

March 31, 2025

This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH (http://www.nih.gov))
Components of Participating Organizations	<div>Office of Data Science Strategy (ODSS (https://datascience.nih.gov/about/odss))</div> <div>National Eye Institute (NEI (https://www.nei.nih.gov/))</div> <div>National Heart, Lung, and Blood Institute (NHLBI (https://www.nhlbi.nih.gov/))</div> <div>National Human Genome Research Institute (NHGRI (https://www.genome.gov/))</div> <div>National Institute on Aging (NIA (https://www.nia.nih.gov/))</div> <div>National Institute on Alcohol Abuse and Alcoholism (NIAAA (https://www.niaaa.nih.gov/))</div> <div>National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS (https://www.niams.nih.gov/))</div> <div>National Institute of Biomedical Imaging and Bioengineering (NIBIB (https://www.nibib.nih.gov/))</div> <div>Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD (https://www.nichd.nih.gov/))</div> <div>National Institute on Deafness and Other Communication Disorders (NIDCD (https://www.nidcd.nih.gov/))</div> <div>National Institute of Dental and Craniofacial Research (NIDCR (https://www.nidcr.nih.gov/))</div> <div>National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK (https://www.niddk.nih.gov/))</div> <div>National Institute on Drug Abuse (NIDA (https://www.drugabuse.gov/))</div> <div>National Institute of Environmental Health Sciences (NIEHS (https://www.niehs.nih.gov/))</div> <div>National Institute of Mental Health (NIMH (https://www.nimh.nih.gov/index.shtml))</div> <div>National Institute of Neurological Disorders and Stroke (NINDS (https://www.ninds.nih.gov/))</div> <div>National Institute on Minority Health and Health Disparities (NIMHD (https://www.nimhd.nih.gov/))</div> <div>National Library of Medicine (NLM (https://www.nlm.nih.gov/))</div> <div>National Center for Complementary and Integrative Health (NCCIH (https://nccih.nih.gov/))</div> <div>National Cancer Institute (NCI (https://www.cancer.gov/))</div>

Funding Opportunity Title	Building Sustainable Software Tools for Open Science (R03 Clinical Trial Not Allowed)
Activity Code	R03 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R03&Search.x=0&Search.y=0&sort=ac&Search_Type=Activity&text_prev=) Small Grant Program
Announcement Type	New
Related Notices	<ul style="list-style-type: none"> • May 15, 2025 - Notice of Early Expiration of Notices of Funding Opportunities Related to the Simplified Review Framework for NIH Research Grant Applications. See Notice NOT-OD-25-113 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-113.html). • March 31, 2025 - This funding opportunity was updated to align with agency priorities. Carefully reread the full funding opportunity and make any needed adjustments to your application prior to submission. • November 4, 2024 - Notice of Change to the Eligibility of Foreign Components in RFA-OD-24-010 "Building Sustainable Software Tools for Open Science (R03 Clinical Trial Not Allowed)". See Notice NOT-OD-25-018 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-018.html). • 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://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-084.html). • August 31, 2022- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198 (https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html). • August 5, 2022- Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html).
Funding Opportunity Number (FON)	RFA-OD-24-010
Companion Funding Opportunity	RFA-OD-24-011 (https://grants.nih.gov/grants/guide/rfa-files/RFA-OD-24-011.html) , R50 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R50&Search.x=0&Search.y=0&Search_Type=Activity) Research Specialist Award
Number of Applications	See Part 2, Section III. 3. Additional Information on Eligibility.
Assistance Listing Number(s)	93.310, 93.865, 93.286, 93.847, 93.846, 93.396, 93.172, 93.307, 93.113, 93.879, 93.867, 93.866, 93.121, 93.242, 93.213, 93.233, 93.837, 93.838, 93.839, 93.840, 93.273, 93.279, 93.173, 93.853
Funding Opportunity Purpose	The purpose of this notice of funding opportunity (NOFO) is to enhance the sustainability and impact of research software tools by enabling the use of best practices and design principles in software development and by leveraging continuing advances in computing. This NOFO is also expected to facilitate the creation of vibrant partnerships between developers and users of software and tools, and to promote FAIR practices for research software to maximize research value.

Key Dates

Posted Date	July 17, 2024
Open Date (Earliest Submission Date)	November 04, 2024
Letter of Intent Due Date(s)	30 days prior to the application due dates

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
December 04, 2024	December 04, 2024	Not Applicable	March 2025	May 2025	July 2025
June 04, 2025	June 04, 2025	Not Applicable	September 2025	January 2026	March 2026
December 04, 2025	December 04, 2025	Not Applicable	March 2026	May 2026	July 2026
June 04, 2026	June 04, 2026	Not Applicable	September 2026	January 2027	March 2027
December 04, 2026	December 04, 2026	Not Applicable	March 2027	May 2027	July 2027

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

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

Expiration Date	New Date May 24, 2025 per NOT-OD-25-113 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-113.html) (Originally December 05, 2026)
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](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 [NIH Guide for Grants and Contracts \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11164\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11164)).

Conformance to all requirements (both in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](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 \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](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 [eRA Commons \(https://public.era.nih.gov/commons/\)](https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=RFA-OD-24-010\)](https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=RFA-OD-24-010) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Background

Investigators often produce innovative, scientifically valuable software tools that are essential for scientists to use and interpret biomedical, clinical, behavioral, social, and health-related research data. Much of this valuable software, however, has been built and supported under conditions that are not optimal in a rapidly changing technical and scientific landscape. Investigators also often lack the resources to adapt and revise the software to take advantage of new technologies and computing paradigms, resulting in lost opportunities and sustainability challenges.

The traditional grant funding process has emphasized innovation for research progress over the use of robust software engineering practices that have become essential for generating reliable, efficient, and scalable software tools in an era of large-scale data and integrated data analytics. There have been few practical ways to support joint efforts between researchers and software engineers to develop and revise research software tools according to well-recognized software engineering best practices and design principles. To transition to operational efficiency and sustainability that is envisioned by the NIH Office of Data Science Strategy (ODSS), new ways to support engagement of software engineers or industry professionals are needed to improve the valuable software tools that have been developed in academic settings for health-related research to process, manage, mine, analyze, visualize, and interpret data.

Building a robust software foundation is essential to the NIH's vision to establish a modernized and integrated biomedical, clinical, behavioral, social, and health-related data and compute ecosystem. Such an ecosystem will foster adoption of robust software development principles, new data science technologies, cloud and hybrid computing, artificial intelligence, and best practice guidelines for open science arising from community consensus, such as the [NIH best practices for sharing research software \(https://datascience.nih.gov/tools-and-analytics/best-practices-for-sharing-research-software-faq\)](https://datascience.nih.gov/tools-and-analytics/best-practices-for-sharing-research-software-faq) and FAIR4RS (Findable, Accessible, Interoperable, and Reusable for Principles for Research Software) principles and open-source development.

To encourage collaboration between scientists and software engineers in research software development efforts, the NIH ODSS has previously issued four rounds of software supplement notices of special interest ([NOT-OD-23-073](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-073.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-073.html>), [NOT-OD-22-068](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-068.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-068.html>), [NOT-OD-21-091](https://grants.nih.gov/grants/guide/notice-files/not-od-21-091.html) (<https://grants.nih.gov/grants/guide/notice-files/not-od-21-091.html>), and [NOT-OD-20-073](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-073.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-073.html>)) to support software development best practices to update, refactor and enhance the design, implementation, and cloud-readiness of research software and to build new communities for open science. Projects which received supplemental support have encompassed a wide range of research and translational projects reaching across NIH Institutes and Centers (ICs) and spanning many scientific domains. This program announcement builds upon these past programmatic activities to further the advancements in these areas.

Purpose

The purpose of this funding opportunity is to enhance the sustainability and impact of research software tools by enabling the use of best practices and design principles in software development and by leveraging continuing advances in computing. The Building Sustainable Software Tools for Open Science (R03) funding opportunity is intended to provide a flexible mechanism to support the use of best practices for scientific software development and to promote community engagement for open science. Successful grants will enable and/or enhance biomedical, clinical, behavioral, social, and health-related research endeavors by (1) developing robust, sustainable, scalable, and reproducible research software tools and workflows, (2) extending the impact of research software by broader dissemination to the scientific community, (3) supporting collaborations between scientists and software engineers to leverage modern, best practices in research software development, and (4) enhancing software skills of the research workforce. This initiative is aligned with the [NIH Strategic Plan for Data Science](https://datascience.nih.gov/nih-strategic-plan-data-science) (<https://datascience.nih.gov/nih-strategic-plan-data-science>), which describes actions aimed at building a better data infrastructure and a modernized data ecosystem.

Scope (Research Objective)

The goal of this NOFO is to enhance the sustainability and impact of research software tools, in accordance with the [NIH Strategic Plan for Data Science](https://datascience.nih.gov/sites/default/files/NIH_Strategic_Plan_for_Data_Science_Final_508.pdf) (https://datascience.nih.gov/sites/default/files/NIH_Strategic_Plan_for_Data_Science_Final_508.pdf). The program will support efforts that address robustness, sustainability, reusability, portability, and scalability of existing biomedical, clinical, behavioral, social, and health-related research software tools and workflows of recognized scientific value. It is primarily intended to provide support for research software development, with some allowance for other costs that may be required to improve tools with significant user base or demonstrate potential for community adoption. Collaborations either within or across institutions are desirable and may include industry or academic partners.

Delivering reliable, sustainable, and reusable software across multiple platforms requires a whole lifecycle approach, as illustrated with a few instances. Software *development* can be improved by enhancing the development process, including the addition of resources for building, testing, and managing change in an open-source community. *Robustness* and *reliability* can be improved through open-source licensing to increase community engagement for (re)usage, testing, and validation. *Reusability* can be enhanced by improving dissemination channels for important algorithms and tools, by publication of tools in shared container registries, and with well-crafted operating manuals. *Interoperability* can be enhanced by incorporating open interfaces and data formats, especially through engagement in relevant communities and standards efforts. *Refactoring* can enhance portability and take advantage of new hardware or compute environments).

Examples that address one or more challenges toward building robust software suitable for open science and modern computing include, but are not limited to:

- Adding application programming interfaces (APIs) and services to software, especially when compliant to community standards;
- Refactoring of software to incorporate standard interfaces and data formats, replace custom code with standard, hardened libraries;
- Refactoring software for portability and to scale efficiently on cloud or hybrid environments;
- Reducing coupling and complex shared state, allowing code to operate on diverse data sources and in collaboration with other services;
- Adopting standard input and output data formats including providing clean and well-documented input, output, and configuration that make scope software components more usable in composition via workflow languages and ensure that data exchanged by services maximizes the use of open data formats;
- Implementing standard logging models, improving performance through improved logging, monitoring, code profiling and optimization, taking advantage of parallelization, or use of graphics processing units (GPUs);
- Enhancing source code, documentation, version management and build/test tools to support community open-source development;
- Developing standard build and packaging tools to manage dependencies and produce containerized runtimes;
- Formatting packages for sharing via common package management tools appropriate to the language and environment;
- Enhancing standard unit and functional testing support and sample data sets for testing patches and upgrades;

This funding opportunity is meant to support development of robust, re-usable scientific software and tools. **Data generation and data analysis projects are NOT in scope of this NOFO.**

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument	Grant: A financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.
Application Types Allowed	<p>New Resubmission</p> <p>The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the How to Apply - Application Guide (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.</p>
Clinical Trial?	<p>Not Allowed: Only accepting applications that do not propose clinical trials.</p> <p>Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.php?id=82370)</p>
Funds Available and Anticipated Number of Awards	The NIH ODSS intends to commit up to \$6 million in FY25 to fund 20-24 awards.
Award Budget	The combined budget for direct costs for the two-year project period may not exceed \$300,000. No more than \$200,000 direct costs may be requested in any single year.
Award Project Period	A project duration of up to two years may be requested.

NIH grants policies as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.php?id=11120\)](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 Applicants

Eligible Organizations

Higher Education Institutions

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Local Governments

- State Governments
- County Governments
- City or Township Governments

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

Federal Governments

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

Other

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

Foreign Organizations

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

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

Foreign components, as [defined in the NIH Grants Policy Statement \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11118\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](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 applicants 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 \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82423\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information

- [System for Award Management \(SAM\) – \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82390\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82390) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
 - [NATO Commercial and Government Entity \(NCAGE\) Code \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11176\)](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.
- [eRA Commons \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) – Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; 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 \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82300\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82300) – Applicants 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)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400)

(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

2. Cost Sharing

This NOFO does not require cost sharing as defined in the [NIH Grants Policy Statement NIH Grants Policy Statement Section 1.2 Definition of Terms. \(//grants.nih.gov/grants/guide/url_redirect.php?id=11126\)](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 scientifically distinct.

The 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 \(//grants.nih.gov/grants/guide/url_redirect.php?id=82415\)](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 \(//grants.nih.gov/grants/guide/url_redirect.php?id=82423\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82423)).

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 applicants follow the instructions in the Research (R) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](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 \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](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.

Letter of Intent

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

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

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel (if known)

The letter of intent should be sent to: [sustainablesoftware@nih.gov \(mailto:sustainablesoftware@nih.gov\)](mailto:sustainablesoftware@nih.gov)

Page Limitations

All page limitations described in the [How to Apply – Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the [Table of Page Limits \(https://grants.nih.gov/grants/guide/url_redirect.php?id=61134\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=61134) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the [How to Apply – Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](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 \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](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 \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

R&R or Modular Budget

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

Applicants are required to include travel support for the PD/PI(s) to attend a meeting/conference. The budget must include one trip per year to these meetings. The meeting location may be at a location in the United States.

R&R Subaward Budget

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

PHS 398 Cover Page Supplement

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

PHS 398 Research Plan

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed, with the following additional instructions:

Research Strategy

Open-source development practices are encouraged. The application must describe the need for sustainable software; present a robust software development plan, including milestones and metrics; provide details of how the best software engineering practices and design principles will be employed in the project; and address plans for disseminating the resulting software to the prospective users. Consideration of relevant research and software engineering collaborations should be addressed. A project timeline must be provided to ensure that the proposed work can be reasonably completed during the requested period of support. URLs of publicly available websites may be cited for the purpose of referencing any existing software or code that is the subject of the proposed software development, or related activities. Please refer to NOT-OD-20-174 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-174.html) for further guidance on use of hyperlinks in NIH applications.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Applicants are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide. A Resource Sharing Plan for proposals submitted in response to this NOFO must address software dissemination, as described below:

Please provide milestones and a timeline for dissemination of software supported by this award. There is no prescribed single license for software produced through grants responding to this announcement. The NIH, however, does encourage the use of the most permissible license possible. To promote dissemination and reuse of the resulting software, the following points should be addressed and should represent a commitment by the institution (and its subcontractors, as relevant):

- The software (e.g., source code) should be freely available to biomedical, clinical, behavioral, and health-related researchers and educators in the non-profit sector, such as institutions of education, research institutions, and government laboratories.
- The terms of software availability should permit the dissemination and commercialization of enhanced or customized versions of the software, or incorporation of the software or pieces of it into other software packages.
- To preserve utility to the community, the software should be transferable such that another individual, team, community can continue development if the original investigators are unwilling or unable to do so.
- The terms of software availability should include the ability of researchers to modify the source code and to share modifications with other colleagues.
- To further enhance the potential impact of their software, applicants may consider proposing a plan to manage and disseminate the improvements or customizations of their tools and resources by others. In support of this goal, awardees are encouraged to manage and disseminate their source code through an open revision control and source code management system such as GitHub.

Prior to funding, program staff may negotiate modifications of the resource sharing plan with the applicant. The final version of the resource sharing plan will become a term of the award.

Other Plan(s):

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed, with the following additional instructions:

- A Data Management and Sharing Plan is not applicable for this NOFO.

Appendix: Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), with the following additional instructions:

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

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed.

PHS Assignment Request Form

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](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

[Part I](#) contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or [Federal holiday \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82380\)](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 [Grants.gov \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11128\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82423\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82423).

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

Information on the submission process and a definition of on-time submission are provided in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](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://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

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](https://grants.nih.gov/grants/guide/redirect.php?id=11120) ([//grants.nih.gov/grants/guide/redirect.php?id=11120](https://grants.nih.gov/grants/guide/redirect.php?id=11120)).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost](https://grants.nih.gov/grants/guide/redirect.php?id=11143) ([//grants.nih.gov/grants/guide/redirect.php?id=11143](https://grants.nih.gov/grants/guide/redirect.php?id=11143)).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/redirect.php?id=82400) (<https://grants.nih.gov/grants/guide/redirect.php?id=82400>). Paper applications will not be accepted.

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

For assistance with your electronic application or for more information on the electronic submission process, visit [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/redirect.php?id=82400) (<https://grants.nih.gov/grants/guide/redirect.php?id=82400>). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Dealing with System Issues](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) (<https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm>) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

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

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 [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/redirect.php?id=82400) (<https://grants.nih.gov/grants/guide/redirect.php?id=82400>).

See [more tips](https://grants.nih.gov/grants/guide/redirect.php?id=11146) ([//grants.nih.gov/grants/guide/redirect.php?id=11146](https://grants.nih.gov/grants/guide/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 and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive 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://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) (<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://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm) (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://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) (<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

Applicants are required to follow the instructions for post-submission materials, as described in [the policy](https://grants.nih.gov/grants/guide/redirect.php?id=82299) ([//grants.nih.gov/grants/guide/redirect.php?id=82299](https://grants.nih.gov/grants/guide/redirect.php?id=82299)).

Section V. Application Review Information

1. Criteria

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

For this particular NOFO, note the following:

The R03 small grant supports discrete, well-defined projects that realistically can be completed in two years and that require limited levels of funding. Because the research project usually is limited, an R03 grant application may not contain extensive detail or discussion. Accordingly, reviewers should evaluate the conceptual framework and general approach to the problem. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or from investigator-generated data. Preliminary data are not required, particularly in applications proposing pilot or feasibility studies.

Overall Impact

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

Scored Review Criteria

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

Significance

Specific to this NOFO: Is the need for development of the proposed software well-justified? Does the involved software have a significant user base or demonstrated potential for community adoption and use? Will its increased availability make a positive impact on the field? Is it likely that the software will be open and available to a broad audience?

Investigator(s)

Specific to this NOFO: Does the investigative team include appropriate research software development expertise?

Innovation

Specific to this NOFO: Will the software tools being developed/refactored enable innovative biomedical/behavioral/health-related research? When scoring this criterion, emphasis should be placed on the innovation that will likely be enabled by the software, rather than innovating approaches to software development. The latter are encouraged, if appropriate, but not required.

Approach

Specific to this NOFO: Is the software development plan reasonable and employs the best software development practices likely to lead to substantial improvements compared to the current state of the research software being developed? Is the proposed dissemination strategy feasible and likely to succeed? Is the study timeline appropriate to accomplish the specific aims?

Environment

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

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

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

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

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of

all ages (including children and older adults), as required by statute, to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(https://grants.nih.gov/grants/guide/redirect.php?id=11174\)](https://grants.nih.gov/grants/guide/redirect.php?id=11174).

Not Applicable

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following three points: (1) a complete description of all proposed procedures including the species, strains, ages, sex, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the [Worksheet for Review of the Vertebrate Animals Section. \(https://grants.nih.gov/grants/guide/redirect.php?id=11150\)](https://grants.nih.gov/grants/guide/redirect.php?id=11150).

Not Applicable

Biohazards

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

Not Applicable

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.

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 line of investigation presented in 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.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

Not Applicable

Select Agent Research

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

Not Applicable

Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., [Sharing Model Organisms \(https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview\)](https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview)) or the rationale for not sharing the resources, is reasonable.

Authentication of Key Biological and/or Chemical Resources

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

Not Applicable

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Center for Scientific Review (CSR), in accordance with [NIH peer review policies and practices \(//grants.nih.gov/grants/guide/redirect.php?id=11154\)](https://grants.nih.gov/grants/guide/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 submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review by the appropriate IC Advisory Council or Board. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

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 \(//grants.nih.gov/grants/guide/redirect.php?id=82418\)](https://grants.nih.gov/grants/guide/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 his or her Summary Statement (written critique) via the [eRA Commons \(//grants.nih.gov/grants/guide/redirect.php?id=11123\)](https://grants.nih.gov/grants/guide/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 Section 2.4.4 Disposition of Applications \(//grants.nih.gov/grants/guide/redirect.php?id=82416\)](https://grants.nih.gov/grants/guide/redirect.php?id=82416).

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](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm). 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 \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) and NIH

Grants & Funding website, see [Award Process. \(https://grants.nih.gov/grants/pre-award-process.htm#award\)](https://grants.nih.gov/grants/pre-award-process.htm#award)

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

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 \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200\)](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 \(https://grants.nih.gov/grants/guide/redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/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 \(https://grants.nih.gov/grants/guide/redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/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 \(https://grants.nih.gov/grants/guide/redirect.php?id=11159\)](https://grants.nih.gov/grants/guide/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 ([HHS-690 \(https://www.hhs.gov/sites/default/files/form-hhs690.pdf\)](https://www.hhs.gov/sites/default/files/form-hhs690.pdf)). To learn more, see the [Laws and Regulations Enforced by the HHS Office for Civil Rights website \(https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html\)](https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html).
 - 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. \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm)

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. NIH may terminate awards under certain circumstances. See [2 CFR Part 200.340 Termination \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR86b76dde0e1e9dc/section-200.340\)](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 \(https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions_suspension_termination_and_withholding_of_support.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.5.2_remedies_for_noncompliance_or_enforcement_actions_suspension_termination_and_withholding_of_support.htm).

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 \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients will be required to submit the [Research Performance Progress Report \(RPPR\) \(https://grants.nih.gov/grants/rppr/index.htm\)](https://grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the [NIH Grants Policy Statement Section 8.4.1 Reporting. \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.4.1_reporting.htm). To learn more about post-award monitoring and reporting, see the NIH Grants & Funding website, see [Post-Award Monitoring and Reporting \(https://grants.nih.gov/grants/guide/redirect.php?id=82428\)](https://grants.nih.gov/grants/guide/redirect.php?id=82428).

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement Section 8.6 Closeout \(https://grants.nih.gov/grants/guide/redirect.php?id=82420\)](https://grants.nih.gov/grants/guide/redirect.php?id=82420). 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.

Section VII. Agency Contacts

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

Application Submission Contacts

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

Finding Help Online: <https://www.era.nih.gov/need-help> (<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 instructions, application processes, and NIH grant resources)

Email: GrantsInfo@nih.gov (<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 Contact(s)

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Peer Review Contact(s)

Center for Scientific Review (CSR)

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Financial/Grants Management Contact(s)

Section VIII. Other Information

Recently issued trans-NIH [policy notices](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) (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](https://grants.nih.gov/grants/guide/url_redirect.php?id=11164) (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](https://grants.nih.gov/grants/guide/url_redirect.php?id=11120) (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 Part 52 and 2 CFR Part 200.

[Weekly TOC for this Announcement](https://grants/guide/WeeklyIndex.cfm?07-19-24) (<https://grants/guide/WeeklyIndex.cfm?07-19-24>)

[NIH Funding Opportunities and Notices](https://grants/guide/index.html) (<https://grants/guide/index.html>)



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Department of Health
and Human Services (HHS)



[\(https://www.usa.gov/\)](https://www.usa.gov/)

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