Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

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

Components of Participating Organizations

National Cancer Institute (NCI (http://www.nci.nih.gov/))

Funding Opportunity Title

The NCI Transition Career Development Award (K22 Independent Clinical Trial Required)

Activity Code

K22 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k22&Search.x=0&Search.y=0&Search_Type=Activity) Career Transition Award

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Announcement Type

Reissue of PAR-16-293 (https://grants.nih.gov/grants/guide/pa-files/PAR-16-293.html)

Related Notices

- **March 15, 2021** - This PAR has been reissued as PAR-21-318 (//grants.nih.gov/grants/guide/pa-files/PAR-21-318.html).
- **March 15, 2021** - This PAR has been reissued as PAR-21-111 (//grants.nih.gov/grants/guide/pa-files/PAR-21-111.html).
- **March 10, 2020** - Reminder: FORMS-F Grant Application Forms & Instructions Must be Used for Due Dates On or After May 25, 2020- New Grant Application Instructions Now Available. See Notice NOT-OD-20-077 (/grants/guide/notice-files/NOT-OD-20-077.html).
- January 22, 2020 (/grants/guide/notice-files/NOT-OD-20-058.html) - Additional Guidance on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. See Notice NOT-OD-20-058 (/grants/guide/notice-files/NOT-OD-20-058.html).
- **August 23, 2019** - Clarifying Competing Application Instructions and Notice of Publication of Frequently Asked Questions (FAQs) Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-137 (/grants/guide/notice-files/NOT-OD-19-137.html).
- **July 26, 2019** - Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research. See Notice NOT-OD-19-128 (/grants/guide/notice-files/NOT-OD-19-128.html).

- **July 22, 2019** - Requirement for ORCID iDs for Individuals Supported by Research Training, Fellowship, Research Education, and Career Development Awards Beginning in FY 2020. See Notice NOT-OD-19-109 (/grants/guide/notice-files/NOT-OD-19-109.html).
- **May 09, 2019** - Notice of Correction to Eligibility Information in PAR-18-466. See Notice NOT-CA-19-050 (/grants/guide/notice-files/NOT-CA-19-050.html).
- **November 26, 2018** - NIH & AHRQ Announce Upcoming Updates to Application Instructions and Review Criteria for Career Development Award Applications. See Notice NOT-OD-18-229 (/grants/guide/notice-files/NOT-OD-18-229.html).
- August 23, 2018 (//grants.nih.gov/grants/guide/notice-files/NOT-CA-18-091.html) - Notice of Change in Eligible Organizations in PAR-18-466. See Notice NOT-CA-18-091 (//grants.nih.gov/grants/guide/notice-files/NOT-CA-18-091.html).

Funding Opportunity Announcement (FOA) Number

PAR-18-466

Companion Funding Opportunity

PAR-18-467 (https://grants.nih.gov/grants/guide/pa-files/PAR-18-467.html), K22 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k22&Search.x=0&Search.y=0&Search_Type=Activity) Career Transition Award

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Number of Applications

See Section III. 3. Additional Information on Eligibility.

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

93.398

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) supports an NCI program that facilitates the transition of investigators in mentored, non-independent cancer research positions to independent faculty cancer research positions. This goal is achieved by providing protected time through salary and research support for the initial 3 years of the first independent tenure-track faculty position, or its equivalent, beginning at the time when the candidate starts a tenure-track faculty position.

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 study to an existing 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 (PAR-18-467 (https://grants.nih.gov/grants/guide/pa-files/PAR-18-467.html)).

Key Dates

Posted Date

December 6, 2017

Open Date (Earliest Submission Date)

January 12, 2018

Letter of Intent Due Date(s)

Not Applicable

Application Due Date(s)

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.

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.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) apply

Advisory Council Review

Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) (http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward) apply

Earliest Start Date

[Standard dates (//grants.nih.gov/grants/guide/url_redirect.htm?id=11113)](//grants.nih.gov/grants/guide/url_redirect.htm?id=11113) apply

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Expiration Date

March 13, 2021

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), 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/))*. 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.**

Table of Contents

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) website.

Doctoral-level investigators pursuing careers in all fields of cancer research often require extended periods of mentored research training beyond their original doctoral degrees (e.g., MD, MD/PhD, or PhD). Postdoctoral investigators who have no more than 4 years of postdoctoral research training experience at the time of initial application have access to the NIH Pathway to Independence Award in Cancer Research (K99/R00) for this purpose. However, because of the prolonged training experiences often needed for biomedical researchers, there is a wealth of talented new investigators still in mentored, non-independent positions who have more than 4 years of postdoctoral training in cancer research. These include investigators at domestic extramural institutions/organizations, as well as investigators working in federal research groups. Many such investigators need additional protected time to develop successful independent research programs.

The objective of the NCI Transition Career Development Award (K22) is to provide support to mentored, non-independent investigators in transitioning to their first independent tenure-track faculty cancer research positions, or their equivalent, with an enhanced probability of success for obtaining independent NIH or other research project grant support. *Candidates in mentored, non-independent cancer research positions may apply, and if successful, must obtain tenure-track faculty, or equivalent, positions, and NCI approval before awards will be issued.*

The NCI K22 award will provide up to 3 years of support for the most promising and exceptionally talented mentored, non-independent investigators. This period of support is to allow the investigator to work towards establishing his/her own independent research program and to prepare an application for research grant support (R01 or equivalent). NIH believes that the creativity and innovation of new independent investigators in their early career stages play an integral role in addressing our Nation's biomedical, behavioral, and clinical research needs.

The candidate submits a K22 application from the institution where he/she currently pursues mentored, non-independent research training. The application will be peer reviewed and assigned an overall impact score. Successful candidates (i.e. whose application has been selected for funding) will receive a Letter of Intent to Commit Funds from NCI that will include the terms and conditions to issue/activate the K22 award. In order to issue/activate the K22 award, the candidate will need to first secure a tenure-track faculty position in an extramural non-federal government institution that is not an agency of the Federal Government, wihin 12 months of the receipt of the Letter of Intent to Commit Funds. Once the faculty position has been secured, the candidate will submit updated information about the K22 application with the support of the awardee institution. The awardee institution can be the same as the submitting institution, except when the submitting institution is a federal agency. The updated information of the transition to a tenure-track faculty position at the awardee institution will be evaluated by NCI staff to ensure that all programmatic requirements are met prior to the issuance/activation of the K22 award. The details of the requirements for the issuance/activation of the K22 award are described in Section VI.

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 a feasibility study, or a separate ancillary study to an existing 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 ([PAR-18-467 (https://grants.nih.gov/grants/guide/pa-files/PAR-18-467.html)](https://grants.nih.gov/grants/guide/pa-files/PAR-18-467.html)).

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

The [OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116)](//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?

Required: Only accepting applications that propose an independent clinical trial(s)

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

Funds Available and Anticipated Number of Awards

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

Award Budget

Award budgets are composed of salary and other program-related expenses, as described below.

Award Project Period

The total project period may not exceed 3 years.

Other Award Budget Information

Salary

NCI will contribute up to $ 100,000 per year toward the salary of the career award recipient. Further guidance on budgeting for career development salaries is provided in the SF424 (R&R) Application Guide.

Other Program-Related Expenses

NCI will contribute $50,000 per year toward the research development costs of the award recipient, which must be justified and consistent with the stage of development of the candidate and the proportion of time to be spent in research or career development activities.

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

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* (//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, including the NIH intramural program
- 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

Private (profit or non-profit) or public institutions, including the NIH intramural programs and other federal laboratories are eligible to submit K22 applications. However, NIH intramural laboratories and other agencies of the Federal Government are not eligible to be the awardee institution.

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* (//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 (//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) - 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/) (formerly CCR) – 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176)](//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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123)](//grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. 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 (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300)](//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) and who has at least 2 years, but, no more than 8 years of mentored, non-independent training experience after the terminal research doctorate or clinical degree, 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. Such individuals may also be eligible for the NCI Transition Career Development Award to Promote Diversity (K22) and are advised to contact the NCI Center to Reduce Cancer Health Disparities.

Multiple PDs/PIs are not allowed.

By the time of award, the PI of a K22 award 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.

 Postdoctoral Investigators:

At the time of the initial application submission (or resubmission), candidates for this award must (1) have earned a terminal research doctorate or clinical degree (including PhD, MD, DO, DC, ND, DDS, DMD, DVM, ScD, DNS, PharmD, or equivalent doctoral degree) or a combined research doctorate/clinical degree; (2) have at least 2 years of postdoctoral, or its equivalent, training in cancer research (e.g., postdoctoral fellow, postdoctoral associate, clinical fellow, clinical associate, or equivalent); (3) have no more than a total of 8 years of mentored, non-independent research training experience after the terminal research doctorate or clinical degree; (4) have not already obtained an individual career development award or research project grant (except R03) from the Federal Government; and (5) have not already had or have a tenure-track faculty position, or its equivalent.

Individuals are eligible for a K22 award if they have been, or currently are, the PD/PI of an NIH R03 or a PHS or non-Federal award that duplicates the specific aims or research goals of an R03 grant.

Other Candidates:

Postdoctoral fellows in mentored, non-independent training positions, but who have job titles such as research associate, instructor, or the equivalent, are encouraged to obtain confirmation of their eligibility before they begin to prepare their applications. It is incumbent upon the candidate to provide evidence that he/she is in a mentored, non-independent position.

A clinical faculty member who does not hold an independent research faculty position may be eligible for the K22 award and are encouraged to obtain confirmation of their eligibility before they begin to prepare their applications.

Investigators in independent positions in Mathematics, Physical Sciences and/or Engineering and who wish to re-orient to cancer-focused research careers are encouraged to apply. Investigators in such positions are encouraged to obtain confirmation of their eligibility before they begin to prepare their applications.

Mentored, non-independent investigators in NIH intramural laboratories and other eligible agencies of the Federal Government are eligible to apply for the NCI K22 award.

Individuals are NOT eligible for the NCI K22 award if they:

- Have less than 2 years of postdoctoral training in cancer research at the time of initial application; or
- Have more than a total of 8 years of mentored, non-independent research training after the terminal research or clinical doctorate at the time of initial application or resubmission; or
- Have currently or previously held an independent research faculty or tenure-track faculty position, or its equivalent, in academia, industry or elsewhere; or
- Have an application pending review for any other PHS career development award, including a Pathway to Independence Award (K99/R00); or
- Have currently or have previously held another NIH career development award (e.g., K01, K07, K08, K18, K22, K23, K25, K99, K99/R00) or other peer-reviewed NIH or non-NIH research grants over $100,000 direct costs per year; or
- Have been an independent PD/PI on NIH research grants (e.g. R01, R21, P01) or a subproject leader on a Program Project (P01) or Center Grant (P50), or a non-NIH research grant equivalent to these grants/awards; or
- Have currently or have previously held other peer-reviewed NIH (except R03) or non-NIH research grants over $100,000 in direct costs per year; or
- Have no affiliation with a domestic extramural institution or Federal institution at the time of initial application or resubmission.

The following is provided as an aid to distinguish independent from non-independent positions: However, it is not sufficient merely to cite one or more of the following items to document eligibility.

Evidence for non-independence may include:

- The candidate's salary is paid by another investigator(s).
- The candidate's research is entirely funded by another investigator's grants.
- The candidate's research is conducted entirely in another investigator's assigned space.

- According to institutional policy, the candidate cannot hire postdoctoral fellows or technical staff or be the responsible supervisor of graduate students.
- According to institutional policy, the candidate is not allowed to submit an application as the PD/PI of an NIH research grant application (e.g., R01).
- The candidate lacks other rights and privileges of faculty, such as attendance at faculty meetings.

Conversely, evidence for independence, and therefore lack of eligibility, includes:

- The candidate has a full-time faculty position.
- The candidate received a start-up package for support of his/her independent research.
- The candidate has research space dedicated to his/her own research.
- The candidate may attend faculty meetings, be the responsible supervisor for graduate students, and/or hire technical support or postdoctoral fellows.
- The candidate is eligible to apply for independent research funding as the PD/PI of an NIH research grant.

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement.* (//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 (//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" tenure-track faculty appointment or an equivalent appointment at the sponsoring awardee 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 and research. 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. Under certain circumstances, an awardee may submit a written request to the awarding component requesting a reduction in minimum required percent effort, which will be considered on a case-by-case basis. Details on this policy are provided in NOT-OD-09-036 (//grants.nih.gov/grants/guide/url_redirect.htm?id=51125).

Special Requirements:

NCI K22 award recipients are expected to apply for NIH or other independent research project grant support (R01 or equivalent) prior to the end of the 2nd year of support. Recipients may hold concurrent research support, and, under certain circumstances, salary support from the final 2 years of their K22 award and a competing NIH research project grant when recognized as the PD(s)/PI(s) or subproject Director of the research project grant. See NOT-OD-08-065 (//grants.nih.gov/grants/guide/notice-files/not-od-08-065.html).

Institutional Environment

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

Section IV. Application and Submission Information

1. Requesting an Application Package

Buttons to access the online ASSIST system or to download application forms 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 (//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.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications (//grants.nih.gov/grants/guide/url_redirect.htm?id=41137).

Page Limitations

All page limitations described in the SF424 (R&R) Application Guide and the Table of Page Limits (//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:

Project Summary/Abstract

Include a description of your current research and the research you propose to perform in the independent K22 award.

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, with the following additional instructions:

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 a biomedical or behavioral research field relevant to the mission of the NCI.
- Describe prior training and research efforts and how it relates to the objectives and long-term career plans of the candidate.
- Describe the candidate's research efforts to this point in his/her research career, including any publications, prior research experience and collaborations with other researchers.

- Describe the candidate's commitment to a career as a cancer-focused research scientist.
- Provide evidence of the candidate's ability to interact and collaborate with other scientists.

Career Goals and Objectives

- Describe a systematic plan: (1) that shows a logical progression from prior research and training experiences to the research and career development experiences that will occur during the career award period and then to independent investigator status; and (2) that justifies the need for further career development to become an independent investigator.
- Describe the candidate's immediate and long-term research and career objectives, explaining how the award will contribute to their attainment. Candidates are encouraged to provide a timeline for accomplishing these objectives.
- If currently supported by an institutional training grant or individual fellowship award (such as provided through the Ruth L. Kirschstein NRSA program), describe the candidate's current research training or fellowship program.

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

- The candidate is responsible for the preparation of the career development plan. A career development timeline, including a publication plan is strongly encouraged.
- A systematic plan should be presented for obtaining biomedical, behavioral, or clinical science background, research experience, and career development activities necessary to launch the stated independent research career. Describe current activities and how they relate to the candidate's career development plans and career goals. Describe proposed activities, e.g., those that will lead to new and/or enhanced research skills and knowledge, as well as related skills such as grant-writing, communication, leadership, and laboratory management.
- The career development plan must be tailored to the needs of the individual candidate with the ultimate goal of achieving independence as a researcher.
- The candidate must justify the need for the K22 award and must provide a convincing case that the proposed period of support (3 years) will substantially enhance his/her career and allow the pursuit of a novel or promising approach to a particular cancer research problem.
- The career development plan should describe the steps that will be undertaken to apply for NIH or other independent research project grant support (R01 or equivalent) prior to the end of the second year of support.
- Although not required, an advisory committee may be formed to monitor the candidate's progress during the career development program. No signed statements, letters of support or NIH biographical sketches for members of an advisory committee, if any, are allowed. If the exact composition of an advisory committee is not known at the time of submission, general roles and contributions of future committee members can be discussed.

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 not only the quality of the candidate's research thus far, but also the novelty, significance, creativity and approach, as well as the ability of the candidate to successfully perform the research.

- Although it is not expected that the description of the research would be as detailed as an application for an investigator-initiated research grant (e.g., R01), enough information should be provided to permit an evaluation of the scientific merit of the candidate's research activities and training.
- If the applicant is proposing to gain experience in a clinical trial, ancillary study to a clinical trial or a clinical trial feasibility study as part of his or her research career development, describe the relationship of the proposed research project to the clinical trial.
- 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 study to an ongoing 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, ancillary or feasibility 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:

- <u>Candidates must include a statement indicating that this is a transition award with no mentor or co-mentor in this section sub-heading.</u>

Letters of Support from Collaborators, Contributors and Consultants

- Signed statements must be provided by all collaborators, contributors and/or consultants confirming their participation in the project and describing their specific roles. Collaborators and contributors should provide their NIH biographical sketches. Consultants do not need to provide their NIH biographical sketches. Consultants are generally not directly involved in the development of the career of the candidate as an independent investigator. However, information should be provided clearly documenting the appropriate expertise in the proposed areas of consulting/collaboration.
- Advisory committee members (if applicable). The composition of an advisory committee, if any, should be described only in general terms. No signed statements, letters of support or biographical sketches of members of a proposed advisory committee are allowed. Candidates will not be expected to know the exact composition of an advisory committee, if any, until they identify awardee institutions if selected for an award. <u>The main purpose of an advisory committee would be to monitor the candidate's progress during the career development program.</u> An advisory committee should not be a mentoring committee.
- Although current and/or past mentors, co-mentors can submit letters of support, it is advised not to do so as this is an independent award. Instead, current and/or past mentors, co-mentors should submit letters of recommendation into eRA Commons.

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

- Due to the nature of this award, the candidate may not have identified a sponsoring awardee institution at the time of submitting the K22 application. Describe the submitting institution's scientific environment, including the resources and facilities that will be available to the candidate in securing a tenure-track faculty position, or its equivalent, in a domestic academic institution.
- 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.

Institutional Commitment to the Candidate's Research Career Development

- The submitting institution must provide a statement of commitment to the candidate's development into 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. This statement is typically signed by the Department Chair or Dean.

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

Use only for applications with due dates on or after January 25, 2018. 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.

Reference Letters

Candidates must carefully follow the SF424 (R&R) Application Guide, **including the time period for when reference letters will be accepted**. Applications lacking the appropriate required reference letters will not be reviewed. This is a separate process from submitting an application electronically. Reference

letters are submitted directly through the eRA Commons Submit Referee Information link (//grants.nih.gov/grants/guide/url_redirect.htm?id=41146) and not through Grants.gov.

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) (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), 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. (//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* (//grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement* (//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 Applying Electronically (//grants.nih.gov/grants/guide/url_redirect.htm?id=11144). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Guidelines for Applicants Experiencing System Issues (//grants.nih.gov/grants/ElectronicReceipt/support.htm#guidelines). 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 (//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)olicy.

Section V. Application Review Information

NEW   **Important Update:** See NOT-OD-18-229 (/grants/guide/notice-files/NOT-OD-18-229.html) for updated review language for due dates on or after January 25, 2019.

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission (//grants.nih.gov/grants/guide/url_redirect.htm?id=11149), all applications submitted to the NIH in support of biomedical and behavioral research 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.

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. Note that as this is not a mentored award, mentors, co-mentors do not submit letters of support with the application.

Candidate

- Does the candidate have the potential for becoming a successful independent investigator who will contribute significantly to the cancer research field?
- What is the quality of the candidate's pre- and postdoctoral research training, with respect to development of appropriate scientific and technical expertise?
- What is the scientific productivity during the postdoctoral period of cancer research training in terms of research experience(s), didactic experiences, and other experiences (e.g., special skills, perspectives, techniques), and has it enhanced the candidate's ability to pursue an independent cancer research career?
- Considering the years of postdoctoral research experience to date, what is the candidate's record of research productivity, including the quality of peer-reviewed scientific publications?
- Is the candidate committed to an independent research career that will be focused on problems clearly relevant to cancer?
- Does the candidate have the potential ability to successfully manage an independent cancer research project?
- Do the reference letters from at least three well-established scientists address the candidate's potential for becoming an independent cancer research investigator?
- Does the candidate have the potential to organize, manage, and implement the proposed clinical trial, feasibility or ancillary study?
- Does the candidate have training (or plans to receive training) in data management and statistics including those relevant to clinical trials?

Career Development Plan/Career Goals and Objectives

- Are the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?
- Are appropriate timelines planned for the candidate's progress?

Research Plan

- Is there a strong scientific premise for the project?
- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Are the scientific and technical merits of the research question, design, and methodology appropriate in the context of prior training and experience?
- Is the proposed research project appropriate to the candidate's stage of research development and as a vehicle for developing the research skills described in the career development plan?

- Is the proposed research plan relevant to the candidate's research career objectives?
- Has the candidate presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Has the candidate presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
- To what extent is the proposed research likely to foster the career of the candidate as an independent investigator in cancer research?
- If proposed, will the clinical trial experience contribute to the research project and/or the applicant's research career development?
- 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 guidelies appropriate?
- Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions?

Consultant(s), Collaborator(s)

- Is adequate information provided that clearly documents expertise in the proposed area(s) of consulting/collaboration?
- Have the proposed consultant(s) and collaborator(s) provided evidence of commitment to the candidate and the candidate's project?
- Do the proposed consultant(s)/collaborator(s) provide the required expertise for successful conduct of the research project?

Environment & Institutional Commitment to the Candidate

- Are there adequate and appropriate research facilities and educational opportunities, including collaborating faculty at the submitting institution to help the candidate secure a tenure-track faculty position, or its equivalent, in a domestic academic institution?
- Is there appropriate commitment from the submitting institution to assist the candidate in career progression to a tenure-track faculty position, or its equivalent?
- Is there appropriate commitment from the submitting institution to assist in the candidate's development into a productive, independent investigator?

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., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

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

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six 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 six 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).

Inclusion of Women, Minorities, and Children

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 children 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).

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)

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

Not Applicable

Revisions

Not Applicable

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).

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); (2) Sharing Model Organisms (//grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and (3) Genomic Data Sharing Plan (GDS) (//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), 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 National Cancer Advisory 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). 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).

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).

A formal notification in the form of a Notice of Award (NoA) will be provided to the sponsoring awardee 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.

 There will not be a formal Notice of Award (NoA) for applications until an awardee institution has been identified by the candidate and approved by the NCI. The NCI will initially notify candidates who have successfully competed for funding with a Letter of Intent to Commit Funds. Selected candidates will then have up to 12 months from the date of the letter to accept an appointment in a domestic academic institution that has offered a position at the tenure-track faculty level, or its equivalent (e.g., Assistant Professor, Assistant Member, Laboratory Head, Principal Investigator, etc.), at which the candidate is expected to

establish his/her own independent research program, prepare applications for regular (non-career development) research project funding, and act as a PI(s)/PD(s) on such independent research projects. No funds will be issued for use while the candidate occupies a mentored, non-independent position at the submitting institution or awardee institution.

In the Request to Activate the K22 Award, the awardee institution needs to:

- Describe the institution's scientific environment, including the resources and facilities that will be available to the candidate to perform the proposed research plan.
- Describe how the institutional research environment is particularly suited for the development of the candidate's research career and the pursuit of the proposed research plan and progression to independence, including a high-quality research environment with key faculty members and other investigators capable of productive collaboration with the candidate.

The awardee institution will also need to provide a description of the institutional commitment to the candidate's career development for the following:

- The institution must provide a statement of commitment to the candidate's development into a productive, independent investigator, and to meeting the requirements of the award.
- The institution must provide a clear statement that describes the commitment to the career progression of the candidate (e.g., tenure-track faculty position).
- The institution must provide a statement that the institutional commitment to the candidate is not contingent upon receipt of this career award.
- The institution must describe the start-up package and salary to be provided and document how it is equivalent to those provided to recent newly hired tenure-track faculty who do not have K22 awards.
- The institution must provide a statement with assurances that the candidate will be able to spend a minimum of 75% effort (9 calendar months) in the conduct of research and career development activities associated with this award, with the remaining 25% effort devoted to other research, clinical, and teaching activities.
- The institution must provide the candidate with the appropriate facilities and other resources to perform the proposed research plan, including laboratory and office space, and for which the sizes should be indicated.

In addition, the candidate and the new awardee institution will also need to provide a revised budget according to the the instructions in the SF424 (R&R) Application Guide, including Supplemental Grant Application Instructions. This information should be provided through the Change of Grantee Organization (Type 7 Parent) Program Announcement if the candidate changes institutions or through "just-in-time" procedures if the candidate obtains a tenure-track faculty position at the postdoctoral institution.

Specific to applications proposing clinical trials, ancillary or feasibility studies

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

ClinicalTrials.gov: If an award provides for one or more clinical trials, or a new ancillary study to an ongoing 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). NIH expects registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

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) 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) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (//grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (//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_ (//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. The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html (http://www.hhs.gov/ocr/civilrights/understanding/section1557/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 http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html). Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-

us/index.html (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53 (http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53).

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

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). The Supplemental Instructions for Individual Career Development (K) RPPRs must be followed.

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).

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) on all subawards over $25,000. See the *NIH Grants Policy Statement* (//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.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Finding Help Online: http://grants.nih.gov/support/ (//grants.nih.gov/support/) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (//grants.nih.gov/grants/guide/url_redirect.htm?id=82301) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov) (preferred method of contact)
Telephone: 301-945-7573

Scientific/Research Contact(s)

Sonia B. Jakowlew, Ph.D
National Cancer Institute (NCI)
Telephone: 240-276-5630
Email:jakowles@mail.nih.gov (mailto:jakowles@mail.nih.gov)

Peer Review Contact(s)

Referral Officer
National Cancer Institute (NCI)
Telephone: 240-276-6390
Email:ncirefof@dea.nci.gov (mailto:ncirefof@dea.nci.gov)

Financial/Grants Management Contact(s)

Jason Gill
Email: gilljas@mail.nih.gov (mailto:gilljas@mail.nih.gov)

Section VIII. Other Information

Recently issued trans-NIH policy notices (//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). 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).
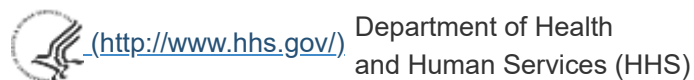
Authority and Regulations

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?12-08-17)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

NIH National Institutes of Health (/grants/oer.htm)
Office of Extramural Research

(http://www.hhs.gov/) Department of Health and Human Services (HHS)

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).