develop and/or enhance research training opportunities for health professional students and for graduate students in the physical or quantitative sciences interested in careers in biomedical, behavioral and clinical research workforce that are relevant to the NIH mission. The T35 program provides short-term support for a period of at least 8, but no more than 12, weeks in a grant year for full-time training experiences under the supervision of experienced researchers. Trainees are exposed to mentors with active research careers and learn about further research training opportunities and research career options. The training program should be of sufficient depth to enable selected trainees, upon completion of the program, to have a thorough exposure to the principles underlying the conduct of biomedical research.

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

### **Program Considerations**

Institutional short-term training grants are intended to introduce predoctoral students to research that would not otherwise be available through their regular course of graduate study. The research experiences should be tailored to the individual to meet their training goals. Didactic instruction must include training in the responsible conduct of research. Positions on NRSA short-term institutional training grants may not be used for courses and study leading to the MD, DDS, DO, DVM, or other clinical, health professional degree, nor to support residency training

Research elective credit may be granted for students who complete a short-term, research training experience supported by the T35. The decision to award elective credit will be at the discretion of the sponsoring institution and must be consistent with the policies of the institution (see Funding Restrictions).

Recipient organizations may be vide training to students enrolled at other institutions through a partnership or consortium structure. Consortium structure of the training program. Consortium partners will be identified by the applicant organization, and each partner institution must identify faculty at their location who have agreed to serve as mentors.

Consistent with existing NIH practices and applicable law: (1) Funded programs may not use the race, ethnicity, or sex (including gender identity, sexual orientation, or transgender status) of a trainee or faculty candidate as an eligibility or selection criterion, and (2) NIH does not use the race, ethnicity, or sex of trainee candidates, trainees, or faculty in the application review process or funding decisions. Applicant organizations and award recipients are encouraged to consult with their General Counsel to ensure all applicable laws and regulations are being followed in program design and implementation.

This Notice of Funding Opportunity (NOFO) 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 NOFO, prospective applicant organizations MUST consult the Table of IC-Specific Information, Requirements and Staff Contacts (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.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

Section II. Award Information				
Funding Instrument	Grant: A <u>financial assistance</u> 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 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the How to Apply Application Guide, (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) provide details on these application types. Only those application types listed here are allowed for this NOFO.			
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.			
Funds Available and Anticipated Number of Awards	Need help determining whether you are doing a clinical trial? (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)  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.			
	Recipients are expected to be familiar with and comply with applicable cost policies and the NRSA Guidelines (NIH Grants Policy Statement - Institutional Research Training Grants (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?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 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url_redirect.php?id=11120), and the NRSA regulations, policies, guidelines, and conditions set forth in this document.			
Award Project Period	Awards for T35 short-term 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	Ruth L. Kirschstein-NRSA awards provide stipends as a subsistence allowance to help defray living expenses during the research training experience.			

Award (NRSA) webpage

### Trainee Travel

Travel for trainees to attend scientific meetings and workshops that the institution determines to be necessary for the individual's research training experience is an allowable expense for predoctoral and postdoctoral trainees. This includes trainees on short-term appointments. Trainees must be appointed to the training grant at the time of the actual travel for

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

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

(https://web.archive.org/web/20250122105054/https://researchtraining.nih.gov/resources/policy-notices).

The amount of funds provided for trainee travel may vary by NIH Institute or Center; applicant organizations are encouraged to consult the <u>Table of IC-Specific Information, Requirements and Staff Contacts</u> (<a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html">https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html</a>) for further information.

### **Training Related Expenses**

NIH will provide funds to help defray other research training expenses, such as health insurance, staff salaries, consultant costs, mentor training activities, 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://web.archive.org/web/20250122105054/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 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11120) will apply to the applications submitted and awards made from this NOFO.

# Section III. Eligibility Information

### 1. Eligible Applicant Organizations

### **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)

### Local 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

### Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

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 Organizations**

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 How to Apply - Application Guide

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400), and the control of the control of

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) 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 applicant organizations should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82423) for additional information.

- System for Award Management 125-CV-110787-WGV/web/2Document 172.76 ants. n. Filed 05/119/25 edirect page 239f Applicant organizations 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 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11176) Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- <u>eRA Commons (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11123)</u> Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; 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 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82300) Applicant organizations must have an active SAM registration in order to complete the Grants.gov registration.

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

All PD(s)/Pl(s) must have an eRA Commons account. PD(s)/Pl(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/Pl 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 their organization to develop an application for support. Individuals from diverse backgrounds, including individuals from underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html) and Notice of NIH's Interest in Diversity, NOT-OD-20-031 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html).

For institutions/organizations proposing multiple PDs/Pls, visit the Multiple Program Director/Principal Investigator Policy

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/multi\_pi/index.htm) and submission details in the Senior/Key Person Profile (Expanded) Component of the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400).

The PD/PI should be an established investigator in the scientific area in which the application is targeted 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 consistent with applicable law, 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.

### 2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement Section 1.2 Definition of Terms (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11126).

### 3. Additional Information on Eligibility

### **Number of Applications**

 $Applicant\ organizations\ may\ submit\ more\ than\ one\ application,\ provided\ that\ each\ application\ is\ programmatically\ distinct.$ 

NIH will not accept duplicate or highly overlapping applications under review at the same time per NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82415). 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 NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82423))

### Preceptors/Mentors

Program faculty should be active researchers in the biomedical sciences as demonstrated by recent publications and research support in the area of the proposed research training program. When building a training team, programs should include faculty who are committed to training, mentoring, and providing inclusive, safe, accessible, and supportive research training environments. All program faculty should have a mentoring philosophy appropriately tailored to the needs of potential trainees that ensures trainees will receive the tailored mentorship needed to develop skills and advance their career. Program faculty should also have sufficient time to commit to training given their other professional obligations.

### **Trainees**

The applicant organization will select the trainees to be supported by the research training program and is responsible for establishing trainee eligibility and selection criteria that are consistent with applicable law.

The individual to be trained must be a citizen or a noncitizen national 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 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?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.

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.

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 individual who are candidates for the Pharmacy degree are eligible for short-term training positions.

## 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 NOFO. 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 applicant organizations follow the Training (T) Instructions in the How to Apply - Application Guide

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the How to Apply - Application Guide

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

### **Page Limitations**

All page limitations described in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) and the Table of Page Limits (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11133) must be followed.

### **Instructions for Application Submission**

The following section supplements the instructions found in the How to Apply - Application Guide

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) and should be used for preparing an application to this NOFO.

### SF424(R&R) Cover

 $All \ instructions \ in \ the \ \underline{How \ to \ Apply - Application \ Guide \ (\underline{https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url \ redirect.php?id=82400}) \ must \ be \ followed.$ 

### SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) must be followed.

### SF424 (R&R) Other Project Information

All instructions in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) must be followed.

**Project Summary/Abstract.** Provide an abstract of the entire application. Include the objectives, rationale and design of the research training/career development program, as well as key activities in the training plan. Indicate the planned duration of appointments, the projected number of trainees/scholars including their levels (i.e., predoctoral, postdoctoral, short-term faculty), and intended trainee/scholar outcomes.

Other Attachments. An Advisory Committee is not a required, but a highly recommended component of a training program. However, if an Advisory Committee is intended, provide a plan for the appointment of an Advisory 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. Please 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 How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400).

### PHS 398 Cover Page Supplement

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400).

### PHS 398 Training Subaward Budget Attachment(s)

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400).

### **Training Budget**

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) 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
- · Faculty, Trainees, and Training Record
- · Other Training Program
- Appendix Note that the Appendix should only be used in circumstances covered in the NIH policy on appendix materials or if the NOFO specifically instructs applicant
  organizations to do so.

Follow all instructions provided in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400).

Particular attention must be given to the required International <u>Training Data Tables (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?</u>
<u>id=61169</u>). Applicant organizations should summarize, in the body of the application, key data from the tables that highlight the characteristics of the prospective trainee candidate pool, faculty mentors, the educational and career outcomes of past participants, and other factors that contribute to the overall environment of the program.

### **Training Program**

### **Program Plan**

### Program Administration (Training Program Director(s)/Principal Investigator(s))

The application should describe how the Training Program Director(s)/Principal Investigator(s) (PDs/Pls) will promote the success of the trainees and training program. Multiple PDs/Pls are encouraged, particularly when each brings a unique background and skill set that will enhance training. The application should expand on the information in the

biosketch(es) to addless to the 257FGVPE-0787-WGY Document 72-6 Filed 05/19/25 Page 9 of 17

- The appropriate expertise (for example, 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 (applicant organizations should indicate the program director's percent effort in the proposed program).
- A demonstrated commitment to training future biomedical research researchers.
- Received training (or have a plan in place to ensure they receive training) on how to effectively mentor trainees from all backgrounds including trainees from groups underrepresented in the biomedical sciences (e.g., see Notice of NIH's Interest in Diversity
   (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html)) prior to the start of the program.

This section should describe how previous mentoring experiences of the PD(s)/PI(s) will support the success of the proposed training program

### **Program Faculty**

The application should describe (a) the faculty participants and (b) planned mentor training and oversight.

Faculty Participants, please describe:

• The efforts made to recruit a pool of prospective program faculty from a wide variety of backgrounds, for example, faculty from underrepresented groups, and a range of career stages and scientific disciplines relevant to the training goals, to provide potential role models within the training program and to enhance the training environment.

Mentor Training and Oversight, please describe:

- The planned strategy and administrative structure to oversee and monitor the program and ensure appropriate and timely trainee progress. This should include a mechanism to
  monitor mentoring, including oversight of the effectiveness of the trainee/participating faculty match, and a plan for removing faculty who continue to display unacceptable
  mentorship qualities from the training program.
- How the participating faculty are trained to ensure the use of evidence-informed mentoring practices that promote the development of trainees from all backgrounds, including
  trainees from groups underrepresented in the biomedical sciences. Include the planned format, duration, and frequency of mentor training activities for program faculty and a
  description of how mentor training has been tailored to the goals and objectives of the broader training program. Describe the major topics covered in mentor training. Examples
  of relevant topics include, but are not limited to:
  - · Aligning expectations.
  - · Maintaining effective communication.
  - · Fostering independence.
  - · Assessing scholars' understanding of scientific research.
  - · Enhancing professional development.
  - · Addressing equity and inclusion.
  - · Articulating your mentoring philosophy and plan.

#### **Proposed Training**

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

- How the training activities will employ evidence-informed approaches to trainee learning, mentorship, inclusion, and professional development, and how these activities will address the program's training goals and objectives.
- 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.

Career Development

The proposed training should include a section on career development activities for trainees involved in the program, and should describe:

- How the pool of potential applicant organizations and trainees will be provided with information about the overall biomedical research workforce employment landscape, the
  variety of careers in the biomedical research workforce for which their training would be useful, and the career outcomes of graduates of the program (e.g., on publicly accessible
  websites).
- How the proposed program will engage a range of potential employers to ensure the trainees will acquire the appropriate skills, knowledge, and steps needed to attain positions in the sectors of the biomedical research workforce that are of interest to them and consistent with their values.
- How the training program or institution will provide appropriate experiential learning opportunities (e.g., internships, shadowing, informational interviews, teaching opportunities)
  that allow trainees to develop the professional skills and networks necessary to transition into careers in the biomedical research workforce.

### **Training Program Evaluation**

The application should describe:

- How the proposed evaluation will assess the extent to which the overall program is effective in meeting its training goals and objectives, and whether the research training environment is inclusive and supportive of trainee development.
- The program's procedures for responding to program evaluation findings.

### **Trainee Candidates and Retention Plans**

Through the narrative and summaries of the information presented in the <u>Training Data Tables</u> (<a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm">https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm</a>) and the attachments, the application should:

- Provide a strong justification for the number of requested trainee positions.
- Describe a multifactorial candidate review process (i.e., a process that considers metrics beyond previous institution, GPA, and standardized test scores) that will allow a broad group of research-oriented trainees who have taken advantage of the research opportunities available to them and are committed to contributing to the biomedical research enterprise the ability to participate in the training program. Programs are encouraged to consider individuals who have the potential to strongly benefit from, and with proper training and support, succeed in the program (see also, Program Considerations in section I above).

Retention Plans

Describe efforts to sustain the scientific interests as well as monitor the academic and research progress of trainees from all backgrounds within the program (i.e., retention), including those from underrepresented groups. Applicant organizations are encouraged to consult the NIH's website to identify promising retention practices (<a href="https://web.archive.org/web/20250122105054/https://extramural-diversity.nih.gov/building-participation/recruitment-retention">https://extramural-diversity.nih.gov/building-participation/recruitment-retention</a>) and to use evidence-informed practices for retention with the recognition that the variety of trainee backgrounds and experiences may necessitate the need to tailor retention approaches. Describe the specific efforts to be undertaken by the training program and how these might coordinate with broader trainee retention efforts of the institution(s).

• The application should describe how the level of institutional and departmental commitment to research training will promote the success of the trainees and training program. This includes providing an inclusive, safe and supportive environment with procedures to ensure accountability and reporting of concerns. 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 NOFO. Do not repeat information contained elsewhere in the application.

### **Training Outcomes**

This section is intended to provide outcomes for the program described in the application (or for new programs, to provide outcomes for recent graduates in similar training to the proposed program). The application should provide the information below about recent outcomes through narrative descriptions and a summary of the data presented in the required <a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm">https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm</a>). The application should describe the following:

- Evidence that recent program graduates conducted rigorous research that advanced scientific knowledge and/or technologies, with increasing self-direction (e.g., peer-reviewed publications in <u>Training Table 5 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm</u>), or other measures of scientific accomplishment appropriate to the field);
- The rate of program completion and length of training (for predoctoral trainees, explain how time-to-degree <u>Training Table 8</u> (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm) ).
- The success of recent graduates transitioning to careers in the biomedical research workforce (<u>Training Table 8</u>). (<a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm">https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/forms/data-tables.htm</a>)

If disparities are observed in trainee outcomes, describe approaches to identify the causes and, where warranted, the approaches to feasibly address the issues in the Program Plan.

### **Progress Report for Renewal Applications**

For renewal applications include information in the "Program Overview" section to demonstrate that the program successfully trained a diverse pool of individuals who have the technical, operational, and professional skills to transition into careers in the biomedical research workforce. 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. Describe successes and challenges with implementation of the programmatic elements described in the previous application (e.g., curricular elements, mentor training activities, efforts to promote inclusive, safe, accessible and supportive research training environments) and provide justifications for failing to implement previously proposed programmatic elements. Include success rates for graduation and successful transitions to postdoc or careers in the biomedical research workforce and describe how the program made aggregate data on training and career outcomes publicly available.

### Faculty, Trainees, and Training Record

### **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 the productivity of its trainees (not to exceed 10 pages). Institutional commitment to the following areas must also 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 safe, accessible, and inclusive and supportive research training environments at all levels (trainees, staff, faculty, and leadership); ensuring the research facilities and laboratory practices promote the safety of trainees (see The NIH Grants Policy Statement Section 4
   <a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section\_4/4\_public\_policy\_requirements\_objectives\_and\_other\_appropriation\_miregarding\_NIH recipient institutions expectations to provide safe and healthful working condition for their employees and foster work environments conducive to high-quality</li>
- regarding NIH recipient institutions expectations to provide safe and nealthrul working condition for their employees and foster work environments conducive to high-quality research); 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 discrimination, harassment and other discriminatory practices and to appropriately respond to allegations of such discriminatory practices, including providing any required notifications to NIH (see NOT-OD-22-129 (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-129.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.

### **Other Training Program Section**

### Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400); any instructions provided here are in addition to the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) instructions.

### **PHS Assignment Request Form**

All instructions in the How to Apply - Application Guide (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400) must be followed.

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

See Part 2. 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 - cv-10787-WGY Document 72-6 Filed 05/19/25 Page 11 of 17

Part I. contains information about Key Dates and times. Applicant organizations 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://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82380), the application deadline is automatically extended to the next business day

Organizations must submit applications to <a href="Grants.gov">Grants.gov</a> (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11128)</a> (the online portal to find and apply for grants across all Federal agencies). Applicant organizations must then complete the submission process by tracking the status of the application in the <a href="eRA Commons">eRA Commons</a> (<a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11123">eRA Commons</a> (<a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11123">eRA Commons</a> (<a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11123">eRA Commons</a> (<a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11123</a>), 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.

Applicant organizations 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 <u>How to Apply - Application Guide</u> (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400).

### 5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/html5/section\_10/10.10.1\_executive\_orders.html).

### 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 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11120). The National Research Service Award (NRSA) policies (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?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 Section 7.9.1 Selected Items of Cost

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?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 <a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400">https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82400</a>). Paper applications will not be accepted.

Applicant organizations 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 <u>How to Apply - Application Guide</u>

(https://web.archive.org/web/20250122105054/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 <a href="Dealing with System Issues">Dealing with System Issues</a>
(https://web.archive.org/web/20250122105054/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 <a href="Dealing with System Issues">Dealing with System Issues</a>

(https://web.archive.org/web/20250122105054/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 form. 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 unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the <a href="https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/quide/url redirect.php?id=82400">https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/quide/url redirect.php?id=82400</a>).

See more tips (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?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.

### **Mandatory Disclosure**

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, 2 CFR 200.113 (https://web.archive.org/web/20250122105054/https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) and NIH Grants Policy Statement Section 4.1.35

 $(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/html5/section\_4/4.1.35\_mandatory\_disclosures.htm). \\$ 

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the HHS Office of Inspector Grant Self Disclosure Program (https://web.archive.org/web/20250122105054/https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) at grantdisclosures@oig.hhs.gov (mailto:grantdisclosures@oig.hhs.gov)

### **Post Submission Materials**

Applicant organizations are required to follow the instructions for post-submission materials, as described in <a href="mailto:the-policy">the-policy</a> (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82299).

Any instructions provided here are in addition to the instructions in the policy.

Substitute the term "scholars" for all references to "trainees" in the SF424 (R&R) Application Guide, and substitute the term "career development" for all references to "training" in the SF424 (R&R) Application Guide.

# Section V. Application Review Information

### 1. Criteria

Only the review criteria described below will be considered in the review process.

Applications submitted to the NIH in Support of the NIH in Support of the NIH in Support of the NIH peer review system. While any information in the application relevant to the program goals can be included as part of the review process, the race, ethnicity, or sex (including gender identity, sexual orientation, or transgender status) of trainee candidates, trainees, or faculty may not, in and of themselves, be used as factors in the evaluation of applications.

### **Overall Impact**

Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the proposed training program will equip the trainees with the skills, knowledge and experiences necessary to transition to successful careers in the biomedical research workforce, 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 biomedical research training impact.

### **Training Program and Environment**

- Does the application provide a compelling rationale for the proposed research training program and propose appropriate training goals and objectives relevant to the rationale?
- Will the courses, structured training activities, mentoring, and research experiences achieve the training program's goals and objectives, and provide opportunities for trainees to acquire skill and expertise in transparent, rigorous, reproducible and relevant research methodologies and tools applicable to the goals of the training program?
- Is there an effective mechanism to monitor mentoring and to promote the development, retention and success of all trainees throughout their training?
- Will the proposed training program provide the trainees appropriate information regarding the breadth of careers in the biomedical research workforce for which their training
  may be useful, and appropriate learning opportunities that allow them to develop the professional skills and networks necessary to transition into those careers?
- · Does the research training environment have adequate and appropriate facilities to support the proposed research training program?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to promote the success of the program?
- Is it clear how the proposed training program is distinguished from other externally funded training programs at the institution?
- Does the application provide a compelling rationale for the proposed short-term research training program and include appropriate training goals and objectives relevant to the rationale? Are the objectives, design, direction, and quality of the proposed short-term research training program likely to ensure effective training?
- Are the proposed courses, structured training activities, mentoring, and research experiences where applicable appropriate for the level of trainees and the area(s) of
  science to be supported by the program? Do the program activities appropriately introduce trainees to transparent, rigorous, and reproducible research methodologies?
- If appropriate, does the program provide training in inter- or multi-disciplinary research and/or provide training in state-of-the-art or novel methodologies and techniques?
  - Is the proposed program of training likely to ensure that trainees will acquire knowledge and skills necessary to prepare them for a research career? Does the program include features likely to encourage short-term trainees to consider careers in health-related research?
- · Does the research training environment have adequate and appropriate facilities to support the proposed research training program?
- Is the level of institutional commitment to the training program, including administrative and research training support, sufficient to promote the success of the program?

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

- Do the PD(s)/Pl(s) have the appropriate background, expertise, and administrative and training experience to provide strong leadership, direction, management, and administration of the proposed research training program?
- Do the PD(s)/PI(s) plan to commit sufficient effort to promote the program's success?
- Have the PD(s)/PI(s) demonstrated a strong commitment to training future researchers?
- Does the application describe how the PD(s)/PI(s) will receive appropriate training on effective mentoring practices to promote trainee 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/Pls?

### **Preceptors/Mentors**

- Does the proposed program demonstrate the presence of a sufficient pool of preceptors/mentors with appropriate expertise and adequate resources available to support the training goals and objectives proposed in the application (including short-term training, if applicable)?
- Is there a strong plan to ensure participating faculty receive appropriate training in the use of evidence-informed mentoring practices that promote the development of trainees from all backgrounds, including trainees from groups underrepresented in the biomedical sciences?
- Do participating faculty appropriately promote the trainees' career progression?
- Do the preceptors/mentors have strong records of training individuals at the level of trainees (including short-term trainees, if applicable) proposed in the program? Are appropriate plans in place to ensure that preceptors lacking sufficient research training experience are likely to provide strong and successful mentoring?

### **Trainees**

- Does the proposed short-term training program demonstrate the presence of a sufficient pool of potential trainees in appropriate disciplines and training stages to achieve the training goals and objectives? Are the outlined recruitment strategies likely to identify trainee candidates with the potential to strongly benefit from, and with proper training and support, succeed in the training program?
- Does the program have access to and the ability to recruit high quality, short-term trainees from the applicant institution or another health-professional school?
- Are the recruiting procedures and trainee selection criteria appropriate and well defined?
- Does the program propose an appropriate multifactorial candidate review process to allow a broad group of research-oriented trainees the ability to participate in the training program (for example, a process that considers, consistent with applicable law, metrics beyond previous institution, GPA, and standardized test scores)?

### **Training Record**

- · How successful are the trainees (or, for new applications, recent graduates in similar training) in completing the program?
- Does the application provide evidence that trainees (or, for new applications, other recent graduates in similar training) conducted rigorous research that, appropriate to the
  training stage of the proposed program, advanced scientific knowledge and/or technologies with increasing self-direction (such as peer-reviewed publications and other
  accomplishments appropriate to the field)?
- How successful are the trainees (or, for new applications, recent graduates in similar training) in transitioning to careers in the biomedical research workforce that utilize their training and directly benefit the broader biomedical research enterprise?
- If disparities are observed in outcomes for trainees (or, for new applications, recent graduates in similar training), has the program proposed adequate approaches to identify the causes and, where warranted, approaches to feasibly address them?
- Does the program propose a rigorous evaluation plan to assess the effectiveness of the training program and the extent to which it is meeting its overall goals and objectives? Are effective mechanisms in place for obtaining feedback from current and former trainees, and appropriate plans to respond to trainee feedback?

• For applications that request short-term research training positions, is there a record of retaining health professionar trainees in general 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**

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.

### **Recruitment Plan to Enhance Diversity**

Reviewers will examine the strategies to be used in the recruitment of prospective candidates from underrepresented groups.

For purposes of this review, "recruitment" refers to outreach efforts intended to encourage individuals to apply for the program. "Recruitment" does not mean the appointment or hiring of an individual into the program. For renewals, the committee may consider the program's account of past experiences, including successful and unsuccessful strategies, but may not use the race, ethnicity, or sex of program trainees appointed during the previous funding period as factors in the evaluation.

### Training in the Responsible Conduct of Research

All applications for support under this NOFO 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?

### Training in Methods for Enhancing Reproducibility

Does the plan for Instruction in Methods for Enhancing Reproducibility describe 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, appropriate to field of study and the level and prior preparation of the trainees?

For renewal applications, does the application document appropriate changes in the plan for Methods for Enhancing Reproducibility in response to feedback and to evolving issues related to the conduct of rigorous and reproducible research?

### 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.

- Does the application describe the program's accomplishments over the past funding period(s)? Is the program achieving its training objectives?
- To what extent have the training goals and objectives been achieved since the last cycle? If certain goals were not met, did the program provide reasonable explanations and describe appropriate alternative approaches taken?
- Has the program evaluated the quality and effectiveness of the short-term training experience, and is there evidence that the evaluation outcomes and feedback from trainees have been acted upon?
- Are appropriate changes proposed that are likely to improve or strengthen the short-term research training experience during the next project period?
- Does the program use current, evidence-informed training and mentoring approaches and 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.

### **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 Cv-10787-WGY Document 72-6 Filed 05/19/25 Page 14 of 17

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

### 2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by {LOCUS OF REVIEW} in accordance with NIH peer review policy and procedures (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?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 will receive a written critique.

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

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. 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, consistent with applicable law:

- · 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.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement Section 2.5.1. Just-in-time Procedures. (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82418) This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

### 3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access their Summary Statement (written critique) via the eRA Commons (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11120).

### Section VI. Award Administration Information

### 1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

In accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk. For more information on the Notice of Award, please refer to the NIH Grants Policy Statement Section 5. The Notice of Award (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section 5/5 the notice of award.htm) and NIH Grants & Funding website, see Award Process. (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/pre-award-process.htm#award)

# 2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through NIH:

- The rules listed at 2 CFR Part 200 (https://web.archive.org/web/20250122105054/https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11120) as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A:

  General (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11120) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url redirect.php?id=11159).
- If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (<a href="https://web.archive.org/web/20250122105054/https://www.hhs.gov/sites/default/files/form-hhs690.pdf">https://web.archive.org/web/20250122105054/https://www.hhs.gov/sites/default/files/form-hhs690.pdf</a>). To learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights website (<a href="https://web.archive.org/web/20250122105054/https://www.hhs.gov/civil-rights/for-providers/laws-regulations-quidance/laws/index.html">https://www.hhs.gov/civil-rights/for-providers/laws-regulations-quidance/laws/index.html</a>).
  - HHS recognizes that NIH 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 NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in NIH Grants Policy Statement Section 4 Public Policy Requirements, Objectives and Other Appropriation Mandates.

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section 4/4 public policy requirements objectives and other appropriation mandate

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See <u>2 CFR Part 200.340 Termination (https://web.archive.org/web/20250122105054/https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340) and NIH Grants Policy Statement Section 8.5.2 Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support</u>

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/html5/section\_8/8.5.2\_remedies\_for\_noncompliance\_or\_enforcement\_actions-

Institutional NRSA training grants must be administered in accordance with the current NRSA section of the NIH Grants Policy Statement - Institutional Research Training Grants (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=61170).

The taxability of stipends is described in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=41171).

Policies regarding the Ruth L. Kirschstein-NRSA payback obligation are explained in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=41171).

Successful recipients under this NOFO agree that:

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by any funded entity, recipients and subrecipient(s) are required to: Use health IT that meets standards and implementation specifications adopted in 45 CFR part 170, Subpart B, if such standards and implementation specifications can support the activity. Visit <a href="https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B">https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-B</a>) to learn more.

Where the award funding involves implementing, acquiring, or upgrading health IT for activities by eligible clinicians in ambulatory settings, or hospitals, eligible under Sections 4101, 4102, and 4201 of the HITECH Act, use health IT certified under the ONC Health IT Certification Program if certified technology can support the activity. Visit <a href="https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-health-it/https://web.archive.org/web/20250122105054/https://www.healthit.gov/topic/certification-ehrs/certification-

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

- 1. ongoing and consistent access to HHS owned or operated information or operational technology systems; and
- 2. receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PII) obtained from the awarding HHS agency for the purposes of executing the award.

Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework (https://web.archive.org/web/20250122105054/https://www.nist.gov/cyberframework), to protect HHS systems and data. Please refer to NIH Post-Award Monitoring and Reporting (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm) for additional information.

### **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 NIH Grants Policy. Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=61131).

### **Cooperative Agreement Terms and Conditions of Award**

Not Applicable

### 3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement.

(https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section 8/8.2.3 sharing research resources.htm#Data)

### 4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR)

(//web.archive.org/web/20250122105054/https://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 recipient 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 award. The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at <a href="https://www.fsrs.gov">www.fsrs.gov</a>

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11170) on all subawards over \$25,000. See the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=82420) for additional information on this reporting requirement.

### **Other Reporting Requirements**

The institution must submit a completed Statement of Appointment (PHS Form 2271 (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php? id=61189)) for each trainee appointed or reappointed to the training grant for 8 weeks or more. Recipients must submit the PHS 2271 data electronically using the xTrain system. More information on xTrain is available at xTrain (eRA Commons) (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?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.

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 Section 8.6 Closeout (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/policy/nihgps/HTML5/section\_8/8.6\_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, 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 and 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

### 5. Evaluation

In carrying out its stewardship of human resource-related programs, 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 Grans of Contracts, riving support from research Grant of Contra

Within ten years of making awards under this program, NIH will assess the program's overall outcomes, gauge its effectiveness in achieving its goals, and consider whether there is a continuing need for the program. Upon the completion of this evaluation, NIH will determine whether to (a) continue the program as currently configured, (b) continue the program with modifications, or (c) discontinue the program.

The overall evaluation of the program will be based on metrics that will include, but are not limited to, the following:

### For programs involving undergraduate students:

- · Successful completion of an undergraduate degree in a STEM field
- · Pending application for and/or enrollment in an advanced degree program in a STEM field
- · Subsequent participation in a formal research training or career development program in a STEM field
- · Subsequent participation in research or employment in a STEM field
- · Authorship of scientific publications in a STEM field

### For programs involving graduate students:

- · Successful completion of a STEM graduate program
- · Subsequent participation in a formal research training or career development program in a STEM field
- · Subsequent participation in research or employment in a STEM field
- · Authorship of scientific publications in a STEM field
- Subsequent independent research grant support from NIH or another source

### For programs involving postdoctorates and early career investigators:

- Subsequent participation in a formal research training or career development program in a STEM field
- · Subsequent participation in research or employment in a STEM field
- · Authorship of scientific publications in a STEM field
- · Subsequent independent research grant support from NIH or another source

# 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 NOFO, prospective applications **MUST** consult the <u>Table of IC-Specific Information</u>, <u>Requirements</u>, and <u>Staff Contacts (Inttps://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.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 Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten on-time submission, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (https://web.archive.org/web/20250122105054/https://www.era.nih.gov/need-help) (preferred method of contact)

Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application processes and NIH grant resources)

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

Telephone: 301-480-7075

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

Contact Center Telephone: 800-518-4726

Email: support@grants.gov\_(mailto:support@grants.gov)

### Scientific/Research Contacts

Please see IC-specific contacts here - https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)

Neeraj Agarwal

NEI - NATIONAL EYE INSTITUTE

Phone: 301-435-8155

E-mail: agarwalnee@nei.nih.gov (mailto:agarwalnee@nei.nih.gov)

Edwin C Clayton

NEI - NATIONAL EYE INSTITUTE

Phone: (301) 480-9350

E-mail: ed.clayton@nih.gov\_(mailto:ed.clayton@nih.gov)

Jennifer N. Baumgartner, Ph.D.

National Center for Complementary and Integrative Health (NCCIH)

Phone: 301-402-4084

 $\textbf{Email:} \underline{jennifer.baumgartner@nih.gov} \underline{(mailto:\underline{jennifer.baumgartner@nih.gov)}$ 

Carol Shreffler, PhD

NIEHS - National Institute of Environmental Health Sciences

Phone: 984-287-3322

Email: Shreffl1@niehs.nih.gov (mailto:Shreffl1@niehs.nih.gov)

### 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 Contacts**

Please see IC-specific contacts here - https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html (https://web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-25-280.html)

Karen Robinson Smith

NEI - NATIONAL EYE IN A PROPE 1:25-cv-10787-WGY Document 72-6 Filed 05/19/25 Page 17 of 17

Phone: 301-435-8178

E-mail: kyr@nei.nih.gov\_(mailto:kyr@nei.nih.gov)

Debbie Chen

National Center for Complementary and Integrative Health (NCCIH)

Phone: 301-594-3788

Email: <u>debbie.chen@nih.gov (mailto:debbie.chen@nih.gov)</u>

Jenny Greer

NIEHS - National Institute of Environmental Health Sciences

Phone: 984-287-3332

Email: jenny.greer@nih.gov (mailto:jenny.greer@nih.gov)

# Section VIII. Other Information

Recently issued trans-NIH policy notices (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?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

(//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (//web.archive.org/web/20250122105054/https://grants.nih.gov/grants/guide/url\_redirect.php?id=11120).

### **Authority and Regulations**

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 63A and 2 CFR Part 200.

Weekly TOC for this Announcement (/web/20250122105054/https://grants.nih.gov/grants/guide/WeeklyIndex.cfm?01-03-25) NIH Funding Opportunities and Notices (/web/20250122105054/https://grants.nih.gov/grants/guide/index.html)







(https://web.archive.org/web/20250122105054/https://www.

(/web/20250122105054/https://grants.nih.gov/grants/oer.htm)

Department of Health and Human Services (HHS)

NIH... Turning Discovery Into Health®