PATHWAY TO INDEPENDENCE (PI) AWARD (K99/R00)
Program Announcement: PA-10-063

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) initiative is to assist postdoctoral investigators in transitioning to a stable independent research position with NIH or other independent research funding. One of the most challenging transitions in any research career is the transition from postdoctoral trainee to independent scientist.

Prospective candidates are encouraged to contact the relevant NIH staff for IC-specific information at: http://grants.nih.gov/grants/guide/contacts/parent_K99_R00.html

Eligibility:

Citizenship and Residency: U.S. citizens and non-U.S. citizens with the skills, knowledge, and resources necessary to carry out the proposed research are invited to develop an application for support. Information on citizenship/residency status must be provided in the application as part of section 9.

Degree and Research: Eligible PD/PIs include outstanding postdoctoral candidates who have a clinical or research doctorate (including Ph.D., M.D., D.O., D.C., N.D., D.D.S., D.M.D., D.V.M., Sc.D., D.N.S., Pharm.D. or equivalent doctoral degrees) and who have no more than 5 years of postdoctoral research training at the time of application (resubmissions must also comply with this requirement). Clinicians (including those with M.D., D.D.S, D.V.M. 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.

Career Level: This award is intended for and limited to postdoctoral scientists who are in mentored training positions and do not have sufficient research experience or institutional authority to lead an independent research program. Individuals with a full-time tenure track assistant professor position (or equivalent) at the time of application are not eligible.

Level of Effort: Candidates must be able to commit a minimum of 9 person-months (75% of full-time professional effort) conducting research career development activities associated with this award. The remaining 3 months (25% effort) can be divided among other research, clinical, and teaching activities only if these activities are consistent with the goals of the NIH K99/R00 Award, i.e., the candidate’s development into an independent investigator.

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 5 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. Candidates in such positions are encouraged to obtain confirmation of their eligibility before they begin to prepare their applications. 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.

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.

Career Development Award Supplemental Form Component Sections

K99/R00 applications follow the format & requirements of other Mentored Career Development Awards and use the Career Development Award Supplemental Form Component Sections.

Candidate Information and Career Development Plan

Candidate’s Background:
• Describe the candidate’s commitment to a career in a biomedical or behavioral 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.
• Describe the candidate’s current as well as long-term research and career objectives.
• If currently supported by an institutional or individual Ruth L. Kirschstein NRSA, describe the candidate’s current research training or fellowship program.
• For individuals in postdoctoral positions with other titles although still in non-independent training positions, describe evidence of non-independence.

Career Goals and Objectives:
• Present a systematic plan 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 independent investigator status (R00); and (2) justifies the need for further mentored career development to become an independent research investigator; and (3) that utilizes the relevant research and educational resources of the institution.
• Candidates planning to be sponsored by an extramural institution should consult with the proposed mentor to discuss the proposed research training/career development plan for the mentored phase and the research plan to be presented in the application for the subsequent independent scientist phase.
• If the candidate is planning an NIH intramural laboratory for the mentored phase, a mentor will need to be selected with whom the candidate can consult in preparing and submitting the application for the intramural mentored phase of the award.
Career Development/Training Activities:

• Describe the career development plan and how it fits with the candidate’s goals and prior experience. A systematic plan should be presented for obtaining the necessary biomedical, behavioral, or clinical science background and research experience to launch an independent research career. The career development plan must be specifically tailored to meet the needs of the candidate and the ultimate goal of achieving independence as a researcher.

• Describe the current training activities and how they relate to the career development plans and the career goals of the candidate. Candidates must justify the need for the award, both the mentored phase and the independent scientist 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.

• The candidate should describe how the career development plan will promote the candidate’s success and scientific independence. This plan should describe activities such as those that will lead to new and/or enhanced research, grant-writing, communication and laboratory management skills and knowledge. The candidate should also describe how these skills will contribute to research productivity and facilitate the development of new approaches and directions for investigation. Courses or other activities that might allow the candidate to expand the scope of his/her research in order to improve the potential for success in gaining further independent funding are particularly encouraged.

• The candidate must describe the plan 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 plans for the transition to the independent phase.

Training in the Responsible Conduct of Research:

• Applications must include a plan to obtain instruction in the responsible conduct of research.

• This section should document prior instruction in responsible conduct of research during the applicant’s current career stage (including the date of last occurrence) and propose plans to receive instruction in responsible conduct of research.

• Such plans must address five instructional components, format, subject matter, faculty participation, duration of instruction, and frequency of instruction, as outlined and explained in NOT-OD-10-019.

• The plan may include career stage-appropriate, individualized instruction or independent scholarly activities that will enhance the applicant’s understanding of ethical issues related to their specific research activities and the societal impact of that research.

• The role of the sponsor/mentor in responsible conduct of research instruction must be described.

• Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process.

Research Plan

• The candidate should describe his/her research that is relevant to the proposed R00 research plan. Ideally, this would include a brief description of research performed prior to the mentored phase, a description of the research planned during the mentored phase and a detailed description of the research planned for the independent 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). It is anticipated that candidates will be best able to describe their current and past research.

• The research description should demonstrate not only the quality of the candidate’s research thus far but also the novelty, significance, creativity and approach of the R00 phase research, as well as the ability of the candidate to carry out the research. Consequently, the research plan should provide a detailed rationale, experimental approach and plan for the independent phase research.
• The application must also describe the relationship between the mentor’s research and the candidate’s proposed research plan. The application should describe how the candidate will gain independence from his/her mentors and achieve separation of his/her scientific research program from that of the mentor(s).
• If more than one K99 phase mentor is proposed, the respective areas of expertise and responsibility should be described.

**Statements of Support**

**Statement by Mentor, Co-Mentors, Consultants, Contributors (combine & upload as single pdf):**

• The candidate must name a primary mentor (sponsor), who, together with the candidate, is responsible for the planning, direction, and execution of the K99 phase program. The candidate may also identify co-mentors as appropriate to the goals of the program.
• The primary mentor should be recognized as an accomplished investigator in the proposed research area and have a track record of success in training individuals in postdoctoral positions who have gone on to become independent investigators.
• The mentor should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award.
• The application must include a statement from the mentor(s) that provides: 1) information on their research qualifications and previous experience as a research supervisor; 2) a plan that describes the nature of the supervision and mentoring that will occur during the proposed 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, including any formal course-work; and 4) a plan for transitioning the candidate from the mentored phase to the independent scientist phase of the award.
• Similar information must be provided by any co-mentor. If more than one mentor is proposed, the respective areas of expertise and responsibility of each should be described. Co-mentors should describe clearly how they will coordinate with the primary mentor and the candidate.
• Consultant(s)/Collaborator(s): Signed statements must be provided by each consultant/collaborator confirming their participation in the project and describing their specific roles. Collaborators and consultants generally 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. Collaborators/consultants are generally not directly involved in the development of the career of the candidate as an independent investigator.
• 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 review and comment on the extramural independent scientist (R00) phase application

**Environment 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 development of the candidate's research career and the pursuit of the proposed research plan and progression to the R00 phase.

**Institutional Commitment to Candidate’s Research Career Development:**

• The sponsoring institution must provide a statement of commitment to the candidate's development into a productive, independent investigator and to meeting the requirements of this award. It should be clear that the institutional commitment to the candidate is not contingent upon receipt of the K99/R00 award.
• Provide assurances that the candidate will be able to devote a minimum of 9 person-months (75% of full-time professional effort) to the development of their research program. The remaining effort should be devoted to activities related to the development of the candidate’s career as an independent scientist.
• Provide assurance that the 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.
• Provide appropriate time and support for any proposed mentor(s) and/or other staff consistent with the career development plan.
• If the candidate is not a U.S. Citizen or permanent resident, the sponsoring institution must include information about their visa status and an assurance that the candidate’s visa provide sufficient time to complete both phases of the K99/R00 award at a U.S. Institution.

Definitions of Criteria and Considerations for Critiques of K99/R00 Awards
Reviews of K99/R00 applications follow the same criteria as other Mentored Career Development Awards (e.g., K01, K08, & K23 Awards). Additional criteria for K99/R00 Awards are shown in italics.

1. Candidate.
   • 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 experience, including expertise gained?
   • Based on the postdoctoral candidate’s experience, track record and prior research training, what is the candidate’s potential to become an outstanding, successful independent investigator who will contribute significantly to his/her chosen field of biomedical-related research?
   • To what extent does the application provide evidence of the candidate’s research creativity, and does this evidence suggest that the candidate has the potential to develop a creative, independent research program?
   • 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 position within the time period requested for the K99 phase of this award?
   • Are there letters of reference from at least three well-established scientists? Relative to the above review criteria, how do these scientists evaluate the candidate? Do the letters provide strong evidence that the candidate has a high potential to become an independent investigator?
   • 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 position within the time period requested for the K99 phase of this award?

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring
   • Are the content and duration of the proposed didactic and research components of the career development plan appropriate for the candidate’s current stage of scientific and professional development and proposed research career goals?
   • Is the proposed career development plan likely to contribute substantially to the scientific and professional development of the candidate including his/her successful transition to independence?
   • Is the additional proposed training needed and appropriate for the proposed research plan and the applicant’s future career plans?
   • For individuals currently supported by research training programs, how does the proposed career development plan enhance or augment the applicant’s training to date?
   • 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 the transition to the independent phase of the award appropriate for the candidate’s current stage of scientific and professional development and the career development proposed for the K99 phase of the award?

- Is the proposed K99 phase research significant?
- Are the scientific and technical merits of the K99 research question, experimental design and methodology appropriate for the candidate’s level of training, an appropriate vehicle 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 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?
- Evaluate the innovation and creativity of the proposed R00 phase research, i.e., does the 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 contribute significantly to our understanding of biomedical problems?
- To what extent is proposed R00 phase research likely to foster the career of the candidate as an independent investigator in biomedical research?

4. Mentor(s), Consultant(s), Collaborator(s).

- To what extent does the mentor 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?
- Does the mentor(s) adequately address the above review criteria including the candidate’s potential as well as his/her strengths and areas needing improvement?
- Evaluate the nature and extent of the proposed supervision that will occur during the mentored phase of support, i.e. is it adequate, and is the commitment of the mentor(s) to the applicant’s continued career development appropriate?
- Does the mentor have a comprehensive plan to support the proposed K99 phase career development and research plans as well as the candidate’s efforts to transition to independence? Is this plan adequate and appropriate?
- Are the consultants/collaborators’ research and/or mentoring qualifications appropriate for their roles in the proposed K99 phase of the award?

5. Environment and Institutional Commitment to the Candidate.

- To what extent does the institution provide a high quality environment for the candidate’s development?
- Is there adequate assurance that the required (minimum of 75%) effort of the candidate will be devoted directly to the research training, career development, and research activities described in the proposed career development and research plans?
- 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?
- What evidence is provided that the K99 sponsoring institution is strongly committed to fostering the candidate’s development and transition to the independent (R00) phase?

Additional Review Criteria:

**Training in the Responsible Conduct of Research.** Does the application include appropriate and adequate documentation in prior instruction, or plans for training in the responsible conduct of research? [scored as Acceptable or Unacceptable]

**Resubmission.** When reviewing a Resubmission application (formerly called an amended application), please 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.

**Protections for Human Subjects, Inclusion of Women, Minorities, and Children, Vertebrate Animals.** For details see original document at: [http://grants.nih.gov/grants/peer/critiques/k.htm](http://grants.nih.gov/grants/peer/critiques/k.htm)
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.

Budget and Period of Support. Is the proposed budget and period of support appropriate in relation to the proposed research and the career development needs of the candidate?

Resource Sharing Plans. Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable.

Additional Comments to the Applicant. Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.

The NIH Grant Application Scoring System

The NIH scoring system uses a 9-point rating scale from 1 = Exceptional to 9 = Poor for the overall impact/priority score as well as the individual review criteria. Ratings are provided only in whole numbers, not decimals.

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

**Non-numeric score options:**

**NR** = Not Recommended for Further Consideration,

**DF** = Deferred, **AB** = Abstention, **CF** = Conflict, **NP** = Not Present, **ND** = Not Discussed

**Minor Weakness:** An easily addressable weakness that does not substantially lessen impact

**Moderate Weakness:** A weakness that lessens impact

**Major Weakness:** A weakness that severely limits impact

7. Supplemental Instructions to the SF 424(R&R) for Preparing an Individual Research Career Development Award (CDA) Application ("K" Series)

7.1 Introduction

All applicants must use the SF 424 R&R Application for Federal Assistance, following the instructional information in this Application Guide. The supplemental instructions found in this section (I.7) are for Individual Career Development Award (CDA) series applications and include guidance and instructional information only when there is a difference in the required information to be submitted or there is a need for more specificity for the individual K program. Therefore, these supplemental instructions must be used along with the information found in Parts I.1 – I.6 of this document.

These instructions do not cover applications for K12 and other institutional career development programs. Institutions planning such applications should consult the applicable Funding Opportunity Announcement (FOA) concerning eligibility, award criteria, and application procedures. Some K-series funded through Requests for Applications (RFAs) may have special instructions.

It is imperative that applicants become familiar with the K activity code for which support is being requested. Before applying for a K award, applicants should carefully review the applicable FOA for the career award of interest, noting especially the eligibility requirements, requirements for a mentor, review criteria, award provisions, and any special application instructions. Each FOA contains more specific information associated with the award mechanism and includes names of individuals that may be contacted prior to submission of an application for additional or clarifying information.

The eligibility criteria, support levels, and other important aspects of specific career awards, including availability, may vary among NIH Institutes or Centers and other PHS agencies. For this reason, it is strongly recommended that applicants consult with the NIH Scientific/Research contact of the appropriate awarding component prior to submitting an application. FOAs and other guidelines are available on the NIH K-Kiosk website [http://grants.nih.gov/training/careerdevelopmentawards.htm](http://grants.nih.gov/training/careerdevelopmentawards.htm). Announcements for various career award opportunities are issued periodically in the NIH Guide for Grants and Contracts, a weekly electronic publication ([http://grants.nih.gov/grants/guide/index.html](http://grants.nih.gov/grants/guide/index.html)).

Note: A few individual K-series programs supported by the NIH include a delayed-award activation and/or two award phases (e.g., K22, K99/R00). NIH intramural researchers may be eligible to apply for these awards. The FOA will include any additional and/or specific instructions that must be followed when applying for such support.

7.2 Individual Career Development Award Programs

The following chart provides a summary of the existing Career Development programs. Since this information is subject to change, prospective applicants are encouraged to review the K-Kiosk for the most current program information. The K-Kiosk includes information on NIH-wide Parent FOAs as well as IC-specific FOAs for a particular K program.
Summary of Research Career Development Award Programs

<table>
<thead>
<tr>
<th>PROGRAM</th>
<th>DESCRIPTION</th>
<th>MENTOR</th>
<th>REFERENCE LETTERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>K01</td>
<td>Mentored Research Scientist Development Award (see K Kiosk)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>K02</td>
<td>Independent Scientist Award (see K Kiosk)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>K05</td>
<td>Senior Scientist Award (see K Kiosk)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>K07</td>
<td>Academic Career Award (see K Kiosk)</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>K08</td>
<td>Mentored Clinical Scientist Development Award (see K Kiosk)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>K18</td>
<td>Career Enhancement Award (see K Kiosk)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>K22</td>
<td>Career Transition Award (see K Kiosk)</td>
<td>*</td>
<td>Yes</td>
</tr>
<tr>
<td>K23</td>
<td>K23 Mentored Patient-Oriented Research Career Development Award (see K Kiosk)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>K24</td>
<td>Mid-Career Investigator Award in Patient Oriented Research (see K Kiosk)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>K25</td>
<td>Mentored Quantitative Research Career Development Award (see K Kiosk)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>K26</td>
<td>Midcareer Investigator Award in Mouse Pathobiology Research (see K Kiosk)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>K99/R00</td>
<td>NIH Pathways to Independence (PI) Award (see K Kiosk)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Varies with career status and source of award. Check the Funding Opportunity Announcement (FOA).

7.3 Letters of Reference (must be submitted electronically through the eRA Commons)

At least three (but no more than 5) Letters of Reference are required for all applications defined as New and Resubmissions (see Note below) for mentored support as indicated in the table above. The letters should be from individuals not directly involved in the application, but who are familiar with the applicant’s qualifications, training, and interests. The mentor/co-mentor(s) of the application cannot be counted toward the three required references. It is important for the applicant to include the names of those individuals in the application so that the NIH staff will be aware of planned reference letter submissions. Within the application, the list of referees (including name, departmental affiliation, and institution) is included in the Other Project Information Component, Item 12. Other Attachments (see special K instructions in Section 7.4.3). In addition, applicants must include the same list and information in the PHS Cover Letter.

The reference letters are critically important and should address the candidate's competence and potential to develop into an independent biomedical or behavioral investigator. Only those individuals who can make the most meaningful comments about the candidate's professional training and qualifications for a research career should be used as referees. Where possible, some referees who are not from the candidate's current department or organization, but are knowledgeable about their qualifications, should be selected.
The candidate should request reference letters only from individuals who will be able to submit them to the NIH no later than 5 business days after the application submission due date.

Applications that are missing the required letters of reference may be delayed in review or may not be accepted.

Note: For resubmission applications, it is critical that NEW Letters of Reference be submitted providing up-to-date evaluation of the applicant’s potential to become an independent researcher, and the continued need for additional supervised research experience.

Electronic submission of a letter of reference is a separate process from submitting an application electronically. Reference letters are submitted directly through the eRA Commons and do not use Grants.gov. Therefore, this process requires that the referee be provided information including (a) the PI’s (candidate’s) eRA Commons user name, (b) the PI’s first and last name as they appear on the PI’s eRA Commons account, and (c) the number assigned to this Funding Opportunity Announcement.

Confirmation emails will be sent to both the referee and the candidate following reference letter submission. The confirmation sent to the candidate will include the referee’s name and the date the letter was submitted. The confirmation sent to the referee will include the referee and applicant’s names, a confirmation number, and the date the letter was submitted.

The candidate may check the status of submitted letters by logging into their Commons account and accessing the “check status” screen for this application. The candidate is responsible for reviewing the status of submitted reference letters and contacting referees to ensure that letters are submitted by the receipt deadline. While the candidate is able to check on the status of the submitted letters, the letters are confidential and he/she will not have access to the letters themselves. Note: Because email can be unreliable, it is the candidate’s responsibility to check the status of his/her letters of reference in the Commons.

Candidates should provide the following instructions to their referees.

**Instructions for Referees:** (these instructions are also found at: http://grants.nih.gov/grants/funding/424/Referee_Instructions_Mentored_Career_Awards.doc)

Name of Candidate (First & Last Name as shown in the eRA Commons): ____________________

Candidate’s eRA Commons UserName: ____________________

FOA Number: ____________________

The candidate is applying to the NIH for a Career Development Award. The purpose of this award is to develop the research capabilities and career of the candidate. These awards provide salary support and guarantee them the ability to devote at least 9 person-months (75% of their total professional effort) to research for the duration of the award. Many of these awards also provide funds for research and career development costs. The award is available to persons who have demonstrated considerable potential to become independent researchers, but who need additional supervised research experience in a productive scientific setting, as well as to newly independent researchers.

In two pages or less (PDF format), describe the qualities and potential of the candidate for the career development award program for which support is being requested. This should include your evaluation with special reference to:

- potential for conducting research;
- evidence of originality;
- adequacy of scientific background;
- quality of research endeavors or publications to date, if any;
• commitment to health-oriented research; and
• need for further research experience and training
• any additional related comments that the referee may wish to provide

Please put the name of the candidate at the top of the letter. Also, be sure to include your name and title in the letter.

Submitting Reference Letters
Letters must be submitted directly to the eRA Commons at: https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp and may be submitted any time after the Funding Opportunity Announcement opens and no later than 5 business days after the application receipt due date.

You will be requested to enter the following information on-line at the time of submission:

**Referee Information:**
- Referee First Name (Required)
- Referee Last Name (Required)
- Referee MI Name (Not Required)
- Referee Email (Required)
- Referee institution/affiliation (Required)
- Referee department (Required)

**Candidate Information:**
- PI Commons User ID (Required)
- PI’s last name, as it appears on the PI’s Commons account (Required) (will be validated to ensure they match)
- Funding Opportunity Announcement (FOA) Number (Required)
- Reference letter confirmation number (Required only if resubmitting a letter; not required otherwise)
- Reference letter – two pages maximum; PDF format

After you have submitted your letter, both you and the candidate will receive a confirmation of receipt by email. The confirmation sent to the candidate will include your name and the date your letter was submitted. However, the letters are confidential and the candidate will not be able to access the letters themselves. Your email confirmation will include a Reference Letter Submission Confirmation Number. The Confirmation Number will be required when resubmitting letters. Please print the confirmation email for your records.

Revised reference letters may be submitted within 5 business days of the application receipt date.

### 7.4 K- Specific Instructions for K Applications using the SF424 (R&R) Application

Standard Instructions found in Parts I.1 – I.6 should be followed with the exceptions found in this section. Section numbers referenced below (e.g. 4.2 – 5.6) reflect those found in Part I.
# 7.5 PHS398 Career Development Award Supplemental Form

The PHS398 Career Development Award Supplemental Form is designed to support applicants in detailing their career development plans and achievements. It includes sections for the candidate's background, career goals, research activities, and institutional commitment. Here’s a breakdown of the form:

### 1. Application Type:
- **New**, **Resubmission**, **Renewal**, **Continuation**, **Revision**

### 2. Career Development Award Attachments:
These sections allow applicants to attach relevant documents:
- **Introduction**
- **Candidate Information**
- **Statements of Support**
- **Environment and Institutional Commitment to Candidate**
- **Research Plan**
- **Human Subject Sections**

### Sections Explained:
- **Candidate's Background**
- **Career Goals and Objectives**
- **Career Development/Training Activities During Award Period**
- **Training in the Responsible Conduct of Research**
- **Mentoring Plan** (when applicable)
- **Statements by Mentor, Co-Mentors, Consultants, Contributors** (as appropriate)
- **Description of Institutional Environment**
- **Institutional Commitment to Candidate's Research Career Development**
- **Specific Aims**
- **Research Strategy**
- **Inclusion Enrollment Report** (for RENEWAL applications only)
- **Progress Report Publication List** (for RENEWAL applications only)
- **Protection of Human Subjects**
- **Inclusion of Women and Minorities**
- **Targeted/Planned Enrollment**
- **Inclusion of Children**
## Candidate Information

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Instructions</th>
</tr>
</thead>
</table>
| 2. Candidate’s Background | Use this section to provide any additional information not described in the Biographical Sketch Format Page such as research and/or clinical training experience.  
Note that the total number of pages for Items 2-5 and Item 11 (Research Strategy) combined may not exceed 12 pages.  
Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open. |
| 3. Career Goals and Objectives | Describe your past scientific history, indicating how the award fits into past and future research career development. If there are consistent themes or issues that have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. It is important to justify the award and how it will enable you to develop or expand your research career. You may include a timeline, including plans to apply for subsequent grant support.  
Note that the total number of pages for Items 2-5 and Item 11 (Research Strategy) combined may not exceed 12 pages.  
Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open. |
| 4. Career Development/Training Activities During Award Period | Stress the new enhanced research skills and knowledge you will acquire as a result of the proposed award. If you have considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance your research career. For mentored awards, describe structured activities, such as course work or technique workshops, which are part of the developmental plan. If course work is included, provide course numbers and descriptive titles. Briefly discuss each of the activities, except research, in which you expect to participate. Include a percentage of time involvement for each activity by year, and explain how the activity is related to the proposed research and the career development plan.  
Note that recipients of mentored K awards may receive concurrent support from an NIH research grant award or cooperative agreement only under certain conditions (see NIH Notice NOT-OD-08-065).  
Note that the total number of pages for Items 2-5 and Item 11 (Research Strategy) combined may not exceed 12 pages.  
Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open. |
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Instructions</th>
</tr>
</thead>
</table>
| 5. Training in the Responsible Conduct of Research | For mentored career development awards, describe a plan to acquire instruction in the responsible conduct of research. For independent career awards, describe a plan to provide instruction in the responsible conduct of research. See Part III Section 1.16 for information on the NIH Policy on Training in the Responsible Conduct of Research (RCR).

Attach a description of plans for obtaining instruction in the responsible conduct of research. This section should document prior instruction or participation in RCR training during the applicant’s current career stage (including the date instruction was last completed) and propose plans to either receive instruction or participate as a course lecturer, etc., in order to meet the once every four-year requirement. The plan should address how applicants plan to incorporate the five instructional components outlined in the NIH Policy on Instruction in the Responsible Conduct of Research: format, subject matter, faculty participation, duration, and frequency. The plan may include career stage-appropriate individualized instruction or independent scholarly activities that will enhance the applicant’s understanding of ethical issues related to their specific research activities and the societal impact of that research. The role of the mentor in RCR instruction must be described.

Where applicable, Renewal applications must describe the RCR instruction activities undertaken during the project period as well as future plans.

Note that the total number of pages for Items 2-5 and Item 11 (Research Strategy) combined may not exceed 12 pages.

Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.

This is a required field. |
| 6. Mentoring Plan (Include only when required by the specific FOA, e.g., K24 and K05) | The plan should provide information about the candidate’s commitment to serve as a mentor to other investigators, and describe previous mentoring activities. The plan should describe the setting and provide information about the available pool of mentees with appropriate backgrounds and interests in the same field of science. It should also include information on the candidate’s past and proposed mentees sufficient to evaluate the quality of prior mentoring experiences, including the professional levels of mentees, and the frequency and kinds of mentoring interactions between the candidate and the mentees. Describe the productivity of the mentoring relationship for the scientific development of the new scientists as judged by their publications and current research activities. Senior level (K05) candidates should describe any financial and material support from their own funded research and research resources that will be available to their mentees. The candidate’s proposed percent effort commitment to the mentoring plan should also be stated.

Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.

This is a required field. |
Statement of Support

Field Name: 7. Statements by Mentor, Co-mentor(s), Consultants, Contributors

Instructions:

This section is to be completed by the mentor, co-mentor(s), consultant(s), and contributor(s), as appropriate. The letters must be appended together and uploaded as a single pdf file.

For mentored awards (see Summary of Career Development Award Mechanisms table), the mentor must explain how they will contribute to the development of the candidate's research career. This statement should include all of the following:

1. The plan for the candidate's training and research career development. This description must include not only research, but also other developmental activities, such as seminars, scientific meetings, training in the responsible conduct of research, and presentations. It should discuss expectations for publications over the entire period of the proposed project and define what aspects of the proposed research project the candidate will be allowed to take with him/her to start their own research program.

2. The source of anticipated support for the candidate’s research project for each year of the award period.

3. The nature and extent of supervision and mentoring of the candidate, and commitment to the candidate's development that will occur during the award period.

4. The candidate's anticipated teaching load for the period of the award (number and types of courses or seminars), clinical responsibilities, committee and administrative assignments, and the portion of time available for research.

5. A plan for transitioning the candidate from the mentored stage of his/her career to the independent investigator stage by the end of the project period of the award. The mentor should describe previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral students), number of persons mentored, and career outcomes.

All mentored career development applications should identify all co-mentors, consultants and collaborators involved with the proposed research and career development program. Briefly describe their roles and anticipated contributions. A co-mentor must specifically address the nature of his/her role in the career development plan and how the responsibility for the candidate’s development is shared with the mentor. Describe respective areas of expertise and how they will be combined to enhance the candidate’s development. Also describe the nature of any resources that will be committed to this CDA. Letters from the mentor(s),
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>co-mentor(s), consultant(s), advisory committee members (if applicable), and contributor(s) documenting their role and willingness to participate in the project must be included in this section of the application. Do not place these letters in the Appendix. Non-mentored career development award applications should list any contributors or consultants. Briefly describe research materials, data, guidance, or advice they will provide. Letters from consultant(s) and contributor(s), documenting their willingness to participate in the project and describing their roles, must be included in this section of the application. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</td>
</tr>
</tbody>
</table>

### Environment and Institutional Commitment to the Candidate

8. **Description of Institutional Environment**

The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's proposed developmental plan. Referring to the resources description (See section 4.4.9 Facilities and Other Resources), indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in this application. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.

9. **Institutional Commitment to Candidate’s Research Career Development**

**Introduction**

The institution should provide a document on institutional letterhead that describes its commitment to the candidate and the candidate’s career development, independent of the receipt of the CDA. The document should include the institution’s agreement to provide adequate time and support for the candidate to devote the proposed protected time to research and career development for the entire period of the proposed award. The institution should provide the equipment, facilities, and resources necessary for a structured research career development experience. It is essential to document the institution's commitment to the retention, development and advancement of the candidate during the period of the award.

Because of the diverse types of K awards, applicants should contact the
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>appropriate awarding component Scientific/Research contact listed in the specific FOA to determine the level of commitment required for this application.</td>
</tr>
</tbody>
</table>

**Agreement**

The applicant organization must:

a. Agree to release the candidate from other duties and activities to devote the required percentage of time for development of a research career. For most K awards, commitment of at least 75 percent of time is required. Describe actions that will be taken to ensure this; e.g., reduction of the candidate's teaching load, committee and administrative assignments, and clinical or other professional activities for the current academic year. (For example, describe the actions that will be taken to compensate for the reduction in clinic responsibilities of the candidate, e.g., hiring of additional staff). Describe the candidate's academic appointment, bearing in mind that it must be full-time, and that the appointment (including all rights and privileges pertaining to full faculty status if in an academic setting) and the continuation of salary should not be contingent upon the receipt of this award. Describe the proportion of time currently available for the candidate's research experience and what the candidate's institutional responsibilities will be if an award is made.

b. Provide the candidate with appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations) to carry out the proposed Research Plan.

c. Provide appropriate time and support for any proposed mentor(s) and/or other staff consistent with the career development plan.

**Signatures**

The institutional commitment must be dated and signed by the person who is authorized to commit the institution to the agreements and assurances listed above. In most cases, this will be the dean or the chairman of the department. The signature must appear over the signer's name and title at the end of the statement. If the candidate will be working away from the home institution, signatures from both the home and the host institution are required.

The sponsoring institution, through the submission of the application and in the institutional commitment section, certifies that all items outlined above will be provided and that the institution will abide by the applicable assurances and PHS policies. See: NOT-OD-06-054.

Create a single file of the institutional letter and save it in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.
Research Plan

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Specific Aims</td>
<td>State precisely the goals of the proposed research and summarize the expected outcome(s) including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. Specific Aims are limited to one page. Save this information in a single file in a location you remember. Click Add Attachment, browse to where you saved the file, select the file, and then click Open.</td>
</tr>
</tbody>
</table>
| 11. Research Strategy | Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section (Part I Section 4.4.9). Note that the total number of pages for Items 2-5 and Item 11 (Research Strategy) combined may not exceed 12 pages, unless otherwise specified in the FOA.  

(a) Significance  
- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.  
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.  
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.  

(b) Innovation  
- Explain how the application challenges current research or clinical practice paradigms.  
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.  

(c) Approach  
- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless
### Field Name | Instructions
--- | ---
| | addressed separately in Item 21 (Resource Sharing Plan), include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of Select Agents should appear in Item 18 below.

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.

**Preliminary Studies for New Applications:** For new applications, include information on Preliminary Studies as part of the Approach section. Discuss the PD/PI’s preliminary studies, data, and or experience pertinent to this application.

**Progress Report for Renewal and Revision Applications.** For renewal/revision applications, provide a Progress Report as part of the Approach section. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant budget reductions. A list of publications, patents, and other printed materials should be included in Item 5 (Progress Report Publication List); do not include that information here.

Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.

| 12. Inclusion Enrollment Report | If the renewal involves clinical research, then you must report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender. See **Part II, Section 4.3** for more detailed instructions on which Target and Enrollment Report or Table to use |

---

**Part I: Instructions for Preparing and Submitting an Application**
Referee Instructions for Mentored Research Career Development Awards:

Name of Candidate (First & Last Name as shown in the eRA Commons): ___________________

Candidate’s eRA Commons UserName: _______________

FOA Number: __________________________

The candidate is applying for a Career Development Award. The purpose of this award is to develop the research capabilities and career of the candidate. These awards provide 3 to 5 years of salary support and guarantee them the ability to devote at least 9 person-months (75% of their total professional effort) to research for the duration of the award. Many of these awards also provide funds for research and career development costs. The award is available to persons who have demonstrated considerable potential to become independent researchers, but who need additional supervised research experience in a productive scientific setting, as well as to newly independent researchers.

In two pages or less (PDF format), describe the qualities and potential of the candidate for the career development award program for which support is being requested. This should include your evaluation with special reference to:

• potential for conducting research;
• evidence of originality;
• adequacy of scientific background;
• quality of research endeavors or publications to date, if any;
• commitment to health-oriented research; and
• need for further research experience and training
• any additional related comments that the referee may wish to provide

Please put the name of the candidate at the top of the letter. Also, be sure to include your name and title in the letter.

Submitting Reference Letters

Letters may be submitted directly to the eRA commons at:

https://commons.era.nih.gov/commons/reference/submitRefereeInformation.jsp

and must be submitted within 5 days after the application receipt due date.

You will be requested to enter the following information on-line at the time of submission:

Referee Information:
• Referee First Name (Required)
• Referee Last Name Required)
• Referee MI Name (Not Required)
• Referee Email (Required)
• Referee institution/affiliation (Required)
• Referee department (Required)

Candidate Information:
• PI Commons User ID (Required)
• PI’s last name, as it appears on the PI’s Commons account (Required) (will be validated to ensure they match)
• Funding Opportunity Announcement (FOA) Number (Required)
• Reference letter confirmation number (Required only if resubmitting a letter; not required otherwise)
• Reference letter – two pages maximum; PDF format

After you have submitted your letter, both you and the candidate will receive a confirmation of receipt by email. The confirmation sent to the candidate will include your name and the date your letter was submitted. However, the letters are confidential and the candidate will not be able to access the letters themselves. Your email confirmation will include a Reference Letter Submission Confirmation Number. The Confirmation Number will be required when resubmitting letters. Please print the confirmation email for your records.

Revised reference letters may be submitted within 7 days of the application receipt date.

(See section I.7.3 of the SF424(R&R) Application Guide for additional information on Reference Letters)