

# Department of Health and Human Services

## Part 1. Overview Information

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**Participating Organization(s)**

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

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**Components of Participating Organizations**

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

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**Funding Opportunity Title**

NIDA Research Center of Excellence Grant Program (P50 Clinical Trial Optional)

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**Activity Code**

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

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**Announcement Type**

Reissue of [PAR-18-224 \(https://grants.nih.gov/grants/guide/pa-files/PAR-18-224.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-18-224.html)

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**Related Notices**

None

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**Funding Opportunity Announcement (FOA) Number**

**PAR-19-259**

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**Companion Funding Opportunity**

None

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**Number of Applications**

See [Section III. 3. Additional Information on Eligibility.](#)

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

93.279

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## Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) is to provide support for research Centers that (1) conduct drug abuse and addiction research in any area of NIDA's mission, (2) have outstanding innovative science, (3) are multidisciplinary, thematically integrated, synergistic, and (4) serve as national resource(s) to provide educational and outreach activities to drug abuse research communities, educational organizations, the general public, and policy makers in the NIDA research fields. It is expected that a Center will transform knowledge in the sciences it is studying. Incremental work should not be the focus of Center activities; rather, new and creative directions are required. The P50 Center of Excellence is expected to foster the career development and mentoring of new investigators who would be given meaningful roles to play in the Center projects. A goal of this program is to create NIDA Centers that are national community resources for furthering drug abuse research by sharing their findings, their data, and their resources as appropriate for researchers to use and build upon and to advance research in this field.

## Key Dates

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### Posted Date

April 24, 2019

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### Open Date (Earliest Submission Date)

August 25, 2019

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### Letter of Intent Due Date(s)

30 days prior to the application due date

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### Application Due Date(s)

September 25, 2019; September 25, 2020; September 25, 2021 , by 5:00 PM local time of applicant organization. All [types of non-AIDS applications](#) allowed for this funding opportunity announcement are due on these dates.

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.

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### AIDS Application Due Date(s)

January 7, 2020; January 7, 2021; January 7, 2022 by 5:00 PM local time of applicant organization. All [types of AIDS and AIDS-related applications](#) allowed for this funding opportunity announcement are due on these dates.

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.

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### Scientific Merit Review

March 2020, March 2021, March 2022

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### Advisory Council Review

May 2020, May 2021, May 2022

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**Earliest Start Date**

July 2020, July 2021, July 2022

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**Expiration Date**

January 8, 2022

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**Due Dates for E.O. 12372**

Not Applicable

**Required Application Instructions**

It is critical that applicants follow the Multi-Project (M) Instructions in the [SF424 \(R&R\) Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000)), except where instructed to do otherwise (in this FOA or in a Notice from the [NIH Guide for Grants and Contracts](https://grants.nih.gov/grants/guide/) ([//grants.nih.gov/grants/guide/](https://grants.nih.gov/grants/guide/))). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in [Section IV](#). When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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

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

Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons](http://public.era.nih.gov/commons/) (<http://public.era.nih.gov/commons/>) to track your application. Check with your institutional officials regarding availability.

## Table of Contents

[Part 1. Overview Information](#)

[Part 2. Full Text of the Announcement](#)

[Section I. Funding Opportunity Description](#)

[Section II. Award Information](#)

[Section III. Eligibility Information](#)

[Section IV. Application and Submission Information](#)

[Section V. Application Review Information](#)

[Section VI. Award Administration Information](#)

[Section VII. Agency Contacts](#)

[Section VIII. Other Information](#)

# Part 2. Full Text of Announcement

## Section I. Funding Opportunity Description

### Research Objectives

NIDA supports research center grants to foster an innovative, synergistic and thematically coherent approach to drug abuse and addiction research and to enable studies that would not occur without the climate, facilities and/or interactive research resources that a research center can uniquely provide. NIDA encourages the application of multiple scientific perspectives and approaches to the problem of addiction to support the highest quality, multidisciplinary programs of innovative research. Through the Centers program, NIDA seeks to encourage outstanding scientists to bring a full range of expertise, approaches, technologies, and creativity to the study of problems related to drug abuse and addiction. Investigative efforts are expected to be broadly based and to encompass a variety of areas, including biological, biomedical, social, behavioral, and/or clinical sciences as well as dissemination sciences to address critical research issues.

NIDA Centers are expected to be scientifically innovative and provide the next generation of ideas and approaches. It is expected that a Center will transform knowledge in the sciences it is studying and be at the cutting edge of science. Incremental work, though valuable, should not be the focus of Center activities.

NIDA Centers are expected to be thematically coherent and demonstrate the highest caliber of multidisciplinary scientific work; there must be an overarching theme that integrates and focuses the Center. Each core and research component should relate to the overall Center theme and to other components of the Center to provide a synergy that leads to creative thinking, novel approaches, innovations, and highly significant findings. Interactions and integration of projects should be clearly evident, so that the Center does not appear to be a collection of independent research projects. There should be linkages among components that result in levels of productivity, quality, and progress that will exceed those expected from combining the individual components in an additive fashion. Linkages may be conceptual, spatial, and/or temporal. Interdependency of the scientific projects may allow for a variety of arrangements, for example, multiple research components sharing a common subject pool managed through a core or a common imaging protocol managed in a core to allow for comparability of data across research projects. The type of integration proposed may be different for different genres of science, including: conceptual integration or sharing of data, instruments, and other resources. Linkages should encourage cross-fertilization of ideas and interactions among investigators that are relevant to the theme. Multidisciplinary research activity is expected across a variety of disciplines or sub-disciplines to bring multiple scientific perspectives and approaches to a research area or question.

In addition, NIDA Research Centers are expected to serve as national research resources in the drug abuse research field to provide educational and outreach activities to drug abuse research communities, educational organizations, the general public, and policy makers in the NIDA research fields. They are expected to attract established and promising investigators into drug abuse research. The P50 Center application is expected to foster the career development and mentoring of new investigators and provide opportunities for effective dissemination of research findings.

### Special Considerations

National Advisory Council on Drug Abuse Recommended Guidelines for the Administration of Drugs to Human Subjects: The National Advisory Council on Drug Abuse (NACDA) recognizes the importance of research involving the administration of drugs with abuse potential, and dependence or addiction liability, to human subjects. Potential applicants are encouraged to obtain and review these recommendations of Council before submitting an application that will administer compounds to human subjects. For more information see

<http://www.drugabuse.gov/funding/clinical-research/nacda-guidelines-administration-drugs-to-human-subjects>

Points to Consider Regarding Tobacco Industry Funding of NIDA Applicants: The National Advisory Council on Drug Abuse (NACDA) encourages NIDA and its grantees to consider the points it has set forth with regard to existing or prospective sponsored research agreements with tobacco companies or their related entities and the impact of acceptance of tobacco industry funding on NIDA's credibility and reputation within the scientific community. For more information see <http://www.drugabuse.gov/about-nida/advisory-boards-groups/national-advisory-council-drug-abuse-nacda/council-statements/points-to-consider-regarding-tobacco-industry-funding-nida>

Data Harmonization for Substance Abuse and Addiction via the PhenX Toolkit: NIDA strongly encourages investigators involved in human-subjects studies to employ a common set of tools and resources that will promote the collection of comparable data across studies and to do so by incorporating the measures from the Core and Specialty collections, which are available in the Substance Abuse and Addiction Collection of the PhenX Toolkit ([www.phenxtoolkit.org](http://www.phenxtoolkit.org)). For more information see <https://grants.nih.gov/grants/guide/notice-files/NOT-DA-12-008.html> (<https://grants.nih.gov/grants/guide/notice-files/NOT-DA-12-008.html>).

See [Section VIII. Other Information](#) for award authorities and regulations.

## Section II. Award Information

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### Funding Instrument

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

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### Application Types Allowed

New  
Renewal  
Resubmission  
Revision

The [OER Glossary \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11116\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types.

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### 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?](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)  
([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82370](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370))

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### Funds Available and Anticipated Number of Awards

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

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### Award Budget

Application budgets for direct costs cannot exceed \$10,000,000 for the entire 5 year project period including no cost extensions, but need to reflect the actual needs of the proposed project.

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## Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

NIH grants policies as described in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120), will apply to the applications submitted and awards made from this FOA.

## Section III. Eligibility Information

### 1. Eligible Applicants

#### Eligible Organizations

##### Higher Education Institutions

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

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

##### Nonprofits Other Than Institutions of Higher Education

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

##### For-Profit Organizations

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

##### 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)
- 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 Institutions

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

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

Foreign components, as [defined in the NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11118](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118)), **are not** allowed.

## Required Registrations

### Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The [NIH Policy on Late Submission of Grant Applications](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html) ([//grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html)) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- [Dun and Bradstreet Universal Numbering System \(DUNS\)](http://fedgov.dnb.com/webform) (<http://fedgov.dnb.com/webform>) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- [System for Award Management \(SAM\)](https://www.sam.gov/portal/public/SAM/) (<https://www.sam.gov/portal/public/SAM/>) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - [NATO Commercial and Government Entity \(NCAGE\) Code](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11176](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176)) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
- [eRA Commons](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)) - Applicants must have an active DUNS number to register in eRA Commons. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration, but all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) ([//grants.nih.gov/grants/guide/url\\_redirect.htm?id=82300](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300)) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

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

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

### Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

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 SF424 (R&R) Application Guide.

## 2. Cost Sharing

This FOA does not require cost sharing as defined in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11126). ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11126](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11126))

## 3. Additional Information on Eligibility

### Number of Applications

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see [NOT-OD-11-101](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html>)).

## 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 FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

### 2. Content and Form of Application Submission

It is critical that applicants follow the Multi-Project (M) Instructions in the [SF424 \(R&R\) Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000)), except where instructed in this funding opportunity announcement to do otherwise and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

#### Letter of Intent

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

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

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to: [NIDALetterofIntent@mail.nih.gov](mailto:NIDALetterofIntent@mail.nih.gov) (<mailto:NIDALetterofIntent@mail.nih.gov>)

If preferred, hard copy (paper) letters may be sent to:

Office of Extramural Policy and Review  
National Institute on Drug Abuse, NIH, DHHS

6001 Executive Boulevard, Room 4243, MSC 9550  
Bethesda, MD 20892

## Page Limitations

Component Types Available in ASSIST	Research Strategy/Program Plan Page Limits
Overall	12
Admin Core	6
Core (use for Research Core Pilot Project Core)	12
Project (use for Research Projects)	12

Additional page limits described in the SF424 Application Guide and the [Table of Page Limits \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11133\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

## Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide, and should be used for preparing a multi-component application.

Revision applications must include an Overall component and the components that are affected by the revision. Therefore, the component requirements listed below may not apply to the revision application.

The application should consist of the following components:

- Overall: required
- Administrative Core: required
- Research Core: optional
- Pilot Project Core: optional
- Research Projects: minimum of 3 required

### Overall Component

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

All instructions in the SF424 (R&R) Application Guide 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.

**Facilities & Other Resources:** The application must document availability of appropriate and adequate facilities dedicated to the conduct of administrative, shared resource, and research activities. While all members of the Center need not be located physically in facilities controlled exclusively by the Center, there must be a clearly identifiable physical location which insures adequate administrative oversight for the Center and associated core units that are providing shared resources. Describe the types and quality of shared laboratory and clinical facilities.

**Other Attachments:** The following information must be loaded as separate PDF attachments. The filename provided for each attachment will be the name used for the bookmark in the application image.

**Center Organizational Structure.** Applicants must include a diagram of the organizational structure of the Center. This diagram should demonstrate how the interactions among the Center components will achieve the stated goals of the Center. The diagram should be attached as a PDF, titled "Center\_Organizational\_Structure".

**Table of Research Core Utilization.** In order to assist the reviewers in determining the relationship between the Research Cores and the Research Projects, a table must be provided that indicates the percentage use of each core relative to the individual projects, if Research Cores are included in the application. The table should be attached as a PDF, titled "Table\_of\_Research\_Core\_Utilization".

### **Project/Performance Site Location(s) (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 & Related Senior/Key Person Profile (Overall)**

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/Pis (if applicable to this FOA) 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:** Specific Aims are required.

### **Research Strategy:**

NIDA now limits Centers to a maximum of two competitive segments, each for a maximum of 5 years of support. All applications for NIDA Centers should include plans for orderly completion of the Center's programs and projects within the 5-year project period.

Each Center application is expected to provide evidence of an environment that promotes the conduct of the highest quality, state-of-the-art research, innovation, and leadership in its areas of investigation. Applicants are expected to demonstrate that the Center is, or would serve as, a significant national scientific research resource soon after its establishment, to provide educational and outreach activities to drug abuse research communities, educational organizations, the general public, and policy makers. For renewals, the application is expected to demonstrate its past success in doing so and how the Center will continue to serve as a national resource.

Much of the shared research environment and many facilities will be located in or funded through the core components. The Overall section should discuss how each core component contributes toward cost-effectiveness and quality control in resource utilization among the research components; how data analytic capacities, database facilities and data resources would be utilized among Center components.

All NIDA Centers are expected to clearly demonstrate that they support innovative, rigorous, thematically focused, and productive research that is the result of interacting components of the research program that would not emerge from the mere collection of those individual components. A cadre of experienced, independent and productive investigators should be present with active collaborations in place or planned. These investigators should evidence productivity, stature and leadership, or a potentially strong leadership role, in their respective fields. A broad range of expertise relevant to the Center's goals should be present. Investigative efforts may encompass researchers with primary appointments at the applicant institution as well as at other collaborating sites. Investigators are expected to commit to data sharing and ongoing communications with other investigators in the Center, consistent with achieving the goals of the program.

Applications should explicitly discuss the integration of work proposed in the application. Further, applications should demonstrate that use of the research Center mechanism is essential to accomplishing studies that would not occur without the climate, facilities and research resources that a research Center can uniquely provide.

For Renewal Applications Only: Include a progress report including a summary of the most significant advances accomplished during the prior period of support. The Progress Report should demonstrate the research environment's conduciveness to productivity by identifying the originally approved specific aims, the progress made on each specific aim, and relevant publications produced in the previous funding period. It is especially important that renewals (1) identify innovative work accomplished by the Center during the current funding period and (2) propose innovative work for the new funding period. Changes in the Specific Aims, including termination of Research Components or Cores, should be described and justified and major findings presented with clear descriptions of the importance of these findings to advances in the field. The application should also address any significant organizational changes, and provide a summary of the career development opportunities and mentoring provided to junior investigators as well as results of education and dissemination activities. Centers that conduct clinical trials must also provide a summary of recruitment, retention, and safety issues, for each trial conducted.

**Progress Report Publication List:** Include also a Progress Report Publication List. Cite complete references to appropriate publications and manuscripts accepted for publication that resulted from the work during the prior funding period.

**Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- NIDA Centers are supported both for their expected crucial scientific accomplishments and for their role as vital resources to the research community. In order to maximize the impact of their work, they are expected to make their data, their methodologies and their findings available in a timely manner to other researchers and those who have a legitimate purpose for the access. In most instances, the data sharing would extend beyond that of one's own Center to the research community. This sharing can be accomplished in many ways, including posting findings on the Center's website or using archival services. Data sharing plans are expected to be provided, consistent with achieving the goals of the program. A plan for development and dissemination of assessments and methodologies and a general publication plan are also expected.

#### **Appendix:**

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

### **PHS Human Subjects and Clinical Trials Information (Overall)**

When involving NIH-defined human subjects research, clinical research, and/or clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, 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 SF424 (R&R) Application Guide 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 SF424 (R&R) Application Guide must be followed

#### **PHS Assignment Request Form (Overall)**

All instructions in the SF424 (R&R) Application Guide must be followed.

### **Administrative Core**

When preparing your application in ASSIST, use Component Type ‘Admin Core.’

All instructions in the SF424 (R&R) Application Guide 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)**

Enter Human Embryonic Stem Cells in each relevant component.

#### **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 'Center Director' and provide a valid eRA Commons ID in the Credential field.
- The Administrative Core is expected to have a scientifically and administratively qualified Center Director with responsibility for the scientific, administrative, budgetary, and operational aspects of the Center. The Center Director should be an outstanding, productive, senior researcher, as documented by publications, patents, honors, and similar indices of stature. The Center Director is responsible for overall coordination and development of the Center with the responsibility to provide leadership essential to the success of the Center program, to ensure interaction and collaboration among scientists conducting research, to monitor ongoing research and identify (with the assistance of colleagues) research and educational activities to be expanded or decreased and needs for additional resources or reallocation of resources.
- 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. In developing the budget, applicants should take into account funds currently available through existing collaborating grants and explain how these funds might be reconfigured to maximize efficient resource utilization. The Center is intended to provide reasonable support for activities clearly related to the specialized research needs of the Center.

It is expected that the Center Director will commit at least 2.4 person months effort to Center administration including the Administrative Core.

*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)**

**Introduction to Application:** For Resubmission and Revision applications, an Introduction to Application is allowed for each component.

**Specific Aims:** Specific Aims are required.

#### **Research Strategy:**

The Administrative Core is expected to have appropriate and effective administrative and organizational capabilities to support multidisciplinary research, to foster synergy, and to support planning and evaluation activities. Administrative and organizational arrangements should promote joint planning and evaluation activities as well as collaborations and interactions within, between and among programmatic elements of the center. This should include: (a) an overall programmatic structure that effectively promotes scientific interactions, provides for internal quality control of research and publications, generation of future grant applications, and also takes maximum advantage of the Center's drug abuse research capability (the description of these attributes is particularly important when there are multiple participating institutions in the Center); (b) an administrative organization that has clear lines of authority, is managed efficiently and

cost effectively, and enables effective use and leverage of resources; (c) the use of an external advisory structure that is charged to provide appropriate and objective advice and evaluation, as needed, to the Center Director; (d) an internal advisory, decision-making, and priority setting process to support the activities of the Center; and (e) appropriate criteria and processes for determining and sustaining individual participation in the Center based on productivity, research direction, and overall contribution.

**Education Activities:** As part of serving as a national resource, a NIDA P50 Center is expected to provide educational and outreach activities to drug abuse research communities, educational organizations, the general public, and policy makers. Activities may include, but need not be limited to, conferences, seminars, webinars, workshops, newsletters, informational websites, or social media initiatives.

**Career Development and Mentoring:** While the primary function of each Center is the conduct of high-quality interdisciplinary research, an important secondary function is fostering the career development and mentoring of research and clinical personnel. Career development and mentoring to enhance junior researchers' or other researchers' skills should be conducted in the context of the research, and funds may not be used for training not required to conduct the research. However, Center staff may participate in the development of related training programs, and Center resources may be made available for use by students, post-doctorates, and new investigators seeking experience in drug abuse research. Centers are expected to recruit and nurture future generations of scientists to engage in drug abuse and addiction research, especially those from underrepresented backgrounds.

**Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- NIDA Centers are supported both for their expected crucial scientific accomplishments and for their role as vital resources to the research community. In order to maximize the impact of their work, they are expected to make their data, their methodologies and their findings available in a timely manner to other researchers and those who have a legitimate purpose for the access. In most instances, the data sharing would extend beyond that of one's own Center to the research community. This sharing can be accomplished in many ways, including posting findings on the Center's website or using archival services. Data sharing plans are expected to be provided, consistent with achieving the goals of the program. A plan for development and dissemination of assessments and methodologies and a general publication plan are also expected.

**Letters of Support:** There should be convincing evidence of the applicant institution's commitment to the Center.

#### **Appendix:**

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

### **PHS Human Subjects and Clinical Trials Information (Admin Core)**

When involving NIH-defined human subjects research, clinical research, and/or clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, 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 SF424 (R&R) Application Guide 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 SF424 (R&R) Application Guide must be followed

### **PHS Assignment Request Form (Admin Core)**

All instructions in the SF424 (R&R) Application Guide must be followed.

## **Research Core**

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

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

### **SF424 (R&R) Cover (Research 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 (Research Core)**

Enter Human Embryonic Stem Cells in each relevant component.

### **Research & Related Other Project Information (Research 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) (Research 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 (Research Core)**

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core 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.
- The Research Core is expected to have a director who is scientifically and administratively well qualified, with responsibility for the scientific, administrative, budgetary, and operational aspects of the core and for coordination with the Center Director and other core/project directors.

### **Budget (Research Core)**

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

In developing the budget for a Research Core, applicants should take into account funds currently available through existing collaborating grants and explain how these funds might be reconfigured to maximize efficient resource utilization. The Center is intended to provide reasonable support for activities clearly related to the specialized research needs of the Center.

It is expected that the Core director will make a substantial commitment of time and effort to the Core, at least 1.8 person months effort to administrative and research-related activities directly supported by the Core.

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 Core)**

**Introduction to Application:** For Resubmission and Revision applications, an Introduction to Application is allowed for each component.

**Specific Aims:** Specific Aims are required.

#### **Research Strategy:**

A Research Core can be a laboratory, a facility, a service, or other shared resource that supports other Center components in their activities. Research Cores are expected to support two or more Research Components and each Research Core should be clearly described in terms of the services and resources to be provided to other Center components. Issues to be addressed include: quality control, procedures for selecting projects that use the Core, cost effectiveness, and increased efficiency. User training in complex techniques and methods should be described if they are functions of the proposed cores. Core components are intended to enhance opportunities for investigators at the Center to include 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.

**Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- NIDA Centers are supported both for their expected crucial scientific accomplishments and for their role as vital resources to the research community. In order to maximize the impact of their work, they are expected to make their data, their methodologies and their findings available in a timely manner to other researchers and those who have a legitimate purpose for the access. In most instances, the data sharing would extend beyond that of one's own Center to the research community. This sharing can be accomplished in many ways, including posting findings on the Center's website or using archival services. Data sharing plans are expected to be provided, consistent with achieving the goals of the

program. A plan for development and dissemination of assessments and methodologies and a general publication plan are also expected.

### **Appendix:**

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

## **PHS Human Subjects and Clinical Trials Information (Research Core)**

When involving NIH-defined human subjects research, clinical research, and/or clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, 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 SF424 (R&R) Application Guide 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 SF424 (R&R) Application Guide must be followed

## **Pilot Project Core**

When preparing your application in ASSIST, use Component Type ‘Core.’

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

A Pilot Project Core is permitted but individual pilot projects within a Pilot Project Core do not count toward the total number of Research Projects. At least three Research Projects must be active at all times.

### **SF424 (R&R) Cover (Pilot Project 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 Project Core)**

Enter Human Embryonic Stem Cells in each relevant component.

### **Research & Related Other Project Information (Pilot Project 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 Project 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 Project Core)**

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core 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 Project Core)**

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

In developing the budget for the Pilot Project Core, applicants should take into account funds currently available through existing collaborating grants and explain how these funds might be reconfigured to maximize efficient resource utilization. The Center is intended to provide reasonable support for activities clearly related to the specialized research needs of the Center.

Direct costs allocated to pilot projects in any year cannot exceed 25% of the Center grant's total direct costs in that year or \$200,000, whichever is smaller.

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 Project Core)**

**Introduction to Application:** For Resubmission and Revision applications, an Introduction to Application is allowed for each component.

**Specific Aims:** Specific Aims are required.

### **Research Strategy:**

Applicants may choose to include pilot projects in the Center, as a separate Core component. Pilot projects may be used for new, early stage or independent investigators and should represent new projects to develop and explore new activities or directions or take advantage of special opportunities. Pilot projects may be "research and development" pilots, feasibility studies, or other pilot work broadly defined as foundation work for further research. Pilot projects may not be used to supplement or prolong ongoing research and should not be used as bridge funds when other research support is no longer available.

The support of individual pilot project studies is typically of relatively short duration (e.g., 1-2 years), depending upon the nature of the research. Applicants may propose and request funding in the first year for specific, already conceptualized pilot projects and also for pilot projects to be added in subsequent years of the project. Applications requesting support for pilot projects must describe a process for within-Center scientific review of new pilot projects to be initiated in future years of the project and a process for evaluation

of ongoing pilot projects for adequate progress. Pilot projects presented in the application will be reviewed as part of the assessment of scientific and technical merit of the application and as examples of the kinds of pilot projects the Center might initiate in the future as a result of its internal within-Center review process.

For all pilot projects, describe the internal institutional plans and procedures to ensure that all projects supported from this award will comply fully with all applicable Federal regulations, policies, and guidelines for research involving human subjects, including the evaluation of risks and protections in project proposals, appropriate ethical oversight and funded projects, and plans for data and safety monitoring for clinical trials, if applicable.

**Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- NIDA Centers are supported both for their expected crucial scientific accomplishments and for their role as vital resources to the research community. In order to maximize the impact of their work, they are expected to make their data, their methodologies and their findings available in a timely manner to other researchers and those who have a legitimate purpose for the access. In most instances, the data sharing would extend beyond that of one's own Center to the research community. This sharing can be accomplished in many ways, including posting findings on the Center's website or using archival services. Data sharing plans are expected to be provided, consistent with achieving the goals of the program. A plan for development and dissemination of assessments and methodologies and a general publication plan are also expected.

#### **Appendix:**

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

### **PHS Human Subjects and Clinical Trials Information (Pilot Project Core )**

When involving NIH-defined human subjects research, clinical research, and/or clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, 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 SF424 (R&R) Application Guide 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 SF424 (R&R) Application Guide must be followed

### **Research Projects**

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

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

#### **SF424 (R&R) Cover (Research Projects)**

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)**

Enter Human Embryonic Stem Cells in each relevant component.

### **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.

It is expected that the Research Project Director will make a substantial commitment of time and effort to the Center, at least 1.8 person months effort to research-related activities directly supported by the Research project

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)**

**Introduction to Application:** For Resubmission and Revision applications, an Introduction to Application is allowed for each component.

**Specific Aims:** Specific Aims are required.

**Research Strategy:**

Research may focus on any area of NIDA's mission, but must bear an essential relationship to the Center's integrating theme and efficiently use and contribute to Center resources. If applicable, the Research Strategy should describe how the Research Project will use Center Research Core facilities and how the Core resources impact the proposed project.

**Resource Sharing Plan:** Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- NIDA Centers are supported both for their expected crucial scientific accomplishments and for their role as vital resources to the research community. In order to maximize the impact of their work, they are expected to make their data, their methodologies and their findings available in a timely manner to other researchers and those who have a legitimate purpose for the access. In most instances, the data sharing would extend beyond that of one's own Center to the research community. This sharing can be accomplished in many ways, including posting findings on the Center's website or using archival services. Data sharing plans are expected to be provided, consistent with achieving the goals of the program. A plan for development and dissemination of assessments and methodologies and a general publication plan are also expected.

#### **Appendix:**

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

### **PHS Human Subjects and Clinical Trials Information (Research Project )**

When involving NIH-defined human subjects research, clinical research, and/or clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, 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 SF424 (R&R) Application Guide 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 SF424 (R&R) Application Guide must be followed

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

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov.

## **4. Submission Dates and Times**

[Part I. Overview Information](#) contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that

might be necessary for successful submission. When a submission date falls on a weekend or [Federal holiday](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82380](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](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11128](https://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](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123](https://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 Policy on Late Application Submission.

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

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

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

This initiative is not subject to [intergovernmental review](#). ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11142](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11142))

## 6. Funding Restrictions

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

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement](#) ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11143](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11143)).

## 7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

For information on how your application will be automatically assembled for review and funding consideration after submission go to: [http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic\\_Multi-project\\_Application\\_Image\\_Assembly.pdf](http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf) ([https://grants.nih.gov/grants/ElectronicReceipt/files/Electronic\\_Multi-project\\_Application\\_Image\\_Assembly.pdf](https://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/how-to-apply-application-guide.html>). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Dealing with System Issues](#) (<https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm>) guidance. For assistance with application submission, contact the Application Submission Contacts in [Section VII](#).

### Important reminders:

All PD(s)/PI(s) and component Project Leads must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package. Failure to register in the

Commons and to include a valid PD/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 DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

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

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

## Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=82299\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82299). Any instructions provided here are in addition to the instructions in the policy.

# Section V. Application Review Information

## 1. Criteria

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

### In addition, for applications involving clinical trials:

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 Center 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 center 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 center that by its nature is not innovative may be essential to advance a field.

#### Significance

Does the center 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 center 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? Is there a clear integration of the Center components - Cores and Projects- to an overarching theme that integrates and focuses the Center, as well as the presence of an essential relationship of each research project and core component to the theme?

### 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 PD(s)/PI(s), collaborators, and other researchers well suited to the center? 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? Does the Center Director have the ability to lead a scientific program as documented by scientific achievements, productivity, stature in a relevant field, and planned activities? Does the Center Director have the ability to lead administrative and operational aspects of the Center, as noted by administrative skills, achievements, and planned activities and is there evidence of ability to develop or maintain a role for the Center as a national resource? Is there adequate commitment of time and effort for the research and administrative functions of the Center? As a group, are Research Project and Core investigators well suited to the projects? Is there evidence of multidisciplinary backgrounds and interests?

### **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 center? Have 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 Center 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/gender, 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?

Does the application clearly demonstrate, in a diagram, the feasibility of the organizational structure? Does the organizational structure have clear lines of authority that allow for efficient and cost-effective management and allocation of funds, as well as leverage of resources to enable additional or future work? Are the organizational and administrative structure and support capable of creating thematic integration that is conducive to research, synergy, and joint planning? Is there an operational programmatic structure that effectively promotes productive scientific interactions, cross fertilization, and takes maximum advantage of the applicant institution's drug abuse research capacity?

Is a process in place for long range planning and evaluation of Center activities? Is there an appropriate, fully described internal process that allows for priority setting and decision making to sustain the Center? Is there appropriate specification of criteria and processes for determining and sustaining individual participation in the Center based on productivity, research direction, and overall contribution? Are there arrangements for internal quality control of research, publications, and grant applications? Does the outside advisory structure have the capacity to provide appropriate and objective advice and evaluation? Are there adequate plans for recruitment, education, and supervision of staff?

Are there sufficient interactions and linkages of components to each other, to show that the impact of a coordinated Center goes beyond the impact of individual research projects? Does the approach taken for Center activities make use of a depth and breadth of expertise and experience not normally present in an individual research project grant?

Do the core components as a group contribute resources that enhance cost-effectiveness and quality control in resource utilization?

Do the Center's activities involve different scientific disciplines or sub-disciplines and demonstrate substantial interaction among scientists from different disciplines or sub-disciplines and different perspectives?

Will the proposed career development and mentoring activities provide high quality, appropriate research career development and are they likely to be effective in attracting and involving junior investigators and students who show potential for significant future contributions and independent research careers in the work of the Center? Are the objectives, design and direction of the proposed career development and mentoring likely to ensure effective career enhancement? Does the program provide appropriate inter- or multidisciplinary research training opportunities? Are the proposed professional development and mentoring activities likely to foster the careers of new investigators?

Do the proposed educational and outreach activities to drug abuse research communities, organizations, general public, and/or policy makers support the ability of the Center to be a national resource?

**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, gender, 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/gender 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?

Are there plans for development and maintenance of an environment that promotes the conduct of the highest quality of research, innovation, and leadership? Are there appropriate and adequate facilities for administrative, research, and shared resources, including a clearly identifiable physical location for the Center, which assures necessary functions can occur? Do the facilities indicate the Center is, or would soon be, a national scientific research resource?

Is there adequate institutional support; for example, letters of support, space and resources to be allocated from the applicant institution, substantial commitment to the Center and appreciation of its goals and role in public health, especially in the drug abuse and addiction research field?

Does the environment provide adequate high quality data analytic capacity, data base facilities, coordination, and data resources? As needed, are there provisions for shared laboratory resources, high quality laboratory space, and clinical facilities?

### **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 center 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., CTSA, 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 - Administrative Core and Research Cores**

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.**

### **Significance**

Does the Core Component address important scientific and administrative activities of the Center? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the Core are achieved, how well will it contribute to the function of the Center? How will successful completion of the aims contribute to support of the concepts, methods, technologies, treatments, services, or preventative interventions carried out in other components of the Center? Is there adequate justification for this Core activity being conducted within a Center structure?

**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 the trial needed to advance scientific understanding?

### **Investigator(s)**

Are the Core Director, the collaborators, and other researchers well suited to the Core? If the Core Director is an Early Stage Investigator or a researcher in the early stages of an independent career, does he/she have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?

**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 Core utilize novel theoretical concepts, approaches or methodologies, instrumentation, or interventions in support of the Center? 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 plans for day to day management well-reasoned and appropriate to accomplish the support of Center activities? Have 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? Are the arrangements and organizational structure adequately developed, well integrated, well-reasoned, and integrated with multiple other components of the Center? Is the justification for the need for Core services or resources clearly stated and are there appropriate plans for resource allocation? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the Core activity involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion 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, gender, 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/gender 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 Core proposed? Will the Core 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 - Pilot Project Cores

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.

### Significance

Does the Core Component address important scientific and administrative activities of the Center? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the Core are achieved, how well will it contribute to the function of the Center? How will successful completion of the aims contribute to support of the concepts, methods, technologies, treatments, services, or preventative interventions carried out in other components of the Center? Is there adequate justification for this Core activity being conducted within a Center structure?

**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 the trial needed to advance scientific understanding?

### Investigator(s)

Are the Core Director, the collaborators, and other researchers well suited to the Core? If the Core Director is an Early Stage Investigator or a researcher in the early stages of an independent career, does he/she have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?

**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 Core utilize novel theoretical concepts, approaches or methodologies, instrumentation, or interventions in support of the Center? 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 plans for day to day management well-reasoned and appropriate to accomplish the support of Center activities? Have 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? Are the arrangements and organizational structure adequately developed, well integrated, well-reasoned, and integrated with multiple other components of the Center? Is the justification for the need for Core services or resources clearly stated and are there appropriate plans for resource allocation? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the Core activity involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion 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, gender, 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/gender 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 Core proposed? Will the Core 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 - Research Projects**

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.

#### **Significance**

Does the Core Component address important scientific and administrative activities of the Center? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the Core are achieved, how well will it contribute to the function of the Center? How will successful completion of the aims contribute to support of the concepts, methods, technologies, treatments, services, or preventative interventions carried out in other components of the Center? Is there adequate justification for this Core activity being conducted within a Center structure?

**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 the trial needed to advance scientific understanding?

#### **Investigator(s)**

Are the Core Director, the collaborators, and other researchers well suited to the Core? If the Core Director is an Early Stage Investigator or a researcher in the early stages of an independent career, does he/she

have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?

**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 Core utilize novel theoretical concepts, approaches or methodologies, instrumentation, or interventions in support of the Center? 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 plans for day to day management well-reasoned and appropriate to accomplish the support of Center activities? Have 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? Are the arrangements and organizational structure adequately developed, well integrated, well-reasoned, and integrated with multiple other components of the Center? Is the justification for the need for Core services or resources clearly stated and are there appropriate plans for resource allocation? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the Core activity involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion 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, gender, 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/gender 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 Core proposed? Will the Core 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?

### **Protections for Human Subjects**

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

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

### **Inclusion of Women, Minorities, and Individuals Across the Lifespan**

When the proposed center involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed.

For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11174\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11150\)](https://grants.nih.gov/grants/guide/url_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, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

## **Renewals**

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

## **Revisions**

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

## **Additional Review Considerations - Overall**

As applicable for the Center 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 following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11151\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); 2) [Sharing Model Organisms \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11152\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and 3) [Genomic Data Sharing Plan \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html) .

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

As part of the scientific peer review, all applications:

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

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute. Applications will compete for available funds with all other recommended applications. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Council on Drug Abuse. The following will be considered in making funding decisions:

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

## 3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11123\)](https://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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11156\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11156).

## Section VI. Award Administration Information

### 1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11157).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in [Section IV.5. Funding Restrictions](#). Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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: Grantee institutions must ensure that all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the awardee must provide NIH copies of documents related to all major changes in the status of ongoing protocols. Data and Safety

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

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

### **Prior Approval of Pilot Projects**

Awardee-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 awardee institution will provide NIH with written study protocols that address risks and protections for human subjects in accordance with [NIH's Instructions for Preparing the Human Subjects Section of the Research Plan \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000).
- The awardee 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=21600\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=21600).

## **2. Administrative and National Policy Requirements**

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11159\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at [Award Conditions and Information for NIH Grants \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and

religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA. HHS provides general guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html>). The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html>); and <https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html> (<https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/index.html>). Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <https://www.hhs.gov/civil-rights/for-individuals/disability/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> (<https://www.hhs.gov/ocr/about-us/contact-us/index.html>) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

## Cooperative Agreement Terms and Conditions of Award

Not Applicable

## 3. Reporting

When multiple years are involved, awardees will be required to submit the [Research Performance Progress Report \(RPPR\)](https://grants.nih.gov/grants/rppr/index.htm) (<https://grants.nih.gov/grants/rppr/index.htm>) annually and financial statements as required in the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11161). ([https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11161](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11161))

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](https://grants.nih.gov/grants/guide/pa-files/PA-19-259.html)

[http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11161](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161)).

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at [www.fsrs.gov](http://www.fsrs.gov) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11170](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170)) on all subawards over \$25,000. See the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11171\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than \$10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 – Award Term and Conditions for Recipient Integrity and Performance Matters.

## Section VII. Agency Contacts

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

### Application Submission Contacts

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

Finding Help Online: <http://grants.nih.gov/support/> (preferred method of contact)

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

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

Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov) (<mailto:GrantsInfo@nih.gov>) (preferred method of contact)

Telephone: 301-945-7573

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

Contact Center Telephone: 800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov) (<mailto:support@grants.gov>)

### Scientific/Research Contact(s)

Kevin Walton, Ph.D.

National Institute on Drug Abuse (NIDA)

Telephone: 301-435-0762

Email: [kevin.walton@nih.gov](mailto:kevin.walton@nih.gov) (<mailto:kevin.walton@nih.gov>)

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Roger Little, Ph.D.  
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Steven Grant, Ph.D.  
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Email: [sgrant@nida.nih.gov](mailto:sgrant@nida.nih.gov) (<mailto:sgrant@nida.nih.gov>)

### Peer Review Contact(s)

Gerald McLaughlin, PhD  
National Institute on Drug Abuse (NIDA)  
Telephone: 301-827-5819  
Email: [gmclaughlin@nida.nih.gov](mailto:gmclaughlin@nida.nih.gov) (<mailto:gmclaughlin@nida.nih.gov>)

### Financial/Grants Management Contact(s)

Cheryl Nathaniel  
National Institute on Drug Abuse (NIDA)  
Telephone: 202-526-0108  
Email: [nathanic@nida.nih.gov](mailto:nathanic@nida.nih.gov) (<mailto:nathanic@nida.nih.gov>)

## Section VIII. Other Information

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

### Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75.

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[Weekly TOC for this Announcement](https://grants.nih.gov/grants/guide/WeeklyIndex.cfm?04-26-19) (<https://grants.nih.gov/grants/guide/WeeklyIndex.cfm?04-26-19>)  
[NIH Funding Opportunities and Notices](https://grants.nih.gov/grants/guide/index.html) (<https://grants.nih.gov/grants/guide/index.html>)

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and Human Services (HHS)



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

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**Note:** For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see [Help Downloading Files \(/grants/edocs.htm\)](http://grants.edocs.htm).