Details of Application Changes for Research Grants and Cooperative Agreements (for due dates on or after January 25, 2010)

November 5, 2009

Contents

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 it 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-09-149 and NOT-OD-10-002.

This document provides details of applications changes to **Research Grants and Cooperative Agreements**. Details of application changes to other types of applications are provided via the Restructured Applications page of the Enhancing Peer Review Web site.

Shortened Page Limits

Shortened page limits are provided at the Table of Page Limits.

Alignment of the Application with Review Criteria

Many of the changes to the application were made to coordinate with review criteria used by reviewers in their assessment of scientific and technical merit. Table 1 shows the scored Enhanced Review Criteria for research grants and cooperative agreements, as announced in NOT-OD-09-025, and the location in the application where a particular criterion is addressed.

Table 1: Enhanced Review Criteria for Research Grants and Cooperative Agreements

Enhanced Peer Review Criteria	Complementary Section of Restructured Application Forms and Instructions
Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration	Entire application

Enhanced Peer Review Criteria	Complementary Section of Restructured Application Forms and Instructions
of the following five core review criteria, and additional review criteria (as applicable for the project proposed).	

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?	5.5 Research Plan [PHS 398 and SF 424 (R&R)]
	    3. Research Strategy
	    (a) Significance

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?	4.6 Biographical Sketch [PHS 398]
	
	4.5 Senior/Key Person Profile [SF 424 (R&R)]
	    Additional NIH & Other Agencies
	    Instructions for a Biographical Sketch
	    &
	
	5.5 Research Plan [PHS 398 and SF 424 (R&R)]
	    12. Multiple PD/PI Leadership Plan

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?	5.5 Research Plan [PHS 398 and SF 424 (R&R)]
	    3. Research Strategy
	    (b) Innovation

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?	5.5 Research Plan [PHS 398 and SF 424 (R&R)]
	    3. Research Strategy
	    (c) Approach

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the	5.5 Content of Research Plan [PHS 398 and SF 424 (R&R)]
	    11. Select Agent Research
	    &

Enhanced Peer Review Criteria	Complementary Section of Restructured Application Forms and Instructions
project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?	4.7 Resources [PHS 398] Resources Format Page 4.4. Other Project Information Component [SF 424 (R&R)] Item 9. Facilities & Other Resources

Tables 2 – 4 provide the text of the current application instructions in the right column, aligned with the corresponding restructured application instructions in the center column; revised text is indicated by Emphasis. The left column corresponds to the Enhanced Review Criteria from Table 1.

Table 2a: Instructions for Selected Sections of the Research Plan (Introduction, Specific Aims, and Research Strategy)

Paper applications: Section 5.5 of the PHS 398

Electronic applications: Section 5.5 of the SF 424 (R&R) PHS 398 Research Plan Component

	Restructured Application Instructions (New Language)	Current Application Instructions
	5.5.1 Introduction (Resubmission or Revision Applications only) See specific instructions in 2.7 Resubmission Applications and 2.8 Revision Applications on the content of the Introduction. First time (new) applications should not include an Introduction unless specified in the FOA. The Introduction is limited to one page unless specified otherwise in the FOA.	**5.5.1 Introduction (Resubmission or Revision Applications only)** All Resubmission and Revision applications must include an Introduction. The Introduction may not exceed three pages for Resubmission applications, or one page for Revision applications. See specific instructions in 2.7 Resubmission Applications and 2.8 Revision Applications on the content of the Introduction. Place the Introduction at the very beginning of the Research Plan.
	5.5.2 Specific Aims State concisely 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.	**5.5.2 Specific Aims** List the broad, long-term objectives and the goal of the specific 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. One page is recommended.

	Restructured Application Instructions (New Language)	Current Application Instructions
	5.5.3 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 (Item 5.5.5). Follow the page limits for the Research Strategy in the Table of Page Limits, unless specified otherwise in the FOA.	
Significance	**(a) Significance** • Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. • Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields. • Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.	**5.5.3. Background and Significance** Briefly sketch the background leading to the present application, critically evaluate existing 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. Two to three pages are recommended.
Innovation	**(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.	

Restructured Application Instructions (New Language)	Current Application Instructions
(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. • 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 5.5.11 below.	**5.5.5 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 17, 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 Methods section, be as succinct as possible. There is no requirement that all 25 total pages allotted for items 2-5 be used.
Preliminary Studies for New Applications. For new applications, include information on Preliminary Studies as part of the Approach section. Discuss the PD/PI's preliminary studies, data, and/or experience pertinent to this application. Except for Exploratory/Development Grants (R21, R33), Small Research Grants (R03), Academic Research Enhancement Award (AREA) Grants (R15), and Phase I Small Business Research Grants (R41/R43), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data. (However, for R01 applications, reviewers will be instructed to place less emphasis on the preliminary data in applications from Early Stage Investigators than on the preliminary data in applications from more established investigators.)	**5.5.4. Preliminary Studies/Progress Report** *(a) Preliminary Studies.* For new applications, use this section to provide an account of the PD/PI's preliminary studies pertinent to this application, including 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. Peer review committees generally view preliminary data as an essential part of

Approach

Restructured Application Instructions (New Language)	Current Application Instructions
	a research grant application. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.
Progress Report for Renewal and Revision Applications. For renewal/revision applications, provide a Progress Report as part of the Approach section. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes 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.	*(b) Progress Report for Renewal and Revision Applications.* A Progress Report must be provided for Renewal and Revision 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.

(Left column label: Approach)

Table 2b: Instructions for the Select Agents Research Section of the Research Plan

Paper applications: Section 5.5.11 of the PHS 398

Electronic applications: Section 5.5, Item 11 of the SF 424 (R&R) PHS 398 Research Plan Component

Restructured Application Instructions (New Language)	Current Application Instructions
5.5.11 Select Agent Research Select Agents are hazardous biological agents and … 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.	**5.5.11 Select Agent Research** Select Agents are hazardous biological agents and … 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).

(Left column label: Environment)

Table 3: Instructions for the Resources Section

Paper applications: Section 4.7, Resources Format Page of the PHS 398
Electronic applications: Section 4.4, Item 9 of the SF 424 (R&R)

	Restructured Application Instructions (New Language)	**Current Application Instructions**
Environment	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.	**4.4 Other Project Information Component** [SF 424 (R&R)] Item 9 – Facilities & Other Resources 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.

	Restructured Application Instructions (New Language)	Current Application Instructions
Environment	• 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: Information about Select Agents must be described in the Research Plan, 5.5.11 (Select Agent Research).	**4.7 Resources** [PHS 398] RESOURCES FORMAT PAGE Follow the sample format and instructions on the Resources Format Page when completing information on resources available for the project. If there are multiple Project/Performance Sites the 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 Project/Performance Site(s), the biocontainment resources available at each site should be described.

Table 4: Instructions for the Biographical Sketch

Paper applications: Section 4.6 of the PHS 398 Section 4.6
Electronic applications: Section 4.5 of the SF 424 (R&R)

	Restructured Application Instructions (New Language)	Current Application Instructions
Investigator(s)	Following the educational block, complete sections A, B, C and D: A. Personal statement. Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor) in the project that is the subject of the application. B. Positions and Honors. List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.	Complete the educational block at the top of the format page, and complete sections A, B, and C: A. Positions and Honors. List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

Restructured Application Instructions (New Language)	**Current Application Instructions**
C. NIH encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. 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 acceptable as appendix material.)	B. Selected peer-reviewed publications or manuscripts in press (in chronological order). Do not include manuscripts submitted or in preparation. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm. 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.)
D. Research Support. List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.	C. Research Support. List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.

Investigator(s)

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).