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.


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-10-056

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://grants.nih.gov/grants/guide/contacts/parent_K01.html
MENTORED CLINICAL SCIENTIST DEVELOPMENT AWARD (K08)
Program Announcement: PA-10-059

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://grants.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-10-060

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://grants.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, Training in the Responsible Conduct of Research, 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:

- 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

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

- 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.

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

**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 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:**

- 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.

<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

PHS 398 Career Development Award Supplemental Form

<table>
<thead>
<tr>
<th>1. Application Type:</th>
<th></th>
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<tbody>
<tr>
<td>From SF424 (R&amp;R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated here for your reference, as you attach the sections that are appropriate for this Career Development Award.</td>
<td></td>
</tr>
<tr>
<td>![New] ![Resubmission] ![Renewal] ![Continuation] ![Revision]</td>
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<tr>
<th>2. Career Development Award Attachments:</th>
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<tbody>
<tr>
<td>Please attach applicable sections, below</td>
<td></td>
</tr>
</tbody>
</table>

## Introduction (if applicable)

1. Introduction to Application (for RESUBMISSION applications only)

## Candidate Information

2. Candidate's Background

3. Career Goals and Objectives

4. Career Development/Training Activities During Award Period

5. Training in the Responsible Conduct of Research

6. Mentoring Plan (when applicable)

## Statements of Support

7. Statements by Mentor, Co-Mentors, Consultants, Contributors (as appropriate)

## Environment and Institutional Commitment to Candidate

8. Description of Institutional Environment

9. Institutional Commitment to Candidate's Research Career Development

## Research Plan

10. Specific Aims

11. *Research Strategy

12. Inclusion Enrollment Report (for RENEWAL applications only)

13. Progress Report Publication List (for RENEWAL applications only)

## Human Subject Sections

14. Protection of Human Subjects

15. Inclusion of Women and Minorities

16. Targeted/Planned Enrollment

17. Inclusion of Children
### Candidate Information

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Instructions</th>
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</thead>
<tbody>
<tr>
<td>2. Candidate’s Background</td>
<td>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 <strong>Add Attachment</strong>, browse to where you saved the file, select the file, and then click <strong>Open</strong>.</td>
</tr>
<tr>
<td>3. Career Goals and Objectives</td>
<td>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 <strong>Add Attachment</strong>, browse to where you saved the file, select the file, and then click <strong>Open</strong>.</td>
</tr>
<tr>
<td>4. Career Development/Training Activities During Award Period</td>
<td>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 <a href="#">NOT-OD-08-065</a>). 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 <strong>Add Attachment</strong>, browse to where you saved the file, select the file, and then click <strong>Open</strong>.</td>
</tr>
<tr>
<td>Field Name</td>
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</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

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<th>Field Name</th>
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<tr>
<td><strong>7. Statements by Mentor, Co-mentor(s), Consultants, Contributors</strong></td>
<td>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:</td>
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<tr>
<td></td>
<td>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.</td>
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<td>2. The source of anticipated support for the candidate’s research project for each year of the award period.</td>
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<td></td>
<td>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.</td>
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<td>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.</td>
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<td>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.</td>
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</table>

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),
### Field Name | Instructions
--- | ---
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.

### Environment and Institutional Commitment to the Candidate

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<th>Field Name</th>
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<tr>
<td><strong>8. Description of Institutional Environment</strong></td>
<td>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.</td>
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<tr>
<th>Field Name</th>
<th>Instructions</th>
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| **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>
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<tr>
<th>Field Name</th>
<th>Instructions</th>
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<tr>
<td>appropriate awarding component Scientific/Research contact listed in the specific FOA to determine the level of commitment required for this application.</td>
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**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>
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<th>Field Name</th>
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</table>
| 10. Specific Aims| 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. |
| 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 |
### 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

(Renewal applications only)

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.
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.

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• Referee MI Name (Not Required)
• Referee Email (Required)
• Referee institution/affiliation (Required)
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**Candidate Information:**
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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)