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## NIH Proposal Outline

Six Page Limit – For Activity Codes R03, R13, R21, R36, SC2, SC3

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### 1. Introduction to Application (for Resubmission or Revision applications only) – LIMITED TO 1 PAGE

- For resubmissions, the introduction should summarize the substantial additions, deletions, and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Summary Statement.
- For revisions, the introduction should describe the nature of the supplement and how it will influence the specific aims, research design, and methods supported by the current award.

### 2. Specific Aims – LIMITED TO 1 PAGE

- State concisely the goals of the proposed research and summarize the expected outcomes, including the impact that the results of the proposed research will exert on the field involved.
- List succinctly the specific aims 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).

### 3. Research Strategy – LIMITED TO 6 PAGES (sections a-c)

- Organize the Research Strategy in the order specified below.
- Start each section with the appropriate section heading – Significance, Innovation, Approach.
- Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.

#### (a) *Significance* – Suggested length 1-2 pages

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

#### (b) *Innovation* – Suggested length 1 page

- 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 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.

**(c) Approach – Suggested length 3-4 pages**

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted, and any resource sharing plans as appropriate, unless addressed separately in Item 15 (Resource Sharing Plan).
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. You also may wish to include a discussion of future directions for your research, as well as a project timeline, in this section.
- 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 Item 11, below.
- **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/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), 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 application from Early Stage Investigators than on the preliminary data in applications from more established investigators).
- **Progress Report for Renewal and Revision Applications.** For renewal/revision applications, provide a Progress Report as part of the Approach section. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant budget reductions. *A list of publications, patents, and other printed materials should be included in Item 5 (Progress Report Publication List); do not include that information here.*

**4. Inclusion Enrollment Report**

If the renewal or revision application involves clinical research, then you must report on the enrollment of research subjects and their distribution by ethnicity/race and sex/gender.

**5. Progress Report Publication List (Renewal Applications Only)**

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. See SF 424/PHS 398 Guidelines for additional instructions.

## **Human Subjects Sections**

Sections 6-9 are required for applicants answering "yes" to the question "Are human subjects involved?" on the R&R Other Project Information form. If the answer is "No" to the question but the proposed research involves human specimens and/or data from subjects, applicants must provide a justification in this section for the claim that no human subjects are involved.

### **6. Protection of Human Subjects**

### **7. Inclusion of Women and Minorities**

### **8. Targeted/Planned Enrollment**

### **9. Inclusion of Children**

## **Other Research Plan Sections**

### **10. Vertebrate Animals**

If Vertebrate Animals are involved in the project, address the five specific criteria listed in the SF424/PHS 398.

### **11. Select Agent Research**

If select agents, defined as hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products, are used in this research, address the three specific criteria listed in the SF434/PHS398.

### **12. Multiple PD/PI Leadership Plan**

For applications designating multiple PD/PIs *only*, a leadership plan must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators.

### **13. 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.

### **14. Letters of Support (e.g., Consultants)**

Attach all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators, such as Senior/Key Personnel and Other Significant Contributors, included in the grant application. 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 rate/charge for consulting services.

### **15. Resource Sharing Plan(s)**

- 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 one-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.

- **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.
- **Genome Wide Association Studies (GWAS):** Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible.

## 16. Appendix

- Only one copy of appendix material is necessary.
- 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.
- Check the FOA for specific instructions regarding Appendix, particularly in regard to inclusion of publications.
- 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.
- New, resubmission, renewal, and revision applications **may** include the following materials in the Appendix (note, however, that some FOAs do not permit publications):
  - **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.
  - 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 SRG. 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 Strategy 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.

## Summary of Revised NIH Page Limits by Application Type and Section

<i>Also refer to the relevant section of the application instructions and the FOA.</i>	<b>PAGE LIMITS *</b>
<b>Introduction to Resubmission Application</b> (3 pages for R25 on PHS398 Research Plan and 3 pages for K12, T and D Training Grants on PHS398 Training Program Plan)	1 page
<b>Introduction to Revision Application</b>	1 page
<b>Specific Aims</b>	1 page
<b>Research Strategy (Item 5.5.3 of Research Plan)</b> For Activity Codes R03, R13, R21, R36, SC2, SC3	6 pages
<b>Research Strategy (Item 5.5.3 of Research Plan)</b> For Activity Codes R01, R10, R15, R18, R21/R33, R24, R33, R34, DP3, G08, G11, G13, SC1, X01	12 pages
<b>Research Strategy (Item 5.5.3 of Research Plan)</b> For all other Activity Codes, including S Activity Codes	Follow FOA instructions
<b>Research Education Program Plan</b> For R25 Research Education Grant Applications	25 pages
<b>Biosketch (per person)</b> (2 pages for DP1 and DP2 Activity Codes)	4 pages
<b>Career Development Award (K) Application</b> Upload to PHS 398 Career Development Award Supplemental Form: Combined Candidate Information (Items 3-5: Candidate's Background, Career Goals and Objectives, Career Development/Training Activities During Award Period, and Training on the Responsible Conduct of Research) and Research Strategy (Item 11)	12 pages
<b>Institutional Research Training and Career Development Applicants, including Ruth L. Kirschstein NRSA Application</b> Research Training Program Plan: Combined Sections 8.7.2.2 – 8.7.2.5 (Background, Program Plan, Recruitment and Retention Plan to Enhance Diversity, and Plan for Instruction in the Responsible Conduct of Research)	25 pages

\* FOA instructions always supersede these instructions.