

## Part I Overview Information

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### Department of Health and Human Services

#### Participating Organizations

National Institutes of Health (NIH), (<http://www.nih.gov>)

#### Components of Participating Organizations

This Funding Opportunity Announcement (FOA) is developed as part of the American Recovery and Reinvestment Act of 2009 (Recovery Act), Pub. L. No. 111-5. All NIH Institutes and Centers with funding authority will participate with the NIH Office of the Director in this initiative. This FOA will be administered by the Office of the Director of the NIH (<http://www.nih.gov>).

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

#### Announcement Type

New

**Notice Number:** NOT-OD-09-025

**Update:** The following update relating to this announcement has been issued:

- [March 6, 2009](#) - See NOT-OD-09-061 This notice clarifies eligibility regarding Foreign Components.
- [March 4, 2009](#) - See Notice (NOT-OD-09-054) Recovery Act of 2009: NIH Review Criteria, Scoring System, and Suspension of Appeals Process.

**Request for Applications (RFA) Number:** RFA-OD-09-003

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (<http://www.grants.gov>) using the SF424 Research and Related (R&R) forms and the SF424

(R&R) Application Guide.

**APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.**

This FOA must be read in conjunction with the application guidelines included with this announcement in [Grants.gov/Apply for Grants](http://grants.gov/Apply%20for%20Grants) (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process at least four (4) weeks prior to the grant submission date. See [Section IV](#).

Apply for Grant Electronically

A compatible version of [Adobe Reader](#) is required for download. For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at <http://grants.gov/CustomerSupport>.

## Catalog of Federal Domestic Assistance Number(s)

93.701

### Key Dates

Release/Posted Date: March 4, 2009

Opening Date: March 27, 2009 (Earliest date an application may be submitted to Grants.gov)

Letters of Intent Receipt Date(s): Not applicable

**NOTE: On-time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization).**

Application Due Date(s): April 27, 2009

Peer Review Date(s): June/July 2009

Council Review Date(s): August 2009

Earliest Anticipated Start Date(s): September 30, 2009

Additional Information To Be Available Date (Activation Date): Not Applicable

Expiration Date: April 28, 2009

### Due Dates for E.O. 12372

Not Applicable

### Additional Overview Content

### Executive Summary

NIH has received new funds for Fiscal Years (FYs) 2009 and 2010 as part of the American Recovery and Reinvestment Act of 2009 (Recovery Act). NIH has designated at least \$200 million for a new initiative called the **NIH Challenge Grants in Health and Science Research** (see [http://grants.nih.gov/grants/funding/challenge\\_award/](http://grants.nih.gov/grants/funding/challenge_award/)). This new program will support research on topic areas which address specific scientific and health research challenges in biomedical and behavioral research that would benefit from significant 2-year jumpstart funds. NIH Institute and Centers have selected specific Challenge Topics within each of the Challenge Areas. The research in these Challenge Areas should have a high impact in biomedical or behavioral science and/or public health.

- **Purpose.** As part of the Recovery Act, the NIH invites, through this limited competition, NIH Challenge Grant (RC1) applications from domestic (United States) institutions/organizations proposing novel research in areas that address specific knowledge gaps, scientific opportunities, new technologies, data generation, or research methods that would benefit from an influx of funds to quickly advance the area in significant ways. This program is designed to support research in scientific areas identified by the Institutes and Centers, as described below.
- **Mechanism of Support.** This FOA will utilize the NIH Challenge Grant (RC1) award mechanism.
- **Funds Available and Anticipated Number of Awards.** This initiative is funded under the Recovery Act. NIH has designated at least \$200 million in FYs 2009 - 2010 to fund 200 or more grants, contingent upon the submission of a sufficient number of scientifically meritorious applications. In addition, Recovery Act funds allocated to NIH specifically for comparative effectiveness research (CER) may be available to support additional grants. Projects receiving these funds will need to meet this definition of CER: "a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients. Such a study may compare similar treatments, such as competing drugs, or it may analyze very different approaches, such as surgery and drug therapy." Such research may include the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data as they apply to CER.
- **Budget and Project Period.** Budget requests should be commensurate with project needs up to a two-year 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.
- **Page Limits: The Research Plan is limited to 12 pages**
- **Eligible Institutions/Organizations.** Institutions/organizations listed in [Section III, 1.A.](#) are eligible to apply. Foreign institutions/organizations are not eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the

skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/ organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

- **Early Stage Investigators (ESIs)/New Investigators (New PIs).** New PIs and Early Stage Investigators (ESIs) are invited to apply for Recovery Act Challenge Grants in Health and Science Research. Because the awards made under this program are substantial competing NIH research grants, recipients will not be considered New PIs or ESIs when they apply for NIH research grants in the future. More information can be found at [http://grants.nih.gov/grants/new\\_investigators/index.htm](http://grants.nih.gov/grants/new_investigators/index.htm).
- **Number of PDs/PIs.** More than one PD/PI (i.e., multiple PDs/PIs) may be designated on the application.
- **Number of Applications.** Applicants may submit more than one application, provided each application is scientifically distinct.
- **Resubmissions.** Because this is a one-time-only solicitation, resubmissions are not permitted.
- **Renewals.** Renewals are not permitted in response to this FOA.
- **Special Date(s).** This FOA uses non-standard due dates. See [Receipt, Review and Anticipated Start Dates](#).
- **Application Materials.** See [Section IV.1](#) for application materials.
- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:
  - SF424 (R&R) Application and Electronic Submission Information: <http://grants.nih.gov/grants/funding/424/index.htm>
  - General information on Electronic Submission of Grant Applications: <http://era.nih.gov/ElectronicReceipt/>
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (301) 451-5936

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## Part II - Full Text of Announcement

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### Section I. Funding Opportunity Description

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#### 1. Research Objectives

The mission of NIH is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. To that end, the NIH, through the extramural grants programs of its Institutes and Centers, supports a broad range of biomedical research. Previous research has enormously increased our understanding of the molecular, cellular and behavioral bases of disease and our approaches to health care. At the same time, these advances have identified new gaps in our knowledge and have created needs for new technologies. This FOA is designed to provide investigators with the opportunity to address these unique challenges by addressing new avenues of research in defined areas where progress would produce a significant impact on biomedical or behavioral science and/or health research.

Applicants to the Challenge Grants Program must specify both the broad Challenge Area and the specific Challenge Topic that their research addresses. Applicants must also clearly articulate how the proposed studies would significantly extend our understanding of biomedical or behavioral science and/or health as it relates to the specific Challenge Topic selected.

#### 2. Challenge Areas

The NIH has identified a range of Challenge Areas that focus on specific knowledge gaps, scientific opportunities, new technologies, data generation, or research methods that would benefit from an influx of funds to quickly advance the area in significant ways. Within each broad Challenge Area the NIH Institutes, Centers, and Offices have specified particular Challenge Topics that address their missions. These broad Challenge Areas are provided below.

Click on the Challenge Area for the detailed description of the specific Challenge Topics within that area that have been accorded the highest priority by the NIH Institute, Center or Office

indicated.

- (01) [Behavior, Behavioral Change, and Prevention](#)
- (02) [Bioethics](#)
- (03) [Biomarker Discovery and Validation](#)
- (04) [Clinical Research](#)
- (05) [Comparative Effectiveness Research \(CER\)](#)
- (06) [Enabling Technologies](#)
- (07) [Enhancing Clinical Trials](#)
- (08) [Genomics](#)
- (09) [Health Disparities](#)
- (10) [Information Technology for Processing Health Care Data](#)
- (11) [Regenerative Medicine](#)
- (12) [Science, Technology, Engineering and Mathematics Education \(STEM\)](#)
- (13) [Smart Biomaterials – Theranostics](#)
- (14) [Stem Cells](#)
- (15) [Translational Science](#)

Also, most Institutes and Centers have identified additional Challenge Topics for funding under this FOA. A compilation of all Challenge Topics can be accessed in a single Omnibus at: [http://grants.nih.gov/grants/funding/challenge\\_award/Omnibus.pdf](http://grants.nih.gov/grants/funding/challenge_award/Omnibus.pdf).

Individual IC's have also listed their particular topics on their own Web sites: [http://grants.nih.gov/grants/funding/challenge\\_award/IC\\_ChallengeWebPage.htm](http://grants.nih.gov/grants/funding/challenge_award/IC_ChallengeWebPage.htm)

**Note:** The broad Challenge Area and the specific Challenge Topic being addressed **must** be explicitly cited in the Project Summary/Abstract Component of the application.

**Applicants must begin their Project Summary/Abstract citing the specific topic identifier listed in the table of Challenge Areas and Topics, e.g.,** *This application addresses broad Challenge Area (01): Behavior, Behavioral Change, and Prevention and specific Challenge Topic, 01-GM-104: Mechanisms of Behavior Change Research.*

See [Section VIII, Other Information - Required Federal Citations](#), for policies related to this announcement.

## Section II. Award Information

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### 1. Mechanism of Support

This FOA will use the (RC1) award mechanism. The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses "Just-in-Time" information concepts (see [SF424 \(R&R\) Application Guide](#)).

### 2. Funds Available

This initiative is funded under the Recovery Act. NIH has designated at least \$200 million in FYs 2009 - 2010 to fund 200 or more grants, contingent upon the submission of a sufficient number of scientifically meritorious applications. In addition, Recovery Act funds allocated to NIH specifically for comparative effectiveness research (CER) may be available to support additional grants. Projects receiving these funds will need to meet this definition of CER: "a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients. Such a study may compare similar treatments, such as competing drugs, or it may analyze very different approaches, such as surgery and drug therapy." Such research may include the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data as they apply to CER.

Budget proposals are limited to \$500,000 total costs per year for a total of \$1,000,000 total costs over two years.

Because the nature and scope of the proposed research will vary, it is anticipated that the size of each award will vary. However, the duration of the awards issued under this FOA will be limited to two years.

NIH awards under the Recovery Act will be for two years. To further sustain the economic growth and progress in health science, awardees are encouraged to explore the development of Public-Private Partnerships (PPPs) during the course of the award. Information on developing PPPs can be found at <http://ppp.od.nih.gov/>.

Note: The development plan is not part of the Challenge Grant application.

NIH grants policies as described in the [NIH Grants Policy Statement](#) will apply to the applications submitted and awards made in response to this FOA.

## Section III. Eligibility Information

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### 1. Eligible Applicants

#### 1.A. Eligible Institutions

The following organizations/institutions are eligible to apply. Consistent with the purposes of the Recovery Act (in particular, to preserve and create jobs and promote economic recovery in the United States, and to provide investments needed to increase economic efficiency by spurring technological advances in science and health), **applicants must be domestic (United States) institutions/ organizations** (i.e., located in the 50 states, territories and possessions of the United States, Commonwealth of Puerto Rico, Trust Territory of the Pacific Islands, or District of Columbia). NIH strongly encourages applications from all interested candidates, including organizations/institutions from [Institutional Development Award \(IDeA\) states](#) and [Academic Research Enhancement Award \(AREA\)-eligible](#) institutions. Applications from foreign institutions are not permitted.

Eligible institutions include:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)

- Alaska Native and Native Hawaiian Serving Institutions
- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Small Businesses
- For-Profit Organizations (Other than Small Businesses)
- State Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribally Designated Organizations
- County Governments
- City or Township Governments
- Special District Governments
- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- U.S. Territory or Possession
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Regional Organizations
- Other(s):
  - Eligible Agencies of the Federal Government
  - Faith-based or Community-based Organizations

## 1.B. Eligible Individuals

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

More than one PD/PI (i.e., multiple PDs/Pis), may be designated on the application for projects that require a "team science" approach and therefore clearly do not fit the single-PD/PI model. Additional information on the implementation plans and policies and procedures to formally allow more than one PD/PI on individual research projects is available at [http://grants.nih.gov/grants/multi\\_pi](http://grants.nih.gov/grants/multi_pi). All PDs/Pis must be registered in the NIH electronic Research Administration (eRA) Commons prior to the submission of the application (see <http://era.nih.gov/ElectronicReceipt/preparing.htm> for instructions).

The decision of whether to apply for a grant with a single PD/PI or multiple PDs/Pis grant is the responsibility of the investigators and applicant organizations and should be determined by the scientific goals of the project. Applications for grants with multiple PDs/Pis will require additional information, as outlined in the instructions below. The NIH review criteria for

approach, investigators, and environment have been modified to accommodate applications involving either a single PD/PI or multiple PDs/Pis. When considering the multiple PD/PI option, please be aware that the structure and governance of the PD/PI leadership team as well as the knowledge, skills and experience of the individual PDs/Pis will be factored into the assessment of the overall scientific merit of the application. Multiple PDs/Pis on a project share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the grantee organization, or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of required reports. For further information on multiple PDs/Pis, please see [http://grants.nih.gov/grants/multi\\_pi](http://grants.nih.gov/grants/multi_pi).

New PIs and Early Stage Investigators (ESIs) are encouraged to apply for Recovery Act Challenge Grants in Health and Science Research. Because the awards made under this program are substantial competing NIH research grants, recipients will not be considered New PIs or ESIs when they apply for NIH research grants in the future. More information can be found at [http://grants.nih.gov/grants/new\\_investigators/index.htm](http://grants.nih.gov/grants/new_investigators/index.htm).

## 2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current [NIH Grants Policy Statement](#).

## 3. Other-Special Eligibility Criteria

This FOA is limited to new applications addressing one of the Challenge Topics stipulated in [Section I, Item 2](#).

Renewal applications and resubmissions will not be accepted.

Applicants may submit more than one application, provided each application is scientifically distinct.

## Section IV. Application and Submission Information

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To download a SF424 (R&R) Application Package and SF424 (R&R) Application Guide for completing the SF424 (R&R) forms for this FOA, use the "Apply for Grant Electronically" button in this FOA or link to <http://www.grants.gov/Apply/> and follow the directions provided on that Web site.

A one-time registration is required for institutions/organizations at **both**:

- Grants.gov ([http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp)) and
- eRA Commons (<http://era.nih.gov/ElectronicReceipt/preparing.htm>)

PDs/PIs should work with their institutions/organizations to make sure they are registered in the NIH eRA Commons.

Several additional separate actions are required before an applicant can submit an electronic application, as follows:

1) Organizational/Institutional Registration in [Grants.gov/Get Registered](#)

- Your organization will need to obtain a [Data Universal Number System \(DUNS\) number](#) and register with the [Central Contractor Registration \(CCR\)](#) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to:  
[Grants.gov Customer Support](#)  
Contact Center Phone: 800-518-4726  
Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time  
Email [support@grants.gov](mailto:support@grants.gov)

2) [Organizational/Institutional Registration in the eRA Commons](#)

- To find out if an organization is already Commons-registered, see the "[List of Grantee Organizations Registered in NIH eRA Commons.](#)"
- Direct questions regarding the Commons registration to:  
eRA Commons Help Desk  
Phone: 301-402-7469 or 866-504-9552 (Toll Free)  
TTY: 301-451-5939  
Business hours M-F 7:00 a.m. – 8:00 p.m. Eastern Time  
Email [commons@od.nih.gov](mailto:commons@od.nih.gov)

3) Project Director/Principal Investigator (PD/PI) Registration in the NIH eRA Commons: Refer

to the [NIH eRA Commons System \(COM\) Users Guide](#).

- The individual(s) designated as PD/PIs on the application must also be registered in the NIH eRA Commons **and be assigned the PD/PI role** in the eRA Commons prior to the submission of the application. It is not necessary for PDs/PIs to register with Grants.gov.
- Each PD/PI must hold a PI account in the Commons. Applicants should not share a Commons account for both a Signing Official (SO) role and a PI role; however, if they have both a PI role and an Internet Assisted Review (IAR) role, both roles should exist under one Commons account.
- When multiple PDs/PIs are proposed, all PDs/PIs at the applicant organization must be affiliated with that organization. When PDs/PIs are located at another institution, only the contact PI (the PI named on the SF424 (R&R) Cover component) must be affiliated with the applicant; other PD/PIs need not be affiliated with the applicant organization, but must be affiliated with their own organization to be able to access the Commons.
- This registration/affiliation must be done by the AOR/SO or their designee who is already registered in the Commons.

Both the PD/PI(s) and AOR/SO need separate accounts in the NIH eRA Commons since both are authorized to view the application image.

Several of the steps of the registration process could take four (4) weeks or more. Therefore, applicants should immediately check with their business official to determine whether their institution is already registered in both [Grants.gov](#) and the [Commons](#). The NIH will accept electronic applications only from organizations that have completed all necessary registrations.

## 1. Request Application Information

Applicants must download the SF424 (R&R) application forms and SF424 (R&R) Application Guide for this FOA using the "Apply for Grant Electronically" button in this FOA or through [Grants.gov/Apply](#).

Note: Only the form packages directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA), although some of the "Attachment" files may be useable for more than one FOA.

For further assistance contact GrantsInfo -- Telephone 301-435-0714, Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

Telecommunications for the hearing impaired: TTY 301-451-5936.

## 2. Content and Form of Application Submission

Prepare all applications using the SF424 (R&R) application forms and in accordance with the SF424 (R&R) Application Guide for this FOA through [Grants.gov/Apply](#).

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to NIH. Some fields within the SF424 (R&R) application components, although not marked as mandatory, are required by NIH (e.g., the "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component must contain the PD/PI's assigned eRA Commons User ID). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see "Frequently Asked Questions – Application Guide, [Electronic Submission of Grant Applications](#)."

The SF424 (R&R) application has several components. Some components are required, others are optional. The form packages associated with this FOA in [Grants.gov/APPLY](#) includes all applicable components, required and optional. A completed application in response to this FOA includes the data in the following components:

### **Required Components:**

- SF424 (R&R) (Cover component)
- Research & Related Project/Performance Site Locations
- Research & Related Other Project Information
- Research & Related Senior/Key Person
- PHS398 Cover Page Supplement
- PHS398 Research Plan
- PHS398 Checklist
- Research & Related Budget

### **Optional Components:**

- PHS398 Cover Letter File
- Research & Related Subaward Budget Attachment(s) Form

### **Applications with Multiple PDs/PIs**

When multiple PDs/PIs are proposed, NIH requires one PD/PI to be designated as the "Contact" PI, who will be responsible for all communication between the PDs/PIs and the NIH, for assembling the application materials outlined below, and for coordinating progress reports for the project. The contact PD/PI must meet all eligibility requirements for PD/PI status in the same way as other PDs/PIs, but has no other special roles or responsibilities within the project team beyond those mentioned above.

Information for the Contact PD/PI should be entered in item 15 of the SF424 (R&R) Cover component. All other PDs/PIs should be listed in the Research & Related Senior/Key Person component and assigned the project role of "PD/PI." Please remember that all PDs/PIs must be registered in the eRA Commons prior to application submission. **The Commons ID of each PD/PI must be included in the "Credential" field of the Research & Related Senior/Key Person component. Failure to include this data field will cause the application to be rejected.**

All projects proposing Multiple PDs/PIs will be required to include a new section describing the leadership plan approach for the proposed project.

Multiple PD/PI Leadership Plan: For applications designating multiple PDs/PIs, a new section of the research plan, entitled "Multiple PD/PI 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, and should include 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 PDs/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PDs/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Award (NoA).

### **Applications Involving a Single Institution**

When all PDs/PIs are within a single institution, follow the instructions contained in the SF424 (R&R) Application Guide.

### **Applications Involving Multiple Institutions**

When multiple institutions are involved, one institution must be designated as the prime institution and funding for the other institution(s) must be requested via a subcontract to be administered by the prime institution. When submitting a detailed budget, the prime institution should submit its budget using the Research & Related Budget component. All other institutions should have their individual budgets attached separately to the Research & Related Subaward Budget Attachment(s) Form. See Section 4.8 of the SF424 (R&R) Application Guide for further instruction regarding the use of the subaward budget form.

### 3. Submission Dates and Times

See [Section IV.3.A](#) for details.

#### 3.A. Submission, Review, and Anticipated Start Dates

Opening Date: March 27, 2009 (Earliest date an application may be submitted to Grants.gov)

Application Due Date(s): April 27, 2009

Peer Review Date(s): June/July 2009

Council Review Date(s): August 2009

Earliest Anticipated Start Date(s): September 30, 2009

#### 3.A.1. Letter of Intent

A letter of intent is not required for the funding opportunity.

#### 3.B. Submitting an Application Electronically to the NIH

To submit an application in response to this FOA, applicants should access this FOA via [http://www.grants.gov/applicants/apply\\_for\\_grants.jsp](http://www.grants.gov/applicants/apply_for_grants.jsp) and follow Steps 1-4. Note: Applications must only be submitted electronically. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

#### 3.C. Application Processing

Applications **may** be submitted on or after the opening date and **must** be successfully received by Grants.gov no later than **5:00 p.m. local time** (of the applicant institution/organization) on the application due date(s). (See [Section IV.3.A](#), for all dates.) If an application is not submitted by the due date(s) and time, the application may be delayed in the review process or not reviewed.

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two weekdays (Monday – Friday, excluding Federal holidays) to view the application image to determine if any further action is necessary.

- If everything is acceptable, no further action is necessary. The application will automatically move forward to the Division of Receipt and Referral in the Center for Scientific Review for processing after two weekdays, excluding Federal holidays.
- Prior to the submission deadline, the AOR/SO can "Reject" the assembled application and submit a changed/corrected application within the two-day viewing window. This

option should be used if it is determined that some part of the application was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to "Reject" the application and submit a Changed/Corrected application. In these cases, please contact the eRA Help Desk to ensure that the issues are addressed and corrected. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12, including the requirement for cover letters on late applications. The "Reject" feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two weekdays if no action is taken. Some warnings may need to be addressed later in the process.

- If the two-day window falls after the submission deadline, the AOR/SO will have the option to "Reject" the application if, due to an eRA Commons or Grants.gov system issue, the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn't transfer correctly during the submission process). The AOR/SO should first contact the [eRA Commons Helpdesk](#) to confirm the system error, document the issue, and determine the best course of action. NIH will not penalize the applicant for an eRA Commons or Grants.gov system issue.
- If the AOR/SO chooses to "Reject" the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted, but it will be subject to the [NIH late policy](#) guidelines and may not be accepted. The reason for this delay should be explained in the cover letter attachment.
- Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two weekdays.

Upon receipt, applications will be evaluated for completeness and responsiveness by CSR. Incomplete and non-responsive applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the [Commons](#). The submitting AOR/SO receives the Grants.gov acknowledgments. The AOR/SO and the PI receive Commons acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

**Note: Since email can be unreliable, it is the responsibility of the applicant to check periodically on the application status in the Commons.**

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the

pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an "Introduction" describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

#### 4. Intergovernmental Review

This initiative is not subject to [intergovernmental review](#).

#### 5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Pre-award costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or renewal award if such costs: 1) are necessary to conduct the project, and 2) would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or renewal award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project (see the [NIH Grants Policy Statement](#)).

#### 6. Other Submission Requirements and Information

##### PD/PI Credential (e.g., Agency Login)

The NIH requires the PD(s)/PI(s) to fill in his/her Commons User ID in the "PROFILE – Project Director/Principal Investigator" section, "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component.

## Organizational DUNS

The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see "Frequently Asked Questions – Application Guide, [Electronic Submission of Grant Applications](#)."

All application instructions outlined in the SF424 (R&R) Application Guide are to be followed, incorporating "Just-in-Time" information concepts, and in accordance with the following additional requirements and special instructions. All attachments must be provided to NIH in PDF format, filenames must be included with no spaces or special characters, and a .pdf extension must be used.

### **Special Instructions for Other Project Information (Section 4.4 of SF424 (R&R) Application)**

**Item 6. 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.*

Continue with the instructions in the SF424 (R&R) Application Guide.

**Item 8. Bibliography and Literature Cited:** Limited to one page.

### **Special Instructions for Senior/Key Person Profile (Expanded) Component (Section 4.5 of SF424 (R&R) Application)**

**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.

### **Special Instructions for PHS398 Research Plan Component (Section 5.5 of SF424 (R&R) Application)**

**Research Plan:** The Research Plan is comprised of special sections noted below and is limited

to a total of 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.

#### PHS398 Research Plan Component Sections

Item Number and Title	Instructions
1. Introduction to Application	Omit (N/A: Resubmissions and Revisions not allowable)
2. Specific Aims	One page maximum. Separate PDF attachment
3. Background and Significance	Omit
4. Preliminary Studies/Progress Report	Omit
5. Research Design and Methods	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.

Excluded from the 12-page Research Plan limit are the following items:

- Specific Aims (1 page maximum)
- Inclusion Enrollment Report
- Protection of Human Subjects
- Inclusion of Women and Minorities
- Targeted/Planned Enrollment
- Inclusion of Children
- Vertebrate Animals
- Select Agent Research
- MPI Leadership Plan
- Consortium/ Contractual Arrangements
- Letters of Support
- Resource Sharing Plans

Note the 12-page limit also excludes the Project Summary/Abstract; Bibliography and Literature Cited; and Biographical Sketches (separate PDFs).

Organize the Research Plan in the specified order using the instructions provided below. Start each section with the appropriate section heading (i.e., Statement of the Challenge Area and the specific Challenge Topic, The Challenge and Potential Impact, The Approach, Timeline and Milestones.)

**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.

**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?

**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.

**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.

Preliminary data are not required but may be included, if necessary to demonstrate the feasibility of the proposed studies. The presentation must be clear and particularly compelling. No detailed scientific plan should be provided, but timelines must be presented.

#### **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.

**No supplemental/update information will be accepted.**

## 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 (see [http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_faqs.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm).)

(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/>.)

## Section V. Application Review Information

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### 1. Criteria

Only the review criteria described below will be considered in the review process.

### 2. Review and Selection Process

Applications that are complete and responsive to this FOA will be evaluated for scientific and technical merit by appropriate peer review groups convened by the Center for Scientific Review (CSR) and in accordance with NIH peer review procedures (<http://grants1.nih.gov/grants/peer/>), using the review criteria stated below.

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned a priority score;
- Receive a written critique; and
- Receive a second level of review by an appropriate national advisory council or board

Applications submitted in response to this FOA will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

**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 of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

**Core Review Criteria.** Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

**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, technological

advances, technical capability, clinical practice, and/or health be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**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?

**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, technological developments, 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?

**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?

**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 project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

## 2.A. Additional Review Criteria

As applicable for the project proposed, reviewers will consider **the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.**

**Protections for Human Subjects.** For research that involves human subjects but does not

involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

***Inclusion of Women, Minorities, and Children.*** When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

***Vertebrate Animals.*** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to 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.

***Biohazards.*** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

## **2.B. Additional Review Considerations**

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score.

***Budget and Period Support.*** Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

***Select Agent Research.*** Reviewers will assess the information provided in this section of the application, including 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).

**Resource Sharing Plans.** Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable:

- Data Sharing Plan. [[http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)]
- Sharing Model Organisms. [<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>]
- Genome Wide Association Studies (GWAS). [<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>]

The NIH will suspend the appeals process for investigators responding to Recovery Act FOAs. (See [NOT-OD-09-054](#)).

### 3. Anticipated Announcement and Award Dates

Not applicable.

## Section VI. Award Administration Information

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### 1. Award Notices

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the NIH eRA [Commons](#).

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](#).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee business official.

**The terms of the NoA will reference the requirements of the Recovery Act.**

In addition to the standard NIH terms of award, all funding provided under the Recovery Act will be subject to the HHS Standard Terms and Conditions for American Recovery and Reinvestment Act of 2009 (ARRA). The full text of these terms approved for NIH awards can be found in the following document: [Standard Terms and Conditions for ARRA Awards](#).

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See [Section IV.5](#), "Funding Restrictions."

The resource sharing plan will become part of the terms and conditions of the award.

## 2. Administrative and National Policy Requirements

A Program Official from one or more of the participating NIH Institutes and Centers will be assigned to each funded application and will assume responsibility for normal stewardship of the awards.

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement* as part of the NoA. For these terms of award, see the [NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General](#) and [Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities](#).

## 3. Reporting

Awardees will be required to submit the [Non-Competing Continuation Grant Progress Report \(PHS 2590\)](#) annually and financial statements as required in the [NIH Grants Policy Statement](#).

In addition, grantees must comply with the requirements set forth in the Recovery Act, including, but not limited to, the quarterly reporting requirements of Section 1512 of the Recovery Act as specified in HHS Standard Terms and Conditions for American Recovery and Reinvestment Act of 2009. The full text of these terms approved for NIH awards can be found in the following document: [Standard Terms and Conditions for ARRA Awards](#).

Recovery Act-related reporting requirements will be incorporated as a special term of award.

## Section VII. Agency Contacts

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We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research (program), peer review, and financial or grants management issues:

### 1. Scientific/Research Contact(s):

Refer to the [specific Challenge Topic](#) for the appropriate person to contact.

### 2. Peer Review Contact(s):

Noni H. Byrnes, Ph.D.  
Chief, Cell Biology Integrated Review Group  
Division of Basic and Integrative Biological Sciences  
Center for Scientific Review (CSR)  
National Institutes of Health  
6701 Rockledge Drive (Rockledge 2), Room 5130  
Room 5130, MSC 7840  
Bethesda, MD 20892 (20817 for Fedex)  
Telephone: (301) 435-1023 (voice)  
Fax: (301) 480-1988 (fax)  
Email: [byrnesn@csr.nih.gov](mailto:byrnesn@csr.nih.gov)

### 3. Financial/Grants Management Contact(s):

Refer to the [specific Challenge Topic](#) for the appropriate person to contact.

## Section VIII. Other Information

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### Required Federal Citations

The American Recovery And Reinvestment Act of 2009 (Pub. L. No. 111-5):  
[http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111\\_cong\\_bills&docid=f:h1enr.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1enr.pdf)

**Standard Terms and Conditions for Recovery Act Awards:** The full text of these terms approved for NIH awards can be found in the following document:

[http://grants.nih.gov/grants/policy/NIH\\_HHS\\_ARRA\\_Award\\_Terms.pdf](http://grants.nih.gov/grants/policy/NIH_HHS_ARRA_Award_Terms.pdf)

**Use of Animals in Research:**

Recipients of PHS support for activities involving live, vertebrate animals must comply with PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable.

**Human Subjects Protection:**

Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

**Data and Safety Monitoring Plan:**

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants ("NIH Policy for Data and Safety Monitoring," *NIH Guide for Grants and Contracts*, <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

**Sharing Research Data:**

Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible ([http://grants.nih.gov/grants/policy/data\\_sharing](http://grants.nih.gov/grants/policy/data_sharing)). Investigators should seek guidance from their institutions, on issues related to institutional policies and local institutional review board (IRB) rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

**Policy for Genome-Wide Association Studies (GWAS):**

NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository.

For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. All applications, regardless of the amount requested, proposing 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. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, [NIH Guide NOT-OD-07-088](#). For additional information, see <http://grants.nih.gov/grants/gwas/>

#### **Sharing of Model Organisms:**

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see [http://grants.nih.gov/grants/policy/model\\_organism/index.htm](http://grants.nih.gov/grants/policy/model_organism/index.htm)). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh-Dole Act (see the [NIH Grants Policy Statement](#)). Beginning October 1, 2004, all investigators submitting an NIH application or contract proposal are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

#### **Access to Research Data through the Freedom of Information Act:**

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are: (1) first produced in a project that is supported in whole or in part with Federal funds; and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at [http://grants.nih.gov/grants/policy/a110/a110\\_guidance\\_dec1999.htm](http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm). Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

**Inclusion of Women And Minorities in Clinical Research:**

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the SF424 (R&R) application; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

**Inclusion of Children as Participants in Clinical Research:**

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (<http://grants.nih.gov/grants/funding/children/children.htm>).

**Required Education on the Protection of Human Subject Participants:**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

**Human Embryonic Stem Cells (hESC):**

Criteria for Federal funding of research on hESCs can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (<http://escr.nih.gov/>). It is the responsibility of the applicant to provide in the project description and elsewhere in the

application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

**NIH Public Access Policy Requirement:**

In accordance with the NIH Public Access Policy, *investigators funded by the NIH must submit or have submitted for them to the National Library of Medicine's PubMed Central (see <http://www.pubmedcentral.nih.gov/>), an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication.* The NIH Public Access Policy is available at (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>). For more information, see the Public Access webpage at <http://publicaccess.nih.gov/>.

**Standards for Privacy of Individually Identifiable Health Information:**

The Department of Health and Human Services (HHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the HHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

**URLs in NIH Grant Applications or Appendices:**

All applications and proposals for NIH funding must be self-contained within specified page limitations. For publications listed in the appendix and/or Progress report, Internet addresses (URLs) or PubMed Central (PMC) submission identification numbers must be used for publicly accessible on-line journal articles. Publicly accessible on-line journal articles or PMC articles/manuscripts accepted for publication that are directly relevant to the project may be included **only** as **URLs** or **PMC submission identification numbers** accompanying the full reference in either the Bibliography & References Cited section, the Progress Report Publication List section, or the Biographical Sketch section of the NIH grant application. A URL or PMC submission identification number citation may be repeated in each of these sections as appropriate. There is no limit to the number of URLs or PMC submission identification numbers

that can be cited.

**Healthy People 2010:**

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

**Authority and Regulations:**

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov> and is not subject to the intergovernmental review requirements of Executive Order 12372. Awards are made under Sections 301 and 405 of the PHS Act, as amended (42 USC 241 and 284) and are subject to 42 CFR Part 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#).

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

**Loan Repayment Programs:**

NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: <http://www.lrp.nih.gov>.

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