

## 7. Supplemental Instructions for Preparing an Individual Research Career Development Award 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 Web site <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>).

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**

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

\*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 on the SF424 (R&R) Cover Component in Item 21. Cover Letter Attachment.

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 e-mails 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 e-mail 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](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 to become an independent research scientist;
- 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 e-mail (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 e-mail. 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 e-mail confirmation will include a Reference Letter Submission Confirmation Number. The Confirmation Number will be required when resubmitting letters for the current round. Please print the confirmation e-mail 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.

### 7.4.1 Special Instructions for 4.2 Cover Component

**Item 8. Type of Application:** Unless stated in the applicable FOA, individual K awards are usually not renewable nor are they supplemented/revised (contact awarding component staff if clarification is needed). Therefore, the applicant should generally check “new” or “resubmission.” “Renewal” applications are accepted only for a few K programs; thus this value should only be checked if a specific FOA states Renewals are accepted.

**Item 12. Proposed Project (Start and Ending Dates):** The requested period of support must be within specified limits for the type of K award requested.

**Item 14. Project Director/Principal Investigator (PD/PI) Contact Information:** Provide the name of the individual candidate (considered the PD/PI for K award programs). If the candidate is not located at the applicant organization at the time the application is submitted, the information in Item 14 should reflect where the candidate can be reached prior to the requested award start date in item 12. If the PD/PI is not located at the applicant organization at the time of submission, the Commons account for the PD/PI must be affiliated with the applicant organization. For additional information on creating affiliations for users in the eRA Commons, see: <https://commons.era.nih.gov/commons-help/175.htm>.

Note: For some career transition award programs (e.g., K22) the applicant may apply WITHOUT an institutional affiliation. These individuals should refer to the specific funding opportunity announcement (FOA) for application instructions.

#### Item 21. Cover Letter Attachment

Mentored CDA applicants must include a cover letter. Applicants for independent CDAs are encouraged to include a cover letter with the application. The cover letter is only for internal use and will not be shared with peer reviewers. For mentored CDA applications, the cover letter must contain the same list of Referees (including name, departmental affiliation, and institution) that is included in the Other Project Information Component Item 12. Other Attachment (see [Part I Section 7.4.3](#)).

For both mentored and non-mentored K applications, the cover letter can also include the information found in Part I.4.2.

### 7.4.2 Special Instructions for 4.3 Research & Related Project/Performance Site Locations Component

Indicate where the work described in the Research and Career Development Plans will be conducted.

### 7.4.3 Special Instructions for 4.4 Other Project Information Component

**Item 7. Project Summary/Abstract** (Do not exceed 1 page): Provide an abstract of the entire application (candidate, environment, and research). Include the candidate's immediate and long-term career goals, key elements of the research career development plan, and a description of the research project, as indicated in Part I.4.4.6.

**Item 10. Facilities & Other Resources:** Provide in the Attachment a detailed description of the institutional facilities and resources available to the candidate, following the instructions in Part I.4.4.10. The information provided is of major importance in establishing the feasibility of the goals of the career development plan.

**Item 12. Other Attachments:** All mentored K applications must include a list of Referees here. The list should include the name of the referee, departmental affiliation and institution. This same list must also be provided in the Cover Letter.

## 7.4.4 Special Instructions for 4.5 Senior/Key Person Profile(s) Component

### 7.4.4.1 The Candidate

For all K applications the K candidate is considered the Project Director/Principal Investigator (PD/PI). Therefore the candidate must be registered in the eRA Commons and be assigned the PI role within the Commons. Follow the instructions in Part I.2 which provides information regarding required registration in the eRA Commons.

Note that agency policies concerning “Multiple PIs” are not applicable to K applications. Therefore, do not use the PD/PI role for any other senior/key personnel.

#### Candidate’s Biographical Sketch

A biographical sketch attachment (limited to 4 pages) is required for the K candidate.

A biosketch for the K applicant should follow the instructions below:

**Position Title:** If the candidate is not currently located at the applicant organization, include both “current” and “projected” position titles, labeling each accordingly.

**Education:** Complete the educational block at the top of the format page beginning with the baccalaureate or other initial professional education, such as nursing, and include postdoctoral training; separately referencing residency training when applicable. For each entry provide the name and location of the institution; the degree received (if applicable); the month and year the degree was received, and the field of study. For residency entries, the Field of Study section should reflect the area of residency. For non-degree education, indicate the time period covered. List professional certifications received within the last 10 years.

**Personal Statement:** Briefly describe why your experience and qualifications make you particularly well-suited to receive the K award for which you are applying.

#### Research and/or Professional Experience:

Use the headings given below instead of the instructions on the Biographical Sketch Format Page. Identify each heading.

#### Employment

Start with the first position held following the baccalaureate and give a consecutive record to date. Indicate the department and organization, department head or supervisor, rank, tenured or non-tenured, status (full- or part-time), and inclusive dates (month and year). When applicable, include information on military service, and, if not referenced under Education above, internships, residencies, research assistantships, fellowships, etc. If the candidate is not currently located at the applicant organization, include the projected employment position in this section as well.

#### Honors

List academic and professional honors chronologically, including research grants and competitive fellowships awarded to the candidate.

#### Professional Societies and Public Advisory Committees

Identify professional societies and related organizations in which membership has been held within the last 10 years, giving dates. Include present membership on any Federal Government public advisory committee.

## Publications

NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the candidate's proposed research. Candidates without 15 publications may substitute the following in lieu of publications:

- o Original research and theoretical treatises;
- o Non-experimental articles, e.g., review of literature in field, book chapters, etc.;
- o Books, pamphlets, etc.

For each publication, list the authors in published sequence, full title of article, journal, volume number, page numbers, and year of publication. Indicate if you previously used another name that is reflected in any of the citations. URLs or NIH PubMed Central (PMC) submission identification numbers may be included along with the full reference. While there is no limit to the number of URLs or PMC submission identification numbers that can be cited, applicants should be both judicious and concise.

Do not include manuscripts submitted or in preparation.

When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: [http://publicaccess.nih.gov/submit\\_process\\_journals.htm](http://publicaccess.nih.gov/submit_process_journals.htm). Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material.)

## Research Support

List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the senior/key person identified on the Biographical Sketch. *Do not include number of person months or direct costs.*

Don't confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards. NIH staff will request complete and up-to-date "other support" information from you after peer review. This information will be used to check that the proposed research has not already been Federally-funded.

### 7.4.4.2 Mentor, Co-mentor, and Other Senior/Key Persons

The mentored K awards require a primary mentor, and there may be co-mentor(s), consultants and contributors. All individuals who have committed to contribute to the scientific development and execution of the project, including mentors and co-mentors, should be identified as senior/key personnel, even if they are not committing any specified measurable effort to the proposed project. Mentors and co-mentors should be assigned the Project Role of "Other Professional" and then enter "Mentor" or "Co-mentor" in the Other Project Role Category field.

Consultants should also be assigned the “Other Professional” role even if they are not committing any specified measurable effort. Then, enter the specific project role under “Other Project Role Category.”

Any individuals identified as senior/key personnel who are committing specified measurable effort should be appropriately assigned under Project Role (and Other Project Role Category, if necessary). Additional information can be found in Section 4.5.1.

**Current and Pending Support for Mentors/Co-mentors:** For Mentored Career Development Awards, as part of the application submission modified Current and Pending Support pages must be submitted for the mentor and co-mentor(s), but not for the candidate, on the R&R Senior/Key Person Profile (Expanded) page. Provide information on the following selected items for the mentor’s and co-mentor’s current and pending research support relevant to the candidate’s research plan. Each attachment is limited to 4 pages. Note, Current and Pending Support for the Candidate will be requested on a Just-In-Time basis.

### **Special Instructions for Selected Items of Current & Pending Support for Mentor/Co-Mentors**

**Project Number:** If applicable, include a code or identifier for the project.

**Source:** Identify the agency, institute, foundation, or other organization that is providing the support.

**Major Goals:** Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

**Dates of Approved/Proposed Project:** Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

**Annual Direct Costs:** In the case of an active project, provide the current year’s direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

<b>Do not include information on overlap and level of effort.</b>
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**For non-mentored CDAs:** Candidates for non-mentored CDAs should not submit Other Support Pages at the time of application unless specified to do so in the applicable FOA.

Updated information on all active support for the candidate, mentor(s), co-mentor(s), and senior/key personnel may be requested by the awarding component prior to award.

**Biographical Sketch for Mentor/Co-mentor and Other Senior/Key Person:** For the biographical sketch for all individuals other than the candidate, follow the biographical sketch instructions found in Part I.4.5.

Note: K22 and K99/R00 candidates should follow instruction in the specific FOA regarding senior/key personnel.

## **7.4.5 Special Instructions for 4.6 Selecting the Appropriate Budget Component**

K award mechanisms are not modular; therefore, only the R&R budget component is applicable and only a few budget categories are actually used. Information regarding allowable costs for the candidate and any allowable research development or other costs is included in each K program FOA. Candidates are advised to contact the targeted awarding component if uncertain about allowable amounts for the applicable K award mechanism, keeping in mind that amounts vary with awarding components. The application forms package associated with CDA funding opportunities includes the R&R Budget Component.



Instructions for completing the R&R Budget Component are provided below. Additional guidance may also be provided in the specific funding opportunity announcement.

Note: NIH intramural candidates applying for transitional career award support (e.g., K22, K99/R00) should follow instructions in the applicable FOA. For the mentored phase of these awards, budgets are negotiated with the sponsoring intramural laboratory. For awardees who receive approval to transition to the extramural phase, a budget will be required as part of the extramural sponsored application.

## 7.4.6 Special Instructions for 4.7 R&R Budget Component

Follow the instructions provided in Part I.4.7 with the following exceptions:

**4.7.1. A. Senior/Key Person:** In general this section should include the name of the candidate only. Do not include the mentor(s) or any other senior/key persons. For the candidate, provide the base salary, person months, and requested salary and fringe benefits. For person months, be reminded that K programs include a minimum effort requirement, usually 75% or 9 academic person months. For the salary column, most NIH ICs limit the amount of salary provided for K programs. However, applicants should include information on actual institutional base salary and the actual amount of salary and fringe being requested. ICs may request updated salary information prior to award. Any adjustments based on policy limitations will be made at the time of the award.

**4.7.1. B. Other Personnel:** In general, leave this section blank.

**4.7.2. C – E:** Leave these sections blank.

**4.7.3 F. Other Direct Costs: In the Material and Supplies field (F.1),** enter the total research development support being requested for the initial year of the K award. Usually, a specific total amount is allowed for research development and other costs (tuition, fees, research supplies, equipment, computer time, travel, etc) that do not require individual cost category identification. Unless instructed differently in the applicable FOA, applicants should enter only the total requested research development support amount in this box. All remaining budget fields in this section should be left blank.

Please note that while this method of entering only the total requested research development support (RDS) costs in section F will be simplest for most applicants, some applicants, including some system-to-system applicants, may instead choose to enter those costs in the applicable detailed budget categories. Please note that when choosing this option it is still the applicant’s responsibility to make certain the total RDS costs do not exceed the allowable total. If there are no costs within the research development support costs that affect the Indirect Cost Base calculation, the total RDS should be entered in total in F.1.

**4.7. 3. H. Indirect Costs:** For all K applications, F&A/indirect costs are reimbursed at 8% of modified total direct costs (exclusive of tuition and fees and expenditures for equipment) rather than on the basis of a negotiated rate agreement. Follow the instructions in the chart below for completing this section.

Field Name	Instructions
Indirect Cost Type	Indicate the Indirect Cost type as Modified Total Direct Costs.
Indirect Cost Rate (%)	Indicate the indirect cost rate (also known as Facilities & Administrative Costs [F&A]) as 8%.
Indirect Cost Base (\$)	Enter the amount of the base for the indirect cost type.
Funds Requested	Enter the funds requested for the indirect cost type.

Field Name	Instructions
Total Indirect Costs	The total funds requested for indirect costs.
Cognizant Federal Agency	Enter 'Not Applicable.' Alternatively, applicants may provide the name of the cognizant Federal agency, name, and phone number of the individual responsible for negotiating your rate. Either response is acceptable since indirect costs will be reimbursed as 8% of modified total direct costs rather than on the basis of a negotiated rate agreement.

**4.7.3.K Budget Justification:** Use this to provide a detailed description and justification for specific items within the Research Development Support costs; e.g., all equipment, supplies, and other personnel that will be used to help achieve the career development and research objectives of this award.

## 7.4.7 Special Instructions for 5. Completing PHS 398 Components

### 5.1 Overview

In conjunction with the SF424 (R&R) components, NIH and other PHS agencies grants applicants should also complete and submit additional components titled “PHS 398.” Note the PHS 398 components include additional data required by the agency for a complete application. While these are not identical to the PHS 398 application form pages, the PHS 398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to NIH and other PHS agencies will include SF424 (R&R) and PHS 398 components. The PHS 398 components for the individual K programs include:

- **PHS 398 Cover Page Supplement (I.5.3):** this supplements the data requirements in the R&R Cover Component. Follow the instructions found in Part I.5.3 and in the K specific instructions below.
- **PHS 398 Career Development Award Supplemental Form (I.7.5)**

Complete each component using the instructions found in Part I.5 and the K specific instructions provided below.

### 5.3 Cover Page Supplement Component

**3. Change of Investigator / Change of Institution Questions:** A change in PD/PI is not allowed for K awards.

## 7.5 PHS 398 Career Development Award Supplemental Form

PHS 398 Career Development Award Supplement Form		OMB Number: 0925-0001		
Please attach applicable sections of the career development award application, below				
<b>Introduction (if applicable)</b>				
1. Introduction to Application (for RESUBMISSION applications only)	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
<b>Candidate Information</b>				
2. Candidate's Background	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
3. Career Goals and Objectives	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
4. Candidate's Plan for Career Development/ Training Activities During Award Period	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
5. Training in the Responsible Conduct of Research	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
6. Candidate's Plan to Provide Mentoring (as applicable)	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
<b>Statements and Letters of Support</b>				
7. Plans and Statements of Mentor and Co- mentor(s)	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
8. Letters of Support from Collaborators, Contributors, and Consultants	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
<b>Environment and Institutional Commitment to Candidate</b>				
9. Description of Institutional Environment	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
10. Institutional Commitment to Candidate's Research Career Development	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
<b>Research Plan</b>				
11. Specific Aims	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment
12. *Research Strategy	<input type="text"/>	Add Attachment	Delete Attachment	View Attachment

The PHS 398 CDA Supplemental Form should include sufficient information needed for evaluation of the project, independent of any other document (e.g., previous application). Be specific and informative, and avoid redundancies. Some sections are required for all K award applications and some sections are only to be used when required by the FOA. Be sure to read all instructions in the FOA before completing this section since errors could lead to incomplete or rejected applications.

### 1. Application Type

This field is pre-populated from the SF424 (R&R) Cover Component. Corrections to this field must be made in that component.

### 2. Career Development Award Attachments (See also [Section 2.3.2 Creating PDFs for Text Attachments](#))

Although many of the sections of this application are separate PDF attachments, page limits referenced in the instructions and/or funding opportunity announcement must still be followed. Agency validations will include checks for page limits (and use of appropriate font). Some accommodation will be made for sections that, when combined, must fit within a specified limitation.

Text attachments should be generated using word processing software and then converted to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application. In addition, be sure to save files with descriptive file names.

Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.

Full-sized glossy photographs of material such as electron micrographs or gels must only be included within the page limits of the Career Development Award application. The maximum size of images to be included should be approximately 1200 x 1500 pixels using 256 colors. Figures must be readable as printed on an 8.5 x 11 inch page at normal (100%) scale.

Candidates must use image compression such as JPEG or PNG. Do not include figures or photographs as separate attachments either in the Appendix or elsewhere in the application.

### **Separate Attachments**

Separate attachments have been designed for the Career Development Award Supplemental Form sections to maximize automatic validations conducted by the eRA system. When the application is received by the agency, all of the CDA Supplemental Form sections will be concatenated in the appropriate order so that reviewers and agency staff will see a single cohesive application.

When attaching a PDF document to the actual forms, please note you are attaching an actual document, not just pointing to the location of an externally stored document. Therefore, if you revise the document after it has been attached, you must delete the previous attachment and then reattach the revised document to the application form. Use the **View Attachment** button to determine if the correct version has been attached.

### **Page Limits**

**The total number of pages for Items 2 – 4 (Candidate’s Background, Career Goals and Objectives, and Career Development/Training Activities During Award Period) and Item 11 (Research Strategy) combined may not exceed 12 pages. Training in the Responsible Conduct of Research (Item 2.5) has its own separate page limit, and is limited to 1 page.** All tables, graphs, figures, diagrams, and charts must be included within the 12-page limit (note that this may span to 15 pages in the eRA Commons application image due to white space inserted at the end of sections when separating files).

### **Follow page limitations as specified in Funding Opportunity Announcements (FOA).**

All applications and proposals for NIH funding must be self-contained within specified page limits. Agency validations will include checks for page limits. Note that while these computer validations will help minimize incomplete and/or non-compliant applications, they do not replace the validations conducted by NIH staff. Applications found not to comply with the requirements may be delayed in the review process. Unless otherwise specified in an NIH solicitation, Internet Web site addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned that they should not directly access an internet site as it could compromise their anonymity.

Applicants are prohibited from using the Appendix to circumvent page limitations in any section of the application for which a page limit applies.” For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html>.

### **Notice of Proprietary Information**

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, or information that is commercial or financial, or information that is confidential or privileged, make sure you have checked the “Yes” box of question #3 in the “Other Project Information” component. Identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (\*) in the left-hand margin. Include a legend at the beginning of Section 2, similar to “The following sections marked with an asterisk contain proprietary/privileged information that (name of Applicant) requests not be released to persons outside the Government, except for purposes of review and evaluation.”

When information in the application constitutes trade secrets or information that is commercial or financial, or information that is confidential or privileged, it is furnished to the Government in confidence with the understanding that the information shall be used or disclosed only for evaluation of this application. If a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government’s right to use the information if it is obtained without restriction from another source.

### **Research Plan**

A Research Plan is required for all types of individual K awards. The Research Plan is a major component of the research career development plan. It is important to relate the research to the candidate's scientific career goals. Describe how the research, coupled with other developmental activities, will provide the experience, knowledge, and skills necessary to achieve the objectives of the career development plan and launch and conduct an independent research career, or enhance an established research career. For mentored K awards, explain the relationship between the candidate’s research on the CDA and the mentor’s ongoing research program.

For most types of research, the plan should include: a specific hypothesis; a list of the specific aims and objectives that will be used to examine the hypothesis; a description of the methods/approaches/techniques to be used in each aim; a discussion of possible problems and how they will be managed; and, when appropriate, alternative approaches that might be tried if the initial approaches do not work.

The Research Plan of a CDA is expected to be appropriate for, and tailored to the experience level of the candidate, and allow him/her to develop the necessary skills needed for further career advancement, and reviewers will evaluate the plan accordingly. The plan should be achievable within the requested time period. Pilot or preliminary studies and routine data gathering are generally not appropriate as the sole component(s) of a CDA research plan. Although candidates for mentored K awards are expected to write the Research Plan, the mentor should review a draft of the plan and discuss it in detail with the candidate. Review by other knowledgeable colleagues is also helpful. Although it is understood that CDA applications do not require the extensive detail usually incorporated into regular research applications, a fundamentally sound Research Plan and a reasonably detailed Approach section should be provided.

In general, less detail will be expected in descriptions of research planned for the future years of the proposed CDA. However, sufficient detail should be provided to enable the peer reviewers to determine

that the plans for those years, including the approach to be used, are worthwhile and are likely to enable the candidate to achieve the objectives of the Research Plan.

The PHS 398 Career Development Award Supplemental Form is comprised of sections for: Candidate Information; Statement of Support (Mentors); Environment & Institutional Commitment to the Candidate; and the Research Plan (including Human Subjects and Other Research Plan Sections).

Begin each text section of the Candidate Information and Research Plan with a section header (e.g., Introduction, Specific Aims, Background & Significance, etc). See Specific FOA for additional information.

Field Name	Instructions
1. Introduction to Application (for Resubmissions only)	<p>There is no time limit for the submission of a resubmission application (A1). See NIH Notice NOT-OD-09-003 and NOT-OD-09-016 for additional information/clarification of NIH policy.</p> <p>Resubmission applications must include an Introduction to Resubmission Application, not to exceed one page. The Introduction must include responses to the criticisms and issues raised in the Summary Statement. Summarize the substantial additions, deletions, and changes. In the body of the application, highlight paragraphs with significant changes by bracketing and changing typography.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

### Candidate Information

Field Name	Instructions
2. Candidate's Background	<p>The total number of pages for Items 2 – 4 and Item 11 (Research Strategy) combined may not exceed 12 pages, unless the FOA specifies otherwise.</p> <p>Use this section to provide any additional information not described in the Biographical Sketch Format Page such as research and/or clinical training experience.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

Field Name	Instructions
<p>3. Career Goals and Objectives</p>	<p>The total number of pages for Items 2 – 4 and Item 11 (Research Strategy) combined may not exceed 12 pages, unless the FOA specifies otherwise.</p> <p>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.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
<p>4. Candidate’s Plan for Career Development/ Training Activities During Award Period</p>	<p>The total number of pages for Items 2 – 4 and Item 11 (Research Strategy) combined may not exceed 12 pages, unless the FOA specifies otherwise.</p> <p>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.</p> <p>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>).</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
<p>5. Training in the Responsible Conduct of Research</p>	<p>This attachment is required and is limited to one page.</p> <p>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 obtain or 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).</p> <p>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</p>

Field Name	Instructions
	<p>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.</p> <p>Where applicable, Renewal applications must describe the RCR instruction activities undertaken during the project period as well as future plans.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
<p>6. Candidate’s Plan to Provide Mentoring (Include only when required by the specific FOA, e.g., K24 and K05)</p>	<p>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.</p> <p>This attachment must not exceed 6 pages. Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

### Statements and Letters of Support

Field Name	Instructions
<p>7. Plans and Statements of Mentor and Co-mentor(s)</p>	<p>This section is to be completed by the mentor and co-mentor(s), as appropriate. The letters must be appended together and uploaded as a single pdf file. This single pdf file is limited to 6 pages.</p> <p>For mentored awards (see <a href="#">Summary of Career Development Award Mechanisms table</a>), 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:</p>



Field Name	Instructions
	<ol style="list-style-type: none"> <li>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.</li> <li>2. The source of anticipated support for the candidate's research project for each year of the award period.</li> <li>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.</li> <li>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.</li> <li>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.</li> </ol> <p>All mentored career development applications should identify any and all co-mentors involved with the proposed research and career development program. Co-mentors must specifically address the nature of their 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) and co-mentor(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.</p> <p>This attachment must not exceed 6 pages. Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
<p>8. Letters of Support from Collaborators, Contributors, and Consultants</p>	<p>Attach all appropriate letters of support. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. For consultants, letters should include rates/charges for consulting services.</p> <p>All <b>mentored career development award applications</b> should identify any and all collaborators, contributors, and consultants involved with the</p>

Field Name	Instructions
	<p>proposed research and career development program not already included in Item 7. Letters should briefly describe their anticipated contributions and document their role and willingness to participate in the project.</p> <p>Additionally, <b>non-mentored career development award applications</b> should include letters from collaborators, consultants and contributors listing their proposed roles and documenting their willingness to participate in the project. The letters should also briefly describe research materials, data, guidance, or advice each person will provide.</p> <p>The letters must be appended together and uploaded as a single pdf file. Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, and the click <b>Open</b>.</p>

**Environment and Institutional Commitment to the Candidate**

Field Name	Instructions
<p>9. Description of Institutional Environment</p>	<p>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 4.4.10 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. This attachment is required and is limited to one page.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
<p>10. Institutional Commitment to Candidate's Research Career Development</p>	<p><b>Introduction</b></p> <p>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.</p> <p>Because of the diverse types of K awards, applicants should contact the appropriate awarding component Scientific/Research contact listed in the</p>

Field Name	Instructions
	<p>specific FOA to determine the level of commitment required for this application.</p> <p><b>Agreement</b></p> <p>The applicant organization must:</p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>c. Provide appropriate time and support for any proposed mentor(s) and/or other staff consistent with the career development plan.</li> </ol> <p><b>Signatures</b></p> <p>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.</p> <p>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: <a href="#">NOT-OD-06-054</a>.</p> <p>This attachment is required and is limited to one page. Create a single file of the institutional letter and save it in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

**Research Plan**

Field Name	Instructions
11. Specific Aims	<p>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.</p> <p>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.</p> <p>The Specific Aims attachment is required and is limited to one page.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
12. Research Strategy	<p>The total number of pages for Items 2 – 4 and Item 11 (Research Strategy) combined may not exceed 12 pages, unless otherwise specified in the FOA.</p> <p>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 (<a href="#">Part I Section 4.4.9</a>).</p> <p>(a) <i>Significance</i></p> <ul style="list-style-type: none"> <li>• Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.</li> <li>• Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.</li> <li>• Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.</li> </ul> <p>(b) <i>Innovation</i></p> <ul style="list-style-type: none"> <li>• Explain how the application challenges current research or clinical practice paradigms.</li> <li>• 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.</li> </ul> <p>(c) <i>Approach</i></p> <ul style="list-style-type: none"> <li>• Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 21 (Resource Sharing Plan),</li> </ul>

Field Name	Instructions
	<p>include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.</p> <ul style="list-style-type: none"> <li>• Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.</li> <li>• If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.</li> <li>• Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in Item 18 below.</li> <li>• If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.</li> </ul> <p>If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.</p> <p>As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.</p> <p><b>Preliminary Studies for New Applications:</b> For new applications, include information on Preliminary Studies. Discuss the PD/PI’s preliminary studies, data, and or experience pertinent to this application.</p> <p><b>Progress Report for Renewal and Revision Applications.</b> For renewal/revision applications, provide a Progress Report. 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.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

PHS 398 Career Development Award Supplement Form			
13. Inclusion Enrollment Report (for RENEWAL applications only)	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
14. Progress Report Publication List (for RENEWAL applications only)	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
<b>Human Subjects Sections</b>			
15. Protection of Human Subjects	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
16. Inclusion of Women and Minorities	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
17. Targeted/Planned Enrollment	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
18. Inclusion of Children	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
<b>Other Research Plan Sections</b>			
19. Vertebrate Animals	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
20. Select Agent Research	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
21. Consortium/ Contractual Arrangements	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
22. Resource Sharing Plan(s)	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
<b>Appendix (if applicable)</b>			
23. Appendix	<input type="text"/>	Add Attachment	Delete Attachment View Attachment
<b>Citizenship</b>			
		<input type="checkbox"/> U.S. Citizen or noncitizen national	<input type="checkbox"/> Permanent Resident of U.S. Pending
		<input type="checkbox"/> Permanent Resident of U.S. (If a permanent resident of the U.S., a notarized statement must be provided by the time of award)	<input type="checkbox"/> Non-U.S. Citizen with temporary U.S. visa

**Research Plan**

Field Name	Instructions
13. Inclusion Enrollment Report (Renewal applications only)	<p>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.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p> <p>See <a href="#">Part II, Section 4.3</a> for more detailed instructions on which Target and Enrollment Report or Table to use</p>

Field Name	Instructions
<p>14. Progress Report Publication List (Renewal applications only)</p>	<p>List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” A list of these journals is posted at: <a href="http://publicaccess.nih.gov/submit_process_journals.htm">http://publicaccess.nih.gov/submit_process_journals.htm</a>.</p> <p>Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of these publications are not accepted as appendix material).</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

### Human Subjects Sections

Field Name	Instructions
<p>15. Protection of Human Subjects</p>	<p>Refer to Part II, <a href="#">Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</a>. This section is required for applicants answering “yes” to the question “Are human subjects involved?” on the R&amp;R Other Project Information form. If the answer is “No” to the question but the proposed research involves human specimens and/or data from subjects applicants must provide a justification in this section for the claim that no human subjects are involved.</p> <p>Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
<p>16. Inclusion of Women and Minorities</p>	<p>Refer to Part II, <a href="#">Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</a>. This section is required for applicants answering “yes” to the question “Are human subjects involved?” on the R&amp;R Other Project Information form and the research does not fall under Exemption 4.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

Field Name	Instructions
17. Targeted/Planned Enrollment	<p>If this application involves the Inclusion of Women and Minorities, complete the Targeted/Planned Enrollment Table for each protocol, see Part II <a href="#">Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Section 4.3</a>. For applicants answering “Yes” to the question “Are human subjects involved?” on the R&amp;R Other Project Information Form and the research does not fall under Exemption 4, complete the Targeted/Planned Enrollment Table for each protocol.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
18. Inclusion of Children	<p>Refer to Part II <a href="#">Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</a>, Sections 4.4 and 5.7. For applicants answering “Yes” to the question “Are human subjects involved” on the R&amp;R Other Project Information Form and the research does not fall under Section 4, this section is required.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

### Other Research Plan Sections

Field Name	Instructions
19. Vertebrate Animals	<p>This section is required for applicants answering “yes” to the question “Are vertebrate animals involved?” on the R&amp;R Other Project Information form.</p> <p>If you indicated that Vertebrate Animals are involved in this project, address the following five key points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points. Although no specific page limitation applies to this section of the application, be succinct.</p> <ol style="list-style-type: none"> <li>1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.</li> <li>2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.</li> <li>3. Provide information on the veterinary care of the animals involved.</li> <li>4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct</li> </ol>



Field Name	Instructions
	<p>of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.</p> <p>5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.</p> <p>If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used. If an award is made, prior to the involvement of animals the grantee must submit to the NIH awarding office detailed information as required in points 1-5 above and verification of IACUC approval. If the grantee does not have an Animal Welfare Assurance then an appropriate Assurance will be required (see <a href="#">Part III Section 2.2 Vertebrate Animals</a> for more information).</p> <p>Do not use the vertebrate animal section to circumvent the page limits of the research strategy.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
	<p>For those applicants familiar with the PHS 398, please note that the Literature Cited section of the Research Plan is now captured as “Bibliography &amp; References Cited.” Refer to Item 8 in the Other Project Information Component for instructions.</p>
<p>20. Select Agent Research</p>	<p>Select agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC maintains a list of these agents. See <a href="http://www.cdc.gov/od/sap/docs/salist.pdf">http://www.cdc.gov/od/sap/docs/salist.pdf</a>.</p> <p>If the activities proposed in your application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.4(f)(5), the select agent requirements do not apply. Use this section to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions at <a href="http://www.cdc.gov/od/sap/sap/exclusion.htm">http://www.cdc.gov/od/sap/sap/exclusion.htm</a>.</p> <p>If the strain(s) is not currently excluded from the list of select agents and toxins but you have applied or intend to apply to DHHS for an exclusion from the list, use this section to indicate the status of your request or your intent to apply for an exclusion and provide a brief justification for the exclusion.</p> <p>If any of the activities proposed in your application involve the use of</p>

Field Name	Instructions
	<p>select agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.</p> <ol style="list-style-type: none"> <li>1. Identify the select agent(s) to be used in the proposed research.</li> <li>2. Provide the registration status of all entities* where select agent(s) will be used. <ul style="list-style-type: none"> <li>• If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.</li> </ul> <p>*An “entity” is defined in 42 CFR 73.1 as “any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.”</p> </li> <li>3. Provide a description of all facilities where the select agent(s) will be used. <ul style="list-style-type: none"> <li>• Describe the procedures that will be used to monitor possession, use and transfer of the select agent(s).</li> <li>• Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).</li> <li>• Describe the biocontainment resources available at all performance sites.</li> </ul> <p>If you are responding to a specific FOA, address any requirements specified by the FOA.</p> <p>Reviewers will assess the information provided in this Section, and any questions associated with select agent research will need to be addressed prior to award.</p> <p>Save this file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p> </li> </ol>
<p>21. Consortium/Contractual Arrangements</p>	<p>Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. The signature of the Authorized Organization Representative on the SF424 (R&amp;R) cover component (Item 17) signifies that the applicant and all proposed consortium participants understand and agree to the following statement:</p> <p style="text-align: center;"><i>The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency’s consortium agreement policy and are prepared to</i></p>

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	<p><i>establish the necessary inter-organizational agreement(s) consistent with that policy.</i></p> <p>A separate statement is no longer required.</p> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>
22. Resource Sharing Plan(s)	<p>NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Part III, 1.5 Sharing Research Resources.</p> <ol style="list-style-type: none"> <li>1. <i>Data Sharing Plan</i>: Investigators seeking \$500,000 or more in direct costs (exclusive of consortium F&amp;A) in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Specific Funding Opportunity Announcements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See <a href="#">Data-Sharing Policy</a> or <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html</a>.</li> <li>2. <i>Sharing Model Organisms</i>: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. See <a href="#">Sharing Model Organisms Policy</a>, and <a href="#">NIH Guide NOT-OD-04-042</a>.</li> <li>3. <i>Genome Wide Association Studies (GWAS)</i>: Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, <a href="#">NIH Guide NOT-OD-07-088</a>, and <a href="http://gwas.nih.gov/">http://gwas.nih.gov/</a>.</li> </ol> <p>Save this information in a single file in a location you remember. Click <b>Add Attachment</b>, browse to where you saved the file, select the file, and then click <b>Open</b>.</p>

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23. Appendix	<p>Do not use the appendix to circumvent the page limits of the Candidate Information (Items 2-4) and the Research Strategy (Item 11) or any other section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, <a href="http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html">http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html</a>.</p> <p>Only one copy of appendix material is necessary. Use the <b>Add Attachments</b> button to the right of this field to complete this entry.</p> <p>A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10. Note that this is the total number of appendix items, not the total number of publications. When allowed there is a limit of 3 publications that are not publicly available (see below for further details and check the FOA for any specific instructions), though not all grant mechanisms allow publications to be included in the appendix.</p> <p>Appendix material may not appear in the assembled application in the order attached, so it is important to use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment. Applications that do not follow the appendix requirements may be delayed in the review process.</p> <p>New, resubmission, renewal, and revision applications <b>may</b> include the following materials in the Appendix:</p> <ul style="list-style-type: none"> <li>• <b>Publications – No longer allowed as appendix materials except in the circumstances noted below.</b> Applicants may submit up to 3 of the following types of publications:</li> <li>• <b>Manuscripts and/or abstracts accepted for publication but not yet published:</b> The entire article should be submitted as a PDF attachment.</li> <li>• <b>Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available:</b> The entire article should be submitted as a PDF attachment.</li> <li>• <b>Patents directly relevant to the project:</b> The entire document should be submitted as a PDF attachment.</li> <li>• Do not include unpublished theses, or abstracts/manuscripts <b>submitted</b> (but not yet accepted) for publication.)</li> <li>• Surveys, questionnaires, and other data collection instruments; clinical protocols and informed consent documents may be submitted in the Appendix as necessary.</li> <li>• For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g.,</li> </ul>

Field Name	Instructions
	<p>medical devices, prototypes, DVDs, CDs), applicants should contact the Scientific Review Officer for instructions following notification of assignment of the application to a study section. Applicants are encouraged to be as concise as possible and submit only information essential for the review of the application.</p> <p>Items that must not be included in the appendix:</p> <ul style="list-style-type: none"> <li>• Photographs or color images of gels, micrographs, etc., <b>are no longer accepted as Appendix material</b>. These images must be included in the Research Plan PDF. However, images embedded in publications are allowed.</li> <li>• Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.</li> </ul>

### 3. Citizenship

The candidate must provide information regarding citizenship status. Other than for the K99/R00 award program, the candidate must be a citizen or non-citizen national of the United States or its possessions and territories, or must have been lawfully admitted to the United States for permanent residence by the time of award.

For those K award programs with a citizenship requirement, an individual who has applied for Permanent Residence and expects to have obtained such status prior to the time award, may submit an application recognizing that no award will be made until legal verification of permanent resident status is provided. If a candidate's citizenship status changes after submission of the application, the new status should be reported in the candidate's Personal Profile in the eRA Commons. Before an award is issued, a permanent resident will be required to submit a notarized statement that a licensed notary has seen the candidate's current and valid Permanent Resident Card or some other valid verification from the U.S. Immigration and Naturalization Service of legal admission to the U.S. as a permanent resident.

It is the responsibility of the sponsoring institution to determine and retain documentation indicating that the individual candidate's visa will allow him/her to reside in the proposed research training/career development setting for the period of time necessary to complete the approved career development program. Information may be requested by the NIH prior to issuance of an award.

Each candidate **must** check the applicable box, check only one:

- **U.S. Citizen or non-citizen national:** Check this box if the candidate is a U.S. Citizen or Noncitizen national. Noncitizen nationals are people, who, although not citizens of the United States, owe permanent allegiance to the United States. They generally are people born in outlying possessions of the United States (e.g., American Samoa and Swains Island).;
- **Permanent Resident of U.S.:** Check this box if the candidate has been lawfully admitted for permanent residence; i.e., is in the possession of a current and valid Permanent Resident Card

or other legal verification of such status. A notarized statement will be required as part of the pre-award process.

- **Permanent Resident of U.S. Pending:** Check this box if the candidate has applied for Permanent Residence and expects to have obtained such status prior to the time of award. A notarized statement will be required as part of the pre-award process.
- **Non-U.S. citizen with temporary U.S. visa:** This box is applicable only to specific programs that do not require U.S. citizenship or permanent residency; e.g. K99/R00. The NIH awarding component may request verifying information as part of the pre-award process.

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Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the **Move Form to Delete** button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.

## 7.6 Career Development Award Peer Review Process

The goal of NIH-supported career development programs is to help ensure that diverse pools of highly trained scientists are available in adequate numbers and in appropriate research areas to address the Nation's biomedical, behavioral, and clinical research needs. Each application must be tailored to the individual candidate.

The general process information (Overview, Streamlining, and Dual-Level Peer Review) found in Part I.6 applies to K applications as well. However, the actual review criteria and other review considerations are different. For K applications, the scientific review group will address individual career development award applications by considering information provided for each of the following elements in the application:

Review Criteria:

- Candidate
- Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring
- Research Plan
- Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)
- Environment and Institutional Commitment to the Candidate

Additional Review Criteria include the following;

- Protection of Human Subjects from Research Risk
- Inclusion of Women, Minorities, and Children in Research
- Care and Use of Vertebrate Animals in Research
- Biohazards
- Resubmission Applications
- Renewal Applications (as applicable)

Additional Review Considerations include the following:

- Training in the Responsible Conduct of Research

- Select Agents
- Resource Sharing Plans
- Budget and Period of Support

Candidates should carefully review the applicable FOA for complete information associated with the peer review process. The FOA will describe essential information to be submitted for each of the above elements.