7. Supplemental Instructions to the SF424 (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.

These supplemental instructions must be used along with the information found in Parts I.1 – I.6 of this document.

These instructions do <u>not</u> 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 or mentors, 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. 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	Yes	Yes
K02	Independent Scientist Award	No	No
K05	Senior Scientist Award	No	No
K07	Academic Career Award	*	*
K08	Mentored Clinical Scientist Development Award	Yes	Yes
K18	Career Enhancement Award	Yes	Yes
K22	Career Transition Award	*	Yes
K23	K23 Mentored Patient-Oriented Research Career Development Award	Yes	Yes
K24	Mid-Career Investigator Award in Patient-Oriented Research	No	No
K25	Mentored Quantitative Research Career Development Award	Yes	Yes
K26	Mid-Career Investigator Award in Mouse Pathobiology Research	No	No
K99/R00	NIH Pathways to Independence (PI) Award	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 five) 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 Other Attachments on the Other Project Information Form (see special K instructions in Section [7.4.3](#)). In addition, applicants must include the same list and information on the SF 424 (R&R) Form in the 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.

Letters of Reference are due by the application receipt deadline date. Although previously NIH provided a 5 business days grace period for the receipt of letters of reference after the application receipt due date, the new policy eliminates the grace period. More information can be found in NIH Guide Notice [NOT-OD-11-079](#).

The candidate should request reference letters only from individuals who will be able to submit them to the NIH at the time of the application submission due date (see NOT-OD-11-079).

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 PD/PI's (candidate's) eRA Commons user name, (b) the PD/PI's first and last name as they appear on the PD/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)

Important Note: If this is a New application, Reference Letters should NOT refer to the applicant's previous, unsuccessful submissions, previous scores, summary statements, etc., since current policy prohibits any reference to previous submissions or reviews.

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 nine 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://public.era.nih.gov/commons/public/reference/submitReferenceLetter.do?mode=new and must be submitted by the application receipt deadline date. More information can be found in NIH Guide Notice NOT-OD-11-079.

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 Middle Initial (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 at the time 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 SF 424 (R&R) Form

Standard Instructions found in Section 4.2 should be followed with the exceptions found in this section

Type of Application: Unless stated in the applicable FOA, individual K awards are usually not renewable nor are they supplemented/revised (contact awarding form 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.

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

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 should reflect where the candidate can be reached prior to the requested award start date. 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.

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 Form. 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 Form

Standard Instructions Found in Section 4.3 should be followed with the exceptions found in this section.

Indicate where the work described in the Research and Career Development Plans will be conducted, including any foreign sites (when applicable).

7.4.3 Special Instructions for 4.4 Other Project Information Form

Standard Instructions found in Section 4.4 should be followed with the exceptions found in this section.

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.

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.

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) Form

Standard Instructions found in Section 4.5 should be followed with the exceptions found in this section.

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 PD/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 is required for the K candidate. Follow the page limits for the biosketch in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.

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 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. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

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.

Contributions to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can list audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment;

models; protocols; and software or netware that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Please also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.

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.

Do not include information on overlap and level of effort.

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 Form

K award mechanisms are not modular; therefore, only the R&R budget form 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 Form.

Instructions for completing the R&R Budget Form 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 Form

Follow the instructions provided in Section 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 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.
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 Forms

5.1 Overview

In conjunction with the SF424 (R&R) forms, NIH and other PHS agencies grants applicants should also complete and submit additional forms titled "PHS 398." Note the PHS 398 forms 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) forms. A complete application to NIH and other PHS agencies will include SF424 (R&R) and PHS 398 forms. The PHS 398 forms for the individual K programs include:

> PHS 398 Cover Page Supplement (I.5.3)**:** this supplements the data requirements in the SF 424 R&R Form. Follow the instructions found in Part I.5.3 and in the K specific instructions below.
>
> {PHS 398} Planned Enrollment Report and Cumulative Inclusion Enrollment Report Follow the instructions found in Part I. 5.8.
>
> PHS 398 Career Development Award Supplemental Form (I.7.5)

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

5.3 Cover Page Supplement Form

> **7. 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 Supplemental Form

OMB Number: 0925-0001

Introduction

1. Introduction to Application (Resubmission)   [Add Attachment] [Delete Attachment] [View Attachment]

Candidate Section

2. Candidate Information and Goals for Career Development   [Add Attachment] [Delete Attachment] [View Attachment]

Research Plan Section

3. Specific Aims   [Add Attachment] [Delete Attachment] [View Attachment]

4. Research Strategy   [Add Attachment] [Delete Attachment] [View Attachment]

5. Progress Report Publications List   [Add Attachment] [Delete Attachment] [View Attachment]

6. Training in the Responsible Conduct of Research   [Add Attachment] [Delete Attachment] [View Attachment]

Other Candidate Information Section

7. Candidate's Plan to Provide Mentoring   [Add Attachment] [Delete Attachment] [View Attachment]

Mentor, Co-Mentor, Consultant, Collaborators Section

8. Plans and Statements of Mentor and Co-Mentor(s)   [Add Attachment] [Delete Attachment] [View Attachment]

9. Letters of Support from Collaborators, Contributors, and Consultants   [Add Attachment] [Delete Attachment] [View Attachment]

Environment and Institutional Commitment to Candidate Section

10. Description of Institutional Environment   [Add Attachment] [Delete Attachment] [View Attachment]

11. Institutional Commitment to Candidate's Research Career Development   [Add Attachment] [Delete Attachment] [View Attachment]

Human Subjects Section

12. Protection of Human Subjects   [Add Attachment] [Delete Attachment] [View Attachment]

13. Data Safety Monitoring Plan   [Add Attachment] [Delete Attachment] [View Attachment]

14. Inclusion of Women and Minorities   [Add Attachment] [Delete Attachment] [View Attachment]

15. Inclusion of Children   [Add Attachment] [Delete Attachment] [View Attachment]

Other Research Plan Sections

16. Vertebrate Animals   [Add Attachment] [Delete Attachment] [View Attachment]

17. Select Agent Research   [Add Attachment] [Delete Attachment] [View Attachment]

18. Consortium/Contractual Arrangements   [Add Attachment] [Delete Attachment] [View Attachment]

19. Resource Sharing   [Add Attachment] [Delete Attachment] [View Attachment]

20. Authentication of Key Biological and/or Chemical Resources   [Add Attachment] [Delete Attachment] [View Attachment]

Appendix

21. Appendix   [Add Attachments] [Delete Attachments] [View Attachments] ☐

* Citizenship

| U.S. Citizen | ☐ U.S. Citizen or Non-Citizen National |
| Non-U.S. Citizen | ☐ With a Permanent U.S. Resident Visa   ☐ With a Temporary U.S. Visa   ☐ Not Residing in the U.S. |

If you are a non-U.S. citizen with a temporary visa who has applied for permanent resident status and expects to hold a permanent resident visa by the earliest possible start date of the award, please also check here. ☐

The PHS 398 Career Development Award 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.

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

Follow the page limits for the Career Development Award Supplemental Form in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm**, unless specified otherwise in the FOA.** 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 (FOAs).

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 website 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 "Yes" for proprietary/privileged information question in the Other Project Information form.

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. However, 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.

Although the grantee institution and the PD/PI will be consulted about any such release, the PHS will make the final determination. Any indication by the applicant that the application contains proprietary or privileged information does not automatically shield the information from release in response to a Freedom of Information Act (FOIA) request should the application result in an award (see 45 CFR Part 5). If an applicant fails to identify proprietary information at the time of submission as instructed in the application guide, a significant substantive justification will be required to withhold the information if requested under FOIA.

Research Plan

A Research Plan is required for all types of individual K awards. The Research Plan is a major part 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 part(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 the following sections:

- Candidate Information
- Research Plan
- Other Candidate Information
- Mentor, Co-Mentor, Consultant, Collaborators
- Environment & Institutional Commitment to the Candidate
- Human Subjects Sections
- Other Research Plan Sections
- Appendix

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.

Introduction

Field Name	Instructions
1. Introduction to Application (for RESUBMISSION applications only)	NIH policy allows a thirty-seven month window for resubmissions (A1 applications). The NIH will not accept a resubmission (A1) application that is submitted later than 37 months after submission of the new (A0) application that it follows. See NIH Notice NOT-OD-12-128 and NOT-OD-14-074 for additional information/clarification of NIH policy. Use only if Type of Application is Resubmission. Resubmission applications must include an Introduction to Resubmission Application attachment. This attachment is required. Follow the page limits for the Individual Career Development Award Introduction to Resubmission or Revision Application in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. 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

Field Name	Instructions
	and changing typography.
	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**.

Candidate Section

Field Name	Instructions
2. Candidate Information and Goals for Career Development	This attachment is required. Follow the page limits for the Career Development Award First three items of Candidate Information in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.
	A) **Candidate's Background:** Use this section to provide any additional information not described in the Biographical Sketch Format Page such as research and/or clinical training experience. 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.
	B) **Career Goals and Objectives:** Describe what your short-term and long-term career goals and objectives are, and how the K award is envisioned to enable you to develop and/or expand your research career. It is important to justify the award and how it will enable you to develop or expand your research career. You are encouraged to include a timeline, including plans to apply for subsequent grant support.
	C) **Candidate's Plan for Career Development/Training Activities During Award Period:** Describe the new or 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, technique workshops or workshops that will help develop needed professional skills, 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. NIH and

Field Name	Instructions
	other PHS agencies use the concept of person months as a metric for determining percent of effort. To assist applicants unfamiliar with this concept, resources are available on the web at: http://grants.nih.gov/grants/policy/person_months_faqs.htm. Frequently asked questions and a conversion calculator are available. Note that recipients of mentored K awards may receive concurrent support from an NIH research grant award or cooperative agreement only under certain conditions (see NIH Notice NOT-OD-08-065). 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**.

Research Plan Section

Field Name	Instructions
3. 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. The Specific Aims attachment is required. Follow the page limits for the Career Development Award Specific Aims in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.
4. Research Strategy	Follow the page limits for the Career Development Award Research Strategy http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. 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). *Significance*

Field Name	Instructions
	Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
	Describe the scientific rationale for the proposed project, including consideration of the strengths and weaknesses of any prior research or preliminary data.
	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.
	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.
	Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
	Approach
	Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
	Describe how the experimental design and methods proposed will achieve robust and unbiased results.
	Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
	If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
	Explain how relevant biological variables, such as sex, are factored into research designs and analyses in vertebrate animal and human studies.
	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.
	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.

Field Name	Instructions
	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.
	As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.
	Preliminary Studies for New Applications: For new applications, include information on Preliminary Studies. 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. 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 the 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**.
5. Progress Report Publication List	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, that 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.
	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).
	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

Field Name	Instructions
	then click **Open**. Attachments will display in the application image in alphabetical order based on the file name.
6. Training in the Responsible Conduct of Research	This attachment is required. Follow the page limits for the Career Development Award Training in the Responsible Conduct of Research in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. 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 Supplemental Instructions 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 parts 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. 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**.

Other Candidate Information Section

Field Name	Instructions
7. Candidate's Plan to Provide Mentoring	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

Field Name	Instructions
(Include only when required by the specific FOA, e.g., K24 and K05)	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. NIH and other PHS agencies use the concept of person months as a metric for determining the percent of effort. To assist applicants unfamiliar with this concept, resources are available on the web at: http://grants.nih.gov/grants/policy/person_months_faqs.htm. Frequently asked questions and a conversion calculator are available. Follow the page limits for the Career Development Award Candidates Plan to Provide Mentoring in the table of page limits http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. 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**.

Mentor, Co-Mentor, Consultant, Collaborators Section

Field Name	Instructions
8. Plans and Statements of Mentor and Co-mentor(s)	This section is to be completed by the mentor and co-mentor(s), as appropriate. The plans and statements must be appended together and uploaded as a single pdf file. Follow the page limits for the Career Development Award Plans and Statements of Mentor and Co-mentors in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. For mentored awards (see Summary of Career Development Award Mechanisms table), the mentor must explain how they will contribute to the development of the candidate's research career. This statement should include all of the following: 1. The plan for the candidate's training and research career development. This description must include not only research, but also other developmental activities, such as seminars, scientific meetings, training in the responsible conduct of research, and presentations. It should discuss expectations for publications over the entire period of the proposed project and define what aspects

Field Name	Instructions
	of the proposed research project the candidate will be allowed to take with him/her to start their own research program.
	2. The source of anticipated support for the candidate's research project for each year of the award period.
	3. The nature and extent of supervision and mentoring of the candidate, and commitment to the candidate's development that will occur during the award period.
	4. The candidate's anticipated teaching load for the period of the award (number and types of courses or seminars), clinical responsibilities, committee and administrative assignments, and the portion of time available for research.
	5. A plan for transitioning the candidate from the mentored stage of his/her career to the independent investigator stage by the end of the project period of the award. The mentor should describe previous experience as a mentor, including type of mentoring (e.g., graduate students, career development awardees, postdoctoral students), number of persons mentored, and career outcomes.
	All mentored career development applications should identify 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 Career Development Award. 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.
	Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click Open.
9. Letters of Support from Collaborators, Contributors, and Consultants	Attach all appropriate letters of support. The letters must be appended together and uploaded as a single pdf file. Follow the page limits for the Career Development Award Letters of Support from Collaborators, Contributors, and Consultants in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA. 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.
	All **mentored career development award applications** should identify any and all collaborators, contributors, and consultants involved with the

Field Name	Instructions
	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.
	Additionally, **non-mentored career development award applications** 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.
	Save this information in a single file in a location you remember. Click **Add Attachment**, browse to where you saved the file, and the click **Open**.

Environment and Institutional Commitment to the Candidate Section

Field Name	Instructions
10. Description of Institutional Environment	The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's proposed developmental plan. Referring to the resources description (See section 4.4.10 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. Follow the page limits for the Career Development Award Description of Institutional Environment in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.
	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. 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

Field Name	Instructions
	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. Follow the page limits for the Career Development Award Institutional Commitment to Candidate's Research Career Development in the Table of Page Limits at http://grants.nih.gov/grants/forms_page_limits.htm, unless specified otherwise in the FOA.
	Because of the diverse types of K awards, applicants should contact the appropriate awarding component Scientific/Research contact listed in the specific FOA to determine the level of commitment required for this application.
	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. NIH and other PHS agencies use the concept of person months as a metric for determining the percent of effort. To assist applicants unfamiliar with this concept, resources are available on the web at: http://grants.nih.gov/grants/policy/person_months_faqs.htm. Frequently asked questions and a conversion calculator are available.
	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)

Field Name	Instructions
	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.
	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 **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.

Human Subjects Section

Field Name	Instructions
12. Protection of Human Subjects	Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. Complete this section if you answered "yes" to the question "are human subjects involved?" on the R&R Other Project Information Form. If you answered "no" to the question but your proposed research involves human specimens and/or data from subjects you must provide a justification in this section for your claim that no human subjects are involved.
	Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.
	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**.
13. Data Safety Monitoring Plan	Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan.
	Complete this section if you answered "yes" to Item 2 Clinical Trial of the Cover Page Supplement Form. Follow the instructions provided in

Field Name	Instructions
	the Application guide and the FOA regarding the attachment.
14. Inclusion of Women and Minorities	Refer to Part II, <u>Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</u>. Complete this section if you answered "yes" to the question "are human subjects involved?" on the R&R Other Project Information Form and the research does not fall under Exemption 4. 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**.
15. Inclusion of Children	Refer to Part II <u>Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan</u>, Sections 4.4 and 5.7 Complete this section if you answered "yes" to the question "are human subjects involved?" on the R&R Other Project Information Form and the research does not fall under Exemption 4. 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**.

Other Research Plan Sections

Field Name	Instructions
16. Vertebrate Animals	Complete this section if you answered "yes" to the question "are Vertebrate Animals Used?" on the R&R Other Project Information Form. If Vertebrate Animals are involved in the project, address each of the criteria below. This section should be a concise, complete description of the animals and proposed procedures. While additional details may be included in the Research Strategy, the responses to the criteria below must be cohesive and include sufficient detail to allow evaluation by peer reviewers and NIH staff. If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites and describe the activities at those locations. Although no specific page limitation applies to this section of the application, be succinct. Failure to address the following criteria will result in the application being designated as incomplete and it will not be considered. 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 the grantee must submit to the NIH awarding office detailed

Field Name	Instructions
	information as required in points 1-5 below and verification of IACUC approval prior to the involvement of animals. If the grantee does not have an Animal Welfare Assurance, then an applicable Animal Welfare Assurance will be required (see Part III, <u>Section 2.2 Vertebrate Animals</u> for more information). The criteria are as follows:
1.	Description of Procedures Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the "Research Strategy" section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.
2.	Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g. computational, human, invertebrate, in vitro). For additional information, see <u>http://grants.nih.gov/grants/olaw/VASchecklist.pdf</u>. Do not use the vertebrate animal section to circumvent the page limits of the Research Strategy. 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**. Do not use the vertebrate animal section to circumvent the page limits of the research strategy. 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**.
	For those applicants familiar with the PHS 398, please note that the Literature Cited section of the Research Plan is now captured as "Bibliography & References Cited" in the Other Project Information Form.
17. Select Agent Research	Select agents are hazardous biological agents and toxins that have been identified by HHS 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 <u>http://www.cdc.gov/od/sap/docs/salist.pdf</u>. 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

Field Name	Instructions
	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 http://www.cdc.gov/od/sap/sap/exclusion.htm.
	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 HHS 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.
	If any of the activities proposed in your application involve the use of 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.
	1. Identify the select agent(s) to be used in the proposed research.
	2. Provide the registration status of all entities* where select agent(s) will be used.
	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.
	1. *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."
	3. Provide a description of all facilities where the select agent(s) will be used.
	Describe the procedures that will be used to monitor possession, use and transfer of the select agent(s).
	Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).
	Describe the biocontainment resources available at all performance sites.
	If you are responding to a specific FOA, address any requirements specified by the FOA.
	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.
	Save this file in a location you remember. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open**.

Field Name	Instructions
18. Consortium/Contractual Arrangements	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 SF 424 (R&R) form signifies that the applicant and all proposed consortium participants understand and agree to the following statement:
	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 establish the necessary inter-organizational agreement(s) consistent with that policy.
	A separate statement is no longer required.
	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**.
19. Resource Sharing	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 [Supplemental Instructions Part III, 1.5 Sharing Research Resources](#).
	1. *Data Sharing Plan:* Investigators seeking $500,000 or more in direct costs (exclusive of consortium F&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 [Data-Sharing Policy](#) or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.
	2. *Sharing Model Organisms:* 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 [Sharing Model Organisms Policy](#), and [NIH](#)

Field Name	Instructions
	[Guide NOT-OD-04-042](#). 3. *Genomic Data Sharing (GDS):* Applicants seeking funding for research that generates large-scale human or non-human genome data are expected to provide a plan for sharing of these data or an appropriate explanation why sharing is not possible. Applicants are expected to outline in the budget section of the application the resources they will need to prepare the data for submission to appropriate repositories. Large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data. Supplemental Information to the NIH GDS Policy, provides examples of genomic research projects that are subject to the Policy. For further information see the NIH GDS Policy, [NIH Guide NOT-OD-14-124](#), and the GDS website at http://gds.nih.gov/. 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**.
20. Authentication of Key Biological and/or Chemical Resources	Briefly describe methods to be used in ensuring the identity and validity of key biological and/or chemical resources used in the proposed studies. • Key biological and/or chemical resources are those that: 1) may differ from laboratory to laboratory or over time; and 2) whose qualities and/or qualifications could influence the research data. These include, but are not limited to, cell lines, antibodies and specialty chemicals. • Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals. Include brief, one paragraph descriptions of how you will ensure the identity and integrity of each class of key resources (e.g., cell lines, antibodies, etc.) you plan to use in your studies. Describe how the effects of resources known to vary in activity, such as serum used in tissue culture, will be monitored and reported in such a way that the experiments can be repeated by other researchers. If authentication of one or more key resources is not possible, explain why this is the case and how the effects on the reproducibility of the experiments and the rigor of the conclusions drawn from them will be mitigated. If you are responding to a specific funding opportunity announcement (e.g., PA or RFA), address any requirements specified by the FOA. Reviewers will assess the information provided in this Section. Any reviewer questions associated with key biological and/or chemical resource authentication will need to be addressed prior to award.

Field Name	Instructions
	Save this information in a single file. Click **Add Attachment**, browse to where you saved the file, select the file, and then click **Open.**
21~~19~~. Appendix	Do not use the appendix to circumvent the page limits of the Candidate Information and the Research Strategy 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, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html.
	Only one copy of appendix material is necessary. Use the **Add Attachments** button to the right of this field to complete this entry.
	Use the Add Attachments button to complete this entry. 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.
	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.
	New, resubmission, renewal, and revision applications **may** include the following materials in the Appendix:
	Publications – No longer allowed as appendix materials except in the circumstances noted below. Applicants may submit up to 3 of the following types of publications:
	Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment.
	Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available: The entire article should be submitted as a PDF attachment.
	Patents directly relevant to the project: The entire document should be submitted as a PDF attachment.
	Do not include unpublished theses, or abstracts/manuscripts **submitted** (but not yet accepted) for publication.
	Surveys, questionnaires, and other data collection instruments; clinical protocols and informed consent documents may be submitted in the Appendix as necessary.

Field Name	Instructions
	For materials that cannot be submitted electronically or materials that cannot be converted to PDF format (e.g., 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. Items that must not be included in the appendix: Photographs or color images of gels, micrographs, etc., **are no longer accepted as Appendix material**. These images must be included in the Research Plan PDF. However, images embedded in publications are allowed. 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.

Citizenship

Please select the most appropriate response from the options provided. If the candidate currently has a temporary U.S. Visa but expects to hold a permanent resident visa at the time of award, please check this box in addition to the Temporary U.S. Visa box. Other than for the K99/R00 award program, or if specified differently in the FOA, 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.

The candidate **must** check the applicable box:

U.S. Citizen or Non-Citizen National: Check this box if the candidate is a U.S. citizen or non-citizen national. Non-citizen 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).

Non-U.S. Citizen With a Permanent U.S. Resident Visa: 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.

Non-U.S. Citizen With a Temporary U.S. Visa: Check this box if the candidate currently holds a 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.

> If the candidate is not a U.S. citizen, but has applied for permanent residence and expects to have obtained such status prior to the time of award, please also check this box at the bottom of the form indicating that permanent residence status is pending. A notarized statement will be required as part of the pre-award process.

Non-U.S. Citizen Not Residing in the U.S.: Check this box if the candidate is a citizen of a country other than the U.S. and plans to pursue career development outside of the U.S. This box is applicable only to specific programs.

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

Authentication of Key Biological and/or Chemical Resources

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.