

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 on Alcohol Abuse and Alcoholism ([NIAAA \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82473\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82473))

Funding Opportunity Title
Specialized Alcohol Research Centers (P50 Clinical trial Optional)

Activity Code
[P50 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=p50&Search.x=0&Search.y=0&Search_Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=p50&Search.x=0&Search.y=0&Search_Type=Activity) Specialized Center

Announcement Type
Reissue of [RFA-AA-24-007 \(https://www.grants.gov/search-results-detail/354051\)](https://www.grants.gov/search-results-detail/354051)

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.
- **January 23, 2026** - NIH Pause on New Submissions to the NIH Human Embryonic Stem Cell Registry and Request for Information on Reducing Reliance on Human Embryonic Stem Cells in NIH-Supported Research. See Notice, [NOT-OD-26-031 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-031.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-031.html).

Funding Opportunity Number (FON)
RFA-AA-28-001

Companion Notice of Funding Opportunity
None

Number of Applications
See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)
93.273

Notice of Funding Opportunity Purpose

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) supports a broad-based Alcohol Research Centers program to foster and conduct interdisciplinary, collaborative research on alcohol misuse, Alcohol Use Disorder (AUD), and alcohol-related problems, and other health-related consequences across the lifespan. The NIAAA Centers Program provides leadership in research, and research methodology development on a wide variety of topics relevant to the Institute's mission. The focus of the NIAAA Centers program should be on generating a critical mass of researchers in a given understudied and/or innovative topic area relevant to the NIAAA mission with an emphasis on interdisciplinary coordination and cooperation among independent researchers and development and mentorship of young investigators. A center must contribute more to the alcohol field than the sum of its parts. Topics include but are not limited to, the nature, etiology, genetics, diagnosis, treatment, and prevention of alcohol misuse, AUD, alcohol-related end-organ diseases, and their biomedical, psychosocial, and population health consequences across the lifespan. Centers are also major contributors to the development of research methods, technologies, and approaches that sustain innovative goal-directed research on understanding the chronic disorder of alcohol misuse that is such a personal, social and medical burden to US society.

Funding Opportunity Goal(s)

To develop a sound fundamental knowledge base which can be applied to the development of improved methods of treatment and more effective strategies for preventing alcoholism and alcohol-related problems. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) supports research in a broad range of disciplines and subject areas related to biomedical and genetic factors, psychological and environmental factors, alcohol-related problems and medical disorders, health services research, and prevention and treatment research.

Key Dates

Posted Date
October 15, 2026

Open Date (Earliest Submission Date)
December 27, 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
January 27, 2027	January 27, 2027	Not Applicable	July 2027	October 2027	December 2027

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

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

No late applications will be accepted for this Notice of Funding Opportunity (NOFO).

Expiration Date
January 28, 2027

Due Dates for E.O. 12372
Not Applicable

Required Application Instructions

It is critical that applicants follow the Multi-Project (M) 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 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)). Conformance to all requirements (both 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) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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

1. Use the [NIH ASSIST system \(https://public.era.nih.gov/assist/landing.era?tabId=0819b5fc-46b7-4f02-b6b7-127e5a4e19fa\)](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.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Research Objectives

This NOFO uses the NIH Specialized Research Center (P50) mechanism to support an integrated, broad-based multidisciplinary, multi-investigator, long-term program of research and research support activities planned around a specific major research theme. Specialized Alcohol Research Centers are also expected to function as a regional and national resource in their particular area of expertise; to provide students and early-stage investigators opportunities to build research expertise; and to develop research collaborations with outside investigators. Centers have the option of proposing pilot projects to support early-stage investigators, attract new scientific perspectives and research sites to the center, and expand research into areas addressing novel research hypotheses relevant to health outcomes associated with AUD (e.g., trauma, adversity). The Alcohol Research Centers program is interrelated with, and complementary to, all other research support mechanisms and scientific activities that comprise NIAAA programs. Center grants help to provide a stable environment for investigators to engage in alcohol research in a coordinated, integrated, and synergistic effort.

The Specialized Alcohol Research Center provides a mechanism for fostering interdisciplinary cooperation within a group of established investigators conducting exceptional alcohol research. Therefore, existence of a strong research capability is fundamental to the establishment of a new Center or the continuation of an existing Center. A Center should be an identifiable organizational unit within an institutional or organizational structure, such as a university, medical center, or a consortium of affiliated cooperating institutions. In addition to providing support for shared resources, this type of Center supports a full range of basic, developmental, clinical, and/or applied research components; allows for growth and development through pilot projects; and is intended to provide state-of-the-art leadership in the alcohol field. Unique scientific opportunities including the sharing of resources or expertise warrant collaboration with investigators from other centers or other institutions, domestic or foreign. The director of component(s) in which collaborative activity with a foreign organization is proposed should be affiliated with a domestic institution.

Applications Not Responsive to this NOFO

The following types of applications are not responsive to this NOFO and will not be reviewed:

- P50 Applications that include one or more components (core, research project, pilot project) focusing on HIV/AIDS-related topics.

Investigators proposing NIH-defined clinical trials may refer to the Research Methods Resources 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

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

Application Types Allowed

New
Renewal

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](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) provides 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).

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

Funds Available and Anticipated Number of Awards

NIAAA intends to commit \$1.5 million in FY 2027 to fund up to one award.

Award Budget

Application budgets may not exceed \$1.15 million direct costs per year.

Award Project Period

Applications may request a project period of up to five years.

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 Organization) **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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11118\)](http://grants.nih.gov/grants/guide/uri_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 \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82423) for additional information.

- [System for Award Management \(SAM\) \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82390\)](https://grants.nih.gov/grants/guide/uri_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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11176\)](http://grants.nih.gov/grants/guide/uri_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 \(https://era.nih.gov/\)](https://era.nih.gov/) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82300\)](http://grants.nih.gov/grants/guide/uri_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. 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.

Eligible Individuals (Program Director/Principal Investigator)

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

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

2. Cost Sharing

This NOFO does not require cost sharing as defined in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11126\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11126) [Section 1.2- Definitions of Terms. \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_1/1.2_definition_of_terms.htm)

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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82415\)](http://grants.nih.gov/grants/guide/uri_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 \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/uri_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 or an institutional system-to-system solution. A button to apply using ASSIST is available in Part 1 of this NOFO. See the administrative office for instructions if planning to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Multi-Project (M) 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), except where instructed in this notice of funding opportunity to do otherwise (in this NOFO, in a [policy notice \(https://grants.nih.gov/grants/guide/uri_redirect.php?id=11163\)](https://grants.nih.gov/grants/guide/uri_redirect.php?id=11163), or other notice from [NIH Guide for Grants and Contracts \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) and where 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) are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to the requirements 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) 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 \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=61134\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=61134) must be followed.

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximum
Overall	Overall	12	Required	1	1
Admin Core	Admin Core	6	Required	1	1

Component	Component Type for Submission	Page Limit	Required/Optional	Minimum	Maximum
Resource Core	Core	6	Optional	0	2
Pilot projects Core	Core	6	Optional	0	1
Research Project	Project	12	Required	3	5

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in [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 a multi-component application.

Overall Component

When preparing the application, use Component Type 'Overall'.

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, as noted.

SF424(R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Note: Human Embryonic Stem Cell lines from other components should be repeated in cell line table in Overall component.

Research & Related Other Project Information (Overall)

Follow standard instructions.

Project/Performance Site Locations (Overall)

Enter primary site only.

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.

Research and Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/PIs (if applicable to this NOFO) for the entire application.

A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.

Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

PHS 398 Research Plan (Overall)

Introduction to Application: For Resubmission and Revision applications, an Introduction to Application is required in the Overall component.

Specific Aims: Describe the theme and goals of the Center and how they will advance research and impact the alcohol research community. Describe how the specific aims of the Center will achieve these goals

Research Strategy: The Research Strategy for the Overall component must describe the central theme, purpose and objectives of the entire Center. It gives the philosophy and general plan for the proposed grant period and how the Center will achieve its major objectives. The reason a Center approach is needed for this work should be well articulated. The unique contribution for the Center and each component (including pilot projects component, if applicable) to the center should be described. The significance of the overall research goal and research theme are described and the importance and relevance of these to the mission of the Center's program.

Research Strategy for the Overall component must also describe the following:

- Evidence of scientific and administrative integration of the proposed program, coordination, interrelationships, and synergy among the individual research projects and core components.
- Thematic cohesion between the support cores and individual research projects and a justification for the proposed administrative and organization structure, including plans for internal quality control of ongoing research and for fair and effective communication and cooperation among center members including resolution of disputes and allocation of resources.

For Renewal applications:

- The Research Strategy for the Overall component must include an introductory overview to provide a history of the Center and, and without duplicating information in the Progress Report, give a summary of major research accomplishments and progress toward achievement of goals since the last competitive application.

Progress Report:

- A comprehensive progress report is required for renewal applications. A statement describing evidence of productive collaborations during the current funding period, and the progress made by the Center as a regional or national research resource should be included. Collaborative activities, if any, with other NIAAA Alcohol Research Centers should be described along with a list of joint accomplishments.
- Describe the evidence of productive collaborations during the current funding period.
- Progress Reports for cores and projects that have been terminated must be included in the Overall Section of the application.

Letters of Support:

Letters of support for the Specialized Center as a whole should be included in this section (e.g., letters of institutional support). Letters of support relevant to specific Projects or Core(s) should be attached to the relevant Project or Core components. Include a table summarizing the names, institutions and role, e.g., collaborator, consultant, resource user, Center Advisory Board (PAB) member.

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 \(https://grants.nih.gov/grants/how-to-apply-application-guide.html\)](https://grants.nih.gov/grants/how-to-apply-application-guide.html) 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 Data Management and Sharing (DMS) Plan must be provided in the Overall component.
- In addition, DMS Plan for applications that include human subject research in one or more components of the P50 should submit grant-related human subjects data to the NIAAA-sponsored data repository, as described in [NOT-AA-23-002 \(https://grants.nih.gov/grants/guide/notice-files/NOT-AA-23-002.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-AA-23-002.html).

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in [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); any instructions provided here are in addition to 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) instructions.

PHS Human Subjects and Clinical Trials Information (Overall)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_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, there must be at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or a **Delayed Onset Study** record within the application. The study record(s) must be included in the component(s) where the work is being done, unless the same study spans multiple components. To avoid the creation of duplicate study records, a single study record with sufficient information for all involved components must be included in the Overall component when the same study spans multiple components.

Study Record: PHS Human Subjects and Clinical Trials Information

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.

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

PHS Assignment Request Form (Overall)

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.

Administrative Core

When preparing your application, use Component Type 'Admin Core.'

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, as noted.

SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Administrative Core)

Follow standard instructions.

Research & Related Other Project Information (Administrative Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Administrative Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Administrative Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Administrative Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Administrative Core)

Specific Aims: Describe the specific aims of the Administrative Core

Research Strategy: The Administrative Core provides the organizational framework for the management, direction, and coordination of the Center. This core should ensure that all proposed components and related activities will function in an optimal and synergistic manner. An important function of this core is also the administration of the budget. It may support scientific enrichment activities such as lectures, symposia, seminars, and workshops for research faculty and staff. This core should be described in sufficient detail to assure that all proposed components and related activities will function optimally. In addition, day-to-day operations involving procurement, finances, personnel, planning, and budgeting should be detailed in the description of this core. In addition, this core should include a detailed description of the leadership succession plan to ensure that a pipeline of leaders will be available when they are needed, in the event that the Center Director retires, becomes incapacitated or for some other reasons. The core should also include a plan to promote future leadership of the center and develop alcohol researchers with experience and expertise to lead multi-investigator research projects.

A Program Advisory Committee (PAC) shall be established and chaired by the Center Director. The PAC will be composed of at least five (5) members, selected by the Center Director from individuals outside the Center. These members should be persons of recognized scientific standing who are generally familiar with the Center's activities and represent a cross-section of disciplines that are relevant to the work of the proposed Center. It shall be the responsibility of the PAC to review and make recommendations to the Center Director on the conduct of all activities of the Center, including the management of pilot projects. For new applications, do not contact, recruit, or name potential external advisory council members in the application (not until after peer review and as directed by NIH Program staff). For renewal applications, provide the names of current and former external advisory council members but do not contact, recruit, or name potential new members. The current PAC members should not be identified as key personnel. Plans should be provided for selection of new PAC members, if applicable.

The Center Director(s) will establish a Steering Committee that will be composed of the Center Director(s) and Core/Research Component Directors. The function of the Steering Committee is to facilitate collaboration by monitoring progress and outcomes of individual projects, develop new collaborations, and review the Center's strategies for achieving its goals.

Renewal Applications: A succinct account of the published and unpublished results must be provided, indicating progress toward achieving aims of the Administrative Core. Ongoing or completed core activity that has enhanced or facilitated alcohol research should be described. Past performance and accomplishments of cores should be described, and the effect of services provided by this core on investigators' productivity.

Progress Report Publications List: Provide a bibliography of publications credited to the Administrative Core.

Letters of Support: Letters of support for the Administrative Core only should be included.

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), with the following modification:

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:

- Do not include a Data Management and Sharing (DMS) Plan within this Component. If a DMS Plan is required for this NOFO, it must be included within the Overall Component.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for 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); any instructions provided here are in addition to those 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) instructions.

PHS Human Subjects and Clinical Trials Information (Administrative Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply-Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_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 a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) 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 \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) must be followed.

Resource Core

When preparing your application, use Component Type 'Core.'

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, as noted.

SF424 (R&R) Cover (Resource Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Resource Core)

Follow standard instructions.

Research & Related Other Project Information (Resource Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Resource Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Resource Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Resource Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Resource Core)

Specific Aims: Describe the specific aims of the Resource Core

Research Strategy: A shared scientific resource core should be clearly described in terms of the services and resources to be provided to investigators. The description should include a discussion of the core's contributions to the research objectives of the Center. Relevant aspects of cost-effectiveness, time saving, and increased efficiency attributable to the existence of the cores should also be addressed.

A core should support two or more of the Center's scientific research components and may also support independently funded research project grants related to the Center's theme. Each separately funded research project associated with the Center and utilizing core facilities should have a brief description that includes its research objectives and how the Center's core facility will impact those objectives. The description of the organization and mode of operation of the shared resource core should include discussion of quality control for the service or resource, and the procedures for evaluating and selecting projects eligible to access the core facility. Cores are intended to enhance opportunities for investigators at the Center to utilize new technologies that broaden their research initiatives. While research per se is not an essential part of a scientific core, quality assurance activities that evaluate its operations and are directed at problem identification and improvement of core functioning are appropriate.

Renewal Applications: A succinct account of the published and unpublished results must be provided, indicating progress toward achieving aims of the Resource Core(s). Ongoing or completed core activity that has enhanced or facilitated alcohol research should be described. Past performance and accomplishments of cores should be described, and the effect of services provided by the Resource Cores on investigators' productivity.

Letters of Support: Letters of support for the Resource Core only should be included.

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), with the following modification:

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:

- Do not include a Data Management and Sharing (DMS) Plan within this Component. If a DMS Plan is required for this NOFO, it must be included within the Overall Component.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for 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); any instructions provided here are in addition to those 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) instructions.

PHS Human Subjects and Clinical Trials Information (Resource Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply- Application Guide \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_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 a **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) 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 \(https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=82400) must be followed.

Pilot Projects Core

When preparing your application, use Component Type 'Core.'

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, as noted.

SF424 (R&R) Cover (Pilot Projects Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Pilot Projects Core)

Follow standard instructions.

Research & Related Other Project Information (Pilot Projects Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Pilot Projects Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Pilot Projects Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Pilot Projects Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Pilot Projects Core)

Specific Aims: Describe the specific aims of the Pilot Projects Core

Research Strategy: The application must provide thorough and concise descriptions of the projects to be supported in the first two years. All proposed pilot projects need not be ongoing at any one time but may be phased in at different points during the life of the proposed Center grant. It is recognized that the relative priority or need for specific pilot projects may change over the course of time. While the Center's framework for the management of pilot project funds and the mechanism for operating the program are left to the discretion of the Center, the application must provide sufficient information to enable adequate scientific evaluation by a peer review committee. The application should include a full description of the management of the pilot projects core, including a description of the process used to solicit, evaluate, and select pilot projects. This includes the selection of new projects to replace those proposed in the application should it become necessary. Each pilot study proposed in the first 2 years should be described, including its rationale, objectives, approach, investigators, and significance for the Center. The research description of any individual pilot project may not exceed two pages. Describe how the projects will benefit from the unique features of the scientific environment, subject populations or collaborative arrangements. Describe how individual pilot projects have the potential to develop into full-scale independent projects.

Renewal Applications: A succinct account of the published and unpublished results must be provided, indicating progress toward achieving the aims of the Pilot Projects. Ongoing or completed activities that have enhanced or facilitated alcohol research should be described. Past performance and accomplishments of the pilot project core should be described. Describe if any of the pilot projects from the previous funding cycle developed into full-scale independent projects.

Progress Report Publications List: Provide a bibliography of publications credited to the Pilot Projects Core.

Letters of Support: Letters of support for the Pilot Projects Core only should be included.

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

Other Plan(s):

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:

- Do not include a Data Management and Sharing (DMS) Plan within this Component. If a DMS Plan is required for this NOFO, it must be included within the Overall Component.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for 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); any instructions provided here are in addition to those 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) instructions.

PHS Human Subjects and Clinical Trials Information (Pilot Projects Core)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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 a **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.

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) 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.

Research Project

When preparing your application, use Component Type 'Project.'

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, as noted.

SF424 (R&R) Cover (Research Project)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Research Project)

Follow standard instructions.

Research & Related Other Project Information (Research Project)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Research Project)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Research Project)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Research Project)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Research Project)

Specific Aims: Describe the specific aims of the Research Project.

Research Strategy: The application should provide a clear description of the project's major goals, and objectives, and how it integrates with the other research components in relation to the overall Center program. The hypotheses to be tested should be focused and fully detailed. The design and procedures should describe the strategies proposed to accomplish the specific aims and the innovative aspects of the approach should be highlighted. If core facilities are utilized, information on their use should be provided.

Renewal Applications: A succinct account of the published and unpublished results must be provided, indicating progress toward achieving aims of the Research Projects. This must include a bibliography of publications credited to this component. Past performance and accomplishments of the research projects should be described.

Progress Report Publications List: Provide a bibliography of publications credited to each Research Project.

Letters of Support: Letters of support for the specific Research Project only should be included.

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

Other Plan(s):

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:

- Do not include a Data Management and Sharing (DMS) Plan within this Component. If a DMS Plan is required for this NOFO, it must be included within the Overall Component.

Appendix:

Only limited items are allowed in the Appendix. Follow all instructions for 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); any instructions provided here are in addition to those 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) instructions.

PHS Human Subjects and Clinical Trials Information (Research Project)

When involving human subjects research, clinical research, and/or NIH-defined clinical trials 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 a **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.

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) 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.

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.htm?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) (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. 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) (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).

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 [How to Apply- Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

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

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

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/url_redirect.htm?id=82400). Paper applications will not be accepted.

For information on how applications will be automatically assembled for review and funding consideration after submission, refer to:

http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf.

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/url_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) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) and component Project Leads 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.

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 [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

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

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

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) 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).

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/) at 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/url_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 NIH in support of the [NIH mission](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

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

Overall Impact - Overall

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

Scored Review Criteria - Overall

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

Significance

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

In addition, for applications involving clinical trials

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

Investigator(s)

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

In addition, for applications involving clinical trials

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

Innovation

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

In addition, for applications involving clinical trials

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

Approach

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

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address:

- 1) the protection of human subjects from research risks, and
- 2) inclusion (or exclusion) of individuals on the basis of sex, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

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

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

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

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Environment

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

In addition, for applications involving clinical trials

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

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

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

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

Additional Review Criteria - Overall

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

Study Timeline

Specific to applications involving clinical trials

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

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

Protections for Human Subjects

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

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

Inclusion of Human Subjects Policies

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for inclusion. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(http://grants.nih.gov/grants/guide/redirect.htm?id=11174\)](http://grants.nih.gov/grants/guide/redirect.htm?id=11174).

Vertebrate Animals

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

Biohazards

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

Resubmissions

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

Renewals

For Renewals (as applicable), the committee will consider the progress made in the last funding period.

Revisions

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

Additional Review Considerations - Overall

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

Applications from Foreign Organizations

Not Applicable

Select Agent Research

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

Resource Sharing Plans

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

Authentication of Key Biological and/or Chemical Resources:

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

Budget and Period of Support

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

Review Criteria - Administrative Core, Resources Core(s), Pilot Project Core, and Research Projects.

For each of the components below (i.e., Administrative Core, Resources Core(s), Pilot Projects Core, Research Projects), reviewers will provide an overall numerical rating to reflect their assessment of the likelihood for the component to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria. Reviewers will consider the following aspects while determining the scientific and technical merit of each component.

Review Criteria for Administrative Core

- Is the plan for managing the Center's research and administration clear and appropriate in order to ensure appropriate prioritization of research, needed course corrections and problem identification and resolution, and effective sharing of resources, that conveys a high likelihood of effective, productive management of the Center as whole?
- Does the administrative plan provide for management of day-to-day program activities?
- Are the core personnel qualified and experienced in the administration of a large, multi-component research program?
- Is the organizational structure appropriately explained and described to facilitate coordination, integration and timely evaluation of activities and progress of the center's research?
- Are there innovative features in the organizational design and decision-making process?
- Is the coordination among the administrative core and the research components adequately explained?
- Is the leadership succession plan clear and appropriate in order to ensure that a pipeline of leaders will be available when they are needed, in the event that the Center Director retires, becomes incapacitated or for some other reasons?
- Is the plan to promote future leadership adequate for the center to develop alcohol researchers with experience and expertise to lead multi investigator research projects?

Review Criteria for Resource Core(s)

- Does the Resource Core describe the essential functions or services for at least two projects?
- Is the proposed Resource Core well-matched to the needs of the overall program?
- What is the overall quality of the proposed core services? Are adequate quality control processes proposed for the facilities or services provided by the Resource Core (including procedures, techniques, and quality control)? What are the criteria for prioritization and usage of Resource Core products and/or services?
- Are the qualifications, experience, and commitment of the leader of the Resource Core and other key personnel adequate and appropriate for providing the proposed facilities or services?
- Will the proposed Resource Core provide cost-effective services to the Program?
- Is the environment for the Resource Core adequate to support the program as proposed?
- Is the coordination among the Resource core and the research components adequately explained?
- Are the resources and environment for the projects adequate?

Review Criteria for Pilot Projects Core

- Is the management plan adequate for the evaluation and selection of the pilot projects?
- Is the selection process adequate for accepting new and replacement projects?
- Are procedures for monitoring oversight and project continuation adequately explained?
- Are the qualifications of the Pilot Project core director and the individual pilot project leaders appropriate for the proposed research?
- Will the scientific environment in which the work will be done contribute to the probability of success?
- Are the resources and environment for the projects adequate?
- Will the projects benefit from the unique features of the scientific environment, subject populations or collaborative arrangements?
- Are pilot research topics important and within the research focus of the center as a whole?
- Do the individual pilot projects have the potential to develop into full-scale independent projects?
- For renewal applications, did any of the pilot projects develop into a full-scale independent project?
- Are there adequate institutional plans and procedures to assure compliance with applicable federal regulations and NIH policies for the protection of human research participants, including the evaluation of risks and protections in project proposals, appropriate ethical oversight of funded projects, and plans for monitoring data and safety in clinical research projects?

Review Criteria for Individual Research Projects

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. The impact score for individual research projects will take into consideration: the scored review criteria and any specified additional review criteria; the extent to which the individual project enhances the strength of the overall Center; and the importance of the individual project to the success of the Center.

Significance

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

In addition, for applications involving clinical trials

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

Investigator(s)

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

In addition, for applications involving clinical trials

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

Innovation

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

In addition, for applications involving clinical trials

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

Approach

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

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

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable?

Study Design

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

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

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

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Environment

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

In addition, for applications involving clinical trials

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

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

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

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

Additional Review Criteria - Individual Research Projects

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

Study Timeline

Specific to applications involving clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified?

Does the project incorporate efficiencies and utilize existing resources (e.g., CTSA's, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

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

Additional Review Criteria - Cores and Projects

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

Protections for Human Subjects

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

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

Inclusion of Human Subjects Policies

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for inclusion. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11174) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

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

Biohazards

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

Resubmissions

Not Applicable

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

Revisions

Not Applicable

Additional Review Considerations - Cores and Projects

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

Applications from Foreign Organizations

Not Applicable

Select Agent Research

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

Resource Sharing Plans

Reviewers will comment on the Resource Sharing Plans(s), (e.g., [Sharing Model Organisms](https://grants.nih.gov/grants/guide/url_redirect.php?id=11152) (https://grants.nih.gov/grants/guide/url_redirect.php?id=11152)), or whether the rationale for not sharing the resources is reasonable:).

Authentication of Key Biological and/or Chemical Resources:

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

Budget and Period of Support

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

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by CSR, in accordance with [NIH peer review policies and practices](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

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

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

[Appeals](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) of initial peer review will not be accepted for applications submitted in response to this NOFO.

Applications will be assigned 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 NIAAA national Advisory Council. 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/url_redirect.htm?id=82418) (http://grants.nih.gov/grants/guide/url_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 their Summary Statement (written critique) via the [eRA Commons \(http://grants.nih.gov/grants/guide/redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/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 \(http://grants.nih.gov/grants/guide/redirect.htm?id=82416\)](http://grants.nih.gov/grants/guide/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 \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_5/5_the_notice_of_award.htm) and NIH Grants & Funding website, see [Award Process. \(https://grants.nih.gov/grants/pre-award-process.htm#award\)](https://grants.nih.gov/grants/pre-award-process.htm#award)

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 organizations 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 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).

Prior Approval of Pilot Projects

Recipient-selected projects that involve {clinical trials or studies involving greater than minimal risk to human subjects} require prior approval by NIH prior to initiation.

- The recipient institution will comply with the NIH [Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html).
- The recipient institution will provide NIH with specific plans for data and safety monitoring, and will notify the IRB and NIH of serious adverse events and unanticipated problems, consistent with [NIH DSMP policies \(http://grants.nih.gov/grants/guide/redirect.htm?id=21600\)](http://grants.nih.gov/grants/guide/redirect.htm?id=21600).

2. Administrative and National Policy Requirements

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

- The rules listed at [2 CFR Part 200 \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200\)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/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 \(http://grants.nih.gov/grants/guide/redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/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 \(http://grants.nih.gov/grants/guide/redirect.htm?id=11159\)](http://grants.nih.gov/grants/guide/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. \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4_public_policy_requirements_objectives_and_other_appropriation_mandates.htm\)](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 \(https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy\)](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 \(https://www.nist.gov/cyberframework\)](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 \(hhs.gov\) \(https://405d.hhs.gov/kod/five-threats\)](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 \(cisa.gov\) \(https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf\)](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 \(https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.samhsa.gov%2Fsites%2Fdefault%2Ffiles%2Fdear-colleague-letter-mat-moud-guidance.pdf&data=05%7C02%7Cchelsey.hughes%40nih.gov%7C725bb62d21f94a2b9ff908dec0bc5a25%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C63916011238415\)](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.samhsa.gov%2Fsites%2Fdefault%2Ffiles%2Fdear-colleague-letter-mat-moud-guidance.pdf&data=05%7C02%7Cchelsey.hughes%40nih.gov%7C725bb62d21f94a2b9ff908dec0bc5a25%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C63916011238415)

Recipients of both Clinical Trial Required and Clinical Trial Optional awards subject to this term shall report standardized clinical trial activation and enrollment performance data for any [interventional \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-063.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-063.html) clinical trial supported under the award. These metrics are intended to assess trial startup efficiency, site activation, and post-activation performance and to support continuous quality improvement in clinical trial operations (see supplemental guidance). Recipients shall report required data annually at the time of Research Performance Progress Report (RPPR) submission on clinical trial activation and enrollment performance milestone dates as calendar dates; NIH will calculate standardized interval metrics from these dates.

Institutions are expected to maintain capabilities that support efficient clinical trial startup, participant enrollment, and performance monitoring, including streamlined workflows and systems for electronic tracking of milestones. Recipients are encouraged to implement and evaluate approaches that improve trial efficiency and the participant experience.

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://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.congress.gov%2Fbill%2F119th-congress%2Fhouse-bill%2F7148&data=05%7C02%7Cantoinette.caliman%40nih.gov%7C68a8e1e3db804c61b38f08deb0e88127%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C63914270982](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.congress.gov%2Fbill%2F119th-congress%2Fhouse-bill%2F7148&data=05%7C02%7Cantoinette.caliman%40nih.gov%7C68a8e1e3db804c61b38f08deb0e88127%7C14b77578977342d58507251ca2dc2b06%7C0%7C0%7C63914270982) 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.

In administering programs under this and all funding announcements, NIH prioritizes:

- Research involving rigorous scientific methods, including for studies related to children and adolescents, where NIH is committed to approaches that reflect the highest standards of clinical care and child safety.
- Biological and physiological integrity: Recognizing the relevance of biological sex to health outcomes, NIH encourages applicants to account for sex-based health factors in program design, data collection, and service delivery where scientifically appropriate.
- NIH will implement these priorities consistent with applicable laws, regulations, court orders, and all required administrative procedures. Applicants are encouraged to describe how their proposed programs align with these priorities in their project narratives. Funded activities must advance NIH's vision of protecting and improving the health and well-being of Americans. The particular focus is on those who are medically vulnerable, or live in areas with limited access to care. NIH's duty is to serve wisely, effectively, and with measurable results that justify every taxpayer dollar invested.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

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. The Data Management and Sharing (DMS) Plan must be provided in the Overall component.

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](http://grants.nih.gov/grants/guide/redirect.htm?id=82419) (<http://grants.nih.gov/grants/guide/redirect.htm?id=82419>). To learn more about post-award monitoring and reporting, see the NIH Grants & Funding website, see [Post-Award Monitoring and Reporting](https://grants.nih.gov/grants/guide/redirect.php?id=82428) (<https://grants.nih.gov/grants/guide/redirect.php?id=82428>).

Progress reports should briefly describe status of pilot projects, including data and safety monitoring, and should notify NIH of serious adverse events and unanticipated problems.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the [NIH Grants Policy Statement Section 8.6 Closeout](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm) (https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR Part 200.301.

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 on Alcohol Abuse and Alcoholism (NIAAA)

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

Peer Review Contact(s)

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

Financial/Grants Management Contact(s)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

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

Section VIII. Other Information

Recently issued trans-NIH [policy notices](http://grants.nih.gov/grants/guide/redirect.htm?id=11163) (<http://grants.nih.gov/grants/guide/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/redirect.htm?id=11164) (<http://grants.nih.gov/grants/guide/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/redirect.htm?id=11120) (<http://grants.nih.gov/grants/guide/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.