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: Superfund Basic Research and Training Program (P42)

Announcement Type
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Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** The National Institute of Environmental Health Sciences (NIEHS) is announcing the continuation of the Superfund Hazardous Substances Basic Research and Training Program [referred to as the Superfund Basic Research Program (SBRP)]. SBRP grants will support coordinated, multi-project, interdisciplinary research programs to address the mandates legislated under the Superfund Amendments and Reauthorization Act of 1986. These mandates include the development of (1) methods and technologies to detect hazardous substances in the environment; (2) advanced techniques for the detection, assessment, and evaluation of the effect on human health of hazardous substances; (3) methods to assess the risks to human health presented by hazardous substances; and (4) basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances. The objective for the SBRP is to develop a holistic research agenda for the protection of human health. This is accomplished by the establishment of interdisciplinary programs that link and integrate biomedical research with related engineering, hydrogeologic, and ecologic components within the context of unique scientific themes developed by the applicant.

- **Mechanism of Support.** This FOA will utilize the NIH P42 multi-project grant mechanism. Successful applicants must include a minimum of two biomedical projects and two non-biomedical projects.
- **Funds Available and Anticipated Number of Awards.** The NIEHS intends to commit a total of approximately $11.0 million dollars in FY 2010 to fund four to five SBRP grants in response to this Funding Opportunity Announcement (FOA).
- **Budget and Project Period.** A new applicant may request a budget for direct costs of up to $1.8 million dollars for the first year. Applicants submitting renewal (competing continuation) applications may request up to a ten percent increase above the budget level (direct cost) of the last year of their continuation project (non-competitive renewal). For all applicants, budgets submitted in subsequent years may not exceed an escalation of three percent on recurring direct costs.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply. Eligible organizations include accredited domestic institutions of higher education.
- **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 Applications.** Only one application per accredited institution of higher education.will be accepted
- **Resubmissions.** Resubmission applications will be accepted. Such applications must include an Introduction addressing the previous peer review critique (Summary Statement).
- **Renewals.** Applicants may submit a renewal application.
- **Special Date(s).** See Receipt, Review and Anticipated Start Dates
- See Section IV.1 for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY 301-451-0088

Table of Contents

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

Purpose

The National Institute of Environmental Health Sciences (NIEHS) invites qualified investigators from domestic institutions of higher education to submit an application for a Superfund Basic Research and Training Program (SBRP) multi-project program grant. With the assignment of the SBRP to NIEHS, the goal of the Program is to improve public health by supporting integrative research that is multidisciplinary in nature and 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.

Applicants responding to this FOA are expected to develop an over-arching conceptual theme to guide the scientific direction of the Program's interdisciplinary/multidisciplinary research team. It is expected that the overall theme will foster collaboration, whereby projects are integrated and specific emphasis is placed on interactions between the biomedical and non-biomedical research projects.

- The research team should focus on environmental exposures encountered at hazardous waste sites currently or emerging contaminants of concern.
- A conceptual theme should be developed that encompasses a holistic approach to protecting human health by

incorporating the principles of environmental health sciences and the engineering, geochemical and ecological sciences within the framework of a basic research program.

- The scientific approaches to be undertaken should focus on improving our understanding of the multiple aspects of environmental health sciences and environmental sciences research.
- A proactive approach should be developed through a required Research Translation Core for translating the scientific accomplishments emanating from the Program to its many stakeholders whether to the public through information dissemination, to industry via technology transfer, or to government through partnerships.

Ultimately, decisions needed to protect human health must be based on mechanistic knowledge gained from the integration of available data from all relevant research disciplines such as toxicology, molecular biology, epidemiology, geology, ecology and engineering. It is expected that the development of integrated and inter-disciplinary research programs will result in an extraordinary level of synergy and technology-transfer opportunities, the outcomes of which have the potential to: (1) improve our understanding of the relationship between exposure and disease; (2) accelerate the development of public health prevention/intervention strategies to improve human health, as well as reduce the risk of exposure to toxic substances found at hazardous waste sites; (3) translate basic non-biomedical research into efficient and cost-effective cleanup strategies; and (4) improve the decision-making process at sites by reducing the uncertainty in human and ecological risk assessments. All are important goals of the SBRP.

Background

The SBRP was created under the Superfund Amendments and Reauthorization Act (SARA) of 1986, when it was realized that that the strategies and technologies for the cleanup of Superfund sites were inadequate to address the magnitude and complexity of the problem. The mandates under which the SBRP operates provides a framework that has allowed NIEHS the flexibility to create a university-based, multi-project research program for conducting science to address the wide array of scientific uncertainties facing the national Superfund program. These mandates include the development of (1) methods and technologies to detect hazardous substances in the environment; (2) advanced techniques for the detection, assessment, and evaluation of the effect on human health of hazardous substances; (3) methods to assess the risks to human health presented by hazardous substances; and (4) basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances.

The assignment of the SBRP to the NIEHS underscores an emphasis on the human health effects resulting from exposure to hazardous substances. However, the Program also supports non-traditional NIH research such as the modeling of fate and transport processes for chemical contaminants and the development of remediation technologies to improve the quality of the environment as a means to reduce exposure and its potential impact on human health. Clearly integration from many different disciplines is needed to address the complex, interdependent yet fundamental issues that arise in relation to hazardous waste. Accordingly, the structure of the Program requires the integration of biomedical, ecological, geological and engineering sciences in order to develop and apply a full range of primary prevention strategies. Ultimately, this holistic approach will enable the transitioning of basic research findings into epidemiological, clinical, ecological and remediation studies which will be important for the decision-making process to protect health. This approach is exemplified by the research being conducted by the Program, see http://tools.niehs.nih.gov/sbrp/programs/index275.cfm.

Research Scope

A central premise of the SBRP is that there is a link between chemical exposure and disease outcome, and that understanding/identifying this link will help to establish new or improved prevention/intervention modalities. Therefore, research supported by the SBRP should emphasize basic and applied research, using state-of-the-art techniques to improve the sensitivity and specificity for detecting adverse effects in humans or in ecosystems exposed to hazardous substances, as well as for developing a better understanding of the underlying biology responsible for these adverse effects. Moreover, the applicant should emphasize research that studies the phenomena affecting transport, fate and transformation of hazardous substances, and develop remediation strategies that attenuate and mitigate exposure as necessary to protect human health and ecosystems.

In addition to the strong basic research focus of the Program, there is an equally important commitment to create an environment that fosters the translation of the scientific accomplishments emanating from the Program to its stakeholders -- whether to industry via technology transfer, to the government through partnerships, or to the public through community outreach. Therefore, research translation is a required element. The training of the next generation of scientists (i.e., graduate, post-doctoral) in interdisciplinary research, and conducting community outreach are highly valued activities and are strongly encouraged.

Goals and Objectives

This FOA encourages the development of multi-project, interdisciplinary research programs with the ultimate purpose of reducing the burden of human illness and dysfunction from environmental causes. Each interdisciplinary research program should develop an overall conceptual theme that fosters collaboration, whereby projects are integrated, and specific emphasis is placed on interactions between the biomedical and non-biomedical research projects to promote the goals of the SBRP. These goals include

- understanding the biology that underlies the relationship between exposure and disease etiology, pathogenesis, susceptibility, progression and phenotype
- accelerating the development of prevention/intervention strategies to improve human health, as well as to reduce the risk of exposure to toxic substances found at hazardous waste sites
- translating basic non-biomedical research into innovative remediation technologies that are efficient and cost-effective

- providing the information necessary to enhance the decision-making process at sites by reducing the uncertainty in human and ecological risk assessments.

Suggested Chemicals

Research must be conducted in the context of:

- hazardous substances found with some frequency at Superfund sites
- hazardous breakdown products of such substances formed in environmental media by physical, chemical or biological (e.g., plants, microorganisms, etc.) processes
- hazardous metabolites of the above substances or their breakdown products formed in humans or experimental animals
- chemicals with structural similarity to hazardous substances found at Superfund sites
- environmental contaminants of emerging and re-emerging interest. Examples include: asbestos, brominated flame retardants, fluorinated compounds such as perfluorooctanoic acid (PFOA), 1,4-dioxane, N-nitrosodimethylamine, engineered nanomaterials, pharmaceuticals and personal care products.

Note: the applicant should refer to the following websites for information on hazardous substances that are relevant to US Environmental Protection Agency (EPA) Superfund program and to the Agency for Toxic Substances and Disease Registry (ATSDR) (http://www.atsdr.cdc.gov/cercla). In addition, the applicant is strongly encouraged to visit the SBRP website's "Additional Resources" page at http://www.niehs.nih.gov/research/supported/sbrp/funding/rfa_resources.cfm

to determine how research that may be proposed fills research gaps or needs not currently addressed within the Program http://tools.niehs.nih.gov/sbrp/programs/index275.cfm.

Suggested Research Topics

The development of a thematic concept for an SBRP application can be focused in many different ways. Often programs are driven thematically by a particular chemical or class of chemicals; by a common mechanistic pathway such as oxidative stress; by a particular disease, dysfunction or organ system such as the neurological system; or by methodological approaches such as biomarker development or the use of "omic" technologies. Within this context, the applicant should

propose individual biomedical and non-biomedical research projects.

Specific Research Needs

There are some specific research needs and new directions within the Program that applicants may wish to consider. These include:

- the study of asbestos (and related mineral fibers or elongated mineral particles) including determinants of fiber toxicity; mutagenicity; fiber dosimetry and its relation to adverse health effects (including autoimmune and cardiovascular diseases); toxicological effects on multiple organ systems; effect of variable levels of exposure (low dose effects); early life exposures - children's exposure to asbestos and susceptibility factors; fiber mechanisms leading to disease; and biomarkers of exposure and disease
- the study of contaminated sediments including the development, demonstration, and validation of technologies or methods to monitor the effectiveness of contaminated sediment remediation in reducing contaminant exposures or adverse biologic effects to receptors of concern at Superfund sites
- the application of “green technology” to current remediation practices to improve energy-efficiency and reduce waste generation, thereby increasing the usability and sustainability of otherwise effective remediation technologies
- the study of the mechanisms and health consequences of exposure to trichloroethylene (TCE), and the development of remediation strategies to mitigate exposure
- the optimization of sequential, compatible remediation strategies for different phases of a cleanup process, also known as “combined remedies” or “treatment train,” to maximize the degradation/removal of hazardous substances at complex sites
- the investigation of effects of multiple stressors (radionuclide and chemical contaminants) on humans or biota in order to identify patterns of synergism, antagonism, or cumulative effects
- the development and application of methods to assess processes leading to vapor intrusion and resultant potential health effects
- the incorporation of high throughput screening methods to develop detailed dose-response studies leading to identification and validation of sensitive biomarkers of biological response anchored to a phenotypic characteristic
- the development and application of bioengineered devices to study the exposure – response – disease paradigm in living cells and tissues.

Broad Research Themes

In addition to the specific research needs listed above, examples of broad scientific themes relevant to the SBRP are provided. These examples are meant to stimulate the thinking of potential applicants by illustrating interdisciplinary linkages between scientific disciplines, and, ultimately, how this knowledge enhances public and environmental health. These examples are not intended to be exhaustive. The applicant is also directed to the following site (http://www.niehs.nih.gov/research/supported/sbrp/funding/rfa.cfm) for the “Suggested Research Topics” document which lists additional research topics and approaches of interest to the SBRP.

Mechanistically-Based Biomedical Research. Understanding the mechanisms whereby toxicants induce adverse human health effects is central to the SBRP. It is believed that environmental factors contribute to the etiology of most human diseases/dysfunctions (e.g., reproductive, immune competence, pulmonary/cardiovascular, cancer, neurodevelopment, neurobehavioral, congenital defects, renal, etc.). Therefore, the SBRP seeks to support mechanistic research that includes laboratory-based and population-based studies for unraveling critical biological pathways that contribute to disease when perturbed by environmental contaminants. Research should focus on environmentally related diseases and pathways of toxicological significance in the exposure-disease paradigm.

- Example: dissecting the molecular, genetic and biochemical events that describe the normal physiological processes that contribute to good health and the roles hazardous substances play in its disruption by studying these issues at multiple system levels, from in vitro cell, tissue or organ culture, to non-mammalian model organisms to whole animals (including genetically manipulated), and to humans

Susceptibility and Predisposition Research. A critical confounding factor underlying the physiological consequences of exposure to hazardous substances is the genetic variability inherent in the population. This variability can lead to sub-populations with unique genetic characteristics that enhance their sensitivity to environmental contaminants or other external insults. The Program recognizes the importance of identifying susceptible populations in order to develop strategies to reduce their burden of environmentally-influenced diseases. It is encouraged that collaborative efforts between biologists, epidemiologists, statisticians, systems engineers, and computer scientists be considered in order to integrate the available information from animal and human studies in such a manner that would inform the risk assessment process.

- Example: clarifying the contribution of genetic and environmental variables in the risk of developing disease by studying the interplay between exposure and intrinsic factors (e.g., genetic polymorphisms, haplotypes, epigenetic factors, gender and age) and host factors (e.g., nutrition, co-morbid disease/conditions, lifestyle habits; and timing of exposure)

Exposure Assessment Research. A priori, an environmentally-influenced disease implies that exposure has occurred within some temporal, spatial framework in relation to the development of disease. Unfortunately, exposure is one of the most difficult parameters to measure due, in part, to the lack of precision in the methods to integrate exposure over time, the inability to characterize the attributable risk from multiple exposures experienced over one's lifetime and the lack of statistical and computational approaches to measure complex gene-environment interactions. Because exposure assessment is so integral to decisions related to protecting human health and ecosystems, understanding the complexities that impact exposure is an important research focus for the SBRP. Exposure assessment within the context of the SBRP falls within three interconnected research domains, (a) site characterization, (b) bioavailability and (c) accurate body burden and response measurements. These are further discussed below.

a) *Site Characterization:* The ability to predict the risk of exposure to contaminants at hazardous waste sites is dependent upon understanding the physical, chemical and geological characteristics of the site. Therefore, site characterization is an integral component of the exposure assessment paradigm. The SBRP seeks to support research that improves site characterization so that the knowledge gained can be incorporated into the exposure assessment paradigm.

- Example: develop advanced technologies that allow for real-time, on site monitoring such as nanotechnology–based sensors and probes, biosensors, new imaging modalities, self-contained miniaturized toxicity-screening kits and miniaturized analytical probes and data analysis tools

b) *Bioavailability:* Bioavailability of a contaminant describes the degree to which it is available for transformation, and transport within environmental media (i.e., soil, sediments and surface and groundwater), as well as the degree by which a contaminant eventually is assimilated by organisms. As an integrating principle, bioavailability crosses all scientific disciplines and is an important factor to consider in understanding the fate and transport of hazardous substances; the ability of hazardous substances to be internalized by microbes, wildlife and humans; and the ability once internalized to be available to tissues and organs. Recent technological advances provide new opportunities to study the complex issues surrounding bioavailability.

- Example: employing an array of multiple, molecular-scale techniques over a range of temporal scales in combination with macroscopic approaches and computational modeling to understand biogeochemical properties and processes important to chemical bioavailability to organisms

c) *Quantifying Body Burden and Response:* The integration of available data from site characterization and bioavailability studies into exposure and risk assessment models provides a means to predict potential exposure levels in human populations and ecosystems. The validation of these models requires the development and application of new methods and technologies that can measure the extent of exposure in disparate populations. Many approaches are available that have the requisite sensitivity and specificity to detect current exposures, or measure contaminants that have a long half-life in biological systems. However, the issues of past exposures and exposure to mixtures are still intractable problems. Hence, SBRP seeks research that accounts for concurrent or sequential routes of exposure to a large number of chemicals over varying periods of time.

- Example: the development of toxicity sensors that rapidly detect and quantify low concentrations of chemicals in cells or tissues

Remediation Research. The SBRP supports the application of engineering and microbial sciences as prevention (i.e., remediation) strategies to improve human health by mitigating exposure and reducing toxicity of environmental contaminants at hazardous waste sites. SBRP seeks research that is focused on the scientific principles and underlying processes that drive different remediation technologies as methods to clean up persistent toxicants in groundwater, sediments and soils. Also important is research that focuses on the translation of these basic principles into efficient and cost-effective technologies to reduce the level of contaminants present in the environment. Accordingly, the SBRP encourages a continuum of research that ranges from basic mechanistic research to technology development.

- Example: the investigation of the mechanistic basis for degradation and sequestration of contaminants by microbial, as well as other biological systems, by assessing the physical, chemical and biological factors that affect movement (or reduction) of site contaminants

Ecological Research. Understanding the ecological impacts resulting from exposure to contaminants found at hazardous waste sites is an important research theme relevant to SBRP and interfaces biology, ecology, microbiology, bioengineering and engineering sciences. An integrated approach is also critical to reducing uncertainty in environmental risk assessments, another important objective of the SBRP. Capitalizing on state-of-the-art methods and genetic approaches that have been primarily applied to human studies provides tools that could be of benefit in advancing the ecological sciences. Accordingly, the SBRP encourages the application of “omics” tools, new sensor technologies and informatics with the goal of enhancing our understanding of ecological succession and biodiversity as a function of exposure to contaminants.

- Example: the development of molecular, cellular, biochemical and population-level baseline data describing the components that define an ecosystem and how these individual components are affected by hazardous substances

Mixtures. A critical issue related to hazardous waste sites for remediation or health effects research is that the concentrations at which chemicals occur in the environment are extremely low and exposures are long-term, continual, with simultaneous exposure to multiple chemicals. Whether one considers remediation strategies, exposure to humans or ecosystems, site characterization, bioavailability or the development of risk assessment models, chemical mixtures are an issue of concern. Furthermore, biomedical research, exposure assessments or remediation strategies based on exposures to single substances in isolation are rarely reflected in real-life scenarios. Hence, the SBRP seeks to support research that considers the effects of mixtures. With the continued development and refinement in the available repertoire of advanced tools and approaches, the scientific community may be in a better position to assess the impact of mixtures on all areas of research important to the SBRP.

- Example: the development of computational toxicology approaches to understand dose/effect relationship in the context of chemical interactions

Risk Assessment. The risk assessment process defines exposures of concern and potential threats. Historically, risk assessments are focused on developing models for either human health or ecological health and decisions are made accordingly. However, within the interdisciplinary framework of the SBRP, opportunities to develop integrated models that incorporate both human and ecological effects need to be encouraged in order to assist in making cost-effective and protective decisions. In addition, the translation of the knowledge gained from high data content approaches, which are increasingly being used to obtain mechanistic data, will require the development of a new generation of risk assessment models. These models will need to take into account biological pathways and networks, susceptible populations, low dose effects and mixtures. Therefore, the SBRP is interested in innovative approaches to risk assessment utilizing research focused on the development of: (1) large datasets to be used in model development, (2) tools to integrate diverse datasets and (3) new risk assessment models that incorporate these diverse datasets.

- Example: the development of robust human and/or ecologically-based genomic, proteomic, metabolomic and functional datasets for model development and validation

For more examples of each of the above Broad Research Themes, applicants are encouraged to refer to the "Suggested Research Topics" document on the following website (http://www.niehs.nih.gov/research/supported/sbrp/funding/rfa.cfm).

CORES – Required and Optional Program Components

Although novel, innovative, cutting-edge research projects are the nucleus of an SBRP grant, it is the intent of the SBRP that the research activities be integrated into an interdisciplinary program. In support of this goal, NIEHS requires the establishment of cores. Each grant application is required to have an Administrative Core, a Research Translation Core, and at least one Research Support Core. Community Outreach and Training Cores may also be included in support of achieving a truly multidisciplinary approach to hazardous substances research.

Administrative Core (required component). The Administrative Core is a required component of a program. Through this core the Principal Investigator provides leadership and guidance in fulfilling the stated objective of his or her program. To accomplish this, the applicant should create within the Administrative Core an infrastructure that promotes cross-discipline interactions among all of the projects and cores. The structure of this Core should provide the Principal Investigator with a mechanism for

- planning and coordinating research activities
- integrating cross-discipline research
- overseeing fiscal and resource management

The applicant should include a plan for conducting the administrative functions of the core, a description of the lines of communication among the program scientists, and a description of the mechanisms to be used to encourage and ensure the integration and interaction between the biomedical and non-biomedical projects within the program.

To aid the Principal Investigator in achieving the goals set forth for his or her program, the establishment of an External Advisory Committee is required. Its role is to provide guidance to the Principal Investigator in the following areas:

- the merit of the research
- the relevance and importance of the individual components to the goals of the program
- the integration of research across disciplines
- the appropriateness and effectiveness of research translation, outreach and training activities

The composition of the committee should include appropriate scientific expertise, as well as represent appropriate stakeholder interests. For example, not only should the academic community be represented on the committee, but also other stakeholders, such as industry, community or government representatives.

Research Translation Core (required component). NIEHS recognizes the importance of translating important research outcomes to appropriate audiences, thereby encouraging the accurate and timely use of these research products. Accordingly, NIEHS requires the inclusion of a Research Translation Core in each SBRP grant. For the purpose of this FOA, the SBRP defines Research Translation as "communicating and facilitating the use of research findings emanating from the Program in the manner most appropriate for their application and the advancement of research objectives." As described below, NIEHS requires that this core be comprised of three specific activities: (a) partnering with governmental agencies, (b) conducting technology transfer and (c) communicating to broad audiences.

a) *Partnerships with Government Agencies:* Establishing ongoing communication with the federal, state and/or local agencies charged with protecting human health and the environment is of high importance. In order to address this need, each applicant should:

- propose a plan explaining how interactions with the appropriate local, regional or national governmental agencies will be achieved. The intent of this is to ensure that governmental offices have first-hand access to the valuable resources the Program can provide, and that the investigators have feedback on the real and immediate needs faced by their

counterparts in the public sector.

Note: Applicants are not required to conduct Superfund site-specific activities; however, if site activities are planned, these activities must be conducted in coordination with appropriate federal or state site officials. Therefore applicants should:

- propose a procedure for coordinating and documenting site activities including record of the research conducted or sample collection,
- delineate the steps to be taken to ensure communication with all appropriate site officials, including a final report-back to the site manager indicating the outcome of the activity.

b) *Technology Transfer:* It is important that each program establish a mechanism to facilitate the transfer of technologies and other research generated by the grantee into the hands of an end-user. In order to meet this objective, each applicant should include a plan for:

- identifying opportunities for moving research findings into application (e.g., determine which methods and technologies can be used for particular site characterizations, remediation and achievement of cleanup goals),
- formal technology transfer (application for patents, Small Business Innovation Research/Small Business Technology Transfer Research (SBIR / STTR)) for non-biomedical research remediation technologies that are ready for field demonstration or commercialization,
- less-formal transfers (i.e., non-patented application of research advances) such as moving research from bench scale to demonstration, developing a new risk assessment paradigm or providing research data to improve upon current risk assessments,
- delineation of milestones or benchmarks to demonstrate progress in meeting its goals.

c) *Communicating to Broad Audiences:* Beyond government officials and the marketplace, there are other stakeholders who should have timely access to SBRP research findings. A variety of mechanisms to reach these stakeholders are appropriate activities for the Research Translation Core.

- for example: sponsorship of workshops, short symposia, or web-based symposia. These would typically be one-day events that are local or regional in nature and could potentially involve not only academics but also other stakeholders (e.g., industry or local or regional health departments), or
- development and use of advanced communication tools or methods such as web-based systems, geographic information systems or other technologically innovative systems, or
- development and use of more traditional communication tools such as the translation of complex research findings into print and web materials intended for the lay public based on communication best practices.

In order to demonstrate how the applicant will meet this need, he/she should

- include a plan detailing the mechanisms to be used for sharing research findings
- identify important stakeholders and propose a mechanism for engaging them
- delineate milestones and benchmarks to demonstrate progress in meeting their goals.

In addition, NIEHS considers communication with SBRP associated staff to be a high priority and places this responsibility within the Research Translation Core. NIEHS requires that a plan be established for ensuring the effective communication and transfer of important research findings and other program outcomes to NIEHS. This plan should also include a direct line of communication between the Administrative Core and the Research Translation Core.

Research Support Cores (required component). The SBRP requires at least one Research Support Core. The intent is that this Core will provide essential, centralized services or resources that will result in an economy of effort and/or savings in the overall costs of a program. Well designed cores also serve as a useful tool in promoting interdisciplinary activities. By definition, a Research Support Core must support two or more research projects. Typical Core facilities include laboratory facilities, biostatistics and/or bioinformatics support, or analytical equipment and services. The applicant should include in

his/her description of these cores the services to be rendered, the methodological approaches to be used and a plan for prioritizing the use of the facility by program members.

Community Outreach Core (optional component). The SBRP strongly encourages the applicant to consider the inclusion of a Community Outreach Core. Outreach to communities is in line with the Superfund Program's mandate to more actively involve the community in the decision-making process. The Core should be designed with a primary focus on health-related issues; however, other topics of interest to the community such as environmental concerns are also acceptable. It is expected that the Core will complement the research strengths of the program.

For the purpose of this FOA, the SBRP defines community outreach as "extending support or guidance to communities, community advocates or community organizations. Appropriate target communities include those that (1) are living in proximity to, or affected by hazardous waste sites or (2) are exposed to hazardous substances via other pathways." For example, appropriate community groups could include local government, tribal councils, established groups/organizations focused specifically on local environmental/site issues, or community service groups focused on educating the community about local issues. As an outgrowth of this activity, it is expected that interactions with the community will also serve to enhance the program's research agenda.

Community outreach activities should be conducted in full partnership with the target community. In other words, the community should participate in the design and approach of the activity at the onset of the project. Note: Any activities conducted at Superfund sites should be coordinated with the appropriate offices in EPA or ATSDR. Likewise, activities conducted at state or tribal sites should be coordinated with appropriate state or tribal agencies. This will ensure that the applicant efforts are not in conflict with nor duplicate other agencies activities. However, this coordination should not compromise the independence of the outreach efforts since the community may value the support of a non-regulatory agency.

Community outreach activities may be either very broad or very focused. Examples that are appropriate for a Community Outreach Core are

- sponsoring workshops or educational materials to improve the community's awareness and understanding of environmental health issues (e.g., conducting a short-course providing information on exposure levels and health risks, or developing health effects fact sheets)
- increasing access to relevant information and serving as a resource (e.g., responding to community's questions, assisting them in accessing pertinent information or translating materials into the community's native language)
- establishing collaborative projects among communities, investigators and other colleagues to address environmental problems (e.g., partnering with tribes in determining exposure pathways specific and relevant to their traditional and cultural practices)

It is important that the Community Outreach Core define the approach it will use to identify a community/organizational unit with which it proposes to collaborate. It should develop a plan detailing the objectives and the methods (e.g., conducting small group discussion or listening sessions, producing informational materials, providing leadership mentoring, etc.) that will be used in establishing and maintaining involvement with the community. The SBRP anticipates that each Community Outreach Core will include in its plan how it will measure milestones or outcomes of these activities. (See Section III.3 for budget details).

Training Core (optional component). SBRP strongly encourages applicants to include a Training Core, which supports graduate level cross-disciplinary training in fields related to environmental health. The Training Core should reflect the interdisciplinary nature of the overall research effort of the program. It is anticipated that the training core will enhance cross training of students and post-doctoral fellows in disciplines not traditionally linked in the university graduate structure. Students pursuing degrees in the non-biomedical areas should be encouraged to place their studies in the context of environmental health sciences and biomedical research. Likewise, students of the biomedical sciences should have cross training opportunities in the non-biomedical areas of study.

In addition to providing students with unique opportunities in interdisciplinary research, the SBRP also encourages the Training Cores to provide students with practical opportunities for communicating research outcomes to diverse audiences. For example, all researchers need to know how to explain their work in a manner easily understood by the intended audience – whether the audience be the public or professionals in other areas of science. Another unique opportunity for students of the SBRP is the participation in the Community Outreach Core. The SBRP encourages the Training Core to formally support cross training of this nature. Opportunities such as this will provide students with valuable insights on the full cycle of the research that they conduct.

NOTE: The training of pre- and post-doctoral students may be carried on outside the structured Training Core. In these cases, the budgets for these students should be part of the project or core budgets rather than the Training Core budget. In keeping with the NIH efforts to train members of minority groups, and those with disabilities, applicants are encouraged to consider these candidates in their recruitment efforts. (See Section III.3 for budget details).

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Section II. Award Information

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1. Mechanism of Support

This funding opportunity announcement (FOA) will use the P42 award mechanism. The applicant will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses “Just-in-Time” information concepts. It also uses non-modular budget formats described in the PHS 398 application instructions (see http://grants.nih.gov/grants/funding/phs398/phs398.html).

2. Funds Available

- The NIEHS intends to commit approximately $11.0 million dollars in FY 2010 in response to this FOA.
- Anticipated number of awards: four to five new and/or renewal SBRP multi-project grants in response to this FOA. An applicant may request a project period of up to five years.
- A new applicant may request a budget for direct costs of up to $1.8 million dollars for the first year. Applicants submitting renewal (competing continuation) applications may request up to a ten percent increase above the budget level (direct cost) of the last year of their continuation project (non-competitive renewal). For all applicants, budgets submitted in subsequent years may not exceed an escalation of three percent on recurring direct costs.

Although the financial plans of the NIEHS provide support for this Program, the funds that are appropriated for the SBRP are determined each year according to the Federal budget process. Because the funding level of this Program may vary from year to year, awards pursuant to this FOA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. The size and duration of each award may vary based on Program balance and the availability of funds, in addition to the scientific merit considerations of the review.

Facilities and Administrative (F&A) costs incurred by requesting third party consortia or subcontracts are not included in the direct cost limitation see NOT-OD-05-004. Applications that exceed the stated allowable budget caps for the first year will be returned as non-responsive to this FOA.

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

You may submit (an) application(s) if your organization has any of 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 his/her 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

This program does not require cost sharing as defined in the current *NIH Grants Policy Statement*.

3. Other-Special Eligibility Criteria

Applicants must propose a multi-project, multi-disciplinary research program that addresses a central theme and that is related to the goals of the SBRP. This multidisciplinary effort should bring together investigators from different scientific disciplines to direct discrete Research Projects, each of which is to be related to the central theme developed for the applicant's program. It is expected that the research team will include the expertise required to perform the research proposed and be comprised of scientists that represent the biomedical and non-biomedical (i.e., engineering, geology, microbiology, ecology, etc.) fields of study.

The applicant must name a Principal Investigator as the designated leader of the SBRP multi-project grant to provide scientific and administrative leadership to the program. The Principal Investigator must commit a minimum of 1.8 person months to the administration of the program.

In order to be considered for funding each applicant must successfully meet the following minimum requirements:

- Two approved biomedical Research Projects (e.g., mechanistic-based studies, epidemiology, human risk assessment, exposure assessment, genetic susceptibility, etc.) and,
- Two approved non-biomedical Research Projects (e.g., fate and transport, hydrogeology, engineering, remediation, ecology, etc.).
- An approved Administrative Core that oversees organizational, budgeting, and reporting functions and provides intellectual leadership to direct the scientific and programmatic activities of the program. The administrative core must include an external advisory committee which should provide oversight and advice to the Principal Investigator in accomplishing program goals.

- One approved Research Support Core. Research Support Cores are shared facilities that enhance or provide cost effectiveness for services, techniques or instrumentation and must be used by at least two of the research projects.
- An approved Research Translation Core which must include: (1) a plan for partnerships with Government agencies; (2) a plan for technology transfer; and (3) a plan for communicating to broad audiences. The intent of the Research Translation Core is to provide a dedicated mechanism for identifying and acting on opportunities for the basic research findings to be used by the program's constituencies.

In addition to these required program components, it is important for the applicant to recognize that the SBRP is more than a basic research program and is strongly encouraged to make investments in other areas crucial to the Program. These include:

- A Community Outreach Core, which is intended to position the SBRP to support the nation's Superfund mandate to more actively involve the community in the decision-making process by translating the scientific accomplishments into a format useful to the needs of the community. The Community Outreach Core is limited to $100,000 direct costs in the first year, with subsequent years subject to the standard three percent cost escalations allowed by NIH. Support for appropriate staff positions, consultants, travel and supplies are allowed. The budget must include travel for the Core director or designee to attend the SBRP annual meeting as it is expected that the Community Outreach Core Leaders will convene during this time.
- A Training Core, which is intended to support graduate and advanced training and should reflect the interdisciplinary nature of the overall research effort proposed within the applicants program. The direct costs for the Training Core are not to exceed six percent of the total direct costs for the total program budget. Individuals in the training positions must be considered employees of the institution and not trainees receiving stipends as in National Research Service Award programs. Salaries and fringe benefits consistent with institutional policies may be requested. Funds may also be requested for tuition, where appropriate, and travel to one scientific meeting per year.
- Applicants may submit only one application. Only one application per accredited institution of higher education will be accepted.

Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement).

Applicants may submit a renewal application.

Section IV. Application and Submission Information

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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 in item (box) 2 only of the face page of the application form

and the YES box must be checked.

Additional information is available in the PHS 398 grant application instructions.

3. Submission Dates and Times

Applications must be received on or before the receipt date described below in Section IV.3.A.

3.A. Receipt, Review and Anticipated Start Dates

Letters of Intent Receipt Date: March 16, 2009
Application Receipt Date: April 15, 2009
Peer Review Date: October 2009
Council Review Date: January 2010
Earliest Anticipated Start Date: April 1, 2010

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 NIEHS staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed in Section IV.3.A.

The letter of intent should be sent to:

Leroy Worth, Ph.D.
Scientific Review Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
PO Box 12233, EC-30
111 T.W. Alexander Drive
Research Triangle Park, NC 27709
Telephone: (919) 541-0670
FAX: (919) 541-2503
Email: worth@niehs.nih.gov

3.B. Sending an Application to the NIH

Applications must be prepared using the research grant application forms 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 materials must be sent to:

Leroy Worth, Ph.D.
Scientific Review Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
PO Box 12233, EC-30
111 T.W. Alexander Drive
Research Triangle Park, NC 27709
Telephone: (919) 541-0670
FAX: (919) 541-2503
Email: worth@niehs.nih.gov

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 CSR and responsiveness by the National Institute of Environmental Health Sciences. Incomplete and non-responsive applications will not be reviewed.

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial merit review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. However, the NIH will accept a resubmission application, but such application must include an Introduction addressing the critique from the previous review.

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 *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 NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm.)

6. Other Submission Requirements and Information

A. Application Guidelines. The applications submitted in response to this FOA are complex, and the scientific and programmatic information needed to adequately assess a grant proposal is not fully accommodated within the instructions accompanying the PHS 398 form. Therefore, applicants need to follow the detailed guidelines that are provided in the "Application Guidelines" document, found on http://www.niehs.nih.gov/research/supported/sbrp/funding/rfa.cfm, to supplement the PHS 398 instructions.

In general an SBRP grant proposal will consist of the following categories of information:

Section I. This section consolidates the budget information, the list of all professional and non-professional personnel, biosketches for all key personnel, institutional environment and resources and tables of core utilization and use of human subjects/vertebrate animals for the entire applicant's program.

Section II. This section is unique to a multi-project application. The information requested in this section, for the most part, is not covered in the PHS 398 and includes: an overall introduction and description of the program that incorporates the major theme, goals and objectives, the multi-disciplinary nature of the program and the interactions between the projects and cores; a description of the role of the Principal Investigator; a description of the organizational structure of the applicant's program including an administrative and a management plan to achieve an integrated coordinated research program; and for competing renewals, a general progress report. For resubmission (amended) applications, an additional introduction section is required.

Section III- VIII. These sections contain the research plans for the individual research projects, research support cores, administrative, research translation, community outreach and training cores and follow the guidelines established in the PHS 398.

Section IX-XI. These sections include the Plan for Data Sharing, the Checklist and Appendix materials.

B. Quality Assurance Statement. Quality Assurance Statements will be necessary ONLY for Research Support Cores that provide analytical, quantitative services to the applicant's program.

EPA regulations as stated in 40CFR30.54 require the inclusion of a Quality Assurance Narrative Statement (QANS, OMB # 2080-0033, approved 8/14/97) for any project application involving data collection or processing, environmental measurements, and/or modeling. The QANS provides information on how quality processes or products will be assured. NIEHS cannot consider applications incomplete without this statement; however, it requests that the QANS be included with all applications that contain analytical and quantitative cores. For awards that involve environmentally related measurements or data generation, a quality system that complies with the requirements of ANSI/ASQC E4, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs," must be in place. The Quality Assurance Statement should not exceed two pages. This Statement should, for each item listed below, present the required information, reference the specific page and paragraph number of the project description containing the information, or provide a justification as to why the item does not apply to the proposed research.

1. Discuss the activities to be performed or hypothesis to be tested and criteria for determining acceptable data quality. (Note: Such criteria may be expressed in terms of precision, accuracy, representativeness, completeness, and comparability or in terms of data quality objectives or acceptance criteria. Furthermore, these criteria must also be applied to determine the acceptability of existing or secondary data to be used in the project. In this context secondary data may be defined as data

collected for other purposes or from other sources, including the literature, compilations from computerized data bases, or results from mathematical models of environmental processes and conditions.)

2. Describe the study design, including sample type and location requirements, all statistical analyses that were or will be used to estimate the types and numbers of samples required for physical samples, or equivalent information for studies using survey and interview techniques.

3. Describe the procedures for the handling and custody of samples, including sample collection, identification, preservation, transportation, and storage.

4. Describe the procedures that will be used in the calibration and performance evaluation of all analytical instrumentation and all methods of analysis to be used during the project. Explain how the effectiveness of any new technology will be measured and how it will be benchmarked to improve an existing process, such as those used by industry.

5. Discuss the procedures for data reduction and reporting, including a description of all statistical methods with reference to any statistical software to be used to make inferences and conclusions. Discuss any computer models to be designed or utilized with associated verification and validation techniques.

6. Describe the quantitative and/or qualitative procedures that will be used to evaluate the success of the project, including any plans for peer or other reviews of the study design or analytical methods prior to data collection.

ANSI/ASQC E4, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs," is available for purchase from the American Society for Quality, phone 1-800-248-1946, item T55. Only in exceptional circumstances should it be necessary to consult this document.

C. Annual Meetings. It is the intent of the NIEHS to hold annual grantee meetings. Funds for travel by appropriate staff (i.e., Principal Investigator, Business Manager, and four students) to attend a three-day meeting shall be included in the Administrative Core's budget for each year. It is also anticipated that the Outreach Core and Research Translation Core Leaders will convene at the annual meeting, and expenses for this travel should be included in their individual budgets. The location of the meeting site will rotate among the different grantees and Research Triangle Park, NC.

Appendix Materials

All paper PHS 398 applications submitted must provide appendix material on CDs only. Include five identical CDs in the same package with the application. See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-031.html.)

Do not use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not observe the required page limitations may be delayed in the review process.

Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value of, and advance, research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. If the final data/resources are not amenable to sharing, this must be explained in 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, investigators are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Applicants are encouraged to discuss data-sharing plans with their NIH program contact. See Data-Sharing Policy or http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.

(b) *Sharing Model Organisms*: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms and related resources, or state appropriate reasons why such sharing is restricted or not possible. See Sharing Model Organisms Policy, and 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 (such as 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, NIH Guide NOT-OD-07-088, and http://grants.nih.gov/grants/gwas/.

Section V. Application Review Information

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1. Criteria (**Update:** Enhanced review criteria have been issued for the evaluation of research applications received for potential FY2010 funding and thereafter - see NOT-OD-09-025).

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

2. Review and Selection Process

Applications that are complete and responsive to 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 and in accordance with NIH peer review procedures (http://grants1.nih.gov/grants/peer/), using the review criteria stated below.

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

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

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

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 public health by supporting integrative research that is multidisciplinary in nature and 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, and weighted 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 meritorious 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.

The initial review for scientific and technical merit will emphasize two major aspects: (1) the multi-project grant as an integrated research effort of projects and support cores focused on a central theme; and (2) the review of each research project, research support core and other core components independently.

The scientific review panel will evaluate the scientific merit of the program as a whole, as well as the inter-relationship and contributions of the research projects and cores to an overall conceptual theme.

Review Criteria for the Overall SBRP Application

The overall multi-project grant application will be based on the following criteria:

Significance: Does the overall program address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice 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 the program were successful, would it lead to incremental advance, or would it provide a substantial step forward that would likely not be achieved through mechanisms other than this multi-project program? If successful, will the program result in knowledge or resources that could be utilized to improve human health, risk assessment, or improve the quality of the environment?
- Is the importance of the proposed research program sufficient to further the knowledge of environmental health sciences to understand the physical, chemical and biological properties of hazardous substances in the environment?

Approach: Are the conceptual or clinical 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?

- Are the research projects and cores well integrated, well reasoned, and appropriate to the overall theme and goals of the proposed program?
- Is there strong synergy among the combined efforts of the various investigators within the overall program?

Innovation: Is the overall program original and innovative? For example: Does the program challenge existing paradigms or address an innovative hypothesis or critical barrier to progress in the field? Does the program 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 overall program?

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?

In addition to the five criteria used to judge the scientific merit of the program as a whole, the following criteria should be considered in reviewing the integration of the overall program.

Multidisciplinary and Interdisciplinary Nature of the Program

- Interdisciplinary nature of the proposed research activities. Is there integration of the projects around a central theme? Are there plans to effectively pursue interdisciplinary research objectives? Does the program propose a plan for the development of interdisciplinary collaboration among all components of the program?

- Coordination and Cohesiveness. Is there evidence of integration of the Administrative, Research Translation, Community Outreach and Training Cores with the Research Projects and Research Support Cores? Is there evidence for the translation and delivery of the research findings to appropriate audiences?
- Synergy of the program. Is there evidence of meaningful interdisciplinary/multidisciplinary collaboration and synergistic potential among the research projects and cores? Is the whole greater than the sum of the parts? Is the size of the program sufficient to afford effective interaction focused on a specific central theme, but diverse in scientific disciplines in order to achieve meaningful contributions to protecting human health and the environment?
- Is there evidence of integration and interaction of the non-health related research with the health-based research as it contributes to the central theme of the program?
- For competing renewals, is there evidence that there were integration and synergy among the projects and cores within the program?

Principal Investigator

- The experience and scientific leadership of the Principal Investigator to effectively direct a large complex multidisciplinary program. Does the Principal Investigator demonstrate the appropriate ability and experience to coordinate the interactions of the Research Projects with effective utilization of cores to achieve programmatic goals?
- Is the level of commitment and ability to develop a well-defined central research focus adequate?

Review Criteria for Renewal Applications

In addition, for renewal applications the following will be considered:

- Is there evidence of progress and achievements specific to this program since the previous competitive review? Is there documentation through publications, conferences, etc. that demonstrates that collaboration between or among projects has occurred?
- Is there evidence that the cores have met their objectives and been well utilized by the individual research projects?
- Is there adequate justification for adding new projects or cores or for deleting components previously supported?
- Is there evidence that the aims of the Research Translation Core for developing approaches for transferring research findings to appropriate audiences such as EPA, EPA Regions, ATSDR, state and local professionals or other professionals working in the field of hazardous waste management have been met? Is there evidence that the transfer of research findings to these audiences has occurred?

Review Criteria for the Research Projects

Review of the individual Research Projects is similar to the review of investigator-initiated individual project grant applications (R01). Accordingly, these projects must have substantial scientific merit. Reviewers will evaluate the individual projects against five review criteria. The four technical review criteria (Significance, Approach, Innovation and Environment) are intended to encourage reviewers to focus on the global impacts of each project, rather than concentrating on the experimental details and their critiques. The review criteria are as follows:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice 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 the study is successful, would it lead to incremental advance, or would it provide a substantial step forward that would likely not be achieved through mechanisms other than this multi-project program? If successful, will the project result in knowledge or resources that could be utilized to improve human health, risk assessment, or improve the quality of the environment?

Approach: Are the conceptual or clinical 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? Is there strong synergy among the combined efforts of the various investigators within the program?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical 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 (if applicable)?

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?

In addition to the standard criteria listed above, reviewers will evaluate each project for its contribution to the overall goals of the SBRP application:

- Does the project contribute scientifically to the overall proposed programmatic theme (i.e., the importance of the ideas or aims, the rationale and originality of the approach, the feasibility of the methods and the value of the result)?
- Will the specific scientific objectives of each project benefit significantly from, or depend upon, collaborative interactions with other projects in the program (i.e., objectives that can be uniquely accomplished, specific contributions to the accomplishments of objectives in other projects, objectives that can be accomplished with greater effectiveness and/or economy of effort, etc.).
- For renewals, reviewers will evaluate whether previous specific aims, as funded, have been accomplished and whether the new research goals are logical extensions of ongoing work.

In addition to the review criteria described above for research projects, the following will be considered by the review panel in evaluating the cores, the multidisciplinary and interdisciplinary nature of the program and the principal investigator.

Review Criteria for the Research Support Cores

The Research Support Cores will be assessed based on the following criteria:

- **The Core's utility to the program.** Does each Research Support Core provide essential facilities or service for two or more of the Research Projects judged to have substantial scientific merit? Is the projected use sufficient to warrant establishment of the core? Are the core facilities contributing to the overall research activities of the program?
- **The quality of the facility or service provided.** Is the Quality Control and Quality Assurance plan for cores providing quantitative analyses adequate?
- **Prioritization.** Is there a prioritization plan for core usage?
- **The cost effectiveness/enhanced efficiencies afforded by the Core.** Are the requests for equipment, supplies and other items to support the activity of the core appropriate and justified?
- **The qualification of the personnel involved.** Does the staff have the appropriate experience and level of commitment?
- **For renewals**. Is there evidence that the previous aims, as funded, were accomplished?

Review Criteria for the Administrative Core

The Administrative Core will be assessed based on the following criteria:

- **Evidence that the lines of authority and the administrative structure are designed for effective management of the program.** Is there a decision-making process for the management of funds and resources? Is there evidence of an ability to provide administrative support to the project and core leaders?
- **Evidence of an internal plan to promote integration and coordination.** Does the program's internal plan promote coordination of interdisciplinary research, stimulate collaborations among constituent Research Projects and Cores,

and evaluate research productivity?

- **External advisory committee.** Is there an appropriate plan to establish and use an external advisory committee? Do the members of the committee have the expertise required to evaluate all projects and cores and appropriately represent the applicant's stakeholders?
- **Qualifications of the senior leaders of the administrative core.** Does the senior leadership have appropriate experience and have they demonstrated effective and responsible leadership in the past? Is the percent effort requested adequate?
- **Qualifications of the administrative staff.** Are the qualifications, duties and time commitments of administrative staff appropriate to contribute to the needs and conduct of the program's research activities?
- **Adequacy of program resources.** Are the resources committed to the Administrative Core adequate?

Review Criteria for the Research Translation Core

The Research Translation Core will be assessed based on the following criteria:

- **Qualifications**. Are the qualifications of proposed personnel adequate to conduct the activities described for the Core?
- **Partnering**. Is the proposed plan to partner with governmental agencies adequate?
- **Technology transfer.** Is the proposed plan to identify technology transfer opportunities and to assist in the advancement of technologies into application appropriate?
- **Communication.** Is the proposed plan to communicate to broad audiences adequate? Is there a plan for identifying and engaging target audiences? Are there adequate commitment and support for the approach being developed? Are the communication tools selected appropriate for the intended audience?
- **Milestones.** Are milestones delineated, realistic and appropriate?
- **Adequacy of the program's coordination with NIEHS**. Is there a plan to coordinate and exchange information with SBRP staff?
- **Adequacy of program resources**. Are the resources committed to the Research Translation Core appropriate for the proposed activities?
- **For renewals**. Is there evidence that the previous aims, as funded, were accomplished?

Review Criteria for the Community Outreach Core

The Community Outreach Core will be assessed based on the following criteria:

- **The adequacy of the approach.** Is the proposed approach appropriate, adequate and feasible? Is there evidence of community involvement in the development of the core's goals?
- **Sensitivity**. Is there evidence that sensitivity to socioeconomic and cultural factors has been adequately addressed?
- **Coordination and collaboration.** Is there evidence that the coordination and collaboration with appropriate community groups, and state, local and federal agencies are adequate?
- **Milestones.** Are milestones delineated, realistic and appropriate?
- **Qualifications.** Are the qualifications of proposed personnel to conduct the activities described appropriate?
- **For renewals**. Is there evidence that the previous aims, as funded, were accomplished?

Review Criteria for the Training Core

The Training Core will be assessed based on the following criteria:

- **Objectives.** Are the objectives, design, and direction for the research-training program appropriate. Are the approaches and methods proposed adequate to develop training curriculum and courses that provide opportunities to interface with different scientific disciplines? Does the training program reflect the interdisciplinary nature of the program?
- **Recruitment and selection**. Are there evidence for, and the appropriateness of, plans for the recruitment and

selection of individuals participating in the Training Core?

- **Adequacy of the training environment.** Is there institutional commitment? Is the quality of the facilities and the availability of courses appropriate to the SBRP? Is there an availability of research support for post-doctoral training?
- **For renewals** Is there evidence that the previous aims, as funded, were accomplished?

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 rating:

Resubmission Applications (formerly "revised/amended" applications): Are the responses to comments from the previous scientific review group adequate? Are the improvements in the resubmission application appropriate?

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan section on Human Subjects in the PHS 398 instructions).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan section on Human Subjects in the PHS 398 instructions).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five points described in the Vertebrate Animals section of the Research Plan 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. Resource Sharing Plan(s)

When relevant, reviewers will be instructed to comment on the reasonableness of the following Resource Sharing Plans, or the rationale for not sharing the following types of resources. However, reviewers will not factor the proposed resource sharing plan(s) into the determination of scientific merit or priority score, unless noted otherwise in the FOA. Program staff within the IC will be responsible for monitoring the resource sharing.

- 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]

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 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*.

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.

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 grantees sites or in Research Triangle Park, NC is planned for the exchange of information among investigators. Applicants must budget travel costs associated with this meeting for the Principal Investigator, Business Manger, at least four students, the Research Translation and Community Outreach Core Leaders for each year.
- The multi-project P42 grant mechanism is under expanded authorities. However, carry-over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

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.*

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

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Because of the complexity of the SBRP, applicants are strongly encouraged to contact NIEHS staff early in the grant preparation process. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific / Research Contacts:

Claudia Thompson, 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: 919-541-4638
FAX: 919-541-4937
Email: thomps14@niehs.nih.gov

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

Beth Anderson, M.A.
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: 919-541-4481
FAX: 919-541-4937
Email: tainer@niehs.nih.gov

2. Peer Review Contacts:

Leroy Worth, Ph.D.
Scientific Review Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
PO Box 12233, EC-30
111 T.W. Alexander Drive
Research Triangle Park, NC 27709
Telephone: (919) 541-0670
FAX: (919) 541-2503
Email: worth@niehs.nih.gov

Sally Eckert-Tilotta, Ph.D.
Scientific Review Branch
Division of Extramural Research and Training

National Institute of Environmental Health Sciences
PO Box 12233, EC-30
111 T.W. Alexander Drive
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-30
Research Triangle Park, North Carolina 27709
Telephone: 919-316-4666
Fax: 301-451-5334
E-mail: ricci@niehs.nih.gov

Lisa Archer Edwards
Grants Management Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233, EC-30
Research Triangle Park, North Carolina 27709
Telephone: 919-541-0751
Fax: 301-451-5334
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/usdaleg1.htm) as applicable.

Human Subjects Protection:
Federal regulations (45CFR46) 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 IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Policy for Genome-Wide Association Studies (GWAS):
NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition. All applications, regardless of the amount requested, proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088. For additional information, see http://grants.nih.gov/grants/gwas/

Sharing of Model Organisms:
NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). 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.

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 new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: (a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and (b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

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

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

Human Embryonic Stem Cells (hESC):
Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (http://escr.nih.gov/). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

NIH Public Access Policy Requirement:
In accordance with the NIH Public Access Policy (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html), investigators must submit or have submitted for them their final, peer-reviewed manuscripts that arise from NIH funds and are accepted for publication as of April 7, 2008 to PubMed Central (http://www.pubmedcentral.nih.gov/), to be made publicly available no later than 12 months after publication. As of May 27, 2008, investigators must include the PubMed Central reference number when citing an article in NIH applications, proposals, and progress reports that fall under the policy, and was authored or co-authored by the investigator or arose from the investigator's NIH award. 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 (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 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 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

Office of Extramural Research (OER)
National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892
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.