

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

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 the **Career Development Instructions for NIH and Other PHS Agencies**

—Forms E required for applications on or after January 25, 2018

Download instructions from: <https://grants.nih.gov/grants/how-to-apply-application-guide.html>

This handout contains the following information:

1. General Features of Mentored K Awards (p1)
2. Objectives, eligibility & special features of K01, K08, K23 Career Development Awards, (pp2–3).
3. Career Development Award Supplemental Form Component Sections (pp4–6).
4. Definitions of Criteria and Considerations for Critiques of K01, K08 & K23 Awards (pp6–7).

General Features of Mentored K Awards

The overall goal of the NIH Research Career Development program is to help ensure that a diverse pool of highly trained scientists is available in appropriate scientific disciplines to address the Nation's biomedical, behavioral, and clinical research needs. NIH Institutes and Centers (ICs) support a variety of mentored career development programs designed to foster the transition of new investigators to research independence.

Eligible Individuals (Program Director/Principal Investigator)

Any candidate with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director/Principal Investigator (PD/PI) is invited to work with his/her mentor and organization to develop an application for support. Multiple PDs/PIs are not allowed.

By the time of award, the individual must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551, or other legal verification of such status). Individuals on temporary or student visas are not eligible.

Former PD/PIs on NIH research project (R01), program project (P01), center grants, FIRST Awards (R29), sub-projects of program project (P01) or center grants, other career development awards (K-awards), or the equivalent are not eligible. Former PD/PIs of an NIH Small Grant (R03), Exploratory/Developmental Grant (R21), Dissertation Award (R36), or SBIR/STTR (R41, R42, R43, R44) remain eligible.

Level of Effort

At the time of award, the candidate must have a full-time appointment at the applicant 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. Candidates may engage in other duties as part of the remaining 25% of their full-time professional effort not covered by this award, as long as such duties do not interfere with or detract from the proposed career development program.

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. The mentor, or a member of the mentoring team, should have a successful track record of mentoring individuals at the candidate's career stage. In such cases, one individual must be identified as the principal mentor who will coordinate the candidate's research. The candidate must work with the mentor(s) in preparing the application.

MENTORED RESEARCH SCIENTIST DEVELOPMENT AWARD (K01)

Program Announcements: **PA-18-369** (Independent Clinical Trial Not allowed)

<https://grants.nih.gov/grants/guide/pa-files/PA-18-369.html>

PA-18-363 (Independent Clinical Trial Required)

<https://grants.nih.gov/grants/guide/pa-files/PA-18-363.html>

The objective of the NIH Mentored Research Scientist Development Award (K01) is to provide salary and research 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 (e.g., R01) funding.

Candidates for this award must have a research or health-professional doctoral degree. Although all of the participating NIH ICs use this 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.

Applicants are cautioned that not all NIH Institutes and Centers (ICs) participate in this program, and that consultation with relevant IC staff prior to submission of an application is strongly encouraged. The participating ICs have different emphases and program requirements for this program. Therefore, a prospective applicant is urged to consult the **Table of IC-Specific Information, Requirements and Staff Contacts** at <https://grants.nih.gov/grants/guide/contacts/parent-K01-CT-required.html> or <https://grants.nih.gov/grants/guide/contacts/parent-K01-CT-not-allowed.html> to determine whether the planned research and training falls within the mission of one of the participating NIH ICs.

MENTORED CLINICAL SCIENTIST DEVELOPMENT AWARD (K08)

Program Announcements: **PA-18-373** (Independent Clinical Trial Not allowed)

<https://grants.nih.gov/grants/guide/pa-files/PA-18-373.html>

PA-18-372 (Independent Clinical Trial Required)

<https://grants.nih.gov/grants/guide/pa-files/PA-18-372.html>

The objective of the NIH Mentored Clinical Scientist Research Career Development Award (K08) program is to provide salary and research support for a sustained period of “protected time” (3-5 years) to support didactic study and/or mentored research for individuals with clinical doctoral degrees (e.g., MD, DDS, DMD, DO, DC, OD, ND, DVM, PharmD, or PhD in clinical disciplines). The K08 provides support 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 mentored 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.

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.

Applicants are cautioned that not all NIH Institutes and Centers (ICs) participate in this program, and that consultation with relevant IC staff prior to submission of an application is strongly encouraged. The participating ICs have different emphases and program requirements for this program. Therefore, a prospective applicant is urged to consult the **Table of IC-Specific Information, Requirements and Staff Contacts** at <https://grants.nih.gov/grants/guide/contacts/parent-K08-CT-required.html> or <https://grants.nih.gov/grants/guide/contacts/parent-K08-CT-not-allowed.html> to determine whether the planned research and training falls within the mission of one of the participating NIH ICs.

MENTORED PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARD (K23)

Program Announcements: **PA-18-375** (Independent Clinical Trial Not allowed)

<https://grants.nih.gov/grants/guide/pa-files/PA-18-375.html>

PA-18-374 (Independent Clinical Trial Required)

<https://grants.nih.gov/grants/guide/pa-files/PA-18-374.html>

The objective of the NIH Mentored Patient-Oriented Research Career Development Award (K23) program is to provide salary and research support for a sustained period of “protected time” (3-5 years) to ensure a future cadre of well-trained scientists conducting NIH-supported Patient-Oriented Research (POR). 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 the K23 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 (or colleague) 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. Excluded from this definition are in vitro studies that utilize human tissues but do not deal directly with patients. In other words, patient-oriented research is research in which it is necessary to know the identity of the patients from whom the cells or tissues under study are derived.

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. Individuals with the Ph.D. or other doctoral degree in clinical disciplines such as clinical psychology, clinical genetics, speech-language pathology, audiology or rehabilitation are also eligible. 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.

Applicants are cautioned that not all NIH Institutes and Centers (ICs) participate in this program, and that consultation with relevant IC staff prior to submission of an application is strongly encouraged. The participating ICs have different emphases and program requirements for this program. Therefore, a prospective applicant is urged to consult the **Table of IC-Specific Information, Requirements and Staff Contacts** at <https://grants.nih.gov/grants/guide/contacts/parent-K23-CT-required.html> or <https://grants.nih.gov/grants/guide/contacts/parent-K23-CT-not-allowed.html> to determine whether the planned research and training falls within the mission of one of the participating NIH ICs.

Career Development Award Supplemental Form Component Sections

(common content of K award applications):

Candidate Information and Goals for Career Development

Candidate's Background:

- Describe the candidate's commitment to a health-related research career [K23: academic career in Patient-Oriented Research]. Describe 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.
- Present evidence of the candidate's ability to interact and collaborate with other scientists. [K23 only]

Career Goals and Objectives:

Describe a systematic plan that

1. shows a logical progression from prior research and training experiences to the research and career development experiences that will occur during the career award period and then to independent investigator status;
2. justifies the need for further career development to become an independent investigator.

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

- 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 a mentoring team (or 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.

Research Plan Section

Research Strategy

- A sound research project that is consistent with the candidate's level of research development and objectives of his/her career development plan must be provided. The research description should demonstrate not only the quality of the candidate's research thus far but also the novelty, significance, creativity and approach, as well as the ability of the candidate to carry out the research.
- The application must also describe the relationship between the mentor's research and the candidate's proposed research plan.
- [K23 only] While the focus of the K23 award is on POR, complementary laboratory research directly related to patient-oriented research may be proposed in the application, thereby providing an opportunity for a career development experience in translational research.

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

All applications must include a plan to fulfill NIH requirements for instruction in the Responsible Conduct of Research (RCR). The plan must address the five, required instructional components outlined in the NIH policy (see NOT-OD-10-019):

1. *Format* - the required format of instruction, i.e., face-to-face lectures, coursework, and/or real-time discussion groups (a plan with only on-line instruction is not acceptable);

2. *Subject Matter* - the breadth of subject matter, e.g., conflict of interest, authorship, data management, human subjects and animal use, laboratory safety, research misconduct, research ethics
3. *Faculty Participation* - the role of the mentor(s) and other faculty involvement in the instruction
4. *Duration of Instruction* - the number of contact hours of instruction, taking into consideration the duration of the program
5. *Frequency of Instruction* –instruction must occur during each career stage and at least once every four years.

Applications lacking a Plan for Instruction in the Responsible Conduct of Research will not be reviewed.

Mentor, Co-Mentor, Consultant, Collaborators Section

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.
- 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.
- 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
 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 all collaborators and consultants 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.
- Signed statements must be provided by each member of the proposed Advisory Committee (if applicable). 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.
- Describe the resources and facilities that will be available to the candidate [K23:, including any resources that 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 assurance that appropriate time and support will be available or 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 their assessment of the likelihood that the proposed career development and research plan will enhance the candidate's potential for a productive, independent scientific research career in a health-related field, taking into consideration the criteria below in determining the overall impact score.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

1. Candidate

- Does the candidate have the potential to develop as an independent and productive researcher?
- Are the candidate's prior training and research experience appropriate for this award?
- 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 [K23: in patient-oriented research]?
- Do the letters of reference address the above review criteria, and do they provide evidence that the candidate has a high potential for becoming an independent investigator?

2. Career Development Plan/Career Goals & Objectives

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

- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?

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?
- 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?

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

- Are the mentor's 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?