

PATHWAY TO INDEPENDENCE AWARD (K99/R00)

Program Announcements: PA-18-398 (Independent Clinical Trial Not allowed)

<https://grants.nih.gov/grants/guide/pa-files/PA-18-398.html>

PA-18-397 (Independent Clinical Trial Required)

<https://grants.nih.gov/grants/guide/pa-files/PA-18-397.html>

Note: the information below is extracted from the current Program Announcement; before applying for a K99/R00 award you should obtain and read the current program announcement and application instructions.

The objective of the NIH Pathway to Independence Award (K99/R00) is to help outstanding 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 a creative, independent research program that will be competitive for subsequent independent funding and that will help advance the mission of the NIH.

Applicants 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 training and career development (K99 phase) before transitioning to the R00 award phase of the program. Consequently, the strongest applicants will require, and will propose, a well-conceived plan for 1–2 years of substantive mentored research training 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 training at the time of award is not a strong candidate for this award.*

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 Physician-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

Prospective candidates are urged to consult the **Table of IC-Specific Information, Requirements and Staff**

Contacts at <https://grants.nih.gov/grants/guide/contacts/parent-K99-CT-required.html> or

<https://grants.nih.gov/grants/guide/contacts/parent-K99-CT-not-allowed.html>

Eligibility

K99 applicants must have no more than 4 years of postdoctoral research experience at the time of the initial or the subsequent resubmission or revision application, and must be in mentored, postdoctoral training positions. If an applicant 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.

Parental leave or other well-justified leave for pressing personal or family situations of generally less than 12 months duration (e.g., family care responsibilities, disability or illness, active military duty) is not included in the

4-year eligibility limit. In addition, time spent conducting postgraduate clinical training that does not involve research is not considered as part of the 4-year research training eligibility limit. Only time dedicated to research activities would count toward the 4-year limit.

There is no citizenship requirement for K99 applicants. An applicant 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.

Candidates 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(s); or
- Have been an independent principal investigator 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 program project (P01) or center (P50) grants.

Ph.D. (or equivalent research doctorate) 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 training positions.

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 other 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 be the responsible supervisor of graduate students.
- According to institutional policy, the candidate is not allowed to submit an application as the principal investigator 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 tenure track assistant professor position (or equivalent).
- The candidate received a startup package for support of his/her independent research.
- The candidate has research space dedicated to his/her own research.
- The candidate may attend faculty meetings, be the responsible supervisor for graduate students, and/or hire postdoctoral fellows.
- The candidate is eligible to apply for independent research funding as the principal investigator of an NIH R01 or other equivalent research grant.

Applicants are encouraged to obtain confirmation of their eligibility before they begin to prepare their applications by contacting a Program Director at the relevant NIH Institute for guidance.

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 career development and research training during the mentored phase. Physician-scientists in surgical specialties may request a minimum of 50% of full-time professional effort.

R00 Phase. Although candidates are required to devote no less than 75% 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 for high-quality research.

Candidates are encouraged to identify more than one mentor, i.e., a mentoring team, 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 principal 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. 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.

PHS 398 Career Development Award Supplemental Form

All instructions in the SF424 (R&R) Application Guide, including Supplemental Instructions to the SF424 (R&R) for Preparing an Individual Research Career Development Award (CDA) Application ("K" Series), must be followed, with the following additional instructions:

Candidate Information

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 training 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 or individual Ruth L. Kirschstein NRSA, 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 the stated independent research career. Describe current activities and how they relate to the candidate's career development plans and career goals. Describe proposed activities, e.g., those that will lead to new and/or enhanced research skills and knowledge, as well as related skills such as grant-writing, communication, leadership, and laboratory management. The career development plan must be 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 his/her 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 training 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 his/her progress during the mentored phase and for the transition to the independent phase.
- The candidate and K99-phase mentor (see below) must describe a specific plan for the transition to the independent phase.

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: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>

Statements and Letters of Support

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

The application must include a statement from the primary mentor that provides:

1. information on his/her 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 his/her mentor(s)
 5. a statement identifying the components of the proposed research that the K99 applicant can take when he/she transitions to research independence and that can be part of his/her independent (R00) phase award
 6. when appropriate, a statement affirming any resources and reagents that can be taken by the applicant to the independent phase of the award. If the primary mentor has limited training experience, a co-mentor with a strong, successful track record as a mentor should be included.
- 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 mentor must agree to 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.

Letters of Support from Collaborators and Consultants

Consultant(s)/Collaborator(s) (if applicable): Signed statements must be provided by each consultant/collaborator confirming their participation and describing their specific roles in the project. Collaborators and consultants generally do not need to provide their biographical sketches. However,

information should be provided in their statement that documents their expertise in the proposed areas of consulting/collaboration. Collaborators/consultants are generally not directly involved in the development of the career of the candidate as an independent investigator.

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. These individuals generally do not need to provide their biographical sketches.

Environmental and Institutional Commitment to the Candidate

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 the sponsoring institution's scientific environment including the resources and facilities that will be available to the candidate.
- Describe how the institutional research environment is particularly suited for the candidate's mentored research and career development during the K99 phase.

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 his/her 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.

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 him/her 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 his/her mentors and separate his/her scientific research program from that of the mentor(s).

Review Criteria

Reviewers should evaluate the candidate's potential for obtaining a tenure-track faculty position and developing an independent research program that will make important contributions to the field, taking into consideration the years of postdoctoral research experience, the likely value of the proposed K99 phase research training and career development in facilitating the candidate's 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.

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 his/her 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 his/her successful transition to independence?
- To what extent are the plans for evaluating the K99 awardee's progress adequate and appropriate for guiding the applicant 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?

Research Plan

- Is the proposed K99 phase research significant and scientifically sound?
- Is there a strong scientific premise for the project? **Note:** after 1/25/19, this will be replaced by
 - 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?

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? Do they provide letters of support that affirm their commitment?

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?