Recovery Act Limited Competition: NIH Challenge Grants in Health and Science Research (RC1)

Application Due Date: April 27, 2009

Required Components:
SF424 (R&R) (Cover component)
Research & Related Project/Performance Site Locations
Research & Related Other Project Information
Item 6. Project Summary/Abstract: Limited to one page
Item 8. Bibliography and Literature Cited: Limited to one page.
Research & Related Senior/Key Person
Biographical Sketches: Each biographical sketch is limited to two pages. The number of publications cited in the PD/PI’s biosketch is limited to ten or fewer items. PD/PIs should cite their most relevant publications and those that highlight the significance of past accomplishments.
PHS398 Cover Page Supplement
PHS398 Research Plan (see below)
PHS398 Checklist
Research & Related Budget

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<thead>
<tr>
<th>PHS398 Research Plan Component Sections</th>
<th>Instructions</th>
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<tbody>
<tr>
<td>1. Introduction to Application</td>
<td>Omit (N/A: Resubmissions and Revisions not allowable)</td>
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<tr>
<td>2. Specific Aims</td>
<td>One page maximum. Separate PDF attachment</td>
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<tr>
<td>3. Background and Significance</td>
<td>Omit</td>
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<td>4. Preliminary Studies/Progress Report</td>
<td>Omit</td>
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<tr>
<td>5. Research Design and Methods</td>
<td>Item 5 consists of the following 4 elements and is limited to 12 pages: A statement of the Challenge Area and specific Challenge Topic; The Challenge and Potential Impact; The Approach; and Timeline and Milestones. Attach the 12-page Research Plan encompassing all of these elements as a single PDF document. Figures and illustrations may be included but must fit within the 12-page limit. Do not include links to Web sites for further information. Do not include animations.</td>
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2. Specific Aims (1 page)
Limit yourself to 1 or 2 Specific Aims.
You can organize your introductory paragraph like this:
Begin with a statement of the big picture/relevance of your work. Clearly state the problem, then describe what you hope to accomplish. Give your overall/organizing hypothesis. Explain the rationale/expected outcomes. Lead into your specific aims:
Specific Aim 1.
Specific Aim 2.

5. Research Design and Methods (12 pages, including tables, graphs, figures, diagrams, and charts. The Research Plan should be self-contained and uploaded as a single attachment in the Research Designs and Methods item.)
PROJECT TITLE (required on 1st page)

1. Challenge Area and Specific Challenge Topic
   *Use this exact sentence format* (with the broad Challenge Area and specific Challenge Topic relevant to your research). *Note: your broad Challenge Area and Specific Challenge Topic may differ from the example. This statement is critical to the correct assignment of your application to an institute and review section:*
   This application addresses broad Challenge Area (01) Behavior, Behavioral Change, and Prevention and specific Challenge Topic, 01-GM-104: Mechanisms of Behavior Change Research.

2. The Challenge and Potential Impact

   2.1. Problem Statement
   Describe the scientific knowledge or technology gap that you will address, clearly illustrating the impact that will be made if your research results are realized.

   2.2. Background
   Show reviewers your intimate familiarity with the field, and refer to all relevant scientific literature.
   Show the breadth of your knowledge of your field and highlight why you are uniquely qualified to do the research.

   2.3. Previous Work
   Make a very strong case for why you are challenging the existing paradigms and have data to support your approach. Reviewers will be focused on the feasibility of producing viable research output in two years.
   Link this background information, preliminary data, and feasibility studies to each of your Specific Aims.

   2.4. Impact
   Convey the significance of your research.
   Describe the areas of science and/or public health that your research will have an impact upon.
   Specifically describe:
   Which communities will be affected?
   How many people will be affected?

3. The Approach

   3.1. Rationale
   How will your rationale and/or approach overcome existing challenges or barriers in the field?
   If you propose to improve existing technologies or to develop new technologies, which needs are being addressed and what is unconventional and exceptionally innovative about your approach?

   3.2. Methods
   How will you attempt to explore or solve the stated research problem? Provide enough information for reviewers to determine what you are proposing to do, but do not include a detailed experimental plan.
   The guiding principle for this section is that it should contain sufficient information for the reader to determine whether your methodology is sound.
3.3. Potential Pitfalls and Alternative Approaches
Discuss the limitations of each approach you are proposing and how they may affect your results and data. Call attention to potential difficulties and propose alternatives. State what you will do if results are negative, how negative findings will also advance the field, and what you will do next.

4. Timeline and Milestones
Provide a timeline for the proposed research indicating points where intermediate objectives will be assessed and decisions will be made regarding the course and direction of the continuing research effort.
Possible alternative paths that may be followed at critical junctures in the project plan should be described and indicated on the timeline.
Describe future research that will result from this funding.

Example:

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<th>Year 1</th>
<th>Year 2</th>
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<td>Months 1-6</td>
<td>Months 7-12</td>
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<td><strong>Aim 1</strong></td>
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**OTHER SECTIONS (Not included in 12 page limit)**

**Protection of Human Subjects**
**Inclusion of Women and Minorities**
**Targeted/Planned Enrollment**
**Inclusion of Children**
For Challenge Grant applications that propose human subjects research, applicants are expected to set forth sex/gender-based and age-appropriate hypotheses and plans for data analysis based on a consideration of the relevant literature if the proposed study has the potential for such consideration. You are also expected to address the inclusion of members of minority groups and their subpopulations in developing a research design appropriate to the scientific objectives of the study and set forth racial/ethnic-based hypotheses and plans for data analyses based on a consideration of the relevant literature. If sex/gender-base or age-appropriate hypotheses or the inclusion of minorities are not relevant to the proposed research, applicants should provide a specific, scientific justification for why these analyses would not be relevant.

**Vertebrate Animals**
Address the following five points: (1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; (2) justifications for the use of animals and for the
appropriateness of the species and numbers proposed; (3) adequacy of veterinary care; (4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and (5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

Select Agent Research
Describe: (1) the Select Agent(s) to be used in the proposed research, (2) the registration status of all entities where Select Agent(s) will be used, (3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and (4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

MPI Leadership Plan
See: http://grants.nih.gov/grants/multi_pi

Consortium/ Contractual Arrangements

Letters of Support

Resource Sharing Plans
(a) Data Sharing Plan: Regardless of the amount requested, applicants under this FOA 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. Applicants are encouraged to discuss data-sharing plans with their NIH program contact (see Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.)

(b) 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 and related resources or state appropriate reasons why such sharing is restricted or not possible (see Sharing Model Organisms Policy, and NOT-OD-04-042.)

(c) Genome-Wide Association Studies (GWAS): Regardless of the amount requested, 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 provide an appropriate explanation why submission to the repository is not possible. A genome-wide association study is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (e.g., blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (go to NOT-OD-07-088, and http://grants.nih.gov/grants/gwas/.)

This document was drafted by the Grants Facilitation Unit of the UC Davis School of Medicine Office of Research (http://www.ucdmc.ucdavis.edu/ctsc/core/core-facilitation.html).