

## SHORT & DIRTY STIMULUS NIH CHALLENGE GRANT INSTRUCTIONS

Full instructions can be found at: <http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-09-003.html> (its highly recommended you read them)

**Application Due Date:** April 27, 2009

**Earliest Anticipated Start Date:** September 30, 2009

### DEADLINES –

**Subcontract Materials:** March 30, 2009

**Everything Due to Me:** April 13, 2009 (unless you make arrangements with me in advance – this should allow enough time for the package to be put together and you to review before routing)

**Routing Begins:** April 16, 2009

**OSR:** April 20, 2009 (package must be complete and routed through all departments by this date)

**Budget and Project Period:** The requested budget may not exceed \$500,000 total costs per year for a maximum of \$1,000,000 total costs over a two-year project period.

**Resubmissions & Renewals:** Not permitted

**Foreign Subcontracts:** Requested funding for any foreign component should not exceed 10% of the total requested direct costs or \$25,000 (aggregate total for all subcontracts and subawards), whichever is less.

### SPECIAL INSTRUCTIONS:

**Project Summary/Abstract:** Limited to one page. Begin this section by stating the broad Challenge Area and the specific Challenge Topic that this application addresses. Use the following format: *This application addresses broad Challenge Area (01) Behavior, Behavioral Change, and Prevention and specific Challenge Topic, 01-GM-104: Mechanisms of Behavior Change Research.*

**Bibliography and Literature Cited:** Limited to one page.

**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.

### Research Plan –

**Specific Aims:** One-page maximum

**Background and Significance:** Omit

**Preliminary Studies:** Omit

**Research Design & Methods:** Consists of the following 4 elements and is limited to 12 pages. Organize this section in the specified order using the instruction provided below. Start each section with the appropriate section heading.

- 1. Research Area:** State which broad Challenge Area (e.g., (01: Behavior, Behavioral Change, and Prevention) described within this FOA and specific Challenge Topic (e.g., *Mechanisms of Behavior Change Research: 01-GM-104*) will be addressed. Also include the project title on the first page.
- 2. The Challenge and Potential Impact:** What is the research opportunity, scientific knowledge gap or technology that will be addressed? How broad is the potential impact in science and/or health? Which community (ies) will be affected? What is (are) the size(s) of the community(ies)? Will the potential impact be major?
- 3. The Approach:** How will you attempt to explore or solve the stated research problem? 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? Provide enough information for reviewers to determine what you are proposing to do, but do not include a detailed experimental plan.

- 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.

**Inclusion of Women, Minorities, and Children in Challenge Grant Studies:** For Challenge Grant applications that propose human subjects research, applicants are expected to set forth sex/gender-based hypotheses and plans for data analysis based on a consideration of the relevant literature if the proposed study has the potential for such consideration. The purpose of this approach is three-fold: to ensure compliance with the NIH Guidelines for Inclusion of Women and Minorities in Clinical Research; to capitalize on the growing body of research demonstrating sex/gender differences in all areas of NIH research from basic to clinical and translational; and to ensure that any sex/gender-specific solutions/answers to the stubborn questions are not overlooked, thus resulting in incorrect conclusions/generalizations with respect to men or women. If these sex/gender-based hypotheses are not relevant to the proposed research, applicants should provide scientific justification for why sex/gender analysis would not be relevant.

Applicants for Challenge Grants are 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.

The purpose of this approach is to: 1) ensure compliance with the NIH Guidelines for Inclusion of Women and Minorities in Clinical Research; 2) address gaps in what is known about health disparities between racial/ethnic groups; and 3) ensure that any potential answers to stubborn questions are not overlooked, thus resulting in incorrect conclusions and/or generalizations. If the inclusion of members of minority groups and their subpopulations is not relevant to the proposed research, applicants should provide scientific justification for why racial/ethnic analyses would not be relevant.

Applicants for Challenge Grants that include children are expected, consistent with the "[NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects](#)," to set forth age-appropriate hypotheses and plans for data analyses based on a consideration of the relevant literature. This approach is designed: 1) to promote better compliance with the NIH Pediatric Inclusion policy; 2) to address wide gaps in what is known about clinically significant differences, between children and adults and among children of different ages and developmental stages, in the diagnosis and treatment of diseases and conditions; and 3) to ensure that any potential answers to stubborn questions in pediatrics, as well as in early origins of adult disease, are not overlooked. If age-appropriate hypotheses are not relevant to the proposed research, applicants should provide a specific, scientific justification for why age-appropriate analyses would not be relevant.

**Appendix Materials:** Appendices are not permitted.

**Resource Sharing Plan(s):** 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. If the final data/resources are not amenable to sharing, this must be explained in the Resource Sharing section of the application.

- 1. 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.
- 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 and related resources or state appropriate reasons why such sharing is restricted or not possible.
- 3. 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.