

Part I Overview Information

Department of Health and Human Services

Participating Organizations

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

Components of Participating Organizations

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

Title: Innovative Approaches to Remediation of Recalcitrant Hazardous Substances in Sediments (R01)

Announcement Type

New

Request For Applications (RFA) Number: RFA-ES-06-006

Catalog of Federal Domestic Assistance Number(s)

93.143

Key Dates

Release Date: November 1, 2006

Letters of Intent Receipt Date(s): December 11, 2006

Application Receipt Date(s): January 11, 2007

Peer Review Date(s): May/June 2007

Council Review Date(s): August 2007

Earliest Anticipated Start Date(s): September 2007

Additional Information To Be Available Date (Url Activation Date): N/A

Expiration Date: January 12, 2007

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- The National Institute of Environmental Health Sciences (NIEHS) is announcing a new funding opportunity to support individual research projects as part of the Superfund Basic Research and Training Program (SBRP).
- The objective for this Funding Opportunity Announcement (FOA) is to encourage research to develop innovative approaches to address the remediation of contaminated sediments, with particular emphasis on in situ remedies.
- The NIEHS intends to commit a total of \$2 million dollars to fund six to eight grants that will be awarded in Fiscal Years 2007 and 2008 from this one solicitation. An applicant may request up to 3 years of support.
- This announcement uses the R01 grant mechanism.
- Eligible organizations include accredited domestic institutions of higher education.
- Eligible principal investigators include any individual with the skills, knowledge, experience and resources necessary to carry out the proposed research. Individuals from underrepresented racial and ethnic groups, as well as individuals with disabilities are always encouraged to apply for NIH support.
- Applicants may submit more than one application, provided they are scientifically distinct.

- See [Section IV.1](#) for application materials.
- Telecommunications for the hearing impaired is available at: TTY 301-451-0088.

Table of Contents

[Part I Overview Information](#)

[Part II Full Text of Announcement](#)

[Section I. Funding Opportunity Description](#)

1. Research Objectives

[Section II. Award Information](#)

1. Mechanism(s) of Support
2. Funds Available

[Section III. Eligibility Information](#)

1. Eligible Applicants
 - A. Eligible Institutions
 - B. Eligible Individuals
2. Cost Sharing or Matching
3. Other - Special Eligibility Criteria

[Section IV. Application and Submission Information](#)

1. Address to Request Application Information
2. Content and Form of Application Submission
3. Submission Dates and Times
 - A. Receipt and Review and Anticipated Start Dates
 1. Letter of Intent
 - B. Sending an Application to the NIH
 - C. Application Processing
4. Intergovernmental Review
5. Funding Restrictions
6. Other Submission Requirements

[Section V. Application Review Information](#)

1. Criteria
2. Review and Selection Process
 - A. Additional Review Criteria
 - B. Additional Review Considerations
 - C. Sharing Research Data
 - D. Sharing Research Resources
3. Anticipated Announcement and Award Dates

[Section VI. Award Administration Information](#)

1. Award Notices
2. Administrative and National Policy Requirements
3. Reporting

[Section VII. Agency Contact\(s\)](#)

1. Scientific/Research Contact(s)
2. Peer Review Contact(s)
3. Financial/ Grants Management Contact(s)

[Section VIII. Other Information - Required Federal Citations](#)

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

Purpose

The mission of the National Institute of Environmental Health Sciences (NIEHS) is to promote research that will ultimately reduce the burden of human illness and dysfunction from environmental causes.

Complementary to this mission are the goals of the national Superfund Program, established by Congress in 1980 to identify uncontrolled hazardous wastes; characterize the impacts of hazardous waste sites and emergency releases on the surrounding environment (i.e., communities, ecological systems, and ambient air, soil, water); and, institute control or remediation approaches to minimize risk from exposure to these contaminants.

In 1986, six years after the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) was enacted, Congress authorized NIEHS to implement a university-based program of basic research and training grants which became known as the "Superfund Basic Research and Training Program" (SBRP). The intent was to improve the ability to identify, assess, and evaluate the potential health effects of exposure to hazardous waste and to develop innovative chemical, physical and biological technologies for remediating sites contaminated by hazardous substances. Much of the basic research supported by the SBRP has been through large multi-project grants. This solicitation represents the initiation of an Individual Research Program, under the auspices of the SBRP, providing opportunities to support individual projects of emerging needs. Grants awarded under this mechanism address specific issues that both complement the multi-project research programs as well as meet high priority research needs of the national Superfund Program.

One such area of emerging needs is the remediation of sediments. New reports issued from the US EPA identify the widespread occurrence of contaminated sediments with nearly 10% of the nation's waterways at potentially harmful levels, contributing to the thousands of fish consumption advisories nationwide. In addition to the impact on human health and ecosystems, contaminated sediments pose a hindrance to navigational uses and are costly for remediation. Costs for 11 of the 150 Superfund sites undergoing sediment remediation are expected to exceed \$50 million dollars each, with more such costly sites expected as investigations continue. Accordingly, the EPA Office of Research and Development has recognized the need to "increase the understanding of different remedial options, in order to optimize the protectiveness to the environment and human health and the cost-effectiveness of remedial decisions" and to do so by 2010 (EPA/ORD, Multi-Year Plan, 2005).

The NIEHS recognizes the need to address remediation alternatives for contaminated sediments and has released this funding opportunity announcement (FOA) to encourage the research community to develop new approaches to sediment remediation with particular focus on novel in situ remedies. Currently, there are only three sediment remediation approaches that receive extensive use: dredging/excavation, capping, and monitored natural attenuation (MNA). However, the shortcomings of these approaches reinforce the need to implement new strategies for the remediation of sediments. Therefore, it is the intent of this solicitation to support research to foster the application of novel remediation technologies that have the potential to substantially reduce the risk posed by contaminated sediments.

Background

Contaminated sediments remain one of the most challenging issues within the national Superfund Program. A considerable effort has been leveraged to address the most immediate needs for sites with contaminated sediments including the development of tools for site assessment, contaminant monitoring, and fate and transport modeling as well as identifying methods to stabilize sediments to minimize risks before an adequate remediation strategy is implemented. Strides have been made to begin the process of mitigating impacted sediment sites; however, the remediation of these sites is difficult. Some of the specific issues that make contaminated sediments challenging and, in some ways, resistant to remediation are outlined below:

- Sediments are reservoirs for mixtures of recalcitrant contaminants,

- Sediments are composed of complex heterogeneous materials which influences binding properties and movement of recalcitrant compounds,
- Disturbances to the system from natural or anthropomorphic processes require long periods of time to achieve equilibrium,
- Changes to the equilibrium of sediment materials may lead to changes in contaminant bioavailability or mobility, which may trigger bioaccumulation within the food chain.

The current state of the practice for remediation of contaminated sediments is primarily limited to only three strategies: dredging/excavation, capping, and monitored natural attenuation (MNA). These strategies can be problematic for various reasons. First, dredging and excavation efforts have long been implicated with the re-suspension and eventual bioaccumulation of contaminants in the food chain. Together with the high costs, the possible risk of re-suspension with dredging makes the use of in situ methods (capping, MNA) preferable in many situations. While capping, in theory, addresses the short-term need to separate contaminated sediments from the rest of the water column, the fact that the contaminants remain in the environment means long-term monitoring and maintenance is required. MNA, as a non-disruptive remedy, accommodates gradual ecological recovery; however, the rate of contaminant degradation/sequestration is slow and the issue of food chain bioaccumulation of pollutants is not eliminated. Hence, there is a need to establish alternatives to the existing, widely accepted sediment remediation approaches.

Objectives and Scope

The goal of this FOA is to support the development of innovative approaches to remediate recalcitrant contaminants in sediments, with particular emphasis on in situ technologies. In situ remediation generally involves biological, chemical or physical approaches to treatment of contaminants in place. In situ strategies show great promise for the remediation of sediments. Given the diversity of options for in situ remediation of other contaminated media, the possibility for application of these technologies to sediments presents opportunities for further research.

For the purposes of this FOA, innovative approaches to sediment remediation are defined as:

- Development and/or advancement of new in situ sediment remediation technologies,
- Adaptation of existing remediation technologies not typically applied to sediments,
- Novel and significant alteration of existing in situ sediment remediation approaches or technologies.

The research opportunities within the scope of this FOA range from basic mechanistic to pilot scale projects with a clearly stated and well-defined application to sediment remediation. As a guide, the scope of this FOA corresponds to the "Research/Proof of Concept" and "Development" stages of the environmental technology development continuum as is defined in the National Advisory Council for Environmental Policy and Technology ([NACEPT, May 2006, p37](#)):

- Research/Proof of Concept: To conduct basic and/or bench-scale research on a technology approach or idea within categories that show the potential for solving various types of intractable, challenging, or expensive environmental problems.
- Development: To move from bench to pilot stage research on a given technology.

Therefore, suggested research approaches appropriate for this initiative include but are not limited to the following:

- Conducting basic mechanistic research to elucidate the underlying principles of a novel in situ technology,
- Developing novel agents that can be used to overcome biological, chemical or physical limitations in the treatment of contaminated sediments,
- Applying knowledge gained from fate and transport models to control movement of sediments during application of a remedy,
- Engineering effective delivery devices for in situ treatment technologies,
- Coupling novel remediation approaches to maximize in situ treatment of contaminants
- Developing control measures to minimize negative side-effects (e.g. re-suspension) encountered when using in situ technologies in the field.

In keeping with the scope of this solicitation, projects may utilize a variety of experimental methodologies

from the use of artificially created sediments, to the use of contaminated sediments from real sites. Applicants are encouraged to take a holistic approach by accounting for the effect of a remedial strategy on the sediment/aquatic system. Accordingly, as part of project specific aims, the use of monitoring devices, fate & transport modeling, biological indicators, and other risk assessment tools are strongly encouraged; however, these components alone will not be considered responsive to this FOA. It is critical that applicants consider the impact of the remediation strategy in terms of protecting human health and the environment. Therefore, applicants should identify potential problems (e.g. re-suspension, bioaccumulation, nutrient demand, biogeochemical cycling, effects on bioavailability, photo activation) and suggest alternative approaches as applicable to the proposed technology.

For the purposes of this FOA, applications should address recalcitrant substances that are currently present or of emerging concern in sediments at Superfund sites. Such recalcitrant substances include but are not limited to metals, polycyclic aromatic hydrocarbons (PAHs), polychlorinated biphenyls (PCBs), and other halogenated organics. Applicants are encouraged to study mixtures of contaminants, reflecting the reality of sediments in need of remediation. As applicable, researchers are encouraged to use, for experimental purposes, sediments from actual Superfund, RCRA corrective action, or other hazardous waste sites.

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

Note: Studies proposed under this FOA will not support human subjects research.

Section II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the R01 award mechanism.

As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

This funding opportunity uses just-in-time concepts. It also uses the modular budget format described in the PHS 398 application instructions (see <http://grants.nih.gov/grants/funding/modular/modular.htm>).

2. Funds Available

- The NIEHS intends to commit \$2 million dollars to fund six to eight new grants that will be awarded in Fiscal Years 2007 and 2008 from this one solicitation.
- An applicant may request a budget for direct costs up to \$200,000 per year. Facilities and Administrative (F&A) costs incurred by including third party consortia or subcontracts in the application are not included in the direct cost limitation; see [NOT-OD-05-004](#).
- An applicant may request up to 3 years of support.
- Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the NIEHS provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit (an) application if your organization has the following characteristic:

- An accredited domestic institution of higher education.

Section 311(a)(3) of SARA limits recipients of awards to "accredited institutions of higher education," which are defined in the Higher Education Act, 20 USC (annotated) 3381. However, grantees are permitted under the law, and encouraged by NIEHS, to subcontract as appropriate with organizations, domestic or foreign, public or private (such as universities, colleges, hospitals, laboratories, faith-based organizations, units of State and local governments, and eligible agencies of the Federal government) as necessary to conduct portions of the research. Examples of other organizations may include generators of hazardous wastes; persons involved in the detection, assessment, evaluation, and treatment of hazardous substances; owners and operators of facilities at which hazardous substances are located; State and local governments and community organizations.

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution 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.

2. Cost Sharing or Matching

Not Applicable

3. Other-Special Eligibility Criteria

Not Applicable

Section IV. Application and Submission Information

1. Address to Request Application Information

The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. Applicants must use the currently approved version of the PHS 398. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dnb.com/us/>. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

3. Submission Dates and Times

Applications must be received on or before the receipt date described below ([Section IV.3.A](#)). Submission times N/A.

3.A. Receipt, Review and Anticipated Start Dates

Letters of Intent Receipt Date(s): December 11, 2006

Application Receipt Date(s): January 11, 2007

Peer Review Date(s): May/June 2007

Council Review Date(s): August 2007

Earliest Anticipated Start Date(s): September 2007

3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- 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 the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. Email submission is preferred.

The letter of intent should be sent to:

Sally Eckert-Tilotta, Ph.D.
Scientific Review Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
PO Box 12233, MD EC-30
79 T.W. Alexander Drive
Building 4401, Room 3173
Research Triangle Park, NC 27709
Telephone: (919) 541-1446
Fax: (919) 541-2503
Email: eckertt1@niehs.nih.gov

3.B. Sending an Application to the NIH

Applications must be prepared using the research grant applications found in the PHS 398 instructions for preparing a research grant application. Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

Personal deliveries of applications are no longer permitted (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-040.html>).

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Sally Eckert-Tilotta, Ph.D.
Scientific Review Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
PO Box 12233, MD EC-30
79 T.W. Alexander Drive
Building 4401, Room 3173
Research Triangle Park, NC 27709
Telephone: (919) 541-1446

Fax: (919) 541-2503
Email: eckertt1@niehs.nih.gov

Using the RFA Label: The RFA label available in the PHS 398 application instructions must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: <http://grants.nih.gov/grants/funding/phs398/labels.pdf>.

3.C. Application Processing

Applications must be **received on or before the application receipt date(s)** described above ([Section IV.3.A.](#)). If an application is received after that date, it will be returned to the applicant without review. Upon receipt, applications will be evaluated for completeness by the CSR and responsiveness by the NIEHS. Incomplete and non-responsive applications will not be reviewed. If the application is not responsive to the FOA, NIH staff may contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next appropriate NIH review cycle.

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.

Information on the status of an application should be checked by the Principal Investigator in the eRA Commons at: <https://commons.era.nih.gov/commons/>.

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. The Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

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 competing continuation award if such costs: are necessary to conduct the project, and 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 competing continuation 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 NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part6.htm.

6. Other Submission Requirements

Specific Instructions for Modular Grant applications.

Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular budget format. The modular budget format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular budgets. Applicants must use the currently approved version of the PHS 398. Additional information on modular budgets is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

Plan for Sharing Research Data

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.

Applicants requesting more than \$500,000 in direct costs in any year of the proposed research must include a plan for sharing research data in their application. The funding organization will be responsible for monitoring the data sharing policy (http://grants.nih.gov/grants/policy/data_sharing).

The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

Sharing Research Resources

NIH policy expects that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm and http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part7.htm#_Toc54600131). Investigators responding to this funding opportunity should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590, <http://grants.nih.gov/grants/funding/2590/2590.htm>). See [Section VI.3. Reporting](#).

Section V. Application Review Information

1. Criteria

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

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 program priorities

2. Review and Selection Process

Applications that are complete and responsive to the FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the National Institute of Environmental Health Sciences in accordance with the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level of review by National Advisory Environmental Health Sciences Council

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. Within this context, the goal of the SBRP is to improve health by supporting research that includes the ability to identify, assess, and evaluate the potential health effects of exposure to hazardous substances and to develop innovative chemical, physical and biological technologies for reducing potential exposure to hazardous substances.

In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? If successful, will the project result in knowledge or resources that could be utilized to improve the quality of the environment to protect health?

Approach: Are the conceptual or technical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or environmental practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Investigators: Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

2.A. Additional Review Criteria:

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel

and/or the environment, determine if the proposed protection is adequate.

2.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

2.C. Sharing Research Data

Data Sharing Plan: The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The funding organization will be responsible for monitoring the data sharing policy. http://grants.nih.gov/grants/policy/data_sharing.

2.D. Sharing Research Resources

NIH policy expects that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (See the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm#availofrr and http://www.ott.nih.gov/policy/rt_guide_final.html). Investigators responding to this funding opportunity should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.

Program staff will be responsible for the administrative review of the plan for sharing research resources.

The adequacy of the resources sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. Program staff may negotiate modifications of the data and resource sharing plans with the awardee before recommending funding of an application. The final version of the data and resource sharing plans negotiated by both will become a condition of the award of the grant. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590). See [Section VI.3. Reporting](#).

3. Anticipated Announcement and Award Dates

N/A

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 [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 (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part4.htm).

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 (designated in item 12 on the Application Face Page). If a grantee is not email enabled, a hard copy of the NoA will be mailed to the business official.

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 Also [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 (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm).

The following Terms and Conditions will be incorporated into the award statement and will be provided to the Principal Investigator as well as to the appropriate institutional official, at the time of award.

- An annual grantee meeting, to be held at one of the of the grantees sites or in Research Triangle Park is planned for the exchange of information among investigators supported by the SBRP. Applicants must include travel costs associated with this meeting for the Principal Investigator and at least one student (if applicable). These funds are restricted and may not be used for any other purpose without written prior approval from the NIEHS.

3. Reporting

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually (<http://grants.nih.gov/grants/funding/2590/2590.htm>) and financial statements as required in the NIH Grants Policy Statement.

Section VII. Agency Contacts

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, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Heather Henry, Ph.D.
Center for Risk and Integrated Sciences
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, MD EC-27
Research Triangle Park, NC 27709
Telephone: (919) 541-5330
Fax: (919) 541-4937
Email: henryh@niehs.nih.gov

2. Peer Review Contacts:

Sally Eckert-Tilotta, Ph.D.
Scientific Review Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
PO Box 12233, MD EC-30
79 T.W. Alexander Drive
Building 4401, Room 3173
Research Triangle Park, NC 27709
Telephone: (919) 541-1446
Fax: (919) 541-2503
Email: eckertt1@niehs.nih.gov

3. Financial or Grants Management Contacts:

Susan Ricci
Grants Management Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, EC-22
Research Triangle Park, North Carolina 27709
Telephone: 919-316-4666
Fax: 301-480-1891
E-mail: ricci@niehs.nih.gov

Lisa Archer
Grants Management Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, EC-22
Research Triangle Park, North Carolina 2770
Telephone: 919-541-075
Fax: 301-480-1891
E-mail: archer@niehs.nih.gov

Section VIII. Other Information

Required Federal Citations

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/usdaleq1.htm>) as applicable.

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 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.

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.

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 http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004 receipt date, 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.

NIH Public Access Policy:

NIH-funded investigators are requested to submit to the NIH manuscript submission (NIHMS) system (<http://www.nihms.nih.gov>) at PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process.

NIH is requesting that authors submit manuscripts resulting from 1) currently funded NIH research projects or 2) previously supported NIH research projects if they are accepted for publication on or after May 2, 2005. The NIH Public Access Policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies. The Policy applies to peer-reviewed, original research publications that have been supported in whole or in part with direct costs from NIH, but it does not apply to book chapters, editorials, reviews, or conference proceedings. Publications resulting from non-NIH-supported research projects should not be submitted.

For more information about the Policy or the submission process please visit the NIH Public Access Policy Web site at <http://publicaccess.nih.gov/> and view the Policy or other Resources and Tools including the Authors' Manual (http://publicaccess.nih.gov/publicaccess_Manual.htm).

Standards for Privacy of Individually Identifiable Health Information:

The Department of Health and Human Services (DHHS) 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 DHHS 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) **must** be used for **publicly** accessible on-line journal articles. Unless otherwise specified in **this** solicitation, Internet addresses (URLs) should **not** be used to provide any **other** information necessary for the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

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 or Health Systems Agency review. Awards are made under authority of the Superfund Amendments and Reauthorization Act of 1986, Title 1, Section III, and Title II, Section 209 (Public Law 99-499); and are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 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 NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

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>.

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

