

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

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

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

National Institute of Dental and Craniofacial Research ([NIDCR \(http://www.nidcr.nih.gov/\)](http://www.nidcr.nih.gov/))

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

National Institute of Environmental Health Sciences ([NIEHS \(http://www.niehs.nih.gov/\)](http://www.niehs.nih.gov/))

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

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest and requirements at the [Table of IC-Specific Information, Requirements and Staff Contacts \(https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html\)](https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html) website. ICs that do not participate in this announcement will not consider applications for funding. Consultation with NIH staff before submitting an application is strongly encouraged.

Funding Opportunity Title

Independent Scientist Award (Parent K02 - Independent Clinical Trial Required)

Activity Code

[K02 \(https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k02&Search.x=0&Search.y=0&Search_Type=Activity\)](https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k02&Search.x=0&Search.y=0&Search_Type=Activity) Research Scientist Development Award – Research

Announcement Type

Reissue of [PA-18-370 \(https://grants.nih.gov/grants/guide/pa-files/PA-18-370.html\)](https://grants.nih.gov/grants/guide/pa-files/PA-18-370.html)

Related Notices

None

Funding Opportunity Announcement (FOA) Number

PA-19-131

Companion Funding Opportunity	PA-19-132 (https://grants.nih.gov/grants/guide/pa-files/PA-19-132.html)
Number of Applications	See Section III. 3. Additional Information on Eligibility .
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.866; 93.273; 93.279; 93.121; 93.113; 93.853
Funding Opportunity Purpose	<p>The purpose of the NIH Independent Scientist Award (K02) is to foster the development of outstanding scientists and enable them to expand their potential to make significant contributions to their field of research. The K02 award provides three to five years of salary support and "protected time" for newly independent scientists who can demonstrate the need for a period of intensive research focus as a means of enhancing their research careers. Each independent scientist career award program must be tailored to meet the individual needs of the candidate.</p> <p>This Funding Opportunity Announcement (FOA) is designed specifically for applicants proposing to serve as the lead investigator of an independent clinical trial, a clinical trial feasibility study, or a separate ancillary clinical trial, as part of their research and career development. Applicants not planning an independent clinical trial, or proposing to gain research experience in a clinical trial led by another investigator, must apply to companion FOA (PA-19-132 (https://grants.nih.gov/grants/guide/pa-files/PA-19-132.html)).</p>

Key Dates

Posted Date	December 20, 2018
Open Date (Earliest Submission Date)	January 12, 2019
Letter of Intent Due Date(s)	Not Applicable
Application Due Date(s)	<p>Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11111) apply by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.</p> <p>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.</p>

AIDS Application Due Date(s)	<p>Standard AIDS dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11112) apply by 5:00 PM local time of applicant organization. All types of AIDS and AIDS-related applications allowed for this funding opportunity announcement are due on these dates.</p> <p>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.</p>
Scientific Merit Review	<p>Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandawa) apply</p>
Advisory Council Review	<p>Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandawa) apply</p>
Earliest Start Date	<p>Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply</p>
Expiration Date	January 8, 2022
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the Career Development (K) 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.
3. Use [Grants.gov \(http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PA-19-131\)](http://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PA-19-131) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application.

Table of Contents

[Part 1. Overview Information](#)

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

[Section I. Funding Opportunity Description](#)

[Section II. Award Information](#)

[Section III. Eligibility Information](#)

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

[Section V. Application Review Information](#)

[Section VI. Award Administration Information](#)

[Section VII. Agency Contacts](#)

[Section VIII. Other Information](#)

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The overall goal of the NIH Research Career Development program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. NIH Institutes and Centers (ICs) support a variety of mentored and non-mentored career development award programs designed to foster the transition of new investigators to research independence and to support established investigators in achieving specific objectives. Candidates should review the different career development (K) award programs to determine the best program to support their goals. More information about Career programs may be found at the [NIH Extramural Training Mechanisms \(//grants.nih.gov/grants/guide/url_redirect.htm?id=41159\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=41159) website.

The NIH Independent Scientist Award (K02) is intended to foster the development of outstanding scientists and enable them to expand their potential to make significant contributions to their field of research. It provides three to five years of salary support and "protected time" for newly independent scientists who can demonstrate the need for a period of intensive research focus as a means of enhancing their research careers.

Candidates must hold a doctoral degree, independent peer reviewed research support at the time the award is made, and commit a minimum of 9 person-months (75% of full-time professional effort) conducting research and relevant career development activities during the period of the award. Depending on the sponsoring Institute or Center (IC), scientists whose work is primarily theoretical may apply for this award in the absence of external research grant support. Receipt of prior support may have an impact on eligibility for the K02 award. Each independent scientist career award program must be tailored to meet the individual needs of the

candidate. The sponsoring institution must demonstrate a commitment to provide the environment, resources and the protected time required for the candidate to perform the activities included in the proposed research and career development plans.

Note: This Funding Opportunity Announcement (FOA) is designed specifically for applicants proposing to serve as the lead investigator of an independent clinical trial, a clinical trial feasibility study, or a separate ancillary clinical trial, as part of their research and career development. Applicants not planning an independent clinical trial, or proposing to gain research experience in a clinical trial led by another investigator, must apply to companion FOA ([PA-19-132 \(https://grants.nih.gov/grants/guide/pa-files/PA-19-132.html\)](https://grants.nih.gov/grants/guide/pa-files/PA-19-132.html)).

NIH defines a clinical trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." (NOT-OD-15-015)

NIH not only supports trials of safety and efficacy, it also supports mechanistic exploratory studies that meet the definition of a clinical trial and are designed to explore or understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention. These studies may focus on basic and/or translational discovery research in healthy human subjects and in human subjects who are affected by the pathophysiology of diseases and disorders. By addressing basic questions and concepts in biology, behavior, and pathophysiology, these studies may provide insight into understanding human diseases and disorders along with potential treatments or preventive strategies. NIH also supports biomarker studies that meet the definition of a clinical trial and that may provide information about physiological function, target engagement of novel therapeutics, and/or the impact of therapeutics on treatment response. NIH thus supports studies that meet the definition of clinical trials (as noted above) but do not seek to establish safety, clinical efficacy, effectiveness, clinical management, and/or implementation of preventive, therapeutic, and services interventions.

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this FOA, prospective applicants are strongly encouraged to consult the [Table of IC-Specific Information, Requirements and Staff Contacts \(https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html\)](https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html), to make sure that their application is appropriate for the requirements of one of the participating NIH ICs.

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

Section II. Award Information

Funding Instrument

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

Application Types Allowed

New
Resubmission
Revision

Renewal

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

Clinical Trial?	<p>Required: Only accepting applications that propose an independent clinical trial(s).</p> <p>Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)</p>
Funds Available and Anticipated Number of Awards	<p>The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.</p>
Award Budget	<p>Award budgets are composed of salary and other program-related expenses, as described below.</p>
Award Project Period	<p>The total project period may not exceed 5 years.</p>

Other Award Budget Information

Salary	<p>The participating NIH Institutes and Centers will provide salary and fringe benefits for the award recipient (see Table of IC-Specific Information, Requirements and Staff Contacts) (https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html). Further guidance on budgeting for career development salaries is provided in the SF424 (R&R) Application Guide. See also NOT-OD-17-094 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-094.html).</p> <p>The total NIH contribution to salary, however, may not exceed the legislatively mandated salary cap. See: http://grants.nih.gov/grants/policy/salcap_summary.htm (//grants.nih.gov/grants/policy/salcap_summary.htm).</p>
Other Program-Related Expenses	<p>It is expected that candidates for a K02 award will have research support at the time of the award. There are some research specialties, however, in which only minimal research support is needed, i.e., theoreticians, statisticians, and computer scientists. In such cases, depending on the participating IC, applicants may request in their application additional funds to cover incidental research expenses. When provided, these funds may be used for: (a) tuition and fees related to career development; (b) research expenses, such as supplies, equipment and technical personnel; (c) travel to research meetings or training; and (d) statistical and computational services including personnel and computer time. In no case may funds be requested that duplicate funds already being provided by other research support. For</p>

IC-specific information, see [Table of IC-Specific Information, Requirements and Staff Contacts](#) (<https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html>)).

Salary for secretarial and administrative assistants, etc. is not allowed.

expected that

Indirect Costs

Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

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

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

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

Nonprofits Other Than Institutions of Higher Education

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

For-Profit Organizations

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

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

- U.S. Territory or Possession

Other

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

Foreign Institutions

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

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

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

Required Registrations

Applicant Organizations

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

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

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

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA

Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any candidate with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) 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. Multiple PDs/Pis are not allowed.

By the time of award, the individual must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status).

Candidates for the K02 award must have a research or clinical doctoral degree, be newly independent, and have peer-reviewed, independent support at the time the award is made. Some of the participating NIH ICs require the candidate to have an NIH research grant at the time of application and that the support be from their IC. Other NIH ICs will accept candidates with peer-reviewed, independent research support from other sources.

Please note that the [NIH Loan Repayment Programs \(LRPs\)](https://www.lrp.nih.gov/) (<https://www.lrp.nih.gov/>) are a set of programs to attract and retain promising early-stage investigators in research careers by helping them to repay their student loans. Recipients of fellowship and career development awards are encouraged to apply for an extramural LRP award.

2. Cost Sharing

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

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct, and each is from a different candidate.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. An individual may not have two or more competing NIH career development applications pending review concurrently. In addition, NIH will not accept:

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

Level of Effort

At the time of award, the candidate must have a “full-time” appointment at the academic institution. Candidates are required to commit a minimum of 75% of full-time professional effort (i.e., a minimum of 9 person-months) to their program of career development during the mentored phase. Candidates may engage in other duties as part of the remaining 25% of their full-time professional effort not covered by this award, as long as such duties do not interfere with or detract from the proposed career development program.

Candidates who have VA appointments may not consider part of the VA effort toward satisfying the full time requirement at the applicant institution. Candidates with VA appointments should contact the staff person in the relevant Institute or Center prior to preparing an application to discuss their eligibility.

After the receipt of the award, adjustments to the required level of effort may be made in certain circumstances. See [NOT-OD-09-036 \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=51125\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=51125) for more details.

Renewals

Depending on the policies of the sponsoring NIH Institute/Center, awardees may apply for a one-time renewal for an additional three to five years of support if the recipient continues to have independent peer-reviewed research support at the time of submission of the renewal application. Candidates should clearly demonstrate their continuing need for protected time to expand their research programs.

Peer-Reviewed Research Support

Depending on the policies of the sponsoring NIH Institute/Center, candidates are expected to continue to hold independent peer-reviewed research support for the period of this award. Candidates losing this support during the award period must document in their annual Progress Reports efforts to replace this support and demonstrate that they continue to meet all other requirements of the career award.

Institutional Environment

The applicant institution must have a strong, well-established record of research and career development activities and faculty qualified to serve as mentors in biomedical, behavioral, or clinical research.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in [Part 1](#) of this 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 Career Development (K) Instructions in the [SF424 \(R&R\) Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the SF424 (R&R) Application Guide and the [Table of Page Limits \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=51132\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=51132) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF 424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

Other Project Information

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

SF424(R&R) Senior/Key Person Profile Expanded

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

R&R Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Career Development Award Supplemental Form

The PHS 398 Career Development Award Supplemental Form is comprised of the following sections:

Candidate

Research Plan

Other Candidate Information

Mentor, Co-Mentor, Consultant, Collaborators

Environment & Institutional Commitment to the Candidate

Other Research Plan Sections

Appendix

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

Candidate Section

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

Candidate Information and Goals for Career Development

Candidate's Background

- Describe the candidate's commitment to a career in biomedical, behavioral or clinical research. Include a description of all of the candidate's professional responsibilities in the grantee institution and elsewhere and show their relationship to the proposed activities of this K02 award.
- Present evidence of the candidate's ability to interact and collaborate with other scientists.
- Present evidence of the candidate's success as an independent investigator and his/her potential to make future contributions to the chosen field of research.
- Describe the candidate's immediate and long-term career objectives. Explain how the K02 award will contribute to these goals, and further the candidate's research career and ultimate impact on science.
- Describe how this award will relieve the candidate of current duties so that a greater portion of the candidate's effort (at least 9 person-months, equivalent to 75% full-time professional effort) may be

devoted to research and related career development activities.

- If applicable, describe the candidate's prior clinical trials research efforts, prior research interests and experience.

Career Goals and Objectives

- Describe the candidate's career goals and objectives under this award, including prior experience, and current research support. Candidates are encouraged to provide a timeline for accomplishing these goals.
- The candidate must demonstrate they have received training or will participate in courses such as: data management, epidemiology, study design (including statistics), hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects and clinical trials.

Candidate's Plan for Career Development/Training Activities During Award Period

- Describe the professional responsibilities/activities including other research projects beyond the minimum required effort commitment to the career award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator.
- The candidate should describe any new or enhanced research skills and knowledge he/she will acquire during the career award period, and how these skills and experiences will significantly enhance his/her ability to continue his/her research programs as an independent scientist.

Research Plan Section

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

Research Strategy

- A sound research project that is consistent with the candidate's level of research development and objectives of his/her career development plan must be provided. The research description should demonstrate the quality of the candidate's research thus far and also the novelty, significance, creativity and approach, as well as the ability of the candidate to carry out the research.
- Applicants proposing a clinical trial, ancillary or feasibility study should describe the planned analyses and statistical approach and how the expected analytical approach is suited to the available resources, proposed study design, scope of the project, and methods used to assign trial participants and deliver interventions.
- If proposing an ancillary clinical trial, provide a brief description of its relationship to the larger clinical trial.
- If proposing a feasibility study, to begin to address a clinical question, provide justification why this is warranted and how it will contribute the overall goals of the research project including planning and preliminary data for future, larger scale clinical trials.
- Describe the proposed timelines for the proposed clinical trial, feasibility or ancillary study, including any potential challenges and solutions (e.g., enrollment shortfalls or inability to attribute causal inference to the results of an intervention when performing a small feasibility study).
- Describe how the proposed clinical trial or ancillary study will test the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy (This would not apply to a feasibility study).

Training in the Responsible Conduct of Research

- All applications must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). See SF424 (R&R) Application Guide for instructions.

Mentor, Co-Mentor, Consultant, Collaborators Section

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

Plans and Statements of Mentor and Co-mentor(s)

- Not Applicable

Letters of Support from Collaborators, Contributors and Consultants

- Signed statements must be provided by all collaborators and/or consultants confirming their participation in the project and describing their specific roles. Collaborators and consultants do not need to provide their biographical sketches unless also listed as senior/key personnel. However, information should be provided clearly documenting the appropriate expertise in the proposed areas of consulting/collaboration.

Environmental and Institutional Commitment to the Candidate

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

Description of Institutional Environment

- The sponsoring institution must document a strong, well-established research and career development program related to the candidate's area of interest, including a high-quality research environment with key faculty members and other investigators capable of productive collaboration with the candidate.
- Describe how the institutional research environment is particularly suited to enhance the development of the candidate's research career as an independent scientist and proposed career and research plans.
- Describe the resources and facilities that will be available to the candidate, including any clinical trial-related resources, such as specialized administrative, data coordinating, enrollment, and laboratory/testing support. If applicable, include a description of the resources and facilities available at international sites.

Institutional Commitment to the Candidate's Research Career Development

- The sponsoring institution must provide a statement of commitment to the candidate's career goals to be a productive, independent investigator and to meeting the requirements of this award. It should be clear that the institutional commitment to the candidate is not contingent upon receipt of this career award.
- Provide assurances that the candidate will be able to devote a minimum of 9 person-months (75% of full-time professional effort) to the development of their research program. The remaining effort should be devoted to activities related to the development of the candidate's career as an independent scientist.
- Provide assurance that the candidate is an integral part of the institution's research and academic program.

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

PHS Human Subjects and Clinical Trials Information

When involving NIH-defined human subjects research, clinical research, and/or clinical trials (and when applicable, clinical trials research experience) 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.

PHS Assignment Request Form

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), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov](#) ([//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](#) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11123](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123)), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date. and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

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

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

5. Intergovernmental Review (E.O. 12372)

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

6. Funding Restrictions

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

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

7. Other Submission Requirements and Information

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

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

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

Post Submission Materials

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

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the [NIH mission](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) ([//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.

Overall Impact

Reviewers should provide their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into consideration the criteria below in determining the overall impact score.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

For this particular announcement, note the following: The reviewers will consider that the clinical trial may include study design, methods, and intervention that are not by themselves innovative, but address important questions or unmet needs. Reviewers should also consider the scope of the clinical trial relative to the available resources, including the possibility that research support provided through K awards may be sufficient to support only small feasibility studies.

Candidate

- Has the candidate demonstrated the capacity to carry out independent research?
- Does the candidate have potential to become an outstanding scientist who will make significant contributions to the field?
- Is there evidence of past and present research productivity as evidenced by contributions to the scientific literature, and success in obtaining independent funding?
- Has the candidate demonstrated the ability to conceptualize and organize a long-term research approach?
- Is there evidence of current independent, peer-reviewed research support?
- Is the candidate's level of training, experience, and competence commensurate with the purposes of the award?

Career Development Plan/Career Goals and Objectives

- What is the likelihood that the award will contribute substantially to the continued scientific development and productivity of the candidate?
- Are the career goals and objectives consistent with the candidate's career goals?
- Is there evidence that the award will enable the candidate to devote full time (at least the required minimum of 75% of full-time professional effort) to research and related duties by release from teaching, administration, clinical work, and other responsibilities?

Research Plan

- Candidates are expected to have independent, peer reviewed research support at the time the career award is made. In such instances, reviewers should not re-evaluate the research plan. Rather, the reviewers should evaluate how the research and career development plans together further the candidate's research career.
- Is the research plan of high quality, and does it have potential for advancing the field of study?
- Is the scientific and technical merit of the proposed research plan of significance?
- When applicable for the specific candidate and situation, do the letters from consultant(s) and collaborator(s) adequately document their willingness to participate in the independent scientist award

program?

- Are the scientific rationale and need for a clinical trial, feasibility or ancillary study well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms?
- If proposing a small feasibility study, is the study warranted and will it contribute to planning and preliminary data needed for design of future larger scale clinical trials?
- Is the clinical trial or ancillary study necessary for testing the safety, efficacy or effectiveness of an intervention, or in the case of a feasibility study necessary to establish feasibility of future clinical trial?
- Is the study design justified and relevant to the clinical, biological, and statistical hypothesis(es) being tested?
- Are the plans to standardize, assure quality of, and monitor adherence to, the protocol and data collection or distribution guidelines appropriate?
- Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions, if interventions are delivered?
- For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Consultant(s), Collaborator(s)

- Are the proposed collaborations with other active investigators and other opportunities for professional growth appropriate and of high quality?
- Is adequate information provided that clearly documents expertise in the proposed area(s) of consulting/collaboration?

Environment & Institutional Commitment to the Candidate

- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program as an independent investigator?
- Are the quality and relevance of the environment for continuing the scientific and professional development of the candidate and for others pursuing research appropriate and adequate?
- Is the commitment from the sponsoring institution to provide adequate protected time for the candidate to conduct the research program adequate?
- 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 feasibility or ancillary study at the proposed site(s) or centers? If applicable, are there 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?

Additional Review Criteria

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

Study Timeline for 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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11175\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed 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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11174\)](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 \(//grants.nih.gov/grants/guide/redirect.htm?id=11150\)](https://grants.nih.gov/grants/guide/redirect.htm?id=11150).

Biohazards

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

Resubmissions

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

Renewals

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

Revisions

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

Additional Review Considerations

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

Training in the Responsible Conduct of Research

All applications for support under this FOA must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). Taking into account the level of experience of the applicant, including any prior instruction or participation in RCR as appropriate for the applicant's career stage, the reviewers will evaluate the adequacy of the proposed RCR training in relation to the following five required components: 1) *Format* - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable); 2) *Subject Matter* - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics; 3) *Faculty Participation* - the role of the mentor(s) and other faculty involvement in the fellow's instruction; 4) *Duration of Instruction* - the number of contact hours of instruction (at least eight contact hours are required); and 5) *Frequency of Instruction* - instruction must occur during each career stage and at least once every four years. Plans and past record will be rated as *ACCEPTABLE* or *UNACCEPTABLE*, and the summary statement will provide the consensus of the review committee. See also: [NOT-OD-10-019 \(http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html\)](http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html).

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 \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); (2) [Sharing Model Organisms \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) [Genomic Data Sharing Plan \(GDS\) \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11153\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

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), 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.

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. Following initial peer review, recommended applications will receive a second level of review by the appropriate national Advisory Council or Board. The following will be considered in making funding decisions:

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

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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11158\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Specific to applications proposing clinical trials, ancillary or feasibility studies

Additionally, ICs may specify any special reporting requirements for the proposed clinical trial to be included under IC-specific terms and conditions in the NoA.

For example: If the proposed clinical trial has elevated risks, ICs may require closer programmatic monitoring and it may be necessary to require the awardee to provide more frequent information and data as a term of the award (e.g., to clarify issues, address and evaluate concerns, provide documentation). All additional communications and information related to programmatic monitoring must be documented and incorporated into the official project file.

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

ClinicalTrials.gov: If an award provides for one or more clinical trials, or a new ancillary clinical trial. By law (Title VIII, Section 801 of Public Law 110-85), the lead investigator must register and submit results information for certain "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration and Results System Information Website (<https://register.clinicaltrials.gov> (<https://register.clinicaltrials.gov>)).

NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see <https://grants.nih.gov/policy/clinical-trials/reporting/index.htm> (<https://grants.nih.gov/policy/clinical-trials/reporting/index.htm>) and [NOT-OD-18-212"](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-212.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-212.html>).

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

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

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

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and [Part II: Terms and Conditions of NIH Grant](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11157)

[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) ([//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) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=11158](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11158)). More specifically, for K Awards, visit the [Research Career Development \(“K”\) Awardees section of the NIH Grants Policy Statement](https://grants.nih.gov/grants/guide/url_redirect.htm?id=51164) ([//grants.nih.gov/grants/guide/url_redirect.htm?id=51164](https://grants.nih.gov/grants/guide/url_redirect.htm?id=51164)).

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person’s race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator’s scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.

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

In accordance with the statutory provisions contained in Section 872 of the *Duncan Hunter National Defense Authorization Act of Fiscal Year 2009* (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (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.

3. Reporting

When multiple years are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11120). The Supplemental Instructions for Individual Career Development (K) RPPRs must be followed. The Mentor’s Report must include an annual evaluation statement of the candidate’s progress.

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 \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11161\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11161).

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

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

4. Evaluation

In carrying out its stewardship of human resource-related programs, the NIH may request information essential to an assessment of the effectiveness of this program from databases and from participants themselves. Participants may be contacted after the completion of this award for periodic updates on various aspects of their employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions

from potential applicants.

Because of the difference in individual Institute and Center (IC) program requirements for this FOA, prospective applications **MUST** consult the [Table of IC-Specific Information, Requirements, and Staff Contacts \(https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html\)](https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html), to make sure that their application is responsive to the requirements of one of the participating NIH ICs. Prior consultation with NIH staff is strongly encouraged.

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/> ([//grants.nih.gov/support/](http://grants.nih.gov/support/)) (preferred method of contact)

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

GrantsInfo (Questions regarding application instructions, application processes, and NIH grant resources)

Email: 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>)

Scientific/Research Contact(s)

See [Table of IC-Specific Information, Requirements and Staff Contacts \(https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html\)](https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html)

Peer Review Contact(s)

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

Financial/Grants Management Contact(s)

See [Table of IC-Specific Information, Requirements and Staff Contacts \(https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html\)](https://grants.nih.gov/grants/guide/contacts/parent-K02-CT-required.html)

Section VIII. Other Information

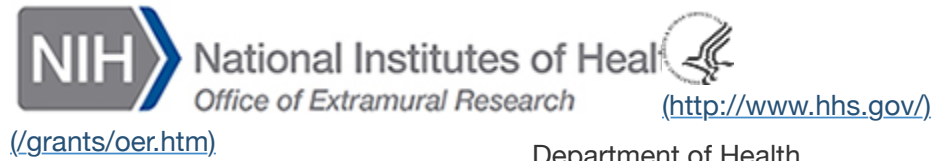
Recently issued trans-NIH [policy notices \(//grants.nih.gov/grants/guide/url_redirect.htm?id=11163\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts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

Authority and Regulations

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

[Weekly TOC for this Announcement \(/grants/guide/WeeklyIndex.cfm?12-21-18\)](https://grants.nih.gov/grants/guide/WeeklyIndex.cfm?12-21-18)

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



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