Details of Career Development Application Changes (for due dates on or after January 25, 2010)

June 2, 2010

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Introduction

One of the priorities of the NIH Enhancing Peer Review initiative is to *Improve the Quality and Transparency of Review*. One of the goals associated with this priority is to shorten the Research Plan and align the application with review criteria.

Restructured paper PHS 398 and electronic SF 424 (R&R) application packages and instructions will be required for all applications submitted for due dates on or after January 25, 2010. Changes were announced in NOT-OD-19-149 and NOT-OD-10-002.

This document provides details of applications changes to the **SF 424 (R&R) Individual Career Development Award (CDA) Supplemental Form (K Series)**. Details of application changes to other types of applications are provided via the <u>Restructured Applications page</u> of the <u>Enhancing Peer Review Web site</u>.

Shortened Page Limits

Shortened page limits are provided at the <u>Table of Page Limits</u>. For all individual Career Development Applications, the first four sections of Candidate Information and the Research Strategy are limited to a combined total of 12 pages.

Enhanced Review Criteria

The Enhanced Review Criteria and Considerations for Individual Career Development (K) application are below. For more details on how these criteria are reviewed, visit the <u>Definitions of Criteria and Considerations for K Critiques</u>.

Overall Impact

Scored Review Criteria

Candidate

Career Development Plan/ Career Goals & Objectives/ Plan to Provide Mentoring Research Plan

Mentor(s), Consultant(s), Collaborator(s)

Environment and Institutional Commitment to the Candidate

Additional Review Criteria

Protections for Human Subjects

Inclusion of Women, Minorities and Children

Vertebrate Animals

Biohazards

Resubmission Applications

Renewal Applications (applicable only for K02 and K24)

Revision Applications

Additional Review Considerations

Training in the Responsible Conduct of Research

Select Agents

Resource Sharing Plans

Budget and Period of Support

Changes to the Career Development Award Supplemental Form

Table 1: Overview of Form Sections

| Adobe-Forms-B Application | Adobe-Forms-A Application |
|---|---|
| 1. Introduction to Application (for | 1. Introduction to Application (for |
| Resubmissions only) | Resubmissions only) |
| Candidate Information $(2-6)$ | Candidate Information (2 – 6) |
| 2. Candidate's Background | 2. Candidate's Background |
| 3. Career Goals and Objectives | 3. Career Goals and Objectives |
| 4. Career Development/Training Activities | 4. Career Development/Training Activities |
| During Award Period | During Award Period |
| 5. Training in the Responsible Conduct of | 5. Training in the Responsible Conduct of |
| Research | Research |
| 6. Mentoring Plan (Include only when | 6. Mentoring Plan (Include only when |
| required by the specific FOA, e.g., K24 | required by the specific FOA, e.g., K24 and |
| and K05) | K05) |
| Statement of Support (7) | Statements of Support (7) |
| 7. Statements by Mentor, Co-mentor(s), | 7. Statements by Mentor, Co-mentor(s), |
| Consultants, Contributors | Consultants, Contributors |
| Environment & Institutional Commitment to | Environment & Institutional Commitment to |
| the Candidate (8 - 9) | the Candidate (8 - 9) |
| 8. Description of Institutional Environment | 8. Description of Institutional Environment |
| 9. Institutional Commitment to Candidate's | 9. Institutional Commitment to Candidate's |
| Research Career Development | Research Career Development |

| Adobe-Forms-B Application | Adobe-Forms-A Application |
|--|---|
| Research Plan (10 – 21) | Research Plan (10 - 23) |
| 10. Specific Aims | 10. Specific Aims |
| 11. Research Strategy | 11. Background and Significance |
| a. Significance | 11. Dackground and Significance |
| b. Innovation | 12. Preliminary Studies/Progress Report |
| c. Approach | 12. Frommary Studies/Frogress Report |
| Preliminary StudiesRenewal Applications | 13. Research Design and Methods |
| 12. Inclusion Enrollment Report (Renewal | 14. Inclusion Enrollment Report (Renewal |
| Applications Only) | Applications Only) |
| 13. Progress Report Publication List (Renewal | 15. Progress Report Publication List (Renewal |
| Applications Only) | Applications Only) |
| 14. Protections of Human Subjects | 16. Protections of Human Subjects |
| 15. Inclusion of Women and Minorities | 17. Inclusion of Women and Minorities |
| 16. Targeted/Planned Enrollment | 18. Targeted/Planned Enrollment |
| 17. Inclusion of Children | 19. Inclusion of Children |
| 18. Vertebrate Animals | 20. Vertebrate Animals |
| 19. Select Agent Research | 21. Select Agent Research |
| 20. Consortium/Contractual Arrangements | 22. Consortium/Contractual Arrangements |
| 21. Resource Sharing Plan(s) | 23. Resource Sharing Plan(s) |
| 22. Appendix | 24. Appendix |

Tables 2 – 4 provide the text of the current application instructions in the right column, aligned with the corresponding restructured application instructions in the left column; revised text is indicated by Emphasis.

Table 2: Instructions for Selected Sections of the Career Development Award Supplemental Form (Introduction, Candidate's Background, Career Goals and Objectives, Career Development/Training Activities During Award Period, Specific Aims, Research Strategy)

Section 7.5 of the SF 424 (R&R) PHS 398 Career Development Award Supplemental Form

| Adobe-Forms-B Instructions (New Language) | Adobe-Forms-A Instructions |
|--|---|
| 7.5.1 Introduction to Application (for Resubmissions only) | 7.5.1 Introduction to Application (for Resubmissions only) |
| 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. | Use only if you are submitting a CDA Resubmission. The Introduction may not exceed 3 pages. See section 2.7 for additional information on Resubmissions. Applicants must follow the page limits that are outlined in the specific |

| Adobe-Forms-B Instructions (New Language) | Adobe-Forms-A Instructions |
|---|---|
| Resubmission applications must include an Introduction to Resubmission Application, not to exceed one page unless the FOA specifies otherwise. 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. | announcement. |
| 7.5.2 Candidate's Background | 7.5.2 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. | Use this section to provide any additional information not described in the Biographical Sketch Format Page such as research and/or clinical training experience. |
| Note that the total number of pages for Items 2-5 and Item 11 (Research Strategy) combined may not exceed 12 pages. | |
| 7.5.3 Career Goals and Objectives | 7.5.3 Career Goals and Objectives |
| 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. | Describe your past scientific history, indicating how the award fits into past and future research career development. If there are consistent themes or issues that have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. It is important to justify the award and how it will enable you to develop or expand your research career. You may include a timeline, including plans to apply for subsequent grant support. |
| Note that the total number of pages for Items 2-5 and Item 11 (Research Strategy) combined may not exceed 12 pages. | |
| 7.5.4 Career Development/ Training Activities During Award Period | 7.5.4 Career Development/ Training Activities During Award Period |
| 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 | 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,

structured activities, such as course work or

technique workshops, which are part of the

developmental plan. If course work is included,

Adobe-Forms-B Instructions (New Language)

provide course numbers and descriptive titles. Briefly discuss each of the activities, except research, in which you expect to participate. Include a percentage of time involvement for each activity by year, and explain how the activity is related to the proposed research and the career development plan.

Note that recipients of mentored K awards may receive concurrent support from an NIH research grant award or cooperative agreement only under certain conditions (see NIH Notice NOT-OD-08-065).

Note that the total number of pages for Items 2-5 and Item 11 (Research Strategy) combined may not exceed 12 pages.

Adobe-Forms-A Instructions

provide course numbers and descriptive titles. Briefly discuss each of the activities, except research, in which you expect to participate. Include a percentage of time involvement for each activity by year, and explain how the activity is related to the proposed research and the career development plan.

Note that recipients of mentored "K" awards may receive concurrent support from an NIH research grant award or cooperative agreement only under certain conditions (see NIH Notice NOT-OD-08-065).

7.5.10 Specific Aims

State precisely the goals of the proposed research and summarize the expected outcome(s) including the impact that the results of the proposed research will exert on the research field(s) involved.

List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Specific Aims are limited to one page.

7.5.10 Specific Aims

List the broad, long-term objectives and the goal of the specific research proposed, for example, 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. One page is recommended.

7.5.11 Research Strategy

Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading—Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section (Part I Section 4.4.9).

Follow the page limits for the Research Strategy in the Table of Page Limits, unless specified otherwise in the FOA.

(a) Significance

• Explain the importance of the problem or

7.5.11 Background and Significance

Briefly sketch the background leading to the present application, critically evaluate existing

Adobe-Forms-B Instructions (New Language)

critical barrier to progress in the field that the proposed project addresses.

- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

(b) Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

(c) Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 5.5.15, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- 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.

Adobe-Forms-A Instructions

knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. If the aims of the application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive this field.

7.5.13. Research Design and Methods

Describe the research design conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in Item 23, include how the data will be collected, analyzed, and interpreted as well as the data-sharing plan as appropriate. Describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Although no specific number of pages is recommended for the Research Design and

| Adobe-Forms-B Instructions (New Language) | Adobe-Forms-A Instructions |
|--|--|
| • 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. | Methods section, be as succinct as possible. There is no requirement that all 25 pages allotted for items 2-5 and 10-13 be used. |
| 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. | |
| <u>Preliminary Studies for New Applications.</u> For new applications, include information on | 7.5.12 Preliminary Studies/Progress Report For new applications |
| 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 resulting from significant budget reductions. A list of publications, manuscripts accepted for publication, patents, and other printed materials should be included in 5.5.5; do not include that information here. | For new applications, use this section to provide an account of the candidate's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members. This information will also help to establish the experience and competence of the investigator to pursue the proposed project. Progress Report for Renewal Applications. A Progress Report must be provided for renewal applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively. Summarize the previous application's specific aims and the importance of the findings. Provide a succinct account of published and unpublished results, indicating progress toward their achievement. Discuss any changes in the specific aims as a result of budget reductions. A list of publications, manuscripts accepted for publication, patents, and other printed materials will be included in Section 15; do not include that information here. |
| | Six to eight pages are recommended for the narrative portion of this section. |

Table 3: Instructions for the Resources Section

Section 4.4, Item 9 of the SF 424 (R&R)

Adobe-Forms-B Instructions (New Language)

This information is used to assess the capability of the organizational resources available to perform the effort proposed.

- Identify the facilities to be used (laboratory, clinical, animal, computer, office, other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.
- Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.
- For Early Stage Investigators, describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESIs project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support.
- If there are multiple performance sites, describe the resources available at each site.
- Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note:

Adobe-Forms-A Instructions

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project. Please click the add attachment button to the right of this field to complete this entry.



No special form is required but this section must be completed and attached for submissions to NIH and other PHS

agencies unless otherwise noted in an FOA. If there are multiple performance sites, then resources available at each site should be described. In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment, or subject populations or employ useful collaborative arrangements. If research involving Select Agent(s) will occur at any performance site(s), the biocontainment resources available at each site should be described.

| Adobe-Forms-B Instructions (New Language) | Adobe-Forms-A Instructions |
|---|----------------------------|
| Information about Select Agents must be described in the Research Plan, 5.5.11 (Select Agent Research). | |

Table 4: Instructions for the Biographical Sketch

Section 7.4 of the SF 424 (R&R)

| Adobe-Forms-B Instructions (New Language) | Adobe-Forms-A Instructions |
|---|---|
| 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. | 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. | Education: Provide the month and year for each degree conferred. 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. | 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 | 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.

inclusive dates (month and year). When applicable, include information on military service, 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.

Honors

List academic and professional honors chronologically, including research grants and 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:

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

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

List your entire bibliography, separating research papers, abstracts, book chapters, and reviews. Within each subsection the list should be chronological. If the list of publications cannot be accommodated within the four-page biosketch limit, select only the most pertinent publications. 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. Manuscripts listed as "pending publication" or "in preparation" should be included and identified.

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:

(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_journal s.htm. Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material.) 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 PMCID 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.

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.

NOTE: This document provides only the details of application changes that are related to Peer Review Enhancements. Other application changes for due dates on or after January 25, 2010 include those required by the Federal Funding Accountability and Transparency Act (FFATA).