

NIH MENTORED CAREER DEVELOPMENT AWARDS (K01, K08, K23)

Note: the information below is extracted from the current Program Announcements; before applying for a K award you should obtain and read the most current program announcement & application instructions.

See also Section 7 of the PHS SF424 (R&R) Adobe Forms Version B Application Guide (“Supplemental Instructions for Preparing an Individual Research Career Development Award Application”)

[download from: http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Adobe_VerC.pdf]

This handout contains the following information:

1. Objectives, eligibility & special features of K01, K08, K23 Career Development Awards, (p 1–3).
2. Career Development Award Supplemental Form Component Sections (p 4–6).
3. Definitions of Criteria and Considerations for Critiques of K01, K08 & K23 Awards (p 6–8).
4. The NIH Grant Application Scoring System (p 9).

MENTORED RESEARCH SCIENTIST DEVELOPMENT AWARD (K01)

Program Announcement: PA-14-044

Complete details at: <http://grants.nih.gov/grants/guide/pa-files/PA-14-044.html>

The objective of the NIH Mentored Research Scientist Development Award (K01) is to provide support for a sustained period of “protected time” (3–5 years) for intensive research career development under the guidance of an experienced mentor, or sponsor, in the biomedical, behavioral or clinical sciences leading to research independence. The expectation is that through this sustained period of research career development and training, awardees will launch independent research careers and become competitive for new research project grant (R01) funding.

- Only U.S. citizens or non-citizen nationals, or individuals lawfully admitted for permanent residence who have a currently valid Permanent Resident Card (USCIS Form I-551), or some other verification of legal admission as a permanent resident prior to the time of award, are eligible for this award.
- 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 K01 award, i.e., the candidate’s development into an independent investigator.
- A candidate for an NIH K01 Award may not simultaneously submit or have an application pending for any other PHS career award (e.g., K07, K08, K22, K23) or any PHS or award that duplicates any of the provisions of the K01 award. Candidates for the K01, under some circumstances, may have been principal investigators on NIH research or career development awards, provided the research experience proposed in the K01 application is in a fundamentally new field of study or there has been a significant hiatus in their research career.

Note: Although all of the participating NIH Institutes and Centers (ICs) use this support mechanism to support career development experiences that lead to research independence, some ICs use the K01 award for individuals who propose to train in a new field or for individuals who have had a hiatus in their research career because of illness or pressing family circumstances. Other ICs utilize the K01 award to increase research workforce diversity by providing enhanced research career development opportunities. Prospective candidates are encouraged to contact the relevant NIH staff for IC-specific information at: http://grants1.nih.gov/grants/guide/contacts/parent_K01.html

MENTORED CLINICAL SCIENTIST DEVELOPMENT AWARD (K08)

Program Announcement: PA-14-046

Complete details at: <http://grants.nih.gov/grants/guide/pa-files/PA-14-046.html>

The objective of the NIH Mentored Clinical Scientist Research Career Development Award (K08) program is to support didactic study and mentored research for individuals with clinical doctoral degrees (see below). This award provides support and “protected time” for an intensive, mentored research career development experience in biomedical or behavioral research, including translational research. For the purpose of this award, translational research is defined as application of basic research discoveries toward the diagnosis, management, and prevention of human disease.

The K08 award may be used by candidates with different levels of prior research training and at different stages in their career development. For example, a candidate with limited experience in a given field of research may use an award to support a career development experience that includes a designated period of didactic training followed by a period of closely supervised research experience. A candidate with previous research experience and training may not require extensive additional didactic preparation, and may use an award to support a career development experience that focuses on an intensive, supervised research experience. NIH Institutes and Centers have unique scientific purviews and different program goals and initiatives. Prospective candidates are encouraged to contact the relevant NIH staff for IC-specific information at: http://grants1.nih.gov/grants/guide/contacts/parent_K08.html

- Candidates for this award must have a clinical doctoral degree. Such degrees include but are not limited to the M.D., D.O., D.D.S., D.M.D., O.D., D.C., Pharm.D., N.D. (Doctor of Naturopathy), D.V.M. Individuals with the Ph.D. or other doctoral degree in clinical disciplines such as clinical psychology, nursing, clinical genetics, speech-language pathology, audiology or rehabilitation are also eligible. Individuals holding the Ph.D. in a non-clinical discipline who are certified to perform clinical duties should contact the appropriate Institute concerning their eligibility for a K08 award.
- Only U.S. citizens or non-citizen nationals, or individuals lawfully admitted for permanent residence who have a currently valid Permanent Resident Card (USCIS Form I-551), or some other verification of legal admission as a permanent resident prior to the time of award, are eligible for this award.
- 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 an NIH K08 Award, i.e., the candidate’s development into an independent investigator.
- Individuals are eligible for a K08 award if they have been, or currently are the PI of an NIH small grant (R03) or exploratory/developmental grant (R21) or a PHS or non-Federal award that duplicates the provisions or research goals of an R03 or R21 grant. Individuals are NOT eligible if they: have pending an application for any other PHS career award (e.g., K01, K23, or another K08), an NIH institute-specific K22, or a Pathway to Independence Award (K99/R00); or have been or are currently a PI on an NIH research grants (such as R01, R29, P01) or a subproject leader on a Program Project (P01) and Center Grant (P50), or a non-NIH equivalent to these grants/awards.

**MENTORED PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARD (K23)
Program Announcement: PA-14-049**

Complete details at: <http://grants.nih.gov/grants/guide/pa-files/PA-14-049.html>

The objective of the NIH Mentored Patient-Oriented Research Career Development Award (K23) program is to ensure a future cadre of well-trained scientists working in POR areas who will become competitive for NIH research project (R01) grant support. The specific objectives are to:

- Encourage research-oriented clinicians to develop independent research skills and gain experience in advanced methods and experimental approaches needed to become an independent investigator conducting patient-oriented research.
- Increase the pool of clinical researchers who can conduct patient-oriented studies, capitalizing on the discoveries of biomedical research and translating them to clinical settings.
- Support the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research.

For the purposes of this award, **Patient-Oriented Research** is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects. This area of research includes: 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials, and; 4) the development of new technologies. Prospective candidates are encouraged to contact the relevant NIH staff for IC-specific information at: http://grants1.nih.gov/grants/guide/contacts/parent_K23.html

- Only U.S. citizens or non-citizen nationals, or individuals lawfully admitted for permanent residence who have a currently valid Permanent Resident Card (USCIS Form I-551), or some other verification of legal admission as a permanent resident prior to the time of award, are eligible for this award. Individuals on temporary or student visas are not eligible.
- Candidates for this award must have a health-professional doctoral degree. Such degrees include but are not limited to the M.D., D.O., D.D.S., D.M.D., O.D., D.C., Pharm.D., N.D. (Doctor of Naturopathy), as well as a doctoral degree in nursing research or practice. Candidates with Ph.D. degrees are eligible for this award if the degree is in a clinical field and they usually perform clinical duties. This may include clinical psychologists, clinical geneticists, social workers, speech and language pathologists, audiologists, and rehabilitationists. Individuals holding the Ph.D. in a non-clinical discipline but who are certified to perform clinical duties should contact the appropriate Institute concerning their eligibility for a K23 award. Candidates also must have completed their clinical training, including specialty and, if applicable, subspecialty training prior to receiving an award. However, candidates may submit an application prior to the completion of clinical training.
- 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 K23 Award, i.e., the candidate's development into an independent investigator in POR.
- A candidate for an NIH K23 award may not simultaneously submit or have an application pending for any other NIH career award (e.g., K01, K07, K08, K22, K23, K25), a research project grant (R01), or any PHS award that duplicates any of the provisions of the K23 award. Ineligible individuals include current and former principal investigators on NIH research project grants, comparable individual career development awards (e.g., K01, K07, K08, K23, K25) equivalent non-PHS peer-reviewed research grants that are over \$100,000 direct costs per year, or project leaders on sub-projects of program project (P01) or center (P50) grants. Former principal investigators of NIH Small Grants (R03) or Exploratory/Developmental Grants (R21) remain eligible.

Career Development Award Supplemental Form Component Sections *(common content of K award applications):*

- **Introduction** (required for a resubmission or revision application) is limited to **1 page**.
- **Specific Aims** is limited to **1 page**.
- **Candidate's Background, Career Goals and Objectives, Career Development/Training Activities During Award Period, and Research Strategy** are limited to a combined total of **12 pages**, including tables, graphs, figures, diagrams, and charts.

Cover Letter: The PHS398 cover letter must include the list of referees (including name, department affiliation, and institution).

Candidate Information and Career Development Plan

Candidate's Background:

- Describe the candidate's commitment to a health-related research career [K23: academic career in Patient-Oriented Research]. Include a description of all the candidate's professional responsibilities in the grantee institution and elsewhere and show their relation to the proposed activities on the career award.
- Describe prior training and how it relates to the objectives and long-term career plans of the candidate.
- Describe the candidate's research efforts to this point in his/her research career, including any publications, prior research interests and experience.
- Provide evidence of the candidate's potential to develop into an independent investigator.
- Include a statement that the candidate will commit at least 9 person-months (75% of full-time professional effort) to the career development program and related career development activities. [K08: The remaining effort may be devoted to clinical, teaching, or other research pursuits and activities consistent with the objectives of the award.] [K23: The mentor or department chair must agree and provide a statement in the application documenting that this percent of the candidate's time will be protected.]

Career Goals and Objectives:

- Describe a systematic plan: (1) that shows a logical progression from prior research and training experiences to the training and research experiences that will occur during the career award period and then to independent investigator status; (2) that justifies the need for further career development to become an independent investigator; and (3) that utilizes the relevant research and educational resources of the institution.

Career Development/Training Activities:

- The candidate and the mentor are jointly responsible for the preparation of the career development plan. A timeline is often helpful. The sponsor/mentor may form an advisory committee to assist with the development of a program of study or to monitor the candidate's progress through the career development program.
- The didactic (if any) and the research aspects of the plan must be designed to develop the necessary knowledge and research skills in scientific areas relevant to the candidate's career goals. [K23: The candidate must demonstrate they have received training or will participate in courses such as: data management, epidemiology, study design(including statistics), hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects..]
- Describe the professional responsibilities/activities including other research projects) beyond the minimum required 75% effort commitment to the career award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator.

Training in the Responsible Conduct of Research *(limited to 1 page):*

- 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-10-19 (which includes the background, rationale and more detail about instruction in the responsible conduct of research).
- 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 research plan should follow instructions outlined in PHS 398 Career Development Award Supplemental form, including sections on Specific Aims and Research Strategy. The candidate should consult with the mentor(s) regarding the development of this section.

- A sound research project that is consistent with the candidate's level of research development and objectives of his/her career development plan must be provided. The research description should demonstrate not only the quality of the candidate's research thus far but also the novelty, significance, creativity and approach, as well as the ability of the candidate to carry out the research.
- The application must also describe the relationship between the mentor's research and the candidate's proposed research plan.
- If more than one mentor is proposed, the respective areas of expertise and responsibility should be described.
- Data and Safety Monitoring (when applicable): Candidates proposing to conduct clinical trials should consult with relevant IC staff.

Statements of Support

Plans and Statements by Mentor and Co-Mentors (*limited to 6 pages*):

- The candidate must name a primary mentor who, together with the candidate, is responsible for planning, directing, monitoring, and executing the program. The candidate may also nominate co-mentors as appropriate to the goals of the program.
- The mentor should be recognized as an accomplished investigator in the proposed research area and have a track record of success in training and placing 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.
- Where feasible, women, individuals from diverse racial and ethnic groups, and individuals with disabilities should be involved as mentors to serve as role models.
- The application must include a statement from the mentor providing: 1) information on his/her 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; 3) a plan for career progression for the candidate to move from the mentored stage of his/her career to the independent research investigator status during the project period of the award; and 4) a plan for monitoring the candidate's research, publications, and progression towards independence.
- Similar information must be provided by any co-mentor. If more than one co-mentor is proposed, the respective areas of expertise and responsibility of each should be described. Co-mentors should clearly describe how they will coordinate the mentoring of the candidate. If any of the co-mentors are

not located at the sponsoring institution, a statement should be provided describing the mechanism(s) and frequency of communication with the candidate, including the frequency of personal meetings.

- The mentor must agree to provide annual evaluations of the candidate's progress as required in the annual progress report

Letters of Support from Consultants and Collaborators (*limited to 6 pages*):

- 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.
- 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.

Environment and Institutional Commitment to the Candidate

Description of Institutional Environment (*limited to 1 page*):

- 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.
[K23: Describe the resources and facilities that will be available to the candidate, including any resources that are within a General Clinical Research Center (GCRC) or Clinical and Translational Science Award (CTSA).]

Institutional Commitment to Candidate's Research Career Development (*limited to 1 page*):

- 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 this career award.
- Provide assurances that the candidate will be able to devote a minimum of 9 person-months (75% of full-time professional effort) to the development of their research program. The remaining effort should be devoted to activities related to the development of the candidate's career as an independent scientist, e.g. clinic responsibilities, teaching and administration, and/or additional research activities.
- 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.
- Provide appropriate time and support for any proposed mentor(s) and/or other staff consistent with the career development plan.
- K23: Candidates who will be using the resources within a General Clinical Research Center (GCRC) or Clinical and Translational Science Award (CTSA) during the course of the award are requested to include a letter of agreement from either the GCRC or CTSA program director or the principal investigator as part of the application.

Definitions of Criteria and Considerations for Critiques of K01, K08 & K23 Awards

From Program Announcements; see also: <http://grants.nih.gov/grants/peer/critiques/k.htm>

Overall Impact. Reviewers should provide an overall impact critique to reflect their assessment of the likelihood for the candidate to maintain a strong research program, taking into consideration the criteria below in determining the overall impact/priority score. Critiques should indicate the most significant strengths and weaknesses. Reviewers should recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator.

The following five criteria are given individual scores on the 1 (exceptional) to 9 (poor) scale (*see p5*), together with a list of strengths and weaknesses.

1. Candidate.

- Does the candidate have the potential to develop as an independent and productive researcher?
- Is the candidate's academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research or patient-oriented research [K23]?
- Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high potential for becoming an independent investigator?

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence?
- Is the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?

3. Research Plan.

- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Is the research plan relevant to the candidate's research career objectives?
- Is the research plan appropriate to the stage of research development and as a vehicle for developing the research skills described in the career development plan?

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

- Are the mentor's research qualifications in the area of the proposed research appropriate?
- Do the mentor(s) adequately address the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?

- Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of previous research productivity and peer-reviewed support [K23: focusing on patient-oriented research]?
- Is there active/pending support for the proposed research project appropriate and adequate?
- Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

5. Environment and Institutional Commitment to the Candidate.

- Is there clear commitment of the sponsoring institution to ensure that a minimum of 75% of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program?

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>

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.

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses
<p>Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed</p>			
<p>Minor Weakness: An easily addressable weakness that does not substantially lessen impact</p>			
<p>Moderate Weakness: A weakness that lessens impact</p>			
<p>Major Weakness: A weakness that severely limits impact</p>			

From: http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf