

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 INSTITUTES OF HEALTH ([NIH \(https://www.nih.gov\)](https://www.nih.gov))

National Eye Institute ([NEI \(https://www.nei.nih.gov\)](https://www.nei.nih.gov))

National Heart, Lung, and Blood Institute ([NHLBI \(https://www.nhlbi.nih.gov\)](https://www.nhlbi.nih.gov))

National Human Genome Research Institute ([NHGRI \(https://www.genome.gov\)](https://www.genome.gov))

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

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

National Institute of Allergy and Infectious Diseases ([NIAID \(https://www.niaid.nih.gov\)](https://www.niaid.nih.gov))

National Institute of Arthritis and Musculoskeletal and Skin Diseases ([NIAMS \(https://www.niams.nih.gov\)](https://www.niams.nih.gov))

National Institute of Biomedical Imaging and Bioengineering ([NIBIB \(https://www.nibib.nih.gov\)](https://www.nibib.nih.gov))

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

National Institute on Deafness and Other Communication Disorders ([NIDCD \(https://www.nidcd.nih.gov\)](https://www.nidcd.nih.gov))

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

National Institute of Diabetes and Digestive and Kidney Diseases ([NIDDK \(https://www.niddk.nih.gov\)](https://www.niddk.nih.gov))

National Institute on Drug Abuse ([NIDA \(https://www.drugabuse.gov\)](https://www.drugabuse.gov))

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

National Institute of General Medical Sciences ([NIGMS \(https://www.nigms.nih.gov\)](https://www.nigms.nih.gov))

National Institute of Mental Health ([NIMH \(https://www.nimh.nih.gov/index.shtml\)](https://www.nimh.nih.gov/index.shtml))

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

National Institute of Nursing Research ([NINR \(https://www.ninr.nih.gov\)](https://www.ninr.nih.gov))

National Institute on Minority Health and Health Disparities ([NIMHD \(https://www.nimhd.nih.gov\)](https://www.nimhd.nih.gov))

National Library of Medicine ([NLM \(https://www.nlm.nih.gov\)](https://www.nlm.nih.gov))

National Center for Complementary and Integrative Health ([NCCIH \(https://nccih.nih.gov\)](https://nccih.nih.gov))

National Cancer Institute ([NCI \(https://www.cancer.gov\)](https://www.cancer.gov))

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

Office of Research on Women's Health ([ORWH \(https://orwh.od.nih.gov\)](https://orwh.od.nih.gov))

Office of Data Science Strategy ([ODSS \(https://datascience.nih.gov/about/odss\)](https://datascience.nih.gov/about/odss))

Special Note: Not all NIH Institutes and Centers participate in Parent Announcements. Candidates 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/IC-specific-information-PA-24-194.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

NIH Pathway to Independence Award (Parent K99/R00 – Independent Clinical Trial Not Allowed)

Activity Code

K99 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=k99&Search.x=0&Search.y=0&Search_Type=Activity)/R00 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r00&Search.x=0&Search.y=0&Search_Type=Activity) Career Transition Award/Research Transition Award

Announcement Type

Reissue of [PA-20-188](https://grants.nih.gov/grants/guide/pa-files/PA-20-188.html) (<https://grants.nih.gov/grants/guide/pa-files/PA-20-188.html>)

Related Notices

See [Notices of Special Interest](https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=40824) (https://grants.nih.gov/grants/guide/NOSIs_targetingList.cfm?GuideDocID=40824) associated with this funding opportunity

- **September 25, 2024** - Notice of a Virtual Question and Answer "Informational Session" with NICHD Staff for the K99/R00 Pathway to Independence Award. See Notice [NOT-HD-24-037](https://grants.nih.gov/grants/guide/notice-files/NOT-HD-24-037.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-HD-24-037.html>).
- **June 4, 2024** - Guidance Regarding Reduction of Effort for NIMHD Individual Mentored K Awards. See Notice [NOT-MD-24-017](https://grants.nih.gov/grants/guide/notice-files/NOT-MD-24-017.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-MD-24-017.html>).
- **May 30, 2024** - Notice to Alert the Public of NIDA's Career Development Award Salary Limits. See Notice [NOT-DA-24-032](https://grants.nih.gov/grants/guide/notice-files/NOT-DA-24-032.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-DA-24-032.html>).
- **May 7, 2024** - Notice of Information: NIAID to Increase K99, K25, and K01 Salary and Research Support and R00 Years of Support. See Notice [NOT-AI-24-038](https://grants.nih.gov/grants/guide/notice-files/NOT-AI-24-038.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-AI-24-038.html>).
- **August 31, 2022**- Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice [NOT-OD-22-198](https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html) (<https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html>).
- **August 5, 2022**- Implementation Details for the NIH Data Management and Sharing Policy. See Notice [NOT-OD-22-189](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html>).

Funding Opportunity Number (FON)

PA-24-194

Companion Funding Opportunity

[PA-24-193](https://grants.nih.gov/grants/guide/pa-files/PA-24-193.html) (<https://grants.nih.gov/grants/guide/pa-files/PA-24-193.html>), K99 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=K99&&Search.x=0&&Search.y=0&&Search_Type=Activity)/ R00 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R00&&Search.x=0&&Search.y=0&&Search_Type=Activity) Career Transition Award/Research Transition Award
[PA-24-195](https://grants.nih.gov/grants/guide/pa-files/PA-24-195.html) (<https://grants.nih.gov/grants/guide/pa-files/PA-24-195.html>), K99 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=K99&&Search.x=0&&Search.y=0&&Search_Type=Activity)/ R00 (https://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=R00&&Search.x=0&&Search.y=0&&Search_Type=Activity) Career Transition Award/Research Transition Award

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.855, 93.213, 93.242, 93.865, 93.846, 93.286, 93.859, 93.866, 93.121, 93.879, 93.172, 93.173, 93.847, 93.867, 93.313, 93.113, 93.279, 93.361, 93.398, 93.307, 93.853, 93.310, 93.837, 93.233, 93.838, 93.839, 93.840, 93.273

Funding Opportunity Purpose

The purpose of the NIH Pathway to Independence Award (K99/R00) program is to facilitate a timely transition of outstanding postdoctoral researchers with a research and/or clinical doctorate degree from mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions. The program will provide independent NIH research support during this transition in order to help awardees to launch competitive, independent research careers.

This Notice of Funding Opportunity (NOFO) is designed specifically for candidates proposing research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary clinical trial. Under this NOFO candidates are permitted to propose a research experience in a clinical trial led by a mentor or co-mentor. Those proposing a clinical trial or an ancillary clinical trial as lead investigator, should apply to the companion NOFO ([PA-24-193 \(https://grants.nih.gov/grants/guide/pa-files/PA-24-193.html\)\)](https://grants.nih.gov/grants/guide/pa-files/PA-24-193.html)).

Key Dates

Posted Date

April 24, 2024

Open Date (Earliest Submission Date)

May 10, 2024

Letter of Intent Due Date(s)

Not Applicable

The following table includes NIH [standard due dates \(https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm\)](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm) marked with an asterisk.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
June 12, 2024 *	July 12, 2024 *	September 07, 2024 *	November 2024	January 2025	April 2025
October 12, 2024 *	November 12, 2024 *	January 07, 2025 *	March 2025	May 2025	July 2025

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS - New/Renewal/Resubmission/Revision, as allowed	Scientific Merit Review	Advisory Council Review	Earliest Start Date
February 12, 2025 *	March 12, 2025 *	May 07, 2025 *	July 2025	October 2025	December 2025
June 12, 2025 *	July 12, 2025 *	September 07, 2025 *	November 2025	January 2026	April 2026
October 12, 2025 *	November 12, 2025 *	January 07, 2026 *	March 2026	May 2026	July 2026
February 12, 2026 *	March 12, 2026 *	May 07, 2026 *	July 2026	October 2026	December 2026
June 12, 2026 *	July 12, 2026 *	September 07, 2026 *	November 2026	January 2027	April 2027
October 12, 2026 *	November 12, 2026 *	January 07, 2027 *	March 2027	May 2027	July 2027
February 12, 2027 *	March 12, 2027 *	May 07, 2027 *	July 2027	October 2027	December 2027

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

Candidates 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.

Expiration Date

May 08, 2027

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Career Development (K) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed to do otherwise (in this NOFO or in a Notice from the [NIH Guide for Grants and Contracts \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11164\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11164)). Conformance to all requirements (both in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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

1. Use the NIH ASSIST system 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](#) (<https://public.era.nih.gov/commons/>) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov](#) ([/grants/guide/ApplyButtonSplash.cfm?dest=https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-24-194](https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-24-194)) Workspace to prepare and submit your application and [eRA Commons](#) (<http://public.era.nih.gov/commons/>) to track your application.

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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 Research Training and Career Development](#) (https://grants.nih.gov/grants/guide/url_redirect.php?id=41159) website.

The purpose of the NIH Pathway to Independence Award (K99/R00) is to help postdoctoral researchers complete needed, mentored training and transition in a timely manner to independent, tenure-track or equivalent faculty positions. The K99/R00 award is intended to foster the development of an independent research program that will be competitive for subsequent independent funding and that will help advance the mission of the NIH. Candidates must have no more than 4 years of postdoctoral research experience at the time of the initial or the subsequent resubmission or revision application. The K99/R00 award is intended for individuals who require at least 12 months of mentored research and career development (K99 phase) before transitioning to the R00 award phase of the program. Consequently, the strongest candidates will require, and will propose, a well-conceived plan for 1–2 years of substantive mentored research and career development that will help them become competitive candidates for tenure-track faculty positions and prepare them to launch robust, independent research programs. *An individual who cannot provide a compelling rationale for at least one year of additional mentored research experience and career development at the time of award is not a strong candidate for this award.*

Individuals must be in mentored, postdoctoral training positions to be eligible to apply to the K99/R00 program. If a candidate achieves independence (any faculty or non-mentored research position) before a K99 award is made, neither the K99, nor the R00 award, will be made.

The K99/R00 award will provide up to 5 years of support in two phases. The initial (K99) phase will provide support for up to 2 years of mentored postdoctoral research training and career development. The second (R00) phase will provide up to 3 years of independent research support, which is contingent on satisfactory progress during the K99 phase and an approved, independent, tenure-track (or equivalent) faculty position. The two award phases are intended to be continuous in time. Therefore, although exceptions may be possible in limited circumstances, R00 awards will generally only be made to those K99 PDs/PIs who accept independent, tenure-track (or equivalent) faculty positions by the end of the K99 award period.

Additional Information for Clinician-Scientists: For the purposes of this program, physician-scientists include individuals with an MD, DO, DDS/DMD, DVM/VMD, or nurses with research doctoral degrees who devote the majority of their time to biomedical research. The K99/R00 is intended for those physician-scientists who already have substantial research training and are dedicated to initiating a strong, research-intensive career as physician-scientists. The K99/R00 program is designed to facilitate a timely transition of outstanding physician-scientists from mentored, research positions to independent, tenure-track or equivalent faculty positions, and to provide independent NIH research support during the transition. Individuals who need a longer period of mentored career development before they are prepared to begin the transition to research independence should consider the K08 or K23 program (see: [K Kiosk \(https://researchtraining.nih.gov/programs/career-development\)](https://researchtraining.nih.gov/programs/career-development))).

Note: This Notice of Funding Opportunity (NOFO) is designed specifically for proposing research that does not involve leading an independent clinical trial, a clinical trial feasibility study, or an ancillary clinical trial. Under this NOFO, candidates are permitted to propose a research experience in a clinical trial led by a mentor or co-mentor. Those proposing a clinical trial or an ancillary clinical trial as lead investigator, should apply to the companion NOFO ([PA-24-193 \(https://grants.nih.gov/grants/guide/pa-files/PA-24-193.html\)](https://grants.nih.gov/grants/guide/pa-files/PA-24-193.html))).

Special Note: Because of the differences in individual Institute and Center (IC) program requirements for this NOFO, prospective candidates are strongly encouraged to consult the [Table of IC-Specific Information, Requirements and Staff Contacts \(https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.html\)](https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.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 financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Resubmission
Revision

The [OER Glossary \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11116\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11116) and the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) provides details on these application types.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials.

Note: Candidates may propose to gain experience in a clinical trial led by a mentor/co-mentor as part of their research career development.

[Need help determining whether you are doing a clinical trial? \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82370\)](https://grants.nih.gov/grants/guide/url_redirect.php?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 5 years.

Other Award Budget Information

Salary

Salary and research costs may be requested to the level provided by the awarding Institute or Center. Candidates should consult the following table for IC-specific, programmatic and budgetary information (see the [Table of IC-Specific Information, Requirements and Staff Contacts \(https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.html\)](https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.html)). Further guidance on budgeting for career development salaries is provided in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

Intramural Program: Mentored award recipients in the NIH intramural program will be supported by intramural funds provided by the NIH Institute/Center intramural laboratory in which they are conducting their research. Budget details for the mentored phase will be negotiated with the sponsoring intramural laboratory. Salary will be consistent with that offered scientists in similar, intramural NIH positions.

Extramural Program: Mentored award recipients at an extramural sponsoring institution/organization will be supported by NIH extramural funds. The requested salary must be consistent both with the established salary structure at the institution and with salaries actually provided by the institution from its own funds to other staff members with equivalent qualifications, rank, and responsibilities in the department concerned. Further guidance on budgeting for career development salaries is provided in the SF424 (R&R) Application Guide.

In addition, the candidate may derive additional compensation for effort associated with other Federal sources or awards provided the total salary derived from all Federal sources does not exceed the maximum legislated salary rate (see https://grants.nih.gov/grants/policy/salcap_summary.htm, (https://grants.nih.gov/grants/policy/salcap_summary.htm)) and the total percent effort does not exceed 100%. See also [NOT-OD-17-094 \(https://grants.nih.gov/grants/guide/notice-files/not-od-17-094.html\)](https://grants.nih.gov/grants/guide/notice-files/not-od-17-094.html).

Independent Phase (R00)

The total cost for the independent phase (R00) may not exceed \$249,000 per year. This amount includes salary, fringe benefits, research costs, and applicable indirect costs. Indirect costs will be reimbursed at the extramural sponsoring institution's indirect cost rate. Indirect costs requested by consortium participants are included in the total cost limitation.

Other Program-Related Expenses

Participating NIH Institutes and Centers will provide research development support for the award recipient (see [Table of IC-Specific Information, Requirements and Staff Contacts \(https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.html\)](https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.html)). These funds may be used for the following expenses (a) tuition and fees related to career development; (b) research-related expenses, such as supplies, equipment and technical personnel; (c) travel to research meetings or training; and (d) statistical services including personnel and computer time. .

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

Indirect Costs

For the extramural K99 phase, Indirect Costs (also known as Facilities & Administrative [F&A] Costs) are reimbursed at 8% of modified total direct costs. For the R00 phase, indirect costs will be reimbursed at the extramural sponsoring institution's indirect cost rate.

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

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- 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)

Local Governments

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

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

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

The sponsoring institution may be private (profit or nonprofit) or public, including the NIH Intramural Programs and other Federal laboratories.

The applicant institution will be the mentored phase (K99) institution. All institution/organization types listed above are eligible for both the mentored (K99) and independent (R00) phase, with the following exceptions: (1) Eligible agencies of the Federal government, such as the NIH intramural program, are eligible only for the mentored phase; and (2) Eligibility of organizations, other than institutions of higher education, for the R00 phase depends on the nature of the appointment, and the ability of the PD/PI to conduct independent research and apply for NIH research (R01 or R01-equivalent) grants.

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **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 \(//grants.nih.gov/grants/guide/url_redirect.php?id=11118\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) to be eligible to apply for or receive an award. All registrations must be completed prior to the application being resubmitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference [NIH Grants Policy Statement 2.3.9.2 Electronically Submitted Applications \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82423\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82423) for additional information.

- [System for Award Management \(SAM\) – \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82390\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82390) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
 - [NATO Commercial and Government Entity \(NCAGE\) Code \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11176\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
 - Unique Entity Identifier (UEI) - A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- [eRA Commons \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82300\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

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

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

All PD(s)/PI(s) must be registered with [ORCID \(https://orcid.org/\)](https://orcid.org/). The personal profile associated with the PD(s)/PI(s) eRA Commons account must be linked to a valid ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the [ORCID topic in our eRA Commons online help \(https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D____29\)](https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D____29).

Eligible Individuals (Program Director/Principal Investigator)

Candidates for the K99/R00 are strongly encouraged to obtain confirmation of their eligibility from the relevant IC before they begin to prepare their applications. It is incumbent upon the candidate to provide evidence that they meet all of the eligibility criteria outlined below.

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 their mentor and organization to develop an application for support. Individuals from diverse backgrounds, including individuals from underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, [NOT-OD-22-019 \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-019.html). Multiple PDs/PIs are not allowed.

K99/R00 applicants must have no more than 4 years of postdoctoral research experience as of the relevant application due date regardless of whether it is a new or resubmission application. Individuals must be in mentored, postdoctoral training positions to be eligible to apply to the K99/R00 program. If the candidate achieves independence (i.e., any faculty or non-mentored research position) before a K99 award is made, neither the K99 award, nor the R00 award, will be issued.

Consistent with the [NIH Extension Policy for Early Stage Investigator Status \(ESI\) \(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-235.html\)](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-235.html), NIH will approve an extension of one year for childbirth within the 4 year K99 eligibility window. Applicants who will be PD/PIs on a K99 application must provide the child's date of birth in the extension request justification submitted to IC program officials and/or scientific/research contacts listed in the NOFO at least 12 weeks before submitting an application.

In addition, parental, medical, military, or other well-justified leave for personal or family situations of generally less than 12 months duration is typically not included in the 4-year eligibility limit, nor is clinical training with no research involvement (e.g., full-time residency training). Only time dedicated to research activities counts toward the 4-year limit. Part-time postdoctoral research

training, related to personal or family situations or occurring during a research residency or fellowship, will be pro-rated accordingly.

Additional clarifications are provided under [Frequently Asked Questions \(https://grants.nih.gov/grants/new_investigators/QsandAs.htm\)](https://grants.nih.gov/grants/new_investigators/QsandAs.htm). Potential candidates are encouraged to discuss their individual situation with a [NIH Institute or Center Scientific Program Contact \(https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.html\)](https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.html) before applying.

There is no citizenship requirement for K99 candidates. A candidate may be a citizen or a non-citizen national of the United States, 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), or be a non-U.S. citizen.

For applications submitted on behalf of non-U.S. citizens with temporary U.S. visas, visa status during each phase of the K99/R00 award must allow the PD/PI to conduct the proposed research at the applicant institution. For the K99 phase of the award, the applicant institution is responsible for determining and documenting, in the K99 application, that the candidate's visa will allow them to remain in the U.S. long enough to complete the K99 phase of the award. For the R00 phase of the award, the U.S. institution at which the R00 phase of the award will be conducted is responsible for determining and documenting, in the R00 application, that the PD/PI's visa will allow the PD/PI to remain in the U.S. for the duration of the R00 award.

Candidates for the K99/R00 award must have a clinical or research doctorate (including PhD, MD, DO, DC, ND, DDS, DMD, DVM, ScD, DNS, PharmD or equivalent doctoral degrees). Clinicians (including those with MD, DDS, DVM and other licensed health professionals) in a clinical faculty position that denotes independence in clinical responsibilities but not in research may also be eligible for the K99/R00 award.

Individuals are NOT eligible if they:

- Have currently or previously held an independent research faculty or tenure-track faculty position, or its equivalent, in academia, industry or elsewhere; or
- Have more than 4 years of related postdoctoral research training at the time of initial application or resubmission; or
- Have been an independent PD/PI on NIH research grants (e.g. R01, R03, R21), NIH career development awards (e.g., K01, K07, K08, K23, K25), or other peer-reviewed NIH or non-NIH research grants over \$100,000 direct costs per year, or Project Leaders on sub-projects of program project (P01) or center (P50) grants or the equivalent.

Ph.D. (or equivalent research doctorate degree) candidates in positions other than postdoctoral fellow positions: It is recognized that some institutions appoint postdoctoral fellows in positions with other titles although they are still in non-independent, mentored training positions. Candidates in such positions are encouraged to obtain confirmation of their eligibility from the relevant IC **before** they begin to prepare their applications. It is incumbent upon the candidate to provide evidence that their position complies with the intent of this eligibility requirement. If a potential candidate is in a position that is not clearly identifiable as a postdoctoral training position, the candidate should provide the relevant NIH Institute or Center an official statement of the institution's policy (e.g. published position description in an official institutional document) which documents the position as a mentored, postdoctoral training position.

Clinicians (including those with M.D., D.D.S, D.V.M. and other licensed professionals) in positions not designated as postdoctoral positions: Following clinical training or fellowship training periods, clinicians often obtain a clinical faculty position that denotes independence in clinical responsibilities but not in research. A clinical faculty member who does not hold an independent research faculty position may be eligible for the K99/R00 award, and should contact a Program Director at the relevant NIH Institute for guidance. Clinicians in such positions are encouraged to obtain confirmation of their eligibility before they begin to prepare their applications. Such individuals may also wish to consider other career awards ([see K Kiosk \(//grants.nih.gov/training/careerdevelopmentawards.htm\)](https://grants.nih.gov/training/careerdevelopmentawards.htm)) available for junior faculty development.

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 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 their independent research.
- The candidate has research space dedicated to their 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 NOFO does not require cost sharing as defined in the [NIH Grants Policy Statement Section 1.2 Definitions of Terms](https://grants.nih.gov/grants/guide/uri_redirect.php?id=11126) ([//grants.nih.gov/grants/guide/uri_redirect.php?id=11126](https://grants.nih.gov/grants/guide/uri_redirect.php?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.

NIH will not accept duplicate or highly overlapping applications under review at the same time per [NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82415) ([//grants.nih.gov/grants/guide/uri_redirect.php?id=82415](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82415)). 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 [NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82423) ([//grants.nih.gov/grants/guide/uri_redirect.php?id=82423](https://grants.nih.gov/grants/guide/uri_redirect.php?id=82423))).

Level of Effort

K99 Phase. 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. 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. Physician-scientists in surgical specialties may request a minimum of 50% of full-time professional effort.

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-18-156](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-156.html) (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-156.html>) and [NIH Grants Policy Statement](https://grants.nih.gov/grants/policy/nihgps/html5/section_12/12.3.6_level_of_effort.htm) (https://grants.nih.gov/grants/policy/nihgps/html5/section_12/12.3.6_level_of_effort.htm), Section 12.3.6.4 Temporary Adjustments to the Percent Effort Requirement for more details

R00 Phase. Although candidates are required to devote no less than 75% (no less than 50% effort for surgical specialties) of their full-time, 12-month professional effort to research (i.e., full-time for 9 person-months), the required 9 person-months of research effort need not be devoted exclusively to the R00-supported research.

Mentor(s)

Before submitting the application, the candidate must identify a mentor who will supervise the proposed career development and research experience. The mentor should be an active investigator in the area of the proposed research and be committed both to

the career development of the candidate and to the direct supervision of the candidate's research. The mentor must document the availability of sufficient research support and facilities. Candidates are encouraged to identify more than one mentor, i.e., a mentoring team (advisory committee), if this is deemed advantageous for providing expert advice in all aspects of the research career development program. In such cases, one individual must be identified as the primary mentor who will coordinate the candidate's research. Candidates holding a clinical doctorate should include at least one individual with a clinical doctorate on the mentoring team. Candidates also are encouraged to propose a mentoring team that will provide additional guidance typically towards professional aspects of the candidate's career development. The candidate must work with the mentor(s) in preparing the application. The mentor, or a member of the mentoring team, should have a successful track record of mentoring individuals at the candidate's career stage. The recruitment of women, individuals from underrepresented racial and ethnic groups, and individuals with disabilities as potential mentors is encouraged.

The mentor(s) or mentoring team must demonstrate appropriate expertise, experience, and ability to guide the candidate. If the primary mentor has limited training experience, a co-mentor with a strong, successful track record as a mentor should also be included.

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

Buttons to access the online ASSIST system or to download application forms are available in [Part 1](#) of this NOFO. 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 instructions in the Career Development (K) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) 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 \(https://grants.nih.gov/grants/guide/url_redirect.php?id=41137\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=41137).

Page Limitations

All page limitations described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and the [Table of Page Limits \(https://grants.nih.gov/grants/guide/url_redirect.php?id=61134\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=61134) must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

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

SF424(R&R) Project/Performance Site Locations

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

Other Project Information

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

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

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

R&R Budget

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

The following additional instructions apply to this NOFO:

Provide itemized budget information for each budget period covered under the K99 phase.

Itemized budget information is not required for the R00 phase; a total requested amount for each budget period is acceptable. However, some basic information must be completed in order for NIH to successfully process the budget form. For each budget period of the R00 phase:

- Select the appropriate Budget Type
- Provide the Budget Period Start Date and End Date
- In Section A: Senior/Key Persons provide an entry for the PD/PI, including the appropriate level of effort, \$0 for Requested Salary and \$0 for Fringe Benefits
- In Section F: Other Direct Costs add a line item titled R00 Independent Phase and provide the total request for that period (up to \$249,000).

At the time of transition to the R00 phase, the R00 applicant institution will submit a detailed budget for each budget period of the R00 project period that reflects the direct and indirect costs at the R00 applicant institution.

PHS 398 Cover Page Supplement

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

Candidate Section

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) 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, behavioral, or clinical research field relevant to the mission of one of the participating NIH ICs.
- Describe the candidate's potential to develop into a successful, independent investigator.

Career Goals and Objectives

- Describe the candidate's current and long-term research and career objectives.
- Present a scientific history that: (1) shows a logical progression from the candidate's prior research and career development experiences to the training and research experiences proposed for the mentored phase of the award (K99) and subsequently to the independent phase of the award (R00); and (2) justifies the need for further mentored career development to become an independent research investigator.
- 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.
- Describe how the candidate plans to separate scientifically from his/her mentor and advance to research independence.

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

- A systematic plan should be presented for obtaining the biomedical, behavioral, or clinical science background, research experience, and career development activities necessary to launch an 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 specifically tailored to meet the needs of the candidate and the goal of achieving independence as a researcher.
- Describe how the skills and knowledge obtained during the mentored phase will enhance research productivity and facilitate the development of new approaches and directions for investigation. Describe how the career development plan will promote the candidate's success and transition to scientific independence. Candidates must justify the need for the award, particularly the mentored (K99) phase, and must provide a convincing case that the proposed period of support (1-2 years as a mentored candidate followed by up to 3 years as an independent scientist) will substantially enhance their career and/or will allow the pursuit of a novel or promising approach to a particular research problem. Candidates should make clear why additional mentored research and career development are critical before transitioning to research independence and pursuit of the proposed independent phase research.
 - The candidate must describe a plan, including a timeline with milestones, for evaluation of their progress during the mentored phase and for the transition to the independent phase.

Research Plan Section

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed, with the following additional instructions:

Research Strategy

- The research plan must span both phases of the K99/R00 award. The candidate should clearly indicate the research planned for each phase. This narrative should describe what the candidate will accomplish during the mentored phase research that will enable them to launch an independent research program (i.e., what does the candidate still need to accomplish during the mentored phase in order to compete successfully once independence is achieved).
- The research plan should state the significance, innovation and approach of the proposed research during the K99 and R00 phases of the award. The research plan should provide a detailed rationale, experimental approach, and expected/alternative outcomes for the proposed studies. Although it is anticipated that candidates will be best able to describe their current and past research, the research plan for the R00 phase of the award should be described in sufficient detail for reviewers to evaluate the merit of this component of the application.
- Describe the relationship between the mentor's research and the candidate's proposed research. Describe how the candidate will gain independence from their mentor(s) and separate their scientific research program from that of the mentor(s).
- If the candidate is proposing to gain experience in a clinical trial, ancillary 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.

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

Mentor, Co-Mentor, Consultant, Collaborators Section

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed, with the following additional instructions:

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

- The application must include a statement from the primary mentor that provides: 1) information on their research qualifications and previous experience as a research supervisor; 2) a plan describing the nature of the supervision and mentoring that will occur during the proposed K99 award period, including how the candidate's scientific and professional independence will be promoted; 3) a description of the elements of the planned research training and career development, including any formal course-work; 4) a plan for transitioning the candidate from the mentored phase to the independent phase of the award and a description of how the mentor will help the candidate achieve scientific independence from their mentor(s); 5) a statement identifying the components of the proposed research that the K99 applicant can take when they transition to research independence and that can be part of their independent (R00) phase award; and 6) when appropriate, a statement affirming any resources and reagents that can be taken by the applicant to the independent phase of the award.

- The mentor should have sufficient independent research support to cover the costs of the proposed K99 research project in excess of the allowable costs of this award, and should state that needed costs will be covered. If funds are needed beyond what will be provided by the mentor, the source of additional funds should be identified and documented in a letter signed by the responsible individual.
- Similar information must be provided by all co-mentors. If more than one mentor is proposed, the respective areas of expertise, the responsibility of each, and the nature of the involvement with the candidate should be explicitly described. Co-mentors should describe clearly how they will coordinate with the primary mentor and the candidate to provide an integrated mentoring effort.
- The primary mentor must agree to write and provide annual evaluations of the candidate's progress for the initial mentored phase as required in the annual progress report.
- The mentor must agree to assist the candidate in transitioning to an independent research position by guiding the candidate during the job search and negotiation process and by commenting on the R00 phase application.
- If the candidate is proposing to gain experience in a clinical trial as part of their research career development, the mentor, co-mentor, or a member of the mentoring team must include a statement to document leadership of the clinical trial, and appropriate expertise to guide the applicant in any proposed clinical trials research experience.

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. Unless also listed as senior/key personnel, collaborators and consultants do not need to provide their biographical sketches. However, information should be provided clearly documenting the appropriate expertise in the proposed areas of consulting/collaboration.
- Advisory committee members (if applicable): Signed statements must be provided by each member of the proposed advisory committee. These statements should confirm their participation, describe their specific roles, and document the expertise they will contribute. Unless also listed as senior/key personnel, these individuals do not need to provide their biographical sketches.

Environmental and Institutional Commitment to the Candidate

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) 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 for the development of the candidate's research career and the pursuit of the proposed research plan.

Institutional Commitment to the Candidate's Research Career Development

- The sponsoring institution must provide a statement of commitment to the candidate's development into a productive, independent investigator, i.e. conducting the proposed mentored research and career development during the K99 phase and competing for, and transitioning to, a tenure-track assistant professor position at an academic institution. While the K99 phase sponsoring institution is not responsible for sponsoring the applicant during the R00 phase, it should be supportive of the candidate prior to initiation of the R00 phase.
- Provide assurance 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 research facilities, resources, and training opportunities, including faculty capable of productive collaboration with the candidate, will be available for the candidate's planned career development and research programs during the K99 award period.
- Provide assurance that appropriate time and support for any proposed mentor(s) and/or other staff consistent with the career development plan will be available during the K99 award period.
- For individuals in postdoctoral positions with other titles although still in non-independent, mentored training positions, provide evidence of eligibility for the K99/R00 program.
- If the candidate is not a U.S. Citizen or permanent resident, the sponsoring institution must include information about the candidate's visa status, an assurance that the candidate's visa provides sufficient time to complete the K99 phase of the

award at a U.S. institution, and assurance that there are no known obstacles (e.g. home country requirement) to the candidate obtaining a visa at the time of the R00 transition.

Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) must be followed, with the following additional instructions:

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

Appendix:

Limited items are allowed in the Appendix. Follow all instructions for the Appendix as described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400); any instructions provided here are in addition to the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400) instructions.

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 [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

- For NOFOs that do not allow independent clinical trials, do not complete Section 4 – Protocol Synopsis information or Section 5 - Other Clinical Trial-related Attachments.

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).

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

PHS Assignment Request Form

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

Reference Letters

Candidates must carefully follow the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400), **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 and not through Grants.gov.

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

See Part 2. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

[Part I](#) contains information about Key Dates and Times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or [Federal holiday \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82380\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(//grants.nih.gov/grants/guide/url_redirect.php?id=11128\)](https://grants.nih.gov/grants/guide/url_redirect.php?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 \(//grants.nih.gov/grants/guide/url_redirect.php?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(//grants.nih.gov/grants/guide/url_redirect.php?id=82423\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82423).

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

Information on the submission process and a definition of on-time submission are provided in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

5. Intergovernmental Review (E.O. 12372)

[This initiative is not subject to \(//grants.nih.gov/grants/guide/url_redirect.php?id=11142\)intergovernmental review. \(https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm\)](https://grants.nih.gov/grants/guide/url_redirect.php?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 Section 7.9.1 Selected Items of Cost \(//grants.nih.gov/grants/guide/url_redirect.php?id=11143\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11143).

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

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). 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 \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Dealing with System Issues \(https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm\)](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 form. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82400).

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

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

Post Submission Materials

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

Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

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

For this particular announcement, note the following: Reviewers should evaluate the candidate's potential for obtaining a tenure-track or equivalent faculty position and developing an independent research program that will make important contributions to the field. Reviewers should consider in their evaluation the likely value of the proposed K99 phase research and career development in facilitating transition to research independence, and the feasibility of the proposed research project as a vehicle for developing a successful, independent research program after transition to the R00 award phase.

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.

Candidate

- Based on the candidate's prior research and training experience, track record, referee's evaluations, and the quality and originality of prior research and the current application, what is the candidate's potential to become a highly successful, independent investigator who will contribute significantly to their chosen field of biomedical, behavioral, or clinical related research?
- 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?
- What is the quality of the candidate's pre- and postdoctoral research training, with respect to development of appropriate scientific and technical expertise?
- Given the candidate's prior training, proposed career development plan, and the referees' evaluations, is it reasonable to expect that the candidate will be able to achieve an independent, tenure-track or equivalent faculty position within the time period requested for the K99 phase of this award?

Career Development Plan/Career Goals and Objectives

- Are the content and duration of the proposed components of the career development plan appropriate and well-justified for the candidate's current stage of scientific and professional development and proposed research career goals?
- To what extent does the proposed career development plan enhance or augment the applicant's research training and skills acquisition to date?
- Is the proposed career development plan likely to contribute substantially to the scientific and professional development of the candidate, and facilitate their successful transition to independence?
- To what extent are the plans for evaluating the K99 recipient's progress adequate and appropriate for guiding the candidate towards a successful transition to the independent phase of the award?
- Is the timeline planned for transition to the independent phase of the award appropriate for the candidate's current stage of scientific and professional development, anticipated productivity, and the career development proposed for the K99 phase of the award?
- If proposed, will the clinical trial experience contribute to the applicant's research career development?

Research Plan

- Is the proposed K99 phase research significant and scientifically sound?
- Is the prior research that serves as the key support for the proposed project rigorous?
- Has the candidate included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?
- 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?

- Are the scientific and technical merits of the K99 research appropriate for developing the research skills described in the career development plan, and appropriate for developing a highly successful R00 research program?
- Is the proposed R00 phase research significant, scientifically sound, and a logical extension of the K99 phase research? Is there evidence of long-term viability of the proposed R00 phase research plan?
- Does the R00 phase project address an innovative hypothesis or challenge existing paradigms? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies?
- To what extent is the proposed R00 phase research likely to foster the career of the candidate as a successful, independent investigator in biomedical, behavioral, or clinical research?
- If proposed, will the clinical trial experience contribute to the research project?

Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)

- To what extent does the mentor(s) have a strong track record in training future independent researchers?
- To what extent are the mentor's research qualifications and experience, scientific stature, and mentoring track record appropriate for the applicant's career development needs?
- Is the supervision proposed for the mentored phase of support adequate, and is the commitment of the mentor(s) to the applicant's career development appropriate and sufficient?
- Does the mentor provide an appropriate plan that addresses the candidate's training needs, and that is likely to foster the candidate's continued development and transition to independence?
- Does the mentor describe an acceptable plan for clear separation of the candidate's research and research career from the mentor's research, including identifying the components of the research plan that the K99 candidate may take to an independent research position?
- Are the consultants /collaborators research and/or mentoring qualifications appropriate for their roles in the proposed K99 phase of the award? Do they provide letters of support that affirm their commitment? If applicable, are the Advisory Committee members qualifications appropriate for their roles in the proposed K99 phase of the award?
- If the candidate is proposing to gain experience in a clinical trial as part of their research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the candidate during participation in the clinical trial?

Environment & Institutional Commitment to the Candidate

- To what extent does the institution provide a high quality environment appropriate for the candidate's development during the K99 phase of the award?
- To what extent are the research facilities and educational opportunities, including collaborating faculty, adequate and appropriate for the candidate's research and career development goals during the K99 phase of the award? Is adequate evidence provided that the K99 sponsoring institution is strongly committed to fostering the candidate's development and preparation for transition to independence?
- Is there adequate assurance that the required minimum of 9 person months (75% of the candidate's full-time professional effort) will be devoted directly to the research training, career development, and research activities proposed for the K99 phase of the award?

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.

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 \(//grants.nih.gov/grants/guide/redirect.php?id=11175\)](https://grants.nih.gov/grants/guide/redirect.php?id=11175).

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of

individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research](https://grants.nih.gov/grants/guide/redirect.php?id=11174) (<https://grants.nih.gov/grants/guide/redirect.php?id=11174>).

Vertebrate Animals

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

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.

Resource Sharing Plans

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

Training in the Responsible Conduct of Research

All applications for support under this NOFO 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 candidate, including any prior instruction or participation in RCR as appropriate for the candidate'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](https://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](https://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).

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 policies and practices \(//grants.nih.gov/grants/guide/redirect.php?id=11154\)](https://grants.nih.gov/grants/guide/redirect.php?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 \(//grants.nih.gov/grants/guide/redirect.php?id=11123\)](https://grants.nih.gov/grants/guide/redirect.php?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement Section 2.4.4 Disposition of Applications \(//grants.nih.gov/grants/guide/redirect.php?id=82416\)](https://grants.nih.gov/grants/guide/redirect.php?id=82416).

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 \(//grants.nih.gov/grants/guide/redirect.php?id=82418\)](https://grants.nih.gov/grants/guide/redirect.php?id=82418). This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

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 recipient's business official.

Recipients must comply with any funding restrictions described in [Section IV.6. 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 NOFO will be subject to terms and conditions found on the [Award Conditions and Information for NIH Grants \(https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/part_ii_subpart_b.htm) 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) associated with the K99 phase of the award conducted in the NIH intramural program. The awarding Institute will transmit to the successful candidate an approval letter which will include the terms and conditions of the NIH intramural K99 award, as well as expectations for the transition to the R00 phase of the award.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the [NIH Grants Policy Statement \(//grants.nih.gov/grants/guide/url_redirect.php?id=11120\)](https://grants.nih.gov/grants/guide/url_redirect.php?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 \(//grants.nih.gov/grants/guide/url_redirect.php?id=11157\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11157) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities \(//grants.nih.gov/grants/guide/url_redirect.php?id=11159\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11159), including of note, but not limited to:

- [Federal-wide Standard Terms and Conditions for Research Grants \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_3/3.1_federalwide_standard_terms_and_conditions_for_research_grants.htm)
- [Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment \(//grants.nih.gov/grants/guide/url_redirect.php?id=82417\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82417)
- [Acknowledgment of Federal Funding \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.2.1_acknowledgement_of_federal_funding.htm)

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance ([HHS-690 \(https://www.hhs.gov/sites/default/files/form-hhs690.pdf\)](https://www.hhs.gov/sites/default/files/form-hhs690.pdf)). To learn more, see [Laws and Regulations Enforced by the HHS Office for Civil Rights website \(https://www.hhs.gov/civil-rights/providers/laws-regulations-guidance/laws/index.html\)](https://www.hhs.gov/civil-rights/providers/laws-regulations-guidance/laws/index.html).

HHS recognizes that NIH 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 NOFO.

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 System for Award Management (SAM.gov) requirements. SAM.gov requires Federal agencies to review and consider information about an applicant in the designated integrity and performance system (currently SAM.gov) prior to making an award. An applicant can review and comment on any information in the responsibility/qualification records available in SAM.gov. NIH will consider any comments by the applicant, in addition to the information available in the responsibility/qualification records in SAM.gov, 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 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

Transition to the Independent Phase

Transition from the mentored phase to the independent phase is intended to be continuous in time and, except in unusual, extenuating circumstances, the awarding NIH Institute/Center will not extend the K99 phase beyond the 2-year limit. ICs may, at their discretion, make exceptions to this time limitation when individuals have been invited for faculty job interviews but final decisions have not yet been made by the potential R00 institution or, rarely, because of unusual, extenuating circumstances. To activate the independent phase of the grant, individuals must have been offered and accepted a tenure-track, full-time assistant professor position (or equivalent) by the end of the K99 project period.

An eligible R00 institution will have appropriate infrastructure to support the proposed research program and a history of external research funding. K99 recipients are free to apply for independent phase positions within the NIH intramural research program (IRP). However, should the individual accept such a position in the IRP, the independent phase of the award will not be activated. This is because NIH intramural scientists are supported directly by NIH intramural funds and are not eligible for NIH extramural grant awards. Eligibility of for-profit organizations for the R00 phase depends on the nature of the appointment, and the ability of the PD/PI to conduct independent research and apply for NIH R01 or R01-equivalent research grants. PIs are encouraged to discuss job offers at for-profit organizations with NIH Program staff well in advance of accepting such an offer.

To avoid potential problems in activating the independent phase, recipients are strongly encouraged to contact their NIH program official as soon as plans to apply for and, assume an independent position develop, and not later than 6 months prior to the termination of the K99 phase of the award.

At that time, individuals should discuss plans for transition to, and application for, the R00 phase with their NIH program official. The application for the R00 phase of the award should be submitted no later than 2 months prior to the proposed activation date of the R00 award by the R00 phase recipient organization.

The independent phase institution will submit an application on behalf of the candidate for the R00 award using the [PHS 398 Application \(//grants.nih.gov/grants/guide/url_redirect.php?id=22000\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=22000). The R00 application must include:

- A new face page signed by the R00 phase institutional representative;
- A new project description page (the project summary or abstract should be updated to reflect current plans for the R00 phase);
- Detailed budget pages for a non-modular budget;
- Biographical sketches for the PD/PI and any other Key Personnel;
- A new Resources page;
- A brief description of progress made during the K99 phase that will serve as the Final Progress Report for the K99 phase;
- An updated research plan (the specific aims should be updated to reflect current plans for the R00 phase and the updated research plan should be briefly described in less than 5 pages);
- Updated Protections for Human Subjects and Inclusion of Women, Minorities and Individuals across the Lifespan (as appropriate);
- Authentication of Key Biological and/or Chemical Resources (as appropriate);
- Updated Vertebrate Animals (as appropriate);
- Updated Biohazards (as appropriate); and
- A new checklist.

These materials should be sent directly to the awarding Institute or Center (IC). The original application plus one copy (preferably in PDF format) are to be mailed (or e-mailed) to the Financial or Grants Management contact person of the awarding NIH Institute or Center listed in the Notice of Award. The R00 application will be evaluated by extramural Program staff of the awarding component for completeness and appropriateness to the program.

Two additional documents are included with the R00 application. A letter from the R00 Department or Division Chairman must be submitted that describes the R00 institution's commitment to the candidate and plans for their career development (see below). If not already provided, the final evaluation statement by the K99 phase mentor, must be provided.

In addition to space, facilities, resources, and other support needed to conduct the proposed research, the sponsoring institution must provide protected research time (minimum of 9 person-months or 75% of the candidate's full time professional effort) at least for the duration of the R00 award. The start-up package and other institutional support must be described in detail and must be comparable to that given to other faculty recently hired into tenure-track or equivalent faculty positions. Institutions must provide a startup and salary package equivalent to that provided to a newly hired faculty member who does not have a grant; R00 funds may not be used to offset the typical startup package or to offset the usual institutional commitment to provide salary for tenure-track (or equivalent) assistant professors who are hired without grant support. The R00 sponsoring institution must describe the candidate's academic appointment, bearing in mind that it must be tenure-track assistant professor (or equivalent), and confirm that the appointment is not contingent on the transfer of the award to the institution. The R00 phase institution must describe how the recipient's ability to apply for and secure independent research grant (R01) support will be fostered and supported during the R00 phase of the award.

The R00 award requires that a minimum of 9 person months (75% of the candidate's full time professional effort) be devoted to research activities. Consequently, teaching, clinical duties and other non-research activities should be minimal during the R00 award period. NIH staff may review start-up packages and other commitments between the institution and candidate prior to activating the independent phase of the award. It is suggested that the applicant and/or the hiring institution discuss the institutional commitment with the relevant NIH institute Program Official prior to finalizing the offer. NIH will not activate the independent phase if the institutional commitment is deemed inadequate. Recipients who are approved to transition will receive a Notice of Award reflecting the new R00 grant mechanism, the dollar amount, and the new recipient organization (if applicable).

The K99/R00 award is intended to facilitate successful transition to independence. Consequently, a requirement for activation of the R00 phase is successful completion of this transition. K99 recipients are encouraged (but not required) to apply for independent positions at departments and institutions different from where they conducted their mentored research. It is important for all recipients, but especially so for those who intend to stay at the mentored phase institution for the independent phase, to provide a plan by which they will separate from their mentor and advance to independence. Recipients are also encouraged to include a plan and timeline for submitting an independent research grant application in a research area relevant to the mission of an NIH awarding component.

Candidates who are not approved to transition will receive written notification from the awarding component communicating the rationale for the disapproval. This notification typically will be sent within 60 days of receipt of the R00 application.

Although the financial plans of the NIH Institute or Center provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds.

Termination of the K99 award phase

If transition from the K99 phase at an extramural institution to the R00 phase occurs at the originally scheduled end date of the K99 award, then no specific steps to terminate the K99 award are necessary. If the transition at an extramural institution occurs prior to the scheduled end date, then a revised Notice of Award will be issued to terminate the K99 phase award. Carry-over of unspent funds from a partially completed year in the K99 phase into the R00 phase may be permitted.

3. Data Management and Sharing

Consistent with the 2023 NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.2.3_sharing_research_resources.htm#Data). Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients will be required to submit the [Research Performance Progress Report \(RPPR\) \(https://grants.nih.gov/grants/rppr/index.htm\)](https://grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82419\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82419). The Supplemental Instructions for Individual Career Development (K) RPPRs must be followed. For mentored awards, 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 \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.6_closeout.htm). NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 2 CFR 200.301.

The Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (https://grants.nih.gov/grants/guide/url_redirect.php?id=11170) on all subawards over the threshold. See the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/guide/url_redirect.php?id=82420\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=82420) for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 2 CFR Part 200.113 and Appendix XII to 2 CFR Part 200, 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 (Responsibility/Qualification in SAM.gov, formerly 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 2 CFR Part 200 – Award Term and Condition for Recipient Integrity and Performance Matters.

5. Evaluation

In carrying out its stewardship of human resource-related programs, 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 NOFO, prospective applications **MUST** consult the [Table of IC-Specific Information, Requirements, and Staff Contacts \(https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.html\)](https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.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 on-time submission, and post-submission issues)

Finding Help Online: <https://www.era.nih.gov/need-help> (<https://www.era.nih.gov/need-help>) (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application processes and NIH grant resources)
Email: GrantsInfo@nih.gov (<mailto:GrantsInfo@nih.gov>) (preferred method of contact)
Telephone: 301-637-3015

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/IC-specific-information-PA-24-194.html) (<https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.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/IC-specific-information-PA-24-194.html) (<https://grants.nih.gov/grants/guide/contacts/IC-specific-information-PA-24-194.html>).

Section VIII. Other Information

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

Please note that the NIH Loan Repayment Programs (LRPs) 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 career development awards are encouraged to consider applying for an extramural LRP award.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 2 CFR Part 75.

[Weekly TOC for this Announcement](https://grants/guide/WeeklyIndex.cfm?04-26-24) ([/grants/guide/WeeklyIndex.cfm?04-26-24](https://grants/guide/WeeklyIndex.cfm?04-26-24))

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



National Institutes of Health [./grants/oer.htm](https://grants/oer.htm)

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