

Part I Overview Information

Participating Organizations

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

Components of Participating Organizations

National Cancer Institute (NCI/NIH), (<http://www.cancer.gov/>)

National Eye Institute (NEI/NIH), (<http://www.nei.nih.gov/>)

National Heart, Lung, and Blood Institute (NHLBI/NIH), (<http://www.nhlbi.nih.gov/index.htm>)

National Human Genome Research Institute (NHGRI/NIH), (<http://www.genome.gov/>)

National Institute on Aging (NIA/NIH), (<http://www.nia.nih.gov/>)

National Institute on Alcohol Abuse and Alcoholism (NIAAA/NIH), (<http://www.niaaa.nih.gov/>)

National Institute of Allergy and Infectious Diseases (NIAID/NIH),
(<http://www3.niaid.nih.gov/>)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS/NIH),
(<http://www.niams.nih.gov/>)

National Institute of Biomedical Imaging and Bioengineering (NIBIB/NIH),
(<http://www.nibib.nih.gov/>)

National Institute of Child Health and Human Development (NICHD/NIH),
(<http://www.nichd.nih.gov/>)

National Institute on Deafness and Other Communication Disorders (NIDCD/NIH),
(<http://www.nidcd.nih.gov/>)

National Institute of Dental and Craniofacial Research (NIDCR/NIH),
(<http://www.nidcr.nih.gov/>)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK/NIH),
(<http://www.niddk.nih.gov/>)

National Institute on Drug Abuse (NIDA/NIH), (<http://www.nida.nih.gov/>)

National Institute of Environmental Health Sciences (NIEHS/NIH),
(<http://www.niehs.nih.gov/>)

National Institute of General Medical Sciences (NIGMS/NIH), (<http://www.nigms.nih.gov/>)

National Institute of Mental Health (NIMH/NIH), (<http://www.nimh.nih.gov/>)

National Institute of Neurological Disorders and Stroke (NINDS/NIH),
(<http://www.ninds.nih.gov/>)

National Institute of Nursing Research (NINR/NIH), (<http://www.ninr.nih.gov/>)

National Library of Medicine (NLM/NIH), (<http://www.nlm.nih.gov/>)

National Center for Complementary and Alternative Medicine (NCCAM/NIH),
(<http://nccam.nih.gov/>)

National Center on Minority Health and Health Disparities (NCMHD/NIH),
(<http://ncmhd.nih.gov/>)

National Center for Research Resources (NCRR/NIH), (<http://www.ncrr.nih.gov/>)

Office of Dietary Supplements, National Institutes of Health (ODS), (www.ods.od.nih.gov)

Title: Recovery Act Limited Competition: Small Business

Catalyst Awards for Accelerating Innovative Research (R43)

Announcement Type

New

Request for Applications (RFA) Number: RFA-OD-09-009

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.

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

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](#) (hereafter called Grants.gov/Apply).

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: June 2, 2009

Opening Date: August 1, 2009 (Earliest date an application may be submitted to Grants.gov)

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).

Letters of Intent Due Date: August 3, 2009

Application Due Date(s): September 1, 2009

Peer Review Date(s): November/December 2009

Council Review Date(s): January 2010

Earliest Anticipated Start Date(s): April 2010

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

Expiration Date: September 2, 2009

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** This NIH Funding Opportunity Announcement (FOA), supported by funds provided to the NIH under the American Recovery & Reinvestment Act of 2009 (“Recovery Act” or “ARRA”), Public Law 111-5, invites grant applications from small business concerns that propose to accelerate innovation through high risk, high reward research and development (R&D) that has commercial potential and is relevant to the mission of the NIH. The Small Business Catalyst Award is further expected to support entrepreneurs of exceptional creativity, drawn from scientific and technological environments beyond NIH, who propose pioneering and possibly transformative approaches to addressing major biomedical or behavioral challenges with the potential for downstream commercial development. The Small Business Catalyst Award for Accelerating Innovative Research funding opportunity seeks to encourage fresh research perspectives and approaches to serve the mission of NIH. In particular, applications from small business concerns without a history of NIH Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) support may receive funding priority. Solicited are applications for support for projects that have the potential to generate high impact results (e.g., products, processes or services) and/or innovative research applications, research tools, techniques, devices, inventions, or methodologies. The outcomes of the research supported should have potential to lead to products that will improve public health and create significant value and economic stimulus. This FOA solicits early-stage ideas that promise to lead to major leaps forward in capabilities important to serving the mission of NIH rather than incremental improvements of existing technologies. In accord with the funding priority of this initiative to attract applicants without a history of SBIR/STTR support from NIH, the focus of the projects solicited by this FOA is on early stage technology development.
- **Mechanism of Support.** This FOA will use the Phase I SBIR (R43) award mechanism.
- **Funds Available and Anticipated Number of Awards.** NIH intends to commit as least \$5 million under this FOA. We anticipate that 20-25 awards will be made for fiscal year 2010, pending the number and quality of applications and availability of funds.
- **Budget and Project Period.** Budget requests are limited to \$200,000 total costs for a maximum project period of one year.
- **Research Plan Component Length:** The Research Plan is limited to a total of 7 pages, including 1 page for the Specific Aims and 6 pages for Research Design and Methods.
- **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.

- **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. NIH will not accept similar grant applications with essentially the same research focus from the same applicant organization. This includes derivative or multiple applications that propose to develop a single product, process, or service that, with non-substantive modifications, can be applied to a variety of purposes. Applicants may **not** simultaneously submit identical/essentially identical applications under both this funding opportunity and any other HHS FOA.
- **Resubmissions.** 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](#) 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

Section I. Funding Opportunity Description

1. Research Objectives

This Small Business Catalyst Award funding opportunity invites grant applications from small business concerns that propose to accelerate innovation through high risk, high reward research and development (R&D) that has commercial potential and is relevant to the mission of the NIH. The Small Business Catalyst Award is further expected to support entrepreneurs of exceptional creativity, drawn from scientific and technological environments beyond NIH, who propose pioneering and possibly transformative approaches to addressing major biomedical or behavioral challenges with the potential for downstream commercial development. The Small Business Catalyst Award for Accelerating Innovative Research funding opportunity seeks to encourage fresh research perspectives and approaches to serve the mission of NIH. In particular, applications from small business concerns without a history of NIH SBIR/STTR support may receive funding priority. Solicited are applications for support for projects that have the potential to generate high impact results (e.g., products, processes or services) and/or innovative research applications, research tools, techniques, devices, inventions, or methodologies. The outcomes of the research supported should have potential to lead to products that will improve public health and create significant value and economic stimulus. Specifically, this FOA solicits early-stage ideas that represent advancement in a technological area that promises to lead to major leaps forward, not merely incremental improvements of existing technologies, e.g., projects that have the potential to generate high impact results and/or innovative research applications, research tools, techniques, devices, inventions, or methodologies. In addition, this FOA encourages technologies stemming from an emerging scientific field or technological capacity that would be beneficial if successfully commercially developed.

High-risk, high reward R&D that is unlikely to be undertaken by ongoing academic efforts or within industrial firms is strongly encouraged. In addition, NIH encourages technologies stemming from an emerging scientific field or technological capacity that would be beneficial if successfully commercially developed. Applicants that have been supported by other Federal agencies for R&D that draw from the mathematical, computational, physical, behavioral or social sciences are encouraged. In addition to seeking to bring new applicants with new ideas to address issues important to NIH, this FOA also seeks to provide an entree to the NIH research portfolio for promising small business concerns. In accord with the funding priority of this initiative to attract applicants without a history of SBIR/STTR support from NIH, the focus of the projects solicited by this FOA is on early stage technology development.

See [Section VIII, Other Information - Required Federal Citations](#), for laws and policies

related to this announcement.

Section II. Award Information

1. Mechanism of Support

This funding opportunity will use the Small Business Innovation Research (SBIR [R43]) grant mechanisms. Applications may be submitted for support as Phase I grants as described in the [SF424 \(R&R\) Application Guide](#).

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](#)). It also uses the modular as well as the non-modular budget formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>).

2. Funds Available

This initiative is supported by funds provided to the NIH under the American Recovery & Reinvestment Act of 2009 (“Recovery Act” or “ARRA”), Public Law 111-5. NIH intends to commit as least \$5 million in response to this FOA in FY2010 to fund 20-25 grants, contingent upon the submission of a sufficient number of scientifically meritorious applications. All awards are subject to the availability of funds. Future year amounts will depend on annual appropriations.

Total costs (sum of direct costs, Facilities & Administrative costs and profit/fee) are limited to \$200,000 over a one-year period. (Note: Although the budgets for SBIR Phase I projects are generally \$100,000 total costs and may be exceeded when justified scientifically, the award amount and project period for this FOA are capped at \$200,000 total costs and one year, respectively. Applicants still must provide scientific justification for total costs that exceed \$100,000.)

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size of each award will also vary. Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds.

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

1. Eligible Applicants

1.A. Eligible Institutions

The following organizations/institutions are eligible to apply:

Only United States small business concerns (SBCs) are eligible to submit SBIR applications. A small business concern is one that, at the time of award of SBIR Phase I and Phase II, meets all of the following criteria:

1. Is organized for profit, with a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials or labor;
2. Is in the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there can be no more than 49 percent participation by foreign business entities in the joint venture;
3. Is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, or it must be a for-profit business concern that is at least 51% owned and controlled by another for-profit business concern that is at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, except in the case of a joint venture, where each entity to the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States; and;
4. Has, including its affiliates, not more than 500 employees.

Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly, (a) one concern controls or has the power to control the other; or (b) a third-party/parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. General principles of "affiliation" are provided in 13 C.F.R. 121.103. The calculation of "number of employees" is described in 13 C.F.R. 121.106.

Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative. Further information may be obtained by contacting the Small Business Administration (SBA) Office of Size Standards (<http://sba.gov/size>); note that SBCs also must meet the other regulatory requirements found in the SBA Small Business Size Regulations, accessible at 13 C.F.R. Part 121.

One of the circumstances that would lead to a finding that an organization is controlling or has the power to control another organization involves sharing common office space and/or employees and/or other facilities (e.g., laboratory space). Access to special facilities or

equipment in another organization is permitted (as in cases where the awardee organization has entered into a subcontractual agreement with another organization for a specific, limited portion of the research project). However, research space occupied by an SBIR awardee organization must be space that is available to and under the control of the SBIR awardee for the conduct of its portion of the proposed project.

Consistent with 13 C.F.R. 121.103, control or the power to control may also exist when “key employees of one concern organize a new concern ... and serve as its officers, directors, principal stockholders, and/or key employees, and one concern is furnishing or will furnish the other concern with subcontracts, financial or technical assistance, and/or other facilities, whether for a fee or otherwise.” Where there is indication of sharing of common employees, a determination will be made on a case-by-case basis of whether such sharing constitutes control or the power to control.

For purposes of the SBIR program, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the awardee, consistent with 13 CFR 121.106.

Note regarding affiliation arising under stock options, convertible securities, and agreements to merge: In determining size, SBA considers stock options, convertible securities, and agreements to merge (including agreements in principle) to have a present effect on the power to control a concern. SBA treats such options, convertible securities, and agreements as though the rights granted have been exercised.

All SBIR grant applications will be examined with the above eligibility considerations in mind. If an applicant’s eligibility status is unclear, NIH may request a size determination by the SBA and refrain from making an SBIR award until the SBA provides the determination.

Note: An applicant organization that has been determined previously by SBA to be “other than small” for a size standard of not more than 500 employees or for purposes of the SBIR program, must be recertified as a small business concern by the SBA prior to any future SBIR awards.

NIH encourages applications from all interested and eligible organizations/institutions, including those from [Institutional Development Award \(IDeA\) states](#) and [Academic Research Enhancement Award \(AREA\)-eligible](#) institutions.

In an effort for NIH to attract new entrants to the SBIR program, small business concerns without a history of SBIR/STTR support from NIH may receive funding priority. Please see Research Objectives section, above.

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. 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 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. 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.

Under the SBIR program, the primary employment of the PD/PI must be with the small business concern at the time of award and during the conduct of the proposed project. For projects with multiple PD/PIs, at least one must meet the primary employment requirement. That individual will serve as the Contact PD/PI. Primary employment means that more than one half of the PD/PI's time is spent in the employ of the small business concern. Primary employment with a small business concern precludes full-time employment at another organization. Occasionally, deviations from this requirement may occur. Such deviations must be approved in writing by the grants management officer after consultation with the NIH SBIR/STTR Program Coordinator.

If the application has been recommended for funding, the awarding component will require documentation to verify the eligibility of the Contact PD/PI, if at the time of submission of the application, the Contact PD/PI is a less-than-full-time employee of the small business concern, is concurrently employed by another organization, or gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position.

If the Contact PD/PI is employed or appears to be employed by an organization other than the applicant organization in a capacity such as Research Fellow, Consultant, Adjunct Professor, Clinical Professor, Clinical Research Professor, or Associate, a letter must be provided by each employing organization confirming that, if an SBIR grant is awarded to the applicant small business concern, the Contact PD/PI is or will become a less-than-half-time employee of such organization and will remain so for the duration of the SBIR project. If the Contact PD/PI is employed by a university, such a letter must be provided by the Dean's office or equivalent; for other organizations, the letter must be signed by a corporate official.

All current employment and all other appointments of the Contact PD/PI must be identified in his or her “Biographical Sketch” required as part of the application. Be certain that correct beginning and ending dates are indicated for each employment record listed.

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

Resubmissions. Resubmission applications are not permitted in response to this FOA.

Renewals. Renewal applications are not permitted in response to this FOA.

Number of Applications. Applicants may submit more than one application, provided each application is scientifically distinct. That is, the NIH will not accept similar grant applications with essentially the same research focus from the same applicant organization. This includes derivative or multiple applications that propose to develop a single product, process, or service that, with non-substantive modifications, can be applied to a variety of purposes. Applicants may not simultaneously submit identical/essentially identical applications under both this SBIR funding opportunity and any other HHS FOA, including the current SBIR and STTR Parent FOAs.

Section IV. Application and Submission Information

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) 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

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

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 PDs/PIs on the application must be registered also in the NIH eRA Commons. In the case of multiple PDs/PIs, all PDs/PIs must be registered **and be assigned the PI role** in the eRA Commons prior to the submission of the application.
- 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. PDs/PIs located at another institution 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 his/her designee who is already registered in the Commons.

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

Several steps of the registration process could take four weeks or more. Therefore, applicants should immediately check with their business official to determine whether their organization/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 the SF424 (R&R) Application Guide for this FOA through Grants.gov/Apply.

Note: Only the forms package 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.

Telecommunications for the hearing impaired: TTY: (301) 451-5936

2. Content and Form of Application Submission

Prepare all SBIR applications using the SF424 (R&R) application forms and in accordance with the SF424 (R&R) SBIR/STTR Application Guide.

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 necessary for processing (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). **Failure to include this data field will cause the application to be rejected.**

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. The forms package 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
- Research & Related Budget
- PHS398 Cover Page Supplement
- PHS398 Research Plan

PHS398 Checklist
SBIR/STTR Information

Optional Components:

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

SPECIAL INSTRUCTIONS**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" [Section 14 of the Research Plan Component in the SF424 (R&R)], 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).

3. Submission Dates and Times

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

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

Opening Date: August 1, 2009 (Earliest date an application may be submitted to Grants.gov)

Letters of Intent Due Date: August 3, 2009

Application Due Date(s): September 1, 2009

Peer Review Date(s): November/December 2009

Council Review Date(s): January 2010

Earliest Anticipated Start Date(s): April 2010

3.A.1. Letter of Intent

Prospective applicants are requested to submit a letter of intent (LOI) that includes the following information:

- Descriptive title of proposed research.
- Name, address, and telephone number of the PD(s)/PI(s).
- Names of other key personnel.
- Participating institutions.
- Number and title of this funding opportunity.

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate and plan for the potential review workload.

The letter of intent is to be sent to the specific scientific/research contact person identified in the table in [Section VII](#). The letter of intent is to be sent by the date listed in [Section IV.3.A](#).

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 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 an application is rejected by the AOR/SO, 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 Policy on Late Submissions of Grant Applications ([NOT-OD-05-030](#)) 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 by the CSR and responsiveness by the IC. 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](#), as indicated in the NIH Grants Policy Statement.

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](#).”

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

Research Plan: The Research Plan is limited to a total of 7 pages, including 1 page for the Specific Aims and 6 pages for Research Design and Methods..

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. Do not include this section in application.
4. Preliminary Studies/Progress Report	Omit. Do not include this section in application.
5. Research Design and Methods	<p>Item 5 is limited to 6 pages and must be attached as a single PDF document with the following headings:</p> <p>SIGNIFICANCE: Describe the significance to public health of the problem addressed by this application.</p> <p>Describe how successful completion of the proposed R&D will result in a transformative solution to a significant biomedical or behavioral challenge/problem (e.g., change the methods, technologies, treatments, services, or preventative interventions that drive the field.)</p> <p>INNOVATION: Describe how the product that will be developed solves the identified problem and creates significant value and economic stimulus. Justify the high risk/high reward nature of the proposed research/R&D and the potential for advancement in an area that promises to be a major leap. Discuss the innovation of the outcomes that are expected from the proposed research activities. As applicable, discuss how the proposed technology development stems from an emerging scientific field or technological capacity that would be beneficial if successfully commercially developed.</p> <p>APPROACH: Describe the high risk/high reward research design. Discuss the potential for the approach to be potentially transformative. Figures and illustrations may be included but must fit within the</p>

specified page limit. Do not include links to Web sites for further information. Do not include animations. If the project involves clinical research, be sure that 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, are justified in terms of the scientific goals and research strategy proposed.

INVESTIGATORS AND COMPANY EXPERIENCE: Describe the experience of the investigator(s), collaborators, and other researchers to give some confidence that the specific aims can be achieved and that the PI/team is well suited to accomplish the work proposed.

Note: As defined in 42 C.F.R. 52.2, the PD/PI is the “single individual designated by the grantee in the grant application ... who is responsible for the scientific and technical direction of the project.” When the proposed PD/PI clearly does not have sufficient qualifications to assume this role, the application is not likely to receive a favorable evaluation.

ENVIRONMENT: Describe the facilities and collaborators that are available for the success of the proposed research.

Excluded from the Research Plan limitation are the following items:

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

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.

Warning: Please be sure that you observe the total cost, project period, and page number limitations specified above for this FOA. Application processing may be delayed or the application may be rejected if it does not comply with these requirements.

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

Item 6. Project Summary/Abstract: Follow instructions in the SF424 (R&R) Application Guide.

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

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

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 each biosketch is limited to ten or fewer items. Individuals should cite their most relevant publications and those that highlight the significance of past accomplishments.

Appendix Materials

Appendices are not permitted.

No supplemental/update/post-submission or other 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, (for example, human subject concerns, the Small Business Act provisions, etc.), 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).

(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](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html) 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 [NIH Guide 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

1. Criteria

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

2. Review and Selection Process

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.

Applications that are complete and responsive to this FOA will be evaluated for scientific and technical merit by Scientific Review Groups (SRGs) convened by [CSR](#) and in accordance with NIH peer review procedures (<http://grants1.nih.gov/grants/peer/>). The SRG will use 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 will be discussed and assigned an overall impact/priority score; and
- Receive a second level of review by the appropriate national advisory council or board.

The NIH Small Business Catalyst Award is an initiative for supporting small businesses proposing novel scientific ideas or new model systems, tools, or technologies that have the potential to significantly advance our knowledge or the status of health-related research. Like all Phase I SBIR applications, preliminary data or observations for novel ideas or totally new research directions will generally not be available, and therefore reviewers will place a minor emphasis on preliminary data or observations. However, appropriate justification for the R&D can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Accordingly, reviewers will focus their evaluation on the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Further, researchers, regardless of career stage, may not have an extensive publication record, but may possess a set of

transferable competencies that will enable them to accomplish the objectives.

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?
- Does the project have potential to have significant impact on the identified problem?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the methods, technologies, treatments, services, or preventative interventions that drive this field?
- If successful, to what extent will the outcomes of the applicant's R&D result in a transformative solution to a significant biomedical or behavioral challenge or problem?
- How critically is the relevant literature appraised and evaluated?

Investigator(s).

- Are the PD/PIs, collaborators, and other researchers well suited to accomplish the work proposed?
- If Early Stage Investigators or New Investigators, do they have appropriate experience and training for the research activities proposed?
- 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, or interventions novel to one field of research or novel in a broad sense?
- Does the proposed R&D have potential to generate high impact results (e.g., products, processes or services) and/or innovative research applications, research tools, techniques, devices, inventions, or methodologies?

- Does the proposed R&D represent advancement in a technological area that promises to be a major leap, not an incremental improvement of existing technologies?
- To what extent does the applicant demonstrate exceptional creativity and a potentially transformative approach?
- Is the proposed R&D considered to be high-risk, high reward (e.g., is it unlikely to be undertaken by ongoing academic efforts or within industrial firms?)
- Does the product that will be developed solve the identified problem and have potential to create significant value and economic stimulus?
- How novel are the outcomes expected from the proposed research activities?
- Does the applicant propose technology development that stems from an emerging scientific field or technological capacity that would be beneficial if successfully commercially developed?
- What is the potential for important new observations, tools/techniques, and/or knowledge in health research, or for the expected outcomes to build a foundation for the pursuit of more comprehensive funding opportunities?

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?
- 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?
- How well has the applicant anticipated difficulties in their approach and considered alternatives?

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?
- Are the facilities and collaborators sufficient for the success of the proposed research?
- Does the proposed R&D support a culture of entrepreneurship and innovation in the United States?

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.

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/priority 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.

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]
- 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>]

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 and technical merit of the proposed project as determined by peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Small businesses with no history of NIH SBIR/STTR support.

Appeals will not be permitted. See [NOT-OD-09-054](#), Recovery Act of 2009: NIH Review Criteria, Scoring System, and Suspension of Appeals Process.

3. Anticipated Announcement and Award Dates

Not applicable.

Section VI. Award Administration Information

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](#). In addition, as part of "just-in-time" information for those Recovery Act awards, for any modular budget application, a detailed budget will be required prior to award.

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 awards will be subject to the HHS 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: [Standard Terms and Conditions for AARA 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."

2. Administrative and National Policy Requirements

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 reporting requirements described in Section 1512 of the Act, as well as applicable OMB guidance regarding the use of Recovery Act funds. As noted above, grantees must also comply with the HHS 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: [Standard Terms and Conditions for AARA Awards](#).

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

A final progress report, invention statement, and Financial Status Report are required when an award is relinquished when a recipient changes institutions or when an award is terminated.

Section VII. Agency Contacts

All applicants are strongly encouraged to visit the web sites of the NIH and its Institutes and Centers, become familiar with missions and priorities, and contact appropriate program staff as the applicants are just formulating their ideas for their projects. 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):

Awarding Component	Scientific/Research Contact	Financial/Grants Mgmt. Contact
National Institute on Aging http://www.nia.nih.gov	Dr. Michael-David A.R.R. Kerns National Institute on Aging, NIH Gateway Building, Suite 2C218 7201 Wisconsin Ave., MSC 9205 Bethesda, MD 20892-9205 Phone: 301-496-9322 Fax: 301-402-2945 Email: mk417e@nih.gov	Ms. Linda Whipp Grants Management Officer National Institute on Aging, NIH Gateway Building, Room 2N212 7201 Wisconsin Ave., MSC 9205 Bethesda, MD 20892 Phone: 301-496-1472 Fax: 301-402-3672 Email: lw17m@nih.gov
National Institute on Alcohol Abuse and Alcoholism http://www.niaaa.nih.gov	Dr. Max Q. Guo National Institute on Alcohol Abuse and Alcoholism Room 2021 5635 Fishers Lane Bethesda, MD 20892 Phone: 301-443-0639 Fax: 301-594-0673 Email: qmguo@mail.nih.gov	Ms. Judy Fox Chief, Grants Management Branch Office of Scientific Affairs National Institute on Alcohol Abuse and Alcoholism Room 3023 5635 Fishers Lane Bethesda, MD 20892 Phone: 301-443-4704 Fax: 301-443-3891 Email: jfox@mail.nih.gov
National Institute of Allergy and Infectious Diseases http://www.niaid.nih.gov	Dr. Gregory Milman Division of Extramural Activities National Institute of Allergy and Infectious Diseases, NIH Room 2153 6700-B Rockledge Drive Bethesda, MD 20892-7610 Phone: 301-496-8666 Fax: 301-402-0369 Email: gm16s@nih.gov	Mr. Michael Wright Grants Management Specialist National Institute of Allergy and Infectious Diseases, NIH 6700B Rockledge Dr, Rm 2249 Bethesda, MD 20892-7614 Phone: 301-451-2688 Fax: 301-493-0597 Email: mawright@mail.nih.gov
National Institute of Arthritis and Musculoskeletal and Skin Diseases http://www.niams.nih.gov/	Mr. Elijah Weisberg Research Program Analyst National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH 6701 Democracy Blvd.	Ms. Sheila Simmons Grants Management Specialist National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH 6701 Democracy Blvd. Suite 800

	<p>Suite 800 Bethesda, MD 20892 Phone: 301-435-1002 Fax: 301-480-4543 Email: weisberge@mail.nih.gov</p>	<p>Bethesda, Maryland 20892 Phone: 301-594-9812 Fax: 301-480-5450 Email: simmonss@mail.nih.gov</p> <p>Mr. Erik (Timothy) Edgerton Grants Management Specialist National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH 6701 Democracy Blvd. Suite 800 Bethesda, Maryland 20892 Phone: 301-594-3968 Fax: 301-480-5450 Email: edgertont@mail.nih.gov</p>
<p>National Institute of Biomedical Imaging and Bioengineering http://www.nibib.nih.gov/</p>	<p>Mr. Todd Merchak Program Director National Institute of Biomedical Imaging and Bioengineering, NIH Two Democracy Plz 6707 Democracy Blvd Suite 200 Bethesda, MD 20892-5477 Phone: 301-496-8592 Fax: 301-480-1614 Email: merchakt@mail.nih.gov</p>	<p>Ms. Florence Turska Grants Management Specialist National Institute of Biomedical Imaging and Bioengineering, NIH 6707 Democracy Blvd. Suite 900 Bethesda, MD 20892-5469 Phone: 301-496-9314 Fax: 301-480-4974 Email: turskaf@mail.nih.gov</p>
<p>National Cancer Institute http://www.nci.nih.gov or http://www.cancer.gov</p>	<p>Mr. Michael Weingarten Program Manager National Cancer Institute, NIH 31 Center Drive Room 10A52 Bethesda, MD 20892 Phone: 301- 496-1550 Fax: 301- 496-7807 Email: mw498z@nih.gov</p>	<p>Ms. Rosemary Ward Grants Management Specialist National Cancer Institute, NIH MSC 7150 6120 Executive Blvd Rockville, MD 20892-7150 Phone: 301-496-3182 Fax: 301-496-8662 Email: wardros@mail.nih.gov</p>
<p>National Institute of Child Health and Human Development http://www.nichd.nih.gov</p>	<p>Dr. Louis A. Quatrano Program Director, BSRE National Center for Medical</p>	<p>Mr. Ted Williams Grants Management Specialist Grants Management Branch</p>

	<p>Rehabilitation Research National Institute of Child Health and Human Development, NIH 6100 Executive Boulevard, Room 2A03 Bethesda, MD 20892-7510 Phone: 301-402-4221 Fax: 301-402-0832 Email: lq2n@nih.gov</p>	<p>Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH 6001 Executive Blvd., Rm. 8A07EA Rockville, MD 20852 Phone: 301-435-6966 Fax: 301-451-5110 Email: williate@mail.nih.gov</p>
<p>National Institute on Drug Abuse http://www.nida.nih.gov</p>	<p>Dr. Cathrine Sasek National Institute on Drug Abuse, NIH 6001 Executive Boulevard Room 5230, MSC 9591 Bethesda, Maryland 20892-9591 Phone: 301-443-6071 Fax: 301-443-6277 Email: csasek@nih.gov</p>	<p>Ms. Diana Haikalis Grants Management Specialist National Institute on Drug Abuse, NIH 6001 Executive Boulevard, Room 3119, MSC 9591 Bethesda, Maryland 20892-9591 Phone: 301-443-6710 Fax: 301-594-6849 Email: dhaikali@mail.nih.gov</p>
<p>National Institute on Deafness and Other Communication Disorders http://www.nidcd.nih.gov</p>	<p>Dr. Roger Miller Program Director, Hearing Program National Institute on Deafness and Other Communication Disorders, NIH 6120 Executive Blvd., 400-C Rockville, MD 20852 Phone: 301-402-3458 Fax: 301-402-6251 Email: rm378j@nih.gov</p>	<p>Mr. Christopher P. Myers Lead Grants Management Specialist National Institute on Deafness and Other Communication Disorders, NIH 45 Center Drive, MSC 6402 Bldg 45 Room 4AN44 Bethesda MD 20895-6402 Phone: 301-402-0909 Fax: 301-402-1758 Email: myersc@nidcd.nih.gov</p>
<p>National Institute of Dental and Craniofacial Research http://www.nidcr.nih.gov</p>	<p>Dr. R. Dwayne Lunsford Coordinator, SBIR/STTR Program Director, Microbiology Program Integrative Biology and Infectious Disease Branch Division of Extramural Research National Institute of Dental and Craniofacial</p>	<p>Ms. Mary Daley Chief Grants Management Officer National Institute of Dental and Craniofacial Research, NIH Building 45, Room 4AN-44B 45 Center Drive Bethesda, MD 20892-6402 Phone: 301-594-4808 Fax: 301-480-3562 Email: md74u@nih.gov</p>

	<p>Research-NIH Building 45, Room 4An18A Bethesda, MD 20892-6402 Phone : 301-594-2421 Fax: 301-480-8319 Email: rl332k@nih.gov</p>	
<p>National Institute of Diabetes and Digestive and Kidney Diseases http://www.niddk.nih.gov</p>	<p>Dr. Sanford A. Garfield Program Director National Institute for Diabetes and Digestive and Kidney Diseases, NIH 6707 Democracy Blvd. Rm. 685 Bethesda, MD 20892-5460 Phone: 301-594-8803 Fax: 301-402-6271 Email: sg50o@nih.gov</p>	<p>Ms. Helen Y. Ling Senior Grants Management Specialist National Institute of Diabetes and Digestive and Kidney Diseases, NIH 2 Democracy Plaza 6707 Democracy Blvd, Room 732 Bethesda, MD 20892-5456 Phone: 301-594-8857 Fax: 301-480-3504 Email: lingh@extra.niddk.nih.gov</p>
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<p>National Human Genome Research Institute http://www.genome.gov</p>	<p>Dr. Bettie J. Graham Program Director National Human Genome Research Institute, NIH Suite 4076 5635 Fishers Lane Rockville, MD 20852 Phone: 301-496-7531 Fax: 301-480-2770 Email: Bettie_graham@nih.gov</p>	<p>Ms. Cheryl Chick Chief Grants Management Officer National Human Genome Research Institute, NIH 5635 Fishers Lane Ste. 4076 Rockville, MD 20852 Phone: 301-435-7858 FAX: 301-402-1951 Email: ChickC@mail.nih.gov</p>
<p>National Institute of Mental Health http://www.nimh.nih.gov</p>	<p>Dr. Michael F. Huerta Associate Director National Institute of Mental Health, NIH 6001 Executive Blvd.</p>	<p>Ms. Rebecca Claycamp Chief Grants Management Officer National Institute of Mental Health, NIH</p>

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<p>National Institute of Neurological Disorders and Stroke http://www.ninds.nih.gov</p>	<p>Dr. Thomas Miller Office of Translational Research National Institute of Neurological Disorders and Stroke National Institutes of Health 6001 Executive Blvd., Room 2139 Bethesda, MD 20892-9527 301-496-1779 301-402-1501 Fax millert@ninds.nih.gov</p>	<p>Ms. Kimberly Campbell Grants Management Specialist National Institute of Neurological Disorders and Stroke, NIH 6001 Executive Blvd., Rm. 3254 Bethesda, MD 20892-9537 Phone: 301-496-7809 Fax: 301-402-0219 Email: campbelk@mail.nih.gov</p>
<p>National Institute of Nursing Research http://www.ninr.nih.gov</p>	<p>Dr. Paul Cotton Program Director Office of Extramural Programs National Institute of Nursing Research, NIH 6701 Democracy Blvd, Room 710 One Democracy Plaza Bethesda, MD 20892 Phone: 301-402-6423 Fax: 301-480-8260 Email: pc272a@nih.gov</p>	<p>Mr. Brian Albertini Chief, Grants and Contracts Management National Institute of Nursing Research, NIH 6701 Democracy Boulevard Room 710 One Democracy Plaza Bethesda, MD 20892-4870 Phone: 301-594-6869 Fax: 301-402-4502 Email: albertib2@mail.nih.gov</p>
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<p>National Center for Complementary and Alternative Medicine http://www.nccam.nih.gov/</p>	<p>SwainA@mail.nih.gov Dr. Carol Pontzer Program Officer National Center for Complementary and Alternative Medicine, NIH 6707 Democracy Blvd. Suite 401, MSC 5475 Bethesda, MD 20892-5475 Phone: 301-435-6286 Fax: 301-480-3621 Email: pontzerc@mail.nih.gov</p>	<p>Mr. George Tucker, M.B.A. Grants Management Officer Complementary and Alternative Medicine, NIH 6707 Democracy Blvd. Suite 401, MSC 5475 Bethesda, MD 20892-5475 Phone: 301-594-8853 Fax: 301-480-1552 Email: gt35v@nih.gov</p>
<p>National Center on Minority Health and Health Disparities http://www.ncmhd.nih.gov</p>	<p>Mr. Vincent A. Thomas, Jr., MSW, MPA National Center on Minority Health and Health Disparities, NIH 6707 Democracy Blvd. Suite 800, MSC 5465 Bethesda, MD 20892-5465 Phone: 301-402-2516 Fax: 301-480-4049 Email: thomasvi@mail.nih.gov</p>	<p>Ms. Priscilla Grant, J.D., C.R.A. Grants Management Specialist National Center on Minority Health & Health Disparities, NIH 6707 Democracy Blvd. Suite 800, MSC 5464 Bethesda, MD 20892-5464 Phone: 301-402-1366 Fax: 301-480-4049 Email: pg38h@nih.gov</p>
<p>National Library of Medicine http://www.nlm.nih.gov</p>	<p>Dr. Jane Ye Program Officer Division of Extramural Programs National Library of Medicine/NIH 6705 Rockledge Drive, Suite 301 Bethesda, MD 20892 Tel: 301-594-4882 Fax: 301-402-2952 Email: yej@mail.nih.gov</p>	<p>Mr. Dwight Mowery Grants Management Officer National Library of Medicine, NIH RKL1 - One Rockledge Ctr Room 301 6705 Rockledge Dr Bethesda, MD 20892 Phone: 301-496-4221 Fax: 301-402-0421 Email: mowerd@mail.nih.gov</p>
<p>Office of Dietary Supplements, National Institutes of Health (ODS), www.ods.od.nih.gov Note: ODS is a part of the NIH's Office of the Director and does</p>	<p>Rebecca B. Costello, PhD Director, Grants and Extramural Activities Office of Dietary Supplements 6100 Executive Boulevard, Room 3B01 Bethesda, MD</p>	<p>Not Applicable</p>

not have its own grant-making authority. ODS does however, co-fund meritorious research through the NIH institutes and centers.	20892-7517 Telephone: (301) 435-3605 Fax: (301) 480-1845 Email: bc135d@nih.gov
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2. Peer Review Contact(s):

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Voice: (301) 435-8367
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Section VIII. Other Information

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

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

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). 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](http://grants.nih.gov/grants/gwas/). 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). 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. 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. 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.

NIH Public Access 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 FOA 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 (LRP):

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/>.

[Weekly TOC for this Announcement](#)
[NIH Funding Opportunities and Notices](#)



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Extramural
Research
(OER)



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Department of
Health
and Human
Services (HHS)



Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, RealPlayer, Video or Flash files, see [Help Downloading Files](#).