

# 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

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

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### Funding Opportunity Title

Contraception Development Research Center 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

New

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### Related Notices

Reissue of [RFA-HD-21-011 \(https://grants.nih.gov/grants/guide/rfa-files/rfa-hd-21-011.html\)](https://grants.nih.gov/grants/guide/rfa-files/rfa-hd-21-011.html) - Contraception Development Research Center Program (P50 Clinical Trial Optional)

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### Funding Opportunity Announcement (FOA) Number

RFA-HD-22-003

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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)

93.865

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## Funding Opportunity Purpose

The primary purpose of this funding opportunity announcement (FOA) is to support and facilitate multidisciplinary approaches towards the development of new and/or improved contraceptive methods for both men and women through the formation of a Contraceptive Research Development Center. This FOA also allows the inclusion of translational studies to facilitate the pre-clinical to clinical transition and increase the likelihood of clinical success. Additionally, it allows for behavioral/social science, including market research to test user acceptability, research projects that are responding and well-coordinated to the contraceptive product being developed. The Center will serve as a national resource for development of early stage investigators electing to pursue careers in contraceptive research.

## Key Dates

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### Posted Date

November 19, 2020

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### Open Date (Earliest Submission Date)

February 28, 2021

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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)

November 29, 2021

All applications are due by 5:00 PM local time of applicant organization. All [types of non-AIDS applications](#) allowed for this funding opportunity announcement are due on the listed date(s). 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)

Not Applicable

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### Scientific Merit Review

(<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>), March 2022

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### Advisory Council Review

May 2022

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### Earliest Start Date

July 2022

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## Expiration Date

**New Date** November 30, 2021 per issuance of [NOT-HD-20-044 \(https://grants.nih.gov/grants/guide/notice-files/NOT-HD-20-044.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-HD-20-044.html). (Original Expiration Date: March 31, 2021 )

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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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000\)](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 \(//grants.nih.gov/grants/guide/\)](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.

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## Part 2. Full Text of Announcement

# Section I. Funding Opportunity Description

## **Purpose**

The primary purpose of this funding opportunity announcement (FOA) is to support and facilitate multidisciplinary approaches towards the development of new and/or improved contraceptive methods for both men and women through the formation of a Contraceptive Research Center. This FOA also allows the inclusion of translational studies to facilitate the pre-clinical to clinical transition and increase the likelihood of clinical success, behavioral and social research projects, including testing user acceptability, that are responding and informative to the contraceptive product being developed. The Center will serve as a national resource for development of early stage investigators electing to pursue careers in contraceptive research.

## **Research Scope**

Since 1994, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) has been directed by federal law to establish three research centers for the purpose of improving methods of contraception (42 USC 285g-5).

The objective of this FOA is to develop new or improve existing methods of contraception for men and women using a multidisciplinary approach. This FOA supports method development projects ('Contraception Development Research Projects'). It also allows the inclusion of translational studies ('Contraception Translational Research Projects') to facilitate the pre-clinical to clinical transition and increase the likelihood of clinical success, and behavioral/social science research projects, including testing user acceptance ('Contraception Behavior Research Projects'), that are responding and informative to the contraceptive product being developed. The ideal application must have two or more highly meritorious Contraception Development Research Projects and may integrate behavioral and/or translational projects that together form a scientifically aligned, conceptually integrated and cohesive center focused on the development of new or improved methods of contraception.

The funded Center will be expected to establish or maintain an organizational infrastructure with the scientific and administrative capabilities to support the proposed research.

Applications of high program priority include:

- Applications focused on the late stage preclinical or clinical development of a single contraceptive product (i.e., drug or medical device)
- Applications focused on the late stage preclinical or clinical development of a single non-hormonal multipurpose prevention technology (MPT, a product with both contraceptive and anti-infective properties)
- Applications for the development of a product (i.e., drug or medical device) which demonstrates current industry interest/support (e.g., advisory)

Contraception Development Research Projects of high program priority are:

- Male or female contraceptive development based on non-steroidal action
- Pre-coital 'on-demand' contraception (e.g., a contraceptive that can be used within less than one hour of administration regardless of route)

Contraception Development Research Projects appropriate for this FOA include, but are not limited to, the following:

- Clinical trials to assess safety and/or efficacy of new contraceptive agents with demonstrated proof of concept in appropriate models

- Development or improvement of vehicles (implants, films, transdermal, etc.) for delivery of non-hormonal contraceptive compounds
- Conduct Investigational New Drug (IND) studies of a lead molecule (e.g., small molecule, large molecule or biological agent)
- Non-hormonal small-molecule lead discovery and optimization for modulation of validated male or female contraceptive targets (e.g., high throughput screening and virtual screening)

## Validation

This FOA requires that applications include data demonstrating that the mechanism proposed for development is validated. Validation, as defined in this RFA, is the demonstration in a mammalian species that the target modulation proposed in the application achieves a contraceptive effect - whether specific (e.g. agonism/antagonism of a single specific enzyme) or non-specific (e.g., sperm motility inhibition by exposure to a high molecular weight polymer) the contraceptive effect is preserved. Subfertility is not sufficient to constitute validation. Subfertility, as defined in this RFA, is the generation of live animals from in vivo mating trials and/or an in vivo or in vitro fertilization rate greater than zero.

Validation is not required for applications focused on the development of devices for the delivery of nonhormonal contraceptive agents.

### Examples of research projects and acceptable forms of validation:

*For applications focused on modulation of defined molecular targets:*

Proposed contraception research projects focused on the modulation of specific molecular interactions between an administered molecule (e.g., chemical, antibody) and a defined molecular target(s) (e.g., enzyme, transporter, ion channel) to achieve modulation of the target (e.g., agonism, antagonism) leading to a contraceptive effect (i.e., infertility). Reversibility does not need to be demonstrated to support validation justification for defined molecular targets.

Examples of validation include but are not limited to:

- Targeted deletion of the gene encoding the target to be modulated, resulting in infertility;
- Development of an antibody that binds specifically to the target and inhibits fertility in a concentration dependent manner in a relevant model (e.g., in vitro fertilization)
- Use of the agent (e.g., small molecule agonist or antagonist) to inhibit sperm motility in vitro to a level consistent with reversible infertility at concentrations consistent with expected in vivo use without demonstrated in vivo toxicity at those doses;
- Specific inhibition of RNA corresponding to target to be modulated leading (e.g., vivo morpholinos) to inhibition of gametogenesis or loss of gamete function as demonstrated by histology, mating studies or in vitro fertilization.

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*For high molecular weight polymers:*

It is generally accepted that natural or synthetic high molecular weight polymers that interact with cells and inhibit transport or motility (e.g., sperm motility) act via multiple non-specific binding events. Validation of these molecules requires (1) supporting evidence that their action is mediated by non-specific binding, (2) demonstration that the agent can achieve a contraceptive effect, and (3) lack of observed toxicity at or above the dose and duration of contact expected to be used to achieve contraceptive effect in a relevant model. If in vivo mating studies were used to demonstrate validation for high molecular weight polymers, then reversibility must be demonstrated as part of the validation justification.

Examples of validation of high molecular weight polymers include but are not limited to:

- Use of the agent in a mammalian animal model resulting in reversible infertility and lack of toxicity

- Use of the agent to inhibit sperm motility in vitro to a level consistent with reversible infertility at concentrations consistent with expected in vivo use without demonstrated in vivo toxicity at those doses
- Use of the agent to inhibit in vitro fertilization when the product is at concentrations consistent with in vivo use without demonstrated in vivo toxicity at those doses.

*For low weight molecules (<2000 Daltons) with contraceptive properties that do not have an identified mechanism of action:*

Demonstration of validation should include (1) that the compound can achieve a contraceptive effect in a relevant model, and (2) a lack of toxicity at the dose and duration of dosing used to demonstrate a contraceptive effect. Reversibility must be demonstrated as part of the validation justification for low molecular weight molecules with contraceptive properties that act via unknown molecular interactions.

Examples of validation for low molecular weight molecules include but are not limited to:

- Mating studies demonstrating a reversible contraceptive effect in all animals at a defined dose/duration, including pharmacokinetic analysis;
- Toxicological assessment demonstrating a lack of toxicity at the dose/duration resulting in a reversible contraceptive effect in all animals.

For projects focused on the development or improvement of vehicles for delivery of nonsteroidal contraceptive agents:

- Validation is not required for vehicles for the delivery of nonsteroidal contraceptive agents.

There are mechanisms that do not correlate to the examples above. Applicants interested in proposing research not directly aligned with the above examples are encouraged to communicate with the Scientific/Research Contact.

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### **Research topics not responsive to this funding announcement:**

Contraception Development Research Projects listed below are not within the scope of this funding announcement. Applications proposing out of scope projects are not responsive to this FOA and will not be reviewed.

- Contraception Development Research Projects not focused on a validated target, validated molecule or a new/improved delivery mechanism
- Contraception Development Research Projects lacking a clear drug/device development plan
- Contraception Development Research Projects not focused on the development of a contraceptive product
- Contraception Development Research Projects based on mechanisms of contraceptive action that may act post-fertilization
- Contraception Development Research Projects that focus on the development of a product that may act via the oviduct or uterus
- Contraception Development Research Projects based on the development of intrauterine devices/intrauterine systems
- Contraception Development Research Projects for the development of molecules for female contraception that act via nuclear steroid receptors
- Contraception Development Research Projects focused on female contraceptive methods based on a classical steroidal mechanism of action
- Contraception Development Research Projects for the development of female contraceptive methods that require the administration of one or more hormones, steroids, or steroidal analogs

- Preclinical Contraception Development Research Projects focused on male contraceptives that act via a hormonal mechanism (e.g., androgen, androgen analogs, or androgen receptor(s))
- Contraception Development Research Projects focused on male or female condom development
- Contraception Development Research Projects focused on the elucidation of biological mechanisms unrelated to a defined lead chemical molecule of interest. A lead chemical molecule is defined as a molecule either being evaluated in Investigational New Drug (IND)-enabling studies or selected to enter IND-enabling studies;
- Contraception Development Research Projects focused on target identification unrelated to a validated small molecule
- Contraceptive Development Research Projects focused on the development of an antibody that:
  - Has an antibody valency greater than two
  - Has an antibody with multiple epitopes
  - Utilizes hetero-valent antigen binding sites (e.g., an antibody which binds multiple epitopes and/or each arm of an antibody binds to multiple different contraceptive targets) to achieve a contraceptive effect
  - Requires systemic antibody administration to women
- Contraception Development Research Projects for the development of the following molecules and/or their chemical derivatives
  - Gamendazole
  - H2-Gamendazole
  - Adjudin
  - Gossypol
  - alpha-chlorohydrin
- Contraception Development Research Projects focused on the development of type I-II kinase inhibitors
- Contraception Development Research Projects focused on the development of inhibitors of Bromodomain Testis-Specific protein (BRDT)
- Contraception Development Research Projects focused on the development of inhibitors that act by a covalent mechanism
- Contraceptive Development Research Projects focused on the development of multiple inhibitors modulating a single target for an additive or synergistic effect
- Contraception Development Research Projects focused on the development of molecules or devices that disrupt the blood-testis and/or blood-epididymal barriers
- Contraception Development Research Projects focused on molecular targets for which there is no human ortholog
- Contraception Development Research Projects focused on the development of a contraceptive product that act by temporary or permanent physical obstruction of the fallopian tubes or reversible/irreversible occlusion of the male reproductive tract
- Contraception Development Research Projects to determine prospective patient/consumer preferences on theoretical product designs except as a specific aim of a Contraception Development Research Project
- Contraception Development Research Projects focused on target validation, although this research may be supported by the pilot program described under "Center Description" below.

Contraception Translational Research Projects for this FOA must be focused on one or both of the following:

- Contraception Translational Research Projects in support of late stage pre-clinical or early stage clinical programs to identify and validate or evaluate one or more of the following:
  - pharmacodynamic biomarker(s)
  - target interaction biomarker(s)
  - patient efficacy biomarker(s)
  - patient safety biomarker(s)
- Contraception Translational Research Projects for the identification and/or validation of novel models (laboratory, animal) to predict clinical efficacy.

Contraception Behavior Research Projects must be aimed at improving understanding of contraceptive acceptance/use/discontinuation of the product being discussed in the contraceptive development research projects. Contraception Behavior Research Projects should be motivated by and explicitly designed based on a theory of human behavior and behavior change. Examples of research projects include, but are not limited to, the following:

- Testing user acceptance
- Integration of existing research on the needs and expectations of women and men who report having had unintended pregnancies into the development and improvement of contraceptive research
- Follow-up studies of clinical trials to identify the characteristics and behaviors of study participants who discontinue or are non-compliant with contraceptive methods and participants with strong method regimen adherence
- Studies to identify the specific characteristics of contraceptive products that affect discontinuation or ineffective and/or inconsistent use of contraceptive products and examination whether reactions to specific characteristics of products differ by demographic and socioeconomic status—e.g., dosing or application processes, frequency of use/administration/duration, partner involvement, texture, or side effects
- Identification of characteristics of contraceptive products that affect the ratio between the actual use Pearl Index and the perfect use or clinical trial Pearl Index;
- Identification of characteristics of contraceptive product users that are associated with low effectiveness in actual use.

The following areas of Contraception Behavior Research Projects are not responsive to this funding announcement and will not be reviewed:

- Research projects that are not focused on or directly related to the contraceptive product being developed or contraceptive development research projects
- Re-analyses of extant data sets examining the determinants of contraceptive use in general, or the collection of new data for that purpose
- Projects that are not focused or directly related to the contraceptive development research projects
- The use of clinical or convenience samples to examine contraceptive use except when the goal is to examine the use of one specific contraceptive product with the aim of improving the acceptability of that particular product
- Research that focuses solely on attitudes on contraceptive products; however, research that focuses primarily on behavior but includes analysis of attitudes as they relate to behavior, is responsive to this announcement.
- For studies on factors affecting discontinuation or ineffective and/or inconsistent use of a contraceptive method, failure to account for selection factors affecting participation in the clinical trial or the individual's or couple's decision to use the method being studied.

## **Center Description**

The Center must include a mandatory Administrative Core and a minimum of three and maximum of four research projects. There must be at least two Contraception Development Research Projects. Funds to support one- to two-year optional pilot projects, focusing on contraception development (including validation), translational medicine or contraception behavior, may be provided as part of the Administrative Core. Technical Service Cores that support and enhance the research projects are optional.

A Center must build its overall research strategy on a scientific theme of contraception method development. If Contraception Behavior Research Projects or Contraception Translational Research Projects are proposed, they must integrate with the other projects to form a scientifically-aligned, conceptually-integrated and cohesive center focused on the development of new or improved methods of contraception. Centers can have an unlimited number of consortium agreements with institutions or organizations outside of their applicant institutions to incorporate sufficient expertise for an effective multidisciplinary approach to contraceptive

research. The ultimate result should be a Center where the best and most innovative science for contraceptive discovery, development and usage will be pursued.

### **Optional Cores:**

Technical Service Cores may be proposed. Examples of optional cores include, but are not limited to, the following:

- Medicinal chemistry core
- Chemical screening core
- Animal facility core
- Protein production core

Optional cores may be designated as closed access structure or open access

- Closed Access Structure: In this center structure, administrative and all technical service cores will be utilized by budgeted center projects only. Utilization by at least two research projects is required to justify a closed Technical Service Core facility. Percent utilization by either of the research projects justifying the core may not exceed 70 percent. No internal charge-back system is required.
- Open Access Structure: In this center structure, budgeted center research projects, as well as research projects from other Contraception Research Centers (CRCs) or laboratories within or outside of the institution may have access to Technical Service Cores. If the Center chooses to operate in an open access format, the PD/PI must have in place management policies that ensure that budgeted center research projects are given highest priority in receiving services provided by the core. In addition, a plan for fair and open access is needed for how the resource, when not in use by Center projects, will be made available to others, including an effective charge-back system. The Center must establish an internal management policy for evaluating the acceptability of proposed projects from other CRCs laboratories or laboratories within or outside of the institution to access the core facilities.
- If the Center chooses to use an open access format, it may also propose one or more technical service cores that will be utilized exclusively by budgeted center research projects. The Center, therefore, may have a mix of open and closed access technical service cores, i.e., in a closed access structure. The administrative Core in open structures may be accessed only by budgeted Center Projects.
- A Center configured as a closed access structure may, at a later time, choose to convert to an open access structure upon approval after requesting such conversion in writing to NICHD.

### **Other Center Requirements:**

- The PD/PI must have sufficient experience, skills, and competence to oversee cooperation within the Center and across funded Centers.
- The Leads of the individual components must have sufficient experience, skills, and competence to oversee the research projects, cores, and core facilities.
- Technical resources and facilities for the conduct of the proposed projects must be available, including appropriate animal facilities.
- The applicant institution must offer an environment that is conducive to the development of early stage investigators in the field of contraception research.
- The Center must have strong departmental and institutional support and commitment.

### **Subcontracting of Research Facilities**

PDs/Pis may sub-contract portions of their research they are not able to conduct at their facility or institute to outside vendors (e.g., animal studies, protein production, high throughput screening, medicinal chemistry and x-ray crystallography). Applicants interested in subcontracting facilities must obtain agreement in advance, provide for the services in the budget, and include letter(s) of support in the application. Applicants who

desire assistance in identifying subcontractors for animal studies or drug development services are advised to consult the NICHD Program Official.

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

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. Only those application types listed here are allowed for this FOA.

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

The NICHD intends to commit up to \$4,000,000 in total costs to fund up to two awards.

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### Award Budget

Each Center should propose a budget that reflects the actual needs of the proposed projects and costs; the budget must not exceed \$1.3 million per year in direct costs, excluding third party F&A. Future year amounts will depend on annual appropriations.

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### Award Project Period

The scope of the proposed project should determine the project period. The maximum period of performance is 4 years.

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

Foreign components, as [defined in the NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11118\)](https://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) (<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) ([http://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) ([http://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) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82300](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300)) – Applicants must have an active 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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126). ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11126](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126))

## **3. Additional Information on Eligibility**

### **Number of Applications**

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

The NIH will not accept duplicate or highly overlapping applications under review at the same time. 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 \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html\)](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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=12000\)](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:

Christopher C. Lindsey, PhD  
Telephone: 301-435-6907  
Email: [chris.lindsey@nih.gov \(mailto:chris.lindsey@nih.gov\)](mailto:chris.lindsey@nih.gov)

#### Page Limitations

| Available Component Types | Research Strategy/Program Plan Page Limits |
|---------------------------|--|
| Overall                   | 12   |
| Admin Core                | 6  |

| Available Component Types | Research Strategy/Program Plan Page Limits |
|---------------------------|--|
| Core                      | 6  |
| Project                   | 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.

The application should consist of the following components:

- o Overall: required
- o Administrative Core: required; maximum 1
- o Technical Service Cores: optional; minimum 0, maximum 3
- o Research Projects: Required; minimum 3, maximum 4. At least 2 Contraceptive Development Projects must be included.

### 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.

#### **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)**

**Specific Aims:** Include Specific Aims for the overall Center.

**Research Strategy:** Describe the major themes of the overall Center, its goals and objectives, background information and the overall importance of the research to the objectives of this program. Explain the strategy for achieving the goals defined for the overall program and how each project and core relate to that strategy. Explain how the different aspects of the organization, including Senior/Key Personnel, will coordinate and communicate, why they are essential to accomplishing the overall goal of the research, and how the combined resources create an overall program that is more than the sum of its parts. Include all necessary tables, graphs, figures, diagrams, and charts in this section. Each project must be defined as to whether it is aimed at basic research, contraceptive research development, translational research, or behavioral research. In addition, provide the following information:

### *History, Purpose, and Objectives of the Program*

Discuss the overall program's objectives and general plans for the proposed grant period, including research grant history (as a P50 Center) with annual funding level (direct costs).

### *Administration, Organization, and Operation*

Provide information on the authority and responsibilities of the PD(s)/PI(s). Describe the organizational framework of the Center and provide an organizational chart. The overall Center plan must include internal priorities, timelines and milestones to evaluate success. Collaboration among Center members is critical.

### *Resources*

Describe how the resources and funding available to the center will contribute to and enhance the objectives of the center. Information in the Research and Related Other Project Information may be referenced and should not be repeated here.

### *Research Program*

Discuss the proposed research program, highlighting its central theme. Describe the relationships between the projects. Describe the relationship of the research projects and any technical service cores; provide the timelines and milestones of projects in tabular form and describe how progress will be evaluated. Describe how the components of the center will promote and develop the careers of early stage investigators in contraceptive research.

### *Description of Assurances and Collaborative Agreement*

Provide an overview and rationale for any collaborative and cooperative endeavors or subcontracts. Letters of Support for these arrangements are included as described below.

**Letters of Support:** Include letters of support/agreement/commitment for any collaborative/cooperative arrangements, subcontracts, or consultants. Letters of support for the overall Center should be included

with the Overall Component. Letters of support for individual projects or cores should be included with those components of the application.

For program activities to be conducted offsite, i.e., at an institution other than the applicant institution, a letter of assurance or comparable documentation, signed by the collaborator as well as the off-site institutional officials, must be submitted with the application.

**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, are expected to provide a Data Sharing Plan. Grantees are encouraged to consider submission of their data to the NICHD Data and Specimen Hub (DASH). Information about DASH may be obtained at <http://dash.nichd.nih.gov/> (<http://dash.nichd.nih.gov/>).

A Resource Sharing Plan is expected to be provided for the overall Center. Any resources to be developed under the individual core components must be included with the Resource Sharing Plan for the Overall Component. Resources to be developed specifically under the Research Projects must be included with those components as indicated below.

#### **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 human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the 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, 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 '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 (Administrative Core)**

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

- *Meetings (required)* - Funds should be allocated for the PD(s)/PI(s) of the P50 Center and the Leads of the research projects and cores to attend an annual Contraception Research and Development Meeting. The location of the meeting may vary, and air travel and hotel fees should be budgeted. Additionally, the PD(s)/PI(s) of the P50 Center are expected to have quarterly meetings with Program discussing advances and pitfall of the projects. These quarterly meetings are expected to occur regularly.
- *Pilot projects (if applicable)* - up to \$100,000 direct costs per year may be requested to support pilot project, contraception, development, behavior or translational pilot projects

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

### **PHS 398 Research Plan (Administrative Core)**

**Specific Aims:** Describe specific aims for the Administrative Core.

**Research Strategy:** Administrative Core will provide scientific and administrative oversight for the cores and projects, and will promote coordination and collaboration within the program, and with investigators and organizations outside the program. The Research Strategy must describe the planning and coordination of research activities, the integration of cross-disciplinary research, allocation of funds, management of resources, quality control, the maintenance of ongoing communication, and plans for evaluation of the Center Project by internal and external advisory committees. Indicate who will be responsible for each of these activities.

The Administrative Core may provide support for short-term (1-2 years) and small (up to \$100,000/year) pilot projects, if applicable, that enhance the research goals. Pilot projects are meant to provide preliminary data leading to larger research efforts and are not renewable. These pilot projects can either be focused on development, translational or behavioral research areas. Unlike research projects, pilot projects may propose to identify and/or validate contraceptive targets. Centers are strongly encouraged to use the funds to support either early stage investigators or investigators who are not already supported by the Contraception Research Centers program and to use the pilots as a means of launching early stage investigators' careers. These funds may also support collaborative projects with investigators supported by other CRC centers. Potential pilot projects should be thoroughly evaluated and selected at the awarded institution.

For the Administrative Core, provide the following information:

*Objectives:* Describe the objectives of the Administrative Core.

*Staffing:*

- Describe the experience of the Administrative Core Lead in research administration without duplicating information in the biosketches.
- Describe how administrative, scientific, technical, and support staff who are not designated as Senior/Key Personnel and other Significant Contributors will interact, and mechanisms of supervision/coordination/governance by the Center Director (PD/PI);
- Provide an organizational chart.

*Resources and Services:*

- Describe how Administrative Core resources and services provided will contribute to the objectives of the Center;
- Describe the method of determining Core access.

*Administration:*

- Describe the strategies and processes that will be used to manage the Center and achieve the overall goals;
- Describe the organizational structures for day-to-day management of the Center, including arrangements for internal quality control of ongoing research;
- Describe how communication will be facilitated among all PD(s)/PI(s) and Project/Core Leads, regardless whether they are focused on a biomedical or behavioral project, and whether they are at institutions other than the lead institution;
- Describe the decision-making process within the proposed Center for the evaluation of research productivity, for allocation of funds and for management of the resources;
- Describe the mechanism for resolving conflicts among investigators;
- Explain the procedures the Center uses, if any, to maximize the efficiency of the Administrative Core;
- Explain the procedures the Center uses to ensure that early stage scientists and investigators who are not already supported by the contraceptive research center have access to Administrative Core services;

- If pilot projects will be solicited during the execution of the awarded grant, describe how those projects will be solicited, evaluated and selected. For example, will advisory panels be used in the selection process?
- Internal and External Advisory Committees: The Administrative Core should establish an Internal Advisory Committee, composed of members of the Center and other institutional faculty, as well as an External Advisory Committee (EAC) composed of members outside the institution. Do not contact or name specific individuals in the application unless the EAC has already been constituted. Describe the general composition of the EAC, the areas of expertise of the proposed members and their role in advising Senior Key Personnel of the Center. Describe how the EAC will contribute to the oversight and evaluation of the Core facilities and specific research projects. Describe a plan for assessing research productivity of the center components.

**Contraceptive Research and Development Meeting:** A Contraceptive Research and Development Meeting will be held annually. The purpose of the meeting is to exchange scientific information, evaluate product development strategy and discuss collaborations within and between Centers. It is expected that the PD(s)/PI(s) and Project Investigators from each of the participating Centers will attend the annual meeting and organize and participate in teleconferences with Program approximately on a quarterly basis or at NICHD's discretion. Core Leads and research fellows participating in the projects should also attend the meeting.

**Letters of Support:** Include Letters of Support specific to the Administrative Core.

**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.

#### **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 (Administrative Core)**

When involving human subjects research, clinical research, and/or NIH-defined clinical trials follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the 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

### **Technical Service Core**

When preparing your application, 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 (Technical Service 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 (Technical Service Core)**

Enter Human Embryonic Stem Cells in each relevant component.

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

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

Costs necessary to utilize a particular core facility by budgeted center research projects must be incorporated into the budget of the project and not the core budget to accommodate participation in the required charge-back system.

If the core structure is open access, describe the use. In addition, a plan for fair and open access is needed for how the resource, when not in use by Center projects, will be made available to others, including an effective charge-back system.

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 (Technical Service Core)**

**Specific Aims:** List the objectives and functions of the Technical Service Core.

**Research Strategy:** Provide the following information:

- *Objectives of the Technical Service Core:* Describe the overall rationale, objectives, and structure of the core, e.g., closed access structure or open access structure.
- *Staffing:* Describe the administrative, technical, and support staff who are not designated as Senior Key Personnel, how those individuals will interact, and mechanisms of supervision/coordination by the Center Director (PD/PI) and Core Lead.
- *Resources and Services provided:* Describe the current and projected services to other core and research components, as well as the process for prioritizing requests for use of Core facilities by the various research projects. If a Core already exists, include a description of past services provided, new technologies developed, changes in protocols or Core administration, and other significant developments.
- *Management:* Describe the overall management of the Core, decision-making process and priorities for use of Core services, and plans for cost-effectiveness and quality control. Budgeted center research projects should be given highest priority in receiving services provided by the core. If the core structure is open access, describe a plan to assure fair and open access to the resource and an effective charge-back system for non-center projects. If appropriate for the core, describe how early investigators in contraceptive research will be involved in core activities.
- *Utilization of Core:* Provide a summary of past and/or projected usage of Core services (e.g., assays performed, animals supplied, etc.). Include estimates of the percentage use of each Core unit by the affiliated Research Project components. Explain the procedures the Center uses to ensure that early stage investigators have access to Technical Core services.

**Letters of Support:** Include Letters of Support specific to the Technical Service Core.

**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, are expected to provide a Data Sharing Plan.

#### **Appendix:**

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 (Technical Service Core)**

When involving NIH-defined human subjects research, clinical research, and/or clinical trial, 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**

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

## **Research Projects**

When preparing your application, 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 Projects)**

Enter Human Embryonic Stem Cells in each relevant component.

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

**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 Projects)**

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 Projects)**

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 Projects)**

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

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

### **PHS 398 Research Plan (Research Projects)**

**Specific Aims:** Include specific aims for the Research Project.

**Research Strategy:** Following the instructions in the SF424 (R&R) Application Guide, start each section with the appropriate section heading—Significance, Innovation, Approach.

- Clearly indicate whether the project is:
  - Contraception Development Research Project
  - Contraception Translational Research Project
  - Contraception Behavior Research Project
  - Cite published experimental details as appropriate and provide the full reference in the Bibliography and References Cited section of the Other Project Information form.
  - Clearly describe the project's objectives and explain its relevance to the overall program's theme.
  - Specify the significance of the work proposed to biomedicine, behavior or both.
  - Include information on preliminary studies pertinent to the project.
  - Describe the Research Project's use of Core services, including why the services are needed and the advantages and cost effectiveness of Core usage for the Project.
  - Described any proposed subcontracted resources.
  - If appropriate for the research project, describe how new investigators in contraceptive research will be involved in research activities.
  - If appropriate, discuss the impact of target modulation when not exclusively expressed to the reproductive tract.
  - Provide timelines, milestones, and metrics for success. Describe how progress will be evaluated during the funding period. If a particular approach proves to not be feasible, describe how the investigators would proceed in future years.

*For Contraception Development Research Projects, also address the following:*

- Describe how the research project(s) relate to the scientific theme of the application.
- For any proposed contraceptive research target, address potential off-target effects based on the target's available tissue distribution profile (e.g. RNA, protein data from public and proprietary resources).
- For any proposed contraceptive research target, identify and address known molecules with high degrees of similarity to the target (isoforms, family members, etc.) and strategies to develop highly specific target modulators with low cross-reactivity to similar non-target molecules.
- For any proposed chemical entity, address all potential issues related to compound molecular weight, mechanism of action, bioavailability (if known), toxicity (if known), feasibility of modification/optimization and intellectual property.

*For Contraception Translational Research Projects, also address the following:*

- Describe how the research fits with the overall theme of the application.
- Describe how the research will impact and improve the likelihood of clinical success.
- If appropriate, discuss for the identification and/or validation of novel models (laboratory, animal) to predict clinical efficacy

*For Contraception Behavior Research Projects, also address the following:*

- Clearly describe the project's objectives and explain its relevance to the overall theme of the application.
- Describe the populations to be studied that will advance scientific knowledge on factors affecting contraceptive acceptance and use.
- Describe the theory of human behavior and behavior change being used to motivate the design of the research

**Letters of Support:** Include Letters of Support specific to the Research 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, are expected to address a Data Sharing Plan.

#### **Appendix:**

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 Projects)**

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**

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) ([//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) ([//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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11142). ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11142](http://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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120). ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)).

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

**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) (<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) (<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](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11146](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146)) for avoiding common errors.

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

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### Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82299) ([http://grants.nih.gov/grants/guide/url\\_redirect.htm?id=82299](http://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 the proposed research likely to improve the development of new and improved contraceptive methods?

### **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?

### **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?

### **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?

#### **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.

#### **Center as an Integrated Effort**

The overall Center will be evaluated as an integrated research effort focused on one or more research areas listed under Research Scope. The review will assess the level of merit of the Center as an integrated effort, including the following criteria:

- Will there be coordination, interrelationships, cohesiveness, and synergy among the research projects and cores as they relate to the common theme of the Center?
- Are there advantages of conducting the proposed research as a program rather than through separate research efforts?
- Will the research efforts taken together have more impact on the field than each separate project conducted in isolation?
- Will the research proposed in individual projects be enhanced by the Center?
- If there is a Contraception Behavior Research Project, does it integrate conceptually or directly with the other research projects to inform contraception method development?
- If there is a Contraception Translational Research Project, does it integrate conceptually or directly with the other research Projects to inform contraception method development?

- Are effective mechanisms proposed for regular communication and coordination among investigators in the Center, especially for those who may not be at the primary site of the Center?
- Is there a coordinated Center-wide plan to encourage and support early stage investigators in pursuing a career in contraceptive research?
- Are administrative structures in place for the day-to-day management of the Center, including arrangements for internal quality control of ongoing research, identification and evaluation of pilot projects, and conflict resolution?
- Are timelines and milestones in-place that will allow an evaluation of progress to be made?
- *For non-reproductive tract specific targets:*
  - Has the applicant effectively addressed target modulation outside contraception?
  - Has the applicant effectively addressed consequences of targeting multiple tissues or organs?
- *For Contraception Translational Research Projects (if relevant) does the research:*
  - Focus on the identification, development, validation or evaluation of efficacy, pharmacokinetic or safety biomarkers for late stage preclinical or clinical programs?
  - Focus on the identification and/or validation of novel models (laboratory, animal) to predict clinical efficacy?

#### 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)?

##### **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/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**

Not Applicable

### **Renewals**

Not Applicable

### **Revisions**

Not Applicable

## **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.

## **Review Criteria - Cores**

As applicable for each individual Core, reviewers will provide an assessment of its strengths and weaknesses. The following items should be evaluated while determining scientific and technical merit, and in providing an overall Impact Score for the Core; however, separate scores will not be given for these items.

*For the Administrative Core:*

- Does the Administrative Core Lead have appropriate experience in research administration?
- Is there a decision-making process within the proposed Center for the evaluation of research productivity, for allocation of funds and for management of the resources?
- Is there a mechanism for resolving conflicts among investigators?
- Is there an effective process by which pilot projects, if applicable, will be selected and evaluated for potential funding?
- Is there a plan for Center evaluation, including the use of internal and external advisory groups in the process?

*For the Technical Service Cores:*

- Is there sufficient justification for proposing either open or closed core facilities?
- Are the qualifications, experience, and commitment of the Core Lead(s) and other core personnel appropriate?
- Will the quality of services provided enable Center investigators to achieve their research goals?
- Is the core cost-effective?
- Are quality control measures in place for core procedures?
- Is the use of core services by the budgeted Center projects and, if applicable, by external projects appropriate?
- Are plans for charge back and priority management procedures for core units configured in an open access format that offer services to research projects from other CRCs?

## **Review Criteria for Research Projects**

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

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.

## **Scored Review Criteria - Research Projects**

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

### **Significance**

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

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

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

change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

## **Investigator(s)**

Are the Project Lead(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers are involved, 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, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

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

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

## **Innovation**

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

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

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

## **Approach**

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

*For Contraceptive Development Research Projects:* Have the investigators addressed potential off-target effects based on the target's tissue distribution profile (e.g. RNA, protein)? Have the investigators identified and addressed known molecules with high degrees of similarity to the target (isoforms, family members, etc.) and strategies to develop highly specific target modulators with low cross-reactivity to

similar non-target molecules? Have the investigators addressed all potential issues related to compound molecular weight, mechanism of action, bioavailability (if known), toxicity (if known), and feasibility of modification/optimization and intellectual property?

*For Contraception Behavior Research Projects:* Are the populations to be studied appropriate to advance scientific knowledge on factors affecting contraceptive acceptance and use? Is a theory of human behavior and behavior change explicitly used to motivate the design of the research?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals based on 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?

### **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**

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

**In addition, for applications involving clinical trials**

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

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

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

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

**Additional Review Criteria - 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.

**Study Timeline**

**Specific to applications involving clinical trials**

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

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

**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 \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

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

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/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 \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11174\)](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 \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11150\)](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**

Not Applicable

## **Renewals**

Not Applicable

## **Revisions**

Not Applicable

## **Additional Review Considerations - Research Projects**

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

### **Applications from Foreign Organizations**

Not Applicable

### **Select Agent Research**

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

### **Resource Sharing Plans**

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) [Data Sharing Plan \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11151\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); 2) [Sharing Model Organisms \(https://grants.nih.gov/grants/guide/url\\_redirect.htm?id=11152\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and 3) [Genomic Data Sharing Plan \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html\)](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 NICHD, 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/url_redirect.htm?id=11154), using the stated [review criteria](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- 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.

[Appeals \(//grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Child Health and Human Development Council (NACHHD). 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/url_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/url_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/url_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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11158\)](#) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

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

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.

Per NICHD Notice NOT-HD-18-020 (<https://grants.nih.gov/grants/guide/notice-files/NOT-HD-18-020.html>), NICHD expects applicants selected for funding to work with NICHD staff on establishing a specific milestone plan for each clinical trial conducted as part of the award. As specified in the NoA, grantee will report on the milestones and associated information.

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>). NIH expects registration of all trials whether required under the law or not. For more information, see [http://grants.nih.gov/ClinicalTrials\\_fdaaa/](http://grants.nih.gov/ClinicalTrials_fdaaa/)

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 comply with the NIH [Guidance on Changes That Involve Human Subjects in Active Awards and That Will Require Prior NIH Approval \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-128.html\)](#).
- 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 \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=21600\)](#).

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

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url\\_redirect.htm?id=11120\)](#) 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](#)

([https://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](#) ([https://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](#) ([https://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 laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> (<https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html>) and <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>).

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.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides 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/fact-sheet-guidance/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html>) and <https://www.lep.gov> (<https://www.lep.gov>). 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 <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53> (<https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>).
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html> (<http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>).
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html> (<https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>); <https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html>; and <https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf> (<https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf>). For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see <https://grants.nih.gov/grants/policy/harassment.htm> (<https://grants.nih.gov/grants/policy/harassment.htm>).
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see <https://www.hhs.gov/conscience/conscience-protections/index.html> (<https://www.hhs.gov/conscience/conscience-protections/index.html>) and <https://www.hhs.gov/conscience/religious-freedom/index.html> (<https://www.hhs.gov/conscience/religious-freedom/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.

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 (FAPIS) requirements. FAPIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIS, 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/uri_redirect.htm?id=11161). ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11161](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11161)) Progress reports, to be conducted quarterly based on a fiscal year calendar, should briefly describe status of pilot projects, including data and safety monitoring, and should notify NIH of serious adverse events and unanticipated problems. It is the responsibility of the awardee to setup, organize and maintain these quarterly progress meetings.

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/uri_redirect.htm?id=11161) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11161](https://grants.nih.gov/grants/guide/uri_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](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11170) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11170](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11170)) on all subawards over \$25,000. See the [NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/uri_redirect.htm?id=11171) ([https://grants.nih.gov/grants/guide/uri\\_redirect.htm?id=11171](https://grants.nih.gov/grants/guide/uri_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 FAPIS). 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)

Christopher. C. Lindsey, PhD

*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

Telephone: 301-435-6907

Email: [chris.lindsey@nih.gov](mailto:chris.lindsey@nih.gov) (<mailto:chris.lindsey@nih.gov>)

### Peer Review Contact(s)

Sherry Dupere, PhD

*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

Telephone: 301-451-3415

Email: [duperes@mail.nih.gov](mailto:duperes@mail.nih.gov) (<mailto:duperes@mail.nih.gov>)

### Financial/Grants Management Contact(s)

Margaret Young

*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

Telephone: 301-642-4552

Email: [Margaret.young@nih.gov](mailto:Margaret.young@nih.gov) (<mailto:Margaret.young@nih.gov>)

## Section VIII. Other Information

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

## Authority and Regulations

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

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[Weekly TOC for this Announcement \(/grants/guide/WeeklyIndex.cfm?11-20-20\)](/grants/guide/WeeklyIndex.cfm?11-20-20)

[NIH Funding Opportunities and Notices \(/grants/guide/index.html\)](/grants/guide/index.html)

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National Institutes of Health [\(/grants/oer.htm\)](/grants/oer.htm)  
*Office of Extramural Research*



[\(http://www.hhs.gov/\)](http://www.hhs.gov/) Department of Health  
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 \(/grants/edocs.htm\)](/grants/edocs.htm).