

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

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

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

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

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

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

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

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

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

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

Funding Opportunity Title

HEAL Initiative: Non-addictive Analgesic Therapeutics Development [Small Molecules and Biologics] to Treat Pain (UG3/UH3 Clinical Trial Optional)

Activity Code

[UG3 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=ug3&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=ug3&Search.x=0&Search.y=0&Search_Type=Activity)/[UH3 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=uh3&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=uh3&Search.x=0&Search.y=0&Search_Type=Activity) Exploratory/Developmental Phased Award Cooperative Agreement

Announcement Type

Reissue of [RFA-NS-24-019 \(https://www.grants.gov/search-results-detail/350837\)](https://www.grants.gov/search-results-detail/350837)

Related Notices

- Check for any recent [Notices of NIH Policy Changes \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11163\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) that may impact application requirements.

Funding Opportunity Number (FON)

RFA-NS-27-007

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.853, 93.395, 93.279, 93.867, 93.840, 93.233, 93.837, 93.838, 93.839, 93.273, 93.213, 93.846, 93.866, 93.865

Funding Opportunity Purpose

The purpose of this Notice of Funding Opportunity (NOFO) is to support the preclinical optimization and development of safe, effective, and non-addictive small molecule and biologic therapeutics for the treatment of pain. The goal of the program is to accelerate the advancement of promising early-stage therapeutic candidates and facilitate their readiness for Phase II clinical trials. Applicants must have a promising small molecule or biologic lead candidate for optimization, a strong biological rationale for the proposed approach, and established assays to guide the optimization process. The scope of the program includes lead optimization, early-stage development activities, IND-enabling studies, development of pharmacodynamic and/or target engagement biomarkers, preparation and submission of an Investigational New Drug (IND) application, and Phase I clinical testing. This is a milestone-driven, phased cooperative agreement program that involves active participation by NIH program staff in project planning and ongoing monitoring of research progress.

Funding Opportunity Goal(s)

To support extramural research funded by the National Institute of Neurological Disorders and Stroke (NINDS) including: basic research that explores the fundamental structure and function of the brain and the nervous system; research to understand the causes and origins of pathological conditions of the nervous system with the goal of preventing these

disorders; research on the natural course of neurological disorders; improved methods of disease prevention; new methods of diagnosis and treatment; drug development; development of neural devices; clinical trials; and research training in basic, translational and clinical neuroscience.

Key Dates

Posted Date

June 16, 2026

Open Date (Earliest Submission Date)

August 21, 2026

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
October 21, 2026	October 21, 2026	Not Applicable	March 2027	May 2027	July 2027
February 19, 2027	February 19, 2027	Not Applicable	July 2027	October 2027	December 2027
June 21, 2027	June 21, 2027	Not Applicable	November 2027	January 2028	April 2028
October 20, 2027	October 20, 2027	Not Applicable	March 2028	May 2028	July 2028
February 22, 2028	February 22, 2028	Not Applicable	July 2028	October 2028	December 2028
June 20, 2028	June 20, 2028	Not Applicable	November 2028	January 2029	April 2029
October 20, 2028	October 20, 2028	Not Applicable	March 2029	May 2029	July 2029
February 20, 2029	February 20, 2029	Not Applicable	July 2029	October 2029	December 2029

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.

Due Dates for E.O. 12372

Not Applicable

Expiration Date

February 21, 2029

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from [NIH Guide for Grants and Contracts \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164)).

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

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

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 \(https://public.era.nih.gov/assist/landing_era?tabId=0819b5fc-46b7-4f02-b6b7-127e5a4e19fa\)](https://public.era.nih.gov/assist/landing_era?tabId=0819b5fc-46b7-4f02-b6b7-127e5a4e19fa) to prepare, submit and track your application online.
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 \(https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-301\)](https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-301) 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:

The NIH HEAL Initiative: This NOFO encourages applications in support of the NIH's Helping to End Addiction Long-term (HEAL) initiative to speed scientific solutions to the national opioid public health crisis. The NIH HEAL Initiative bolsters research across NIH to (1) improve treatment for overdose, opioid misuse and addiction and (2) enhance pain management. More information about the HEAL Initiative is available at: <https://heal.nih.gov/> (<https://heal.nih.gov/>).

More than 25 million Americans suffer from chronic pain, a highly debilitating medical condition that is complex and lacks effective treatments. In recent decades, there has been an over reliance on opioids for the treatment of pain. This contributed to a significant and alarming epidemic of opioid overdose deaths and addictions. Innovative scientific solutions to develop alternative treatment options for pain are thus critically needed. As part of the mission of the HEAL Initiative, NINDS is working with other NIH Institutes and Centers to encourage the translation of basic research into new non-addictive pain treatments. This program announcement is intended to create a foundation to initiate the optimization and development of pain therapeutics and catalyze the development of partnerships between the academic and industrial sectors so that translational research in pain can flourish as a cooperative, iterative process leading to safe, effective, and non-addictive treatments for pain.

Through this Notice of Funding Opportunity (NOFO), the NIH offers researchers funding for drug discovery and development activities that can be conducted in their own laboratories. In addition, researchers have the opportunity to collaborate with NIH-funded subject-matter experts and contract research organizations (CROs) that specialize in medicinal chemistry and Good Manufacturing Practices (GMP) manufacturing, pharmacokinetics, biodistribution, protein and virus production, cell line and process development, QC release testing, toxicology, formulations development, and Phase I clinical studies.

The Program Director/Principal Investigator (PD/PI) will be responsible for conducting or leading all studies that involve disease- or target-specific assays, disease models, pharmacodynamic biomarkers and verification of the association between the therapeutic target or pathway and modulation by the therapeutic agent. A PD/PI with, for example, medicinal chemistry expertise and resources, may request funding to conduct structure-activity relationship (SAR) studies in their own lab but collaborate with contractors on in vitro ADMET, in vivo PK, drug manufacturing and IND-enabling toxicology studies. By contrast, a PD/PI with limited experience in drug discovery and development may opt to collaborate with NIH contractors for all activities not related to disease or target biology. Applicants may propose to conduct all drug discovery and development activities themselves or collaborate with NIH contractors on activities of their choice, however, it is expected that all staff be in place at the start of the grant if not utilizing NIH resources for the work.

For each project funded under this NOFO, the NIH will assemble a customized Lead Development Team (LDT). The LDT will be co-chaired by the PD/PI and a NIH subject-matter expert and will include members of the PD/PI's team, additional subject-matter experts, and NIH staff. The LDT will establish an overall strategy for the project, plan studies to be conducted by NIH contractors, and coordinate activities across different research sites.

Potential applicants are strongly encouraged to contact NIH Scientific/Research staff and participating NIH Institutes/Centers prior to preparing an application to discuss how they may best utilize NIH contract resources and whether their application fits the mission of a particular NIH IC. See also Webinar information under Section IV.7 below ("Other Submission Requirements and Information").

The NIH HEAL Initiative will require a high level of coordination and sharing between HEAL investigators. It is expected that NIH HEAL Initiative recipients will cooperate and coordinate their activities after awards are made by participating in Program Director/Principal Investigator (PD/PI) meetings, including an annual HEAL Investigators Meeting, as well as other activities.

Scope:

This program announcement is specifically focused on providing the expertise, resources and funding to expedite the preclinical translational development process necessary to advance small molecule and biologic non-addictive therapeutics for pain to Phase I clinical testing. The program supports preclinical optimization and development of small molecules and biologics leading to the assembly and submission of an IND application and the implementation of Phase I clinical testing. The scope of this program excludes basic research, and projects focused on disease mechanism or mechanistic/mechanism of action studies of the intended therapeutic. Further, development of animal models, diagnostics, rehabilitation strategies, or therapeutic devices is nonresponsive as are Phase II and Phase III clinical studies. Finally, this program is intended to provide support of the early therapeutic development process; therefore, requests that support only a single component of the process, such as GLP toxicology studies alone, or only a Phase I clinical trial, are considered non-responsive.

General Entry Criteria:

This is a two-phased program that is organized into a preparatory UG3 phase and an execution UH3 phase. Projects must enter at the UG3 phase of the program, and this phase must not exceed 2 years. Projects may enter the program at the Discovery or Development stage. All projects must have the ultimate end goal of assembling an IND application and beginning a Phase I study by the end of the project. For entry at the Discovery Stage, projects must have a promising small molecule or biologic starting point for optimization, a rigorous biological rationale for the intended approach, and scientifically sound assays to test the agent. Applications for entry at the Development stage must have identified the candidate therapeutic; no further optimization will be supported, including back-up programs. In addition, a strong package of data linking the putative therapeutic target to the proposed disease indication and supporting the hypothesis that altering the target activity will produce desirable outcomes for the disease is required. Finally, the proposed therapeutic must have in vitro and in vivo biological activity and ADMET properties appropriate for the intended clinical use.

For the UG3 phase, this NOFO encourages projects proposing the following optimization activities:

Discovery

- Optimization using potency and efficacy screens
- Preliminary efficacy testing in appropriate animal models for pain
- Characterization and in-vitro testing for ADMET (absorption, distribution, metabolism, excretion and toxicity)
- Initial development or optimization of pharmacodynamic/target engagement biomarkers associated with the therapeutic target or pathway
- In vivo PK studies

Development

- Activities that fill in efficacy, in vitro non-GLP ADMET and in vivo PK gaps necessary to begin IND-enabling work

It is expected that by the end of the UG3 phase, recipients will have characterized and selected lead candidates that are ready for in vivo efficacy testing, though additional optimization may be necessary.

After successful completion of the UG3 phase, a project may proceed to the UH3 phase. Progression from the UG3 award to the UH3 award will be based on administrative review.

For the UH3 phase, the following are examples of in-scope development activities:

- Any further optimization activities as listed above, if needed
- Non-GLP toxicology studies (e.g. dose range finding toxicology)
- Pharmacokinetics (PK)
- Pharmacodynamic (PD) and related target engagement biomarker studies
- Formulation and stability studies
- Cell bank development and testing
- Gene expression level determination
- Biodistribution, tumorigenicity, and immunogenicity
- Process development
- Manufacturing of candidate therapeutic for IND
- IND-enabling safety pharmacology, genotoxicity, hERG and toxicology studies
- IND assembly and submission
- Phase I Clinical Studies

It is expected that at the end of the UH3 phase, recipients will have advanced their therapeutic to Phase I clinical testing.

Intellectual Property:

Since the ultimate goal of this program is to bring new pain therapeutics to the market, the creation and protection of appropriate intellectual property are significant considerations in designing research strategies and prioritizing projects for funding. Each applicant is expected to address intellectual property issues (including permission to utilize proprietary reagents or materials if applicable) related to the proposed therapeutics, with input from the institution's technology transfer officials, if applicable. Peer reviewers will be instructed to comment on the intellectual property landscape for each application. The project milestone plan may include commercialization milestones to protect and leverage intellectual property. Recipients of awards are encouraged to identify potential licensing and commercialization partners early in the therapy development process. The PD(s)/PI(s) is encouraged to work closely with technology transfer officials at their institution, if applicable, to ensure that royalty agreements, patent filings, and all other necessary intellectual property arrangements are completed in a timely manner. See Section IV.2. Other Project Information for details.

Implementation:

The program provides funding through the UG3/UH3 cooperative agreement mechanism. As a cooperative agreement, implementation will involve participation of NIH program staff in the planning and execution of the therapy-directed projects. The UG3 portion of the award is designed to support optimization research for the first 1-2 years. Based on the progress to milestones, only a limited number of projects will proceed to the UH3 phase for the remainder of the award period which will include final optimization and development leading to assembling an IND application and beginning a Phase I clinical study, either through the grant budget or through NIH contract resources outlined above.

Milestones:

Because therapeutics optimization and development are inherently high risk, it is expected that there will be significant attrition as projects progress. Annual go/no-go milestones must outline achievements necessary for the project to progress through the stages of therapeutic development and be tailored to the specific therapeutic and its intended disease indication. Proposed milestones will be used for measuring success in achieving each of the research plan key objectives. One or more milestone(s) must be used for each key objective. More details can be found in Section IV. Application and Submission Information.

Annual go/no-go milestones listed in the application will be finalized by a team consisting of the PD/PI and NIH program staff at the start of each project and updated as needed. If justified, future year milestones may be revised based on data and information obtained during the previous project period.

NIH program staff and leadership will conduct annual administrative reviews. At the end of the UG3 phase, NIH program staff and leadership will determine if the project will advance to the UH3 phase. Annual and UH3 transition administrative reviews will be based on:

- Successful achievement of milestones
- The overall feasibility of project advancement, considering data that may not have been captured in the milestones
- Competitive landscape for the disease indication and drug target
- HEAL Programmatic priorities
- Availability of funds

Applications will be considered nonresponsive of this announcement if they include:

- Screening to identify initial hit compounds
- Basic research and studies of disease mechanism
- Animal model development
- Development of diagnostics and therapeutic or diagnostic devices
- Clinical formulation studies
- Studies directed beyond Phase I clinical testing
- Opioid sparing projects and projects targeting the mu-opioid receptor

Non-responsive applications will be withdrawn.

Applications will be considered incomplete if they are missing any of the following:

- Go/no-go milestones
- A target product profile (TPP) table
- Activities for both the UG3 (preparatory) and UH3 (execution) phases
- A budget for each year of the proposed project, including both UG3 and UH3 phases
- An Intellectual Property (IP) plan attachment

Incomplete applications will be withdrawn. See section IV for instructions for each of these elements.

Additional Resources:

To support these projects, additional existing NIH resources may be made available to the applicant outside this grant budget and are described below. Applicants are strongly encouraged to contact NIH staff to discuss these options. These resources include, but are not limited to the following:

NINDS

NINDS has established contract support for medicinal chemistry (including synthesis/SAR, computational chemistry and in vitro ADMET), biodistribution, protein and virus production, antisense oligonucleotide production, antibody production, cell line process and development, cell banking, pharmacokinetic studies, toxicology (GLP and non-GLP) and safety testing,

drug formulation and GMP manufacturing, QC release testing and Phase I clinical studies. Contractors will provide data and reports in a format suitable for inclusion in an IND application. NIH also provides access to experts in therapeutics development through consulting contracts. Applicants must contact NINDS staff (contacts provided below) in order to utilize these resources and determine how to best leverage these as part of the application. To learn more, visit the HEAL PTDP webpage: <https://www.ninds.nih.gov/current-research/trans-agency-activities/ninds-role-heal-initiative/pain-therapeutics-development-program-ptdp> (<https://www.ninds.nih.gov/current-research/trans-agency-activities/ninds-role-heal-initiative/pain-therapeutics-development-program-ptdp>). As appropriate, applicants are encouraged to make use of the NINDS Common Data Elements (<https://www.commondataelements.ninds.nih.gov/#page=Default> (<https://www.commondataelements.ninds.nih.gov/#page=Default>)).

NIDA

Pursuant to the development of analgesic medications without the liability of producing OUD following chronic use, the National Institute on Drug Abuse (NIDA) offers resources to conduct and support all phases of medications development. These programs include synthesis and preclinical evaluation of potential therapeutics, clinical trial design and execution, and preparing regulatory submissions. More information can be found at: <https://nida.nih.gov/about-nida/organization/divisions/division-therapeutics-medical-consequences-dtmc/research-programs#PDP> (<https://nida.nih.gov/about-nida/organization/divisions/division-therapeutics-medical-consequences-dtmc/research-programs#PDP>)

Complementary Resources:

The NIH HEAL Initiative supports the following resources outside this funding opportunity that are also focused on the development of safe, effective, and non-addictive therapeutics to treat pain. Applicants that are interested in utilizing these complementary resources should contact PSPP or NCATS directly.

NINDS

PSPP: Within the NIH HEAL Initiative, NINDS created the Preclinical Screening Platform for Pain (PSPP) to identify and profile non-opioid, non-addictive therapeutics (small molecules, biologics, natural products, or devices) for pain. NIH staff assess the suitability of assets for acceptance into the PSPP on an ongoing basis. Within PSPP, lead assets are profiled for efficacy in models relevant to human pain conditions. Program staff work with the asset owner to plan the evaluation and direct the studies, which are performed by a contract facility at no cost to the PSPP participants. All evaluation is done under a defined participant agreement that outlines confidentiality and intellectual property protection. More information can be found at: <https://heal.nih.gov/research/preclinical-translational/screening-platform> (<https://heal.nih.gov/research/preclinical-translational/screening-platform>)

NCATS

Applicants are also encouraged to potentially develop collaborations with NIH National Center for Advancing Translational Sciences (NIH/NCATS) to access the state-of-the-art capabilities at the Center. If selected for a collaboration, NCATS will make available capabilities in support of HEAL initiatives. The capabilities include, screening and scalable production of relevant stem cells and quantitative high-throughput screening to identify promising compounds to be optimized by medicinal chemists. A more detailed description of the capabilities can be found at: <https://ncats.nih.gov/heal/intramural-capabilities>

Other considerations:

Community-Engaged Research Methods in HEAL Research Studies:

People with lived/living experience (e.g., patients, people in recovery, caregivers, families, community leaders) have important insights that can improve meaningful outcomes and uptake of research findings across the continuum of research from basic through implementation studies. The NIH HEAL Initiative strongly encourages the use of community-engaged research methods (e.g., the promotion of bi-directional communication between the researchers and the relevant community throughout the research project). Community-engaged research methods will vary with the focus and approach used in each project but should at minimum ensure that researchers are connecting with people with lived/living experience to incorporate their input throughout the conception, implementation, and dissemination of the research. See this resource for more information on community-engaged research methods: <https://heal.nih.gov/resources/engagement> (<https://heal.nih.gov/resources/engagement>)

Clinical Trial Accrual:

This NOFO will support applications that include a series of milestones for completion of the clinical trial and provide contingency plans to proactively confront potential delays or disturbances in attaining the milestones. Continuation of the award is conditional upon satisfactory progress, availability of funds, and scientific priorities of the HEAL Initiative. If, at any time, recruitment falls significantly below the projected milestones for recruitment, NIH will consider ending support and negotiating an orderly phase-out of the award. NIH retains the option of periodic external peer review of progress. NIH program staff will closely monitor progress at all stages for milestones, accrual, and safety. Please refer to the [HEAL Policy for the Enrollment of Participants in Clinical Trials](https://heal.nih.gov/funding/clinical-trials-policy) (<https://heal.nih.gov/funding/clinical-trials-policy>) for additional information. .

Investigators proposing NIH-defined clinical trials may refer to the [Research Methods Resources](https://researchmethodsresources.nih.gov/) (<https://researchmethodsresources.nih.gov/>) website for information about developing statistical methods and study designs.

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

Section II. Award Information

Funding Instrument

Cooperative Agreement: A financial assistance mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, NIH scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this NOFO.

Application Types Allowed

New
Resubmission
Revision

The [OER Glossary](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the How to Apply Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

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

Funds Available and Anticipated Number of Awards

The NIH HEAL (Helping to End Addiction Long-term) Initiative intends to commit an estimated total of \$11,000,000 to fund 3 awards in FY 2027. Awards pursuant to this funding opportunity are contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets must reflect the actual needs of the proposed project but should not include the costs of NIH contract resources requested.

Award Project Period

The UG3 phase of the grant must be at least 1 year and cannot exceed 2 years. The UH3 phase cannot exceed 4 years. The total duration may not exceed 5 years. The actual duration of individual projects will depend upon successful achievement of milestones and conditions as described in the Milestones and Implementation sections of the program overview.

NIH grants policies as described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?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 - Includes all types

- 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/International Collaborations

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply- Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference the [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423) for additional information.

- [System for Award Management \(SAM\) \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390\)](https://grants.nih.gov/grants/guide/url_redirect.htm?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. Foreign organizations must obtain a [NATO Commercial and Government Entity \(NCAGE\) Code \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) (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 \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300\)](http://grants.nih.gov/grants/guide/url_redirect.htm?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.

All PD(s)/PI(s) must be registered with [ORCID \(https://orcid.org/\)](https://orcid.org/). The personal profile associated with the PD(s)/PI(s) eRA Commons account must be linked to a valid ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the [ORCID topic in our eRA Commons online help \(https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D29\)](https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D29).

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.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per [NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82415\)](http://grants.nih.gov/grants/guide/url_redirect.htm?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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?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 \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) except where instructed in this notice of funding opportunity to do otherwise (in this NOFO, in a [policy notice \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11163\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163), or other 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 the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

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

Instructions for Application Submission

The following section supplements the instructions found in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](https://grants.nih.gov/grants/how-to-apply-application-guide.html) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

SF424(R&R) Other Project Information

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

The following additional instructions apply:

Facilities & Other Resources

All applicants must describe their institutions' existing or planned infrastructure for bringing the compound or biologic to practical application (e.g., licensing for further drug development, managing IP, commercializing discoveries) consistent with achieving the program goals. For a multiple-PD/PI, multiple-institution application, applicants should describe the infrastructure of each institution for bringing the technologies to practical application and for coordinating these efforts (e.g., licensing, managing intellectual property) among institutions consistent with achieving the goals of the program. Applicants must clarify how IP will be shared or otherwise managed if there are multiple PD/PIs and institutions involved in the UG3/UH3-supported work, to ensure that IP remains unencumbered.

Other Attachments:

Intellectual Property (IP) Strategy

In an "Other Attachment" entitled "IP Strategy", all applicants must include an Intellectual property (IP) strategy (2 pages maximum). Applicants are encouraged to prepare this section in consultation with their institutions' technology transfer officials.

For Discovery stage projects, applicants must describe any constraints of which they are aware that could impede their use of compounds, biologics, assays, or models for research purposes and/or commercial development (e.g., certain restrictions under transfer or sharing agreements, applicants' previous or present intellectual property filings and publications, similar compounds or therapies that are under patent and/or on the market, etc.) and how these issues would be addressed. If the applicant's institution has filed pertinent patents, the applicant should indicate filing dates, the type of patent, and application status.

For Development stage projects, applicants must describe their efforts to confirm that there are unlikely to be IP or other legal constraints that could block or impede development or commercialization of the proposed therapeutic. If the applicant's institution has filed pertinent patents, the applicant should indicate filing dates, the type of patent, and application status.

SF424(R&R) Senior/Key Person Profile

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

R&R Budget

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

A budget for each year of the proposed project, including both UG3 and UH3 phases, must be included. The UG3/UH3 award is intended to support studies to be conducted by the PD/PIs and associated personnel. The UG3/UH3 budget may not support drug development activities that the applicant proposes to conduct through NIH contracts. Equipment requests are allowed but not encouraged. Equipment requests should be considered only if the equipment is absolutely necessary to the success of the project and cannot be supported by any other means. This is likely to be a subject of negotiation before an award is made. Some budget requests may be made for the PD/PI's Institution to assemble and file the IND.

It is expected that the PD/PI will dedicate at least 20% level of effort (2.4 calendar months) to managing the proposed project. It is strongly recommended that potential applicants consult NIH staff about their anticipated budget in the early stages of preparing an application.

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

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

Specific Aims:

The Specific Aims section must include Aims delineated for both the UG3 and UH3 phases.

Research Strategy:

The Research Strategy section must include the following subsections:

- Clinical Impact (Significance subsection)
- Biological Rationale (Significance subsection)
- Innovation
- Testing strategy (Approach subsection)
- Team management (Approach subsection)
- Table of proposed activities that provides the following information: Activity (optimization effort, assays, PK, etc.), throughput (e.g., samples per month), source (PD/PI lab, sub recipient, NIH Contractor, etc.), and advancement criteria. (Approach subsection) Clearly indicate which activities will be conducted by the PD/PI and associated personnel (i.e., funded by the UG3/UH3 award) and which activities will be conducted by NIH contract research organizations and/or subject-matter experts. Include experimental designs and justification for all studies that will be conducted by the PD/PI and associated personnel. Activities that will be conducted by NIH contractors need not be described in detail in the application since these will be planned after the award by the lead development team (LDT), but the overall goal of the activities must be provided.

Clinical Impact (Significance):

Each application generally must focus on one or more specific pain condition(s). The target patient population and intended use guide the design of the drug and of the preclinical studies, such as toxicology and formulation.

For the specific pain condition(s) proposed, briefly describe the current state of knowledge of the etiology, clinical characteristics, and current and projected prevalence of the proposed condition indication.

- Briefly discuss available treatments, including all treatment modalities, and their limitations.
- Discuss how the proposed project relates to therapeutics development efforts underway in academia and industry.
- Provide a [Target Product Profile \(TPP\) \(https://seed.nih.gov/sites/default/files/2023-12/Creating-Target-Profile-for-New-Drug-Products.pdf\)](https://seed.nih.gov/sites/default/files/2023-12/Creating-Target-Profile-for-New-Drug-Products.pdf), a table based on an FDA template that summarizes the minimal/ideal profile of the final marketed product and shows the ultimate goals of the proposed drug development effort, such as disease indication, patient population, delivery mode, treatment duration, treatment regimen, and standards for clinical efficacy (see guidance and example at <http://neuroscienceblueprint.nih.gov/resources/target-product-profile.htm>). Explain why the minimally acceptable and ideal parameters offer advantages over currently available treatments and how they relate to other therapeutics under development. Applications that fail to include a TPP will be considered incomplete.
- Briefly comment on the feasibility of conducting clinical trials toward the goals in the TPP (e.g., availability of patients for clinical trials).
- Describe the clinical expertise used to determine the goals of the drug development program and the clinical trial.

Biological Rationale (Significance):

- Describe the intended biological target/pathway and pathophysiology. Indicate whether evidence from multiple groups supports this is a compelling target for the condition.
- Provide the evidence that links this target to the particular pain condition proposed.
- Provide the evidence that altering target activity as proposed will give desirable outcomes for the proposed pain condition.
- Describe what is known about your agent(s) i.e., structure, function, identity, selectivity, bioactivity, potency, stability, production, etc.
- Define desired characteristics of an optimized candidate including but limited to quantitative characteristics for structure/identity, in vitro testing activities and in vivo pharmacology, specificity, selectivity, stability, etc. Explain how the desired quantitative characteristics are consistent with the desired TPP. Introduce what parameters of the agent(s) will be modified during the funding period.
- NINDS urges investigators to follow the NIH guidance for rigor and transparency in grant applications (<https://grants.nih.gov/policy/reproducibility/guidance.htm>) (<https://grants.nih.gov/policy/reproducibility/guidance.htm>). These recommended research practices include, where applicable, expressing clear rationale for the chosen model(s) and primary/secondary endpoint(s), describing tools and parameters clearly, blinding, randomizing, ensuring adequate sample size, pre-specifying inclusion/exclusion criteria,

appropriately handling missing data and outliers, implementing appropriate controls, preplanning analyses, and using appropriate quantitative techniques. Investigators must indicate whether data presented or cited in the application as key support for the proposed work were collected, analyzed, and reported in a rigorous and transparent manner as described above.

Innovation:

Applications must explain how the project offers a novel approach to treating the proposed disease indication:

- If therapeutics that target the same molecule, pathway, or cellular process have been tested in clinical trials for the proposed disease indication, explain why the proposed approach would be expected to provide a benefit over those therapeutics.
- If similar drugs have been tested in clinical trials for the proposed disease indication, explain why the proposed drug would be expected to give significantly better clinical outcomes.
- Comment on the novelty of proposed approach, target, pathway, assays or models.

Testing Strategy (Approach):

In this section, applicants must elaborate on their research plans to achieve the ultimate goal of assembling an IND application and beginning a Phase I Clinical Trial by the end of the project. This can include a table indicating acceptable and ideal characteristics of the eventual lead therapeutic and a diagram of in vitro and in vivo screening funnels. Applications that fail to include activities for both the UG3 (preparatory) and UH3 (execution) phases will be considered incomplete.

Include details on efforts to ensure the experimental design is rigorous. This includes, but is not limited to justification for model systems, endpoints, minimal requirements for agent purity, route and timing of delivery, adequacy of controls and sample sizes, description of statistical analyses, inclusions of measures to reduce bias, and plans for replication, if applicable.

Milestones:

Annual milestones to be used for measuring success in achieving each of the research plan key objectives must be provided. One or more milestone(s) must be used for each key objective. Applications that fail to include milestones will be considered incomplete.

- For each milestone, provide details on methods, assumptions, experimental designs, and data analysis plans.
- Specify the quantitative criteria for measuring success and related rationale. The quantitative criteria must be robust and be consistent with the state-of-the-art in the field. The quantitative criteria for success in the milestones will also be used for making go/no-go decisions.
- Specify the timeline for each milestone. There must be at least one milestone each year.
- NIH recognizes time sensitivity in developing therapeutics for patients who urgently need new or better treatment. If the research contains parallel activities from an independently funded, ongoing study prior or during the funding period, it must be noted with appropriate milestones.
- Specify and provide details on what other NIH resources may be utilized in the project.

Team management (Approach):

Team building is an essential step in the development of the overall plan for therapeutics development. Because translational research is intrinsically interdisciplinary, the plan will often involve cooperation among basic researchers, experts in preclinical development, and clinicians, and may include the participation of private-sector companies and voluntary organizations.

- Any collaborators, subject-matter experts, or subcontractors outside of NIH resources must be identified, no matter when during the conduct of the research activity the proposed interaction occurs.
- Describe how the team, including subject-matter experts, has already been engaged and a plan as to how they will continue working together over the course of the project (e.g., recurring team meetings, review and report of data across disciplines, decision-making, participate in meetings with NIH, communication, etc.).
- Explain how other NIH resources are or are not applicable to the project as appropriate.
- Explain the plan for collaboration to develop pharmacodynamic or target engagement biomarkers.
- Letters of support must be included and must not be generic, but instead indicate what has been contributed so far and what they expect to provide during the project to allow an evaluation of team engagement (see below).
- Indicate the willingness of the PD/PI(s) and key personnel to operate under the cooperative agreement terms and conditions outlined in section VI.2. of the NOFO.

Letters of Support:

Applicants must include letters of support from subject-matter experts, contractors, and collaborators not provided through NIH.

If applying from an academic institution, include a letter of support from the technology transfer official who will be managing intellectual property associated with this project.

- If research will be performed at more than one institution, include a letter of support from each institution clarifying how intellectual property will be shared or otherwise managed across the institutions.
- If collaborating with a private entity, include a letter of support that addresses any agreement to provide agent(s), any limits on the studies that can be performed with said agent(s), any limitations on sharing of data (including negative results), and whether a licensing agreement(s) will be needed and in place once the project is funded. This letter must come from a high official within the private entity who has authority to speak on these issues.

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/uri_redirect.htm?id=82400) (https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400).

Other Plan(s):

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

- A Data Management and Sharing Plan (DMS Plan) is required for any NIH-funded or conducted research that will generate scientific data. Applicants must submit the DMS Plan at the time of application using the [NIH DMS Plan Format Page](https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page) (<https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page>). The DMS Plan must address the elements in the structured format. Where the DMS Plan Format Page requires a "Yes or No" response, no additional narrative is allowed.

The NIH notices referenced below provide additional NIH guidance that should be considered in developing a strong data management and sharing plan. The list is instructive but not comprehensive.

- NIH has provided guidance around selecting a repository for data generated by NIH-supported research and has developed desirable characteristics for all data repositories ([NOT-OD-21-016](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-016.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-016.html>)).
- NIH encourages the use of data standards including the PhenX Toolkit (www.phenxtoolkit.org) (for example, see [NOT-DA-12-008](https://grants.nih.gov/grants/guide/notice-files/NOT-DA-12-008.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-DA-12-008.html>)), [NOT-MH-15-009](https://grants.nih.gov/grants/guide/notice-files/NOT-MH-15-009.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-MH-15-009.html>)).
- Data should be organized according to a standard model that is widely accepted within the field. An example for the clinical research studies would be the OMOP Common Data Model, which has also been successfully adapted for use with observational (including survey) studies more generally. In addition, the HL7 FHIR® (Fast Healthcare

Interoperability Resources) standard ([NOT-OD-19-122 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-122.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-122.html)) may facilitate the flow of data with EHR-based datasets, tools, and applications.

- NIH encourages clinical research programs and researchers to adopt and use the standardized set of data classes, data elements, and associated vocabulary standards specified in the [United States Core Data for Interoperability \(USCDI\) \(https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi\)](https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi) standards, as they are applicable ([NOT-OD-20-146 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-146.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-146.html)). Use of the USCDI can complement the FHIR® standard and enable researchers to leverage structured EHR data for research and enable discovery. In addition to USCDI, OMOP, and FHIR standards for enhanced interoperability, investigators and data centers should align their data collection and management practices with recommended guidance emerging from the HEAL CDE and Data Ecosystem programs.

HEAL Public Access and Data Sharing Policy:

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

All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

Data and metadata generated by HEAL Initiative-funded projects must be submitted to study-appropriate, HEAL-compliant, data repositories to ensure the data is accessible via the HEAL Initiative Data Ecosystem. Guidance is available at (<https://www.healdatafair.org/resources/guidance/selection>) (<https://www.healdatafair.org/resources/guidance/selection>) and follow requirements of the selected repository.

The HEAL Initiative has additional requirements for awarded applications that must be addressed in the Data management and Sharing plan. All HEAL-generated data must be shared through the [HEAL Initiative Data Ecosystem \(https://heal.nih.gov/about/heal-data-ecosystem\)](https://heal.nih.gov/about/heal-data-ecosystem) following HEAL's compliance guidance (<https://heal.nih.gov/data/complying-heal-data-sharing-policy>) (<https://heal.nih.gov/data/complying-heal-data-sharing-policy>). See "writing an application" section).

For additional details, see Part 2 Section VI "Awards Administration Information, Data Management and Sharing."

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

Note that if human subject work in the application is proposed to be conducted by NIH contracts (i.e. not part of the grant budget), you should answer "No" to the question "Are Human Subjects Involved?", and you do not need to describe the clinical trial research plan in your application.

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 \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

For this NOFO, if you are proposing to perform a Phase I clinical study and are not proposing to utilize NIH contracts to conduct the study please code your application as 'Delayed Onset'.

PHS Assignment Request Form

All instructions in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?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 \(https://grants.nih.gov/grants/guide/url_redirect.html?id=82380\)](https://grants.nih.gov/grants/guide/url_redirect.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?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 \(https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide\)](https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide).

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review. \(https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

Webinar

In order to learn more about this NOFO, visit our website to access past webinars: <https://www.ninds.nih.gov/current-research/trans-agency-activities/ninds-role-heal-initiative/pain-therapeutics-development-program-ptdp> (<https://www.ninds.nih.gov/current-research/trans-agency-activities/ninds-role-heal-initiative/pain-therapeutics-development-program-ptdp>)

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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11120).

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

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the [How to Apply – Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?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 \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?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 \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400).

See [more tips \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11146\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11146) for avoiding common errors.

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

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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82299\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11149\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

The NIH is encouraging applications for translational research that may involve standard methodologies applied toward novel therapeutic approaches. Therefore, a project that does not necessarily employ novel methodologies may still be essential to advance the field.

Projects should not be penalized if the mechanism of action of the compound is unknown. While this may add to the risk, the increased risk may be counterbalanced by increased novelty.

Evaluation of the approach should emphasize the biological rationale, the potential for identifying a candidate with suitable properties, potential patient benefit, competitive landscape (novelty), and strengths/weaknesses of studies to be conducted by the PD/PI. Any additional resources (e.g., contracts or subject-matter experts) provided by NIH should be presumed to be industry standard.

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

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following scored review criteria and additional review criteria (as applicable for the project proposed). An application does not need to be strong in all categories to be judged likely to have a major scientific impact.

Scored Review Criteria

Reviewers will consider Factors 1, 2 and 3 in the determination of scientific merit, and in providing an overall impact score. In addition, Factors 1 and 2 will each receive a separate factor score.

Factor 1. Importance of the Research (Significance and Innovation)

Significance

- Evaluate the importance of the proposed research in the context of current scientific challenges and opportunities, either for advancing knowledge within the field, or more broadly. Assess whether the application addresses an important gap in knowledge in the field, would solve a critical problem, or create a valuable conceptual or technical advance.
- Evaluate the rationale for undertaking the study, the rigor of the scientific background for the work (e.g., prior literature and/or preliminary data) and whether the scientific background justifies the proposed study.

Innovation

- Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field.

- Evaluate whether the proposed work applies novel concepts, methods or technologies or uses existing concepts, methods, technologies in novel ways, to enhance the overall impact of the project.
- If the proposal is clinical trial-oriented, evaluate if there is innovation in trial design. For example, innovative designs such as platform trials, adaptive, including real-time adaptive methods, seamless Phase I/II designs, and Bayesian designs are encouraged as applicable. Decentralized trial elements, including remote informed consent, remote study visits, and use of wearables are also encouraged as applicable.

Specific to this NOFO:

- Evaluate the robustness of the preliminary data provided to support the target/intervention for the intended pain condition.
- Evaluate the plans provided for candidate identification and optimization and whether these plans are consistent with the Target Product Profile.
- Evaluate whether the essential assays (in vitro and in vivo) proposed for identification and optimization of the candidate therapeutic are suitable (variability, dynamic range, etc).
- Evaluate whether the proposed project would produce a therapeutic that would be expected to provide significantly better clinical outcomes than observed in previous efforts focused on the same target (if applicable). In addition consider whether it will offer a safer more effective and non-addictive therapeutic to treat pain.

Factor 2. Rigor and Feasibility (Approach)

Approach

- Evaluate the scientific quality of the proposed work. Evaluate the likelihood that compelling, reproducible findings will result (rigor) and assess whether the proposed studies can be done well and within the timeframes proposed (feasibility).

Rigor:

- Evaluate the potential to produce unbiased, reproducible, robust data.
- Evaluate the rigor of experimental design and whether appropriate controls are in place.
- Evaluate whether the sample size is sufficient and well-justified.
- Assess the quality of the plans for analysis, interpretation, and reporting of results.
- Evaluate whether the investigators presented adequate plans to address relevant biological variables, such as sex or age, in the design, analysis, and reporting.
- For applications involving human subjects or vertebrate animals, also evaluate:
 - the rigor of the intervention or study manipulation (if applicable to the study design).
 - whether outcome variables are justified.
 - whether the results will be generalizable or, in the case of a rare disease/special group, relevant to the particular subgroup.
 - whether the study population appropriately models the target population.
- For applications involving human subjects, including clinical trials, assess the adequacy of inclusion plans as appropriate for the scientific goals of the research. Considerations of appropriateness may include disease/condition/behavior incidence, prevalence, or population burden, population representation, and/or current state of the science.

Feasibility:

- Evaluate whether the proposed approach is sound and achievable, including plans to address problems or new challenges that emerge in the work. For proposed studies in which feasibility may be less certain, evaluate whether the uncertainty is balanced by the potential for major advances.
- For applications involving human subjects, including clinical trials, evaluate the adequacy and feasibility of the plan to recruit and retain a study population that appropriately models the target population. Additionally, evaluate the likelihood of successfully achieving the proposed enrollment based on age, race, ethnicity, and sex.
- For clinical trial applications, evaluate whether the study timeline and milestones are feasible.

Specific to this NOFO:

- Evaluate the importance of the activities proposed in the UG3 and UH3 phases in contributing to the success of the overall project and whether certain activities or milestones are lacking or could be better articulated.

Factor 3. Expertise and Resources (Investigator(s) and Environment)

Investigator(s)

Evaluate whether the investigator(s) have demonstrated background, training, and expertise, as appropriate for their career stage, to conduct the proposed work. For Multiple Principal Investigator (MPI) applications, assess the quality of the leadership plan to facilitate coordination and collaboration.

Environment

Evaluate whether the institutional resources are appropriate to ensure the successful execution of the proposed work.

Specific to this NOFO:

- Evaluate the multi-disciplinary nature of the team and whether it includes the necessary expertise and whether NIH resources are appropriately leveraged. Note that the work performed by NIH contractors is assumed to be industry standard and not subject to review.
- Evaluate the extent to which the features of the environment described in the Team Management Plan (e.g., collaborative arrangements, geographic location, institutional support) contribute to the success of the project.

Additional Review Criteria

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

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, 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, 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 \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11175).

Vertebrate Animals

When the proposed research includes Vertebrate Animals, evaluate the involvement of live vertebrate animals according to the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. For additional information on review of the Vertebrate Animals section, please refer to the [Worksheet for Review of the Vertebrate Animals Section \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11150\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11150).

Biohazards

When the proposed research includes Biohazards, evaluate whether specific materials or procedures that will be used are significantly hazardous to research personnel and/or the environment, and whether adequate protection is proposed.

Resubmissions

As applicable, evaluate the full application as now presented.

Renewals

As applicable, evaluate the progress made in the last funding period.

Revisions

As applicable, evaluate the appropriateness of the proposed expansion of the scope of the project.

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.

Authentication of Key Biological and/or Chemical Resources

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

Budget and Period of Support

Evaluate 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 CSR, in accordance with [NIH peer review policy and procedures \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11154\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications 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.

[Requests for reconsideration of initial peer review \(https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm) will not be accepted for applications submitted in response to this NOFO.

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 national Advisory Council or Board. The following will be considered in making funding decisions:

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

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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82418\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement Section 2.4.4 Disposition of Applications \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82416\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?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](#). 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) and NIH Grants & Funding website, see [Award Process](#). (<https://grants.nih.gov/grants/pre-award-process.htm#award>)

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

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

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

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

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

2. Administrative and National Policy Requirements

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>), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?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](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?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](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159).

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)

By applying for or accepting federal funds from HHS, recipients certify compliance with all federal antidiscrimination laws and these requirements and that complying with those laws is a material condition of receiving federal funding streams. Recipients are responsible for ensuring subrecipients, contractors, and partners also comply.

Applicants and recipients are strongly encouraged to refer to the [NIH Director's Statement of Priorities](#) (<https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy>), entitled "Advancing NIH's Mission Through a Unified Strategy."

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. Pursuant to 2 CFR 200.340, by accepting an NIH award, the recipient agrees that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates the program goals or agency priorities, in line with 2 CFR 200.340(a)(4).

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:

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

Cybersecurity plans and procedures **must** at minimum include the following:

- Develop cybersecurity plans and procedures, modeled after the [NIST Cybersecurity framework](#) (<https://www.nist.gov/cyberframework>), to protect HHS systems and data:
 - **Identify:**
 - Develop an inventory of all assets and accounts with access to HHS owned and operated information or operational technology systems or which obtain PII or PHI for the purposes of the award.
 - **Protect:**
 - Limit access to HHS owned and operated systems to only those in need of access to complete reward activities.
 - Require all staff to complete annual cybersecurity and privacy awareness training. Visit [405\(d\): Knowledge on Demand \(hhs.gov\)](#) (<https://405d.hhs.gov/kod/five-threats>) to obtain free trainings, if needed.
 - Enable multifactor authentication for all employees, subrecipients, and third-party entities to access HHS owned and operated information or operational technology systems.
 - Regularly backup sensitive data and test backups.
 - **Detect:**
 - Install anti-virus or anti-malware software on all devices, servers, and accounts used to connect to HHS owned and operated systems.
 - **Respond:**
 - Develop an incident response plan. See [Incident-Response-Plan-Basics_508c.pdf \(cisa.gov\)](#) (https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf) to learn about developing incident response plans.
 - Have cybersecurity incident reporting procedures that ensure the relevant HHS awarding agencies are notified of a cybersecurity incident within 48 hours of discovery. A cybersecurity incident is defined as an unplanned interruption to a technology service or reduction in the quality of a technology service, or an occurrence that actually or potentially jeopardizes the confidentiality, integrity, or availability of an information system or the information the system processes, stores, or transmits.
 - **Recover:**

- Investigate incidents and plug any security gaps identified.

All activities proposed in your application and budget narrative must align with applicable law, including but not limited to statutes, executive orders, federal regulations and applicable judicial holdings. Accordingly, discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate; racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation; denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic; illegal immigration; or any other initiatives that compromise public safety. If an application does not align, the application will not receive funding to the extent permitted by law and applicable court orders.

For applications involving substance abuse, the application must not support harm reduction. Please see [Updated Funding Guidance for Recipients on Supplies and Services](https://www.samhsa.gov/sites/default/files/dear-colleague-letter-updated-hr-funding-guidance.pdf) (<https://www.samhsa.gov/sites/default/files/dear-colleague-letter-updated-hr-funding-guidance.pdf>).

For applications involving funding Medication-Assisted Treatment (MAT) or medications for opioid use disorder (MOUD), this funding should be used to provide comprehensive treatment and recovery support services rather than medication-only models for opioid use disorder. Services should include medications, where clinically indicated, in conjunction with psychosocial and other treatment and recovery support services. Funding can also be used to support individualized tapering and discontinuation of medications when clinically indicated. Please see [Updated Funding Guidance for Recipients on MAT/MOUD](https://www.samhsa.gov/sites/default/files/dear-colleague-letter-mat-moud-guidance.pdf). (<https://www.samhsa.gov/sites/default/files/dear-colleague-letter-mat-moud-guidance.pdf>)

As of October 1, 2025, HHS has adopted [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>), with some modifications included in 2 CFR Part 300. These regulations replace those in 45 CFR Part 75. However, for NIH, under the Consolidated Appropriations Act for FY 2026, (P.L. 119-75 (<https://www.congress.gov/bill/119th-congress/house-bill/7148>), Division B, Title II, Sec. 224), the provisions relating to indirect costs in 45 CFR 75 continue to apply to NIH awards. Consistent with the statute, NIH will not apply updated thresholds outlined within 2 CFR Part 200, at this time.

Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (HHS) grant administration regulations at 2 CFR Part 200, and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and NIH as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Determining experimental approaches, designing protocols, conducting experiments, and analyzing and interpreting research data for studies funded through this UG3/UH3.
- Serving as co-chair of the project Lead Development Team (LDT).
- With the LDT, assisting in the finalization of a project milestone plan at the outset of the project.
- Hosting a virtual or face-to-face meeting at the outset of the project and working with NIH staff to assist in the finalization of a project milestone plan.
- Presenting project updates (including raw data, when requested) in regular conference calls or other intermittent face-to-face meetings.
- Coordinating and participating with NIH staff in all aspects of scientific and technical management of the project, including the development of meeting agendas and minutes.
- Collaborating and communicating effectively with NIH service contractors to achieve project goals.
- Implementing all scientific and policy decisions approved by NIH staff or an oversight committee.
- Submitting periodic milestone progress reports in a standard format, as agreed upon at the initiation.
- Preparing for administrative site visits as necessary, by NIH Program staff.
- Ensuring that all data, including primary and secondary screening data and assay protocols developed as a part of this project are deposited in a centralized relational database (NIH provided access) according to the timeline agreed upon by the LDT and the NIH Program Official and according to program policies.
- Recipients agree to participate in the overall coordination of NIH research efforts in translational research in pain. This participation may include collaboration and consultation with other translational research recipients, and the sharing of information, data, and research materials.
-
- Working closely with their institution's technology transfer officials to ensure that royalty agreements, patent filings, and all other necessary intellectual property arrangements are completed in a timely manner. Recipients are responsible for pursuing patent protection.
- Submission of the IND application and scheduling meetings with the FDA.
- Ensuring that the NIH staff and subject-matter experts on the LDT are included in all meetings with the FDA.
- Ensure all correspondence with regulatory agencies is shared promptly with NIH Program Manager and NIH subject-matter experts.
- Providing protocol, supporting clinical documents and regulatory documents required for administrative review prior to clinical trial.
- Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

NIH staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- Each project will have the support of one or more Project Scientists from NIH program staff who are assigned an administrative role for the target or pain condition being studied and have expertise in the implementation of NINDS cooperative agreement programs.
- The NIH Project Scientists will have substantial scientific/programmatic involvement during conduct of this activity, through technical assistance, advice, and coordination above and beyond normal program stewardship for grants.
- Providing the LDT with NIH subject-matter experts who can provide strategic and technical guidance.
- NIH Project Scientists will coordinate and participate in LDT meetings to discuss project status, planning, and implementation.
- NIH Project Scientists will facilitate collaboration and data exchange among the recipient, NIH-contracted subject-matter experts, and service providers.
- NIH Project Scientists will enhance the project progress by providing access to various NIH resources when appropriate.
- NIH Project Scientists will assist in the development of a finalized project milestone plan at the outset of the project and approve the final milestone language for incorporation into the award notice.
- NIH Program Officer, named in the notice of award is responsible for the normal scientific and programmatic stewardship, assessing the progress of the projects toward the accomplishment of specified milestones, and for recommending further funds should be released to the project.
- The NIH Project scientists will serve as scientific liaisons among the recipient and other NIH program staff and report periodically on the progress of the project to NIH leadership.
- NIH Project Scientists will facilitate the establishment of contacts and collaborations between recipients and other persons or organizations whose participation will assist with the accomplishment of project goals. These persons or organizations may include the FDA, disease voluntary organizations, pharmaceutical companies, or research organizations that can provide essential services on contract.
- An important part of the NIH HEAL Initiative is the coordination of research efforts across different funding mechanisms and research structures, and coordination among efforts aimed at different pain conditions. NIH Project Scientists will have the primary responsibility for this overall coordination and provide a perspective on the priorities of the HEAL Initiative and other NIH translational programs.

Leadership of the Institute/Center funding the project will make decisions on project continuation with input from NIH staff and/or any established oversight committee, based on:

- Successful achievement of milestones
- The overall feasibility of project advancement, considering data that may not have been captured in milestones
- Based on emerging and published literature on competition for the disease indication and drug target
- Program priorities
- Availability of funds

Areas of Joint Responsibility include:

Project Lead Development Team (LDT): The LDT typically will be co-chaired by the PD/PI and an NIH-contracted drug development subject-matter expert and will include additional members from the PI's group, subject-matter experts and NIH staff. This team will collaboratively set strategic direction and guide the workflow for the project on an ongoing basis. The LDT will meet approximately every two weeks via teleconference to analyze and interpret data from the PD/PI and contracted laboratories and to formulate the subsequent experimental plan. The LDT will propose milestones and produce progress reports for evaluation by an External Oversight Committee and program staff as needed. The members of this collaborative effort are all made aware of the requirement for confidentiality due to the intent of the recipient to pursue commercialization of any qualified outcomes. Contractors and subject-matter experts of NIH will be made aware of the confidential nature of work done under this collaborative effort. The handling and disposition of this confidential data and business privileged information may be covered by the Trade Secrets Act, 18 U.S.C. Section 1905.

Dispute Resolution:

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between recipients and NIH may be brought to Dispute Resolution. A Dispute Resolution Panel composed of three members will be convened: a designee of the recipient, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the External Oversight Committee. This special dispute resolution procedure does not alter the recipient's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulation 42 CFR Part 50, Subpart D and HHS regulation 45 CFR Part 16.

3. Data Management and Sharing

A Data Management and Sharing Plan (DMS Plan) is required for any NIH-funded or conducted research that will generate scientific data. Applicants must submit the DMS Plan at the time of application using the [NIH DMS Plan Format Page \(https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page\)](https://grants.nih.gov/grants-process/write-application/forms-directory/data-management-and-sharing-plan-format-page). The DMS Plan must address the elements in the structured format. Where the DMS Plan Format Page requires a "Yes or No" response, no additional narrative is allowed.

HEAL Data Sharing Requirements

NIH intends to maximize the impact of HEAL Initiative-supported projects through broad and rapid data sharing. All HEAL Initiative award recipients, regardless of the amount of direct costs requested for any one year, are required to comply with the HEAL Public Access and Data Sharing Policy. HEAL award recipients must follow all requirements and timelines developed through the [HEAL Initiative Data Ecosystem \(https://heal.nih.gov/data/heal-data-ecosystem\)](https://heal.nih.gov/data/heal-data-ecosystem), as described in HEAL's [compliance guidance \(https://heal.nih.gov/data/complying-heal-data-sharing-policy\)](https://heal.nih.gov/data/complying-heal-data-sharing-policy). (See "Already Funded" section: <https://heal.nih.gov/data/complying-heal-data-sharing-policy>); (<https://heal.nih.gov/data/complying-heal-data-sharing-policy>);

1. Within one year of award,

- [Register your study with the HEAL platform \(https://heal.github.io/platform-documentation/study-registration/\)](https://heal.github.io/platform-documentation/study-registration/) (<https://heal.github.io/platform-documentation/study-registration/>). This process will connect the Platform to information about your study and data, including variable level metadata and any data dictionaries, and identify the selected repository. HEAL requests initial submission within one year of award, with annual updates, and to be updated in accordance with any release of study data.
- [Submit study-level metadata](https://github.com/HEAL/heal-metadata-schemas/blob/main/for-investigators-how-to/study-level-metadata-fields/study-metadata-schema-for-humans.pdf) Some of the required [study-level metadata \(https://github.com/HEAL/heal-metadata-schemas/blob/main/for-investigators-how-to/study-level-metadata-fields/study-metadata-schema-for-humans.pdf\)](https://github.com/HEAL/heal-metadata-schemas/blob/main/for-investigators-how-to/study-level-metadata-fields/study-metadata-schema-for-humans.pdf) will be auto-populated as part of the registration process.

2. Submit data and metadata (and code, if applicable) to HEAL-Compliant repository

- At the completion of the study and/or when prepared to make the final data deposits in the repository(ies) of choice, ensure your [study registration \(https://heal.github.io/platform-documentation/study-registration/\)](https://heal.github.io/platform-documentation/study-registration/) is complete.
- **Submit data dictionaries/variable level metadata to the HEAL data ecosystem, if applicable (e.g., studies collecting structured data, including clinical data).**
 - Submit data dictionaries /variable level metadata through repository curation processes, if applicable at your choice repository
 - Use [HEAL Data Ecosystem utility tools \(https://github.com/HEAL/platform-documentation/blob/main/docs/vlmd/vlmd_healdata_utils.md\)](https://github.com/HEAL/platform-documentation/blob/main/docs/vlmd/vlmd_healdata_utils.md) to create a HEAL-compliant data dictionary, and then submit to the HEAL Platform (https://github.com/HEAL/platform-documentation/blob/main/docs/vlmd/vlmd_submission.md) (https://github.com/HEAL/platform-documentation/blob/main/docs/vlmd/vlmd_submission.md); OR send to the HEAL Data Stewardship Group ([HEALStewards@RENCI.org \(mailto:HEALStewards@RENCI.org\)](mailto:HEALStewards@RENCI.org)).
- The NIH HEAL Initiative expects data sharing timelines to align with timeline requirements stated in the Final NIH Policy for Data Management and Sharing ([NOT-OD-21-013 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html)). Scientific data should be made accessible as soon as possible, and no later than at the time of an associated publication, or the end of performance period, whichever comes first.

3. Additional Requirements for HEAL Initiative studies involving human subjects.

These studies must meet the following additional requirements:

- HEAL Initiative trials that are required to register in clinicaltrials.gov should reference support from and inclusion in the HEAL Initiative by including the standardized terms "the HEAL Initiative (<https://heal.nih.gov/>)" in the Study Description Section.
- All new HEAL pain studies conducting research involving human participants are required to use core questionnaires required by the [HEAL Common Data Elements \(CDE\) Program \(https://heal.nih.gov/data/common-data-elements\)](https://heal.nih.gov/data/common-data-elements). In addition to the core questionnaires, studies are encouraged to select supplemental questionnaires from the repository of measures used by other HEAL studies, which is housed in an NIH Box account. To gain access to this Box account, please email heal_cde@hsc.utah.edu (mailto:heal_cde@hsc.utah.edu). The program has created the CDE files containing standardized variable names, responses, coding, and other information for all of these questionnaires. The program has also formatted the case-report forms (CRFs) in a standardized way that is compliant with accessibility standards under Section 508 of the Rehabilitation Act of 1973 (29 U.S.C § 794 (d); <https://www.govinfo.gov/content/pkg/USCODE-2011-title29/html/USCODE-2011-title29-chap16-subchapV-sec794d.htm>) which "require[s] Federal agencies to make their electronic and information technology accessible to people with disabilities."
 - Studies that wish to use questionnaires not already included in the HEAL CDE Repository should consult with their program official and the HEAL CDE team. New questionnaires will be considered for inclusion in the repository on a case-by-case basis and only when appropriate justification is provided.

- HEAL Initiative studies that are using copyrighted questionnaires are required to obtain licenses for use prior to initiating data collection. Licenses must be shared with the HEAL CDE team and the program officer prior to use of copyrighted materials. For additional information, visit the [HEAL CDE Program \(https://heal.nih.gov/data/common-data-elements\)](https://heal.nih.gov/data/common-data-elements).
- To the extent possible, all other (non-pain) HEAL studies conducting research involving human subjects are expected to use questionnaires by the [HEAL Common Data Elements \(CDE\) Program \(https://heal.nih.gov/data/common-data-elements\)](https://heal.nih.gov/data/common-data-elements) if applicable and relevant to their research.
 - Studies involving human participants, regardless of the research focus area, are expected to report CDE usage through appropriate channels.
- To the extent possible, HEAL awardees are expected to integrate broad data sharing consent language into their informed consent forms.

Additional details, resources, and tools to assist with data related activities can be found at <https://www.healdatafair.org/> (<https://www.healdatafair.org/>).

All data collected as part of the NIH HEAL Initiative are so collected under a Certificate of Confidentiality and entitled to the protections thereof. Institutions who receive Data and/or Materials from this award for performance of activities under this award are required to use the Data and/or Materials only as outlined by the NIH HEAL Initiative, in a manner that is consistent with applicable state and federal laws and regulations, including any informed consent requirements and the terms of the institution's NIH funding, including NOT-OD-17-109 and 42 U.S.C. 241(d). Failure to adhere to this criterion may result in enforcement actions.

4. Reporting

When multiple years are involved, recipients will be required to submit the [Research Performance Progress Report \(RPPR\) \(http://grants.nih.gov/grants/rppr/index.htm\)](http://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 \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82428\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82428).

- Recipients will be required to submit a Non-Competing Continuation Progress Report at the time of transition to the UH3 phase.
- Report and ensure immediate public access to HEAL-funded publications:
 - Publications resulting from NIH HEAL Initiative funded studies must be immediately publicly available upon publication.
 - For manuscripts published in journals that are not immediately open access, authors should arrange with journals in advance to pay for immediate open access
 - Costs to ensure manuscripts are immediately publicly available upon publication should be included in budget requests
 - Prior to publication, HEAL expects investigators to alert their program officers of upcoming manuscripts to ensure coordination of communication and outreach efforts.
 - Award recipients and their collaborators are required to acknowledge HEAL Initiative support by referencing in the acknowledgment sections of any relevant publication:
 - "This research was supported by the National Institutes of Health through the NIH HEAL Initiative (<https://heal.nih.gov/>) (<https://heal.nih.gov/>) under award number [include specific grant/contract/award number; with NIH grant number(s) in this format: R01GM987654]."

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82420\)](http://grants.nih.gov/grants/guide/url_redirect.htm?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 \(https://www.era.nih.gov/need-help\)](https://www.era.nih.gov/need-help) - Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues.

[Grants.gov Support Center \(https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoinette.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b\)](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoinette.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b)

- Questions regarding Grants.gov registration and services (e.g., Workspace, subscriptions).

Scientific/Research Contact(s)

National Institute of Neurological Disorders and Stroke (NINDS)

Email: PTDP@ninds.nih.gov (<mailto:PTDP@ninds.nih.gov>).

National Center for Complementary and Integrative Health (NCCIH)

Email: NCCIHDERFunding@nih.gov (<mailto:NCCIHDERFunding@nih.gov>).

NATIONAL EYE INSTITUTE

Email: NEI_extramural@nih.gov (mailto:NEI_extramural@nih.gov).

National Institute on Aging

Email: NIA-NOFO-Scientific@nih.gov (<mailto:NIA-NOFO-Scientific@nih.gov>).

National Institute on Alcohol Abuse and Alcoholism

Email: NIAAA-HEAL@mail.nih.gov (<mailto:NIAAA-HEAL@mail.nih.gov>).

National Institute on Drug Abuse (NIDA)

Email: NIDACPPPProgram@mail.nih.gov (<mailto:NIDACPPPProgram@mail.nih.gov>).

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Email: NIAMS_Pain@mail.nih.gov (mailto:NIAMS_Pain@mail.nih.gov).

Eunice Kennedy Shriver National Institute of Child Health and Human Development

Email: NICHDHEAL@nih.gov (<mailto:NICHDHEAL@nih.gov>).

National Cancer Institute

Email: DCPSymptomScience@nih.gov (<mailto:DCPSymptomScience@nih.gov>).

National Heart, Lung, and Blood Institute

Email: NHLBIOGMInbox@nhlbi.nih.gov (<mailto:NHLBIOGMInbox@nhlbi.nih.gov>).

Peer Review Contact(s)

Center for Scientific Review (CSR)

NOFORReviewContact@csr.mail.nih.gov (<mailto:NOFORReviewContact@csr.mail.nih.gov>).

Financial/Grants Management Contact(s)

Chief Grants Management Officer

National Institute of Neurological Disorders and Stroke (NINDS)

Email: ChiefGrantsManagementOfficer@ninds.nih.gov (mailto:ChiefGrantsManagementOfficer@ninds.nih.gov)

National Center for Complementary and Integrative Health (NCCIH)

Division of Extramural Research email

Email: NCCIHDERFunding@nih.gov (mailto:NCCIHDERFunding@nih.gov)

NATIONAL EYE INSTITUTE

Email: NEI_extramural@nih.gov (mailto:NEI_extramural@nih.gov)

National Institute on Aging

Email: NIA-NOFO-Grants@nih.gov (mailto:NIA-NOFO-Grants@nih.gov)

National Institute on Alcohol Abuse and Alcoholism

Grants Management Branch

Email: NIAAA-GMB@mail.nih.gov (mailto:NIAAA-GMB@mail.nih.gov)

Chief Grants Management Officer

National Institute of Drug Abuse (NIDA)

Email: nidagmbemail@nida.nih.gov (mailto:nidagmbemail@nida.nih.gov)

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Email: NIAMSGrants@nih.gov (mailto:NIAMSGrants@nih.gov)

Eunice Kennedy Shriver National Institute of Child Health and Human Development

Email: nichdgrantsmanagement@mail.nih.gov (mailto:nichdgrantsmanagement@mail.nih.gov)

National Cancer Institute

Email: NCIFinancialContact@nih.gov (mailto:NCIFinancialContact@nih.gov)

National Heart, Lung, and Blood Institute

Email: NHLBIOGMInbox@nhlbi.nih.gov (mailto:NHLBIOGMInbox@nhlbi.nih.gov)

Section VIII. Other Information

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

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 2 CFR Part 200.