

## Part I Overview Information

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Department of Health and Human Services

### Participating Organizations

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

### Components of Participating Organizations

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

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

Title: Childhood Obesity Prevention and Treatment Research Coordinating Unit (U01)

### Announcement Type

New

Request For Applications (RFA) Number: RFA-HL-10-005

Catalog of Federal Domestic Assistance Number(s)

93.837, 93.865

### Key Dates

Release Date: February 2, 2009

Letters of Intent Receipt Date: September 8, 2009

Application Receipt Date: October 6, 2009

Peer Review Date: March 2010

Council Review Date: May 2010

Earliest Anticipated Start Date: July 2010

Additional Information To Be Available Date (Url Activation Date):

FAQs <http://www/funding/inits/faq-hl-10-004andhl-10-005.htm>

Expiration Date: October 7, 2009

Specialized Dates  
for the RFA



Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** This FOA, issued by the National Heart, Lung, and Blood Institute (NHLBI) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), solicits cooperative agreement grant applications from

institutions to conduct Coordinating Functions for the Childhood Obesity Prevention and Treatment Research Consortium and runs parallel with a separate Funding Opportunity Announcement (FOA) that solicits applications for 4 awards for clinical trials (see FOA HL-10-004 (<http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-10-004.html>)). For the purposes of this FOA (RFA HL-10-005) and RFA HL-10-004, prevention of obesity is defined as prevention of excess weight in non-overweight youth (primary prevention), as well as prevention of additional weight gain in those already overweight or obese. Treatment is defined as reduction of weight (including weight loss or weight maintenance during linear height growth) in those already obese or severely obese. The whole program is designed to promote collaboration, coordination and exchange of scientific information among institutions, and partnerships with local, state and national agencies. The ultimate goal is to improve children's health by preventing obesity-related morbidity and mortality from cardiovascular and other chronic diseases.

- **Mechanism of Support.** This FOA will utilize the Research Project Cooperative Agreement (U01) grant mechanism.
- **Funds Available and Anticipated Number of Awards.** The participating organizations intend to commit approximately \$750,000 total costs for FY2010. The total amount to be awarded through this announcement will be a maximum of \$5,250,000 total costs for the seven-year project period. It is anticipated that up to one Research Coordinating Unit (RCU) will be awarded.
- **Budget and Project Period.** The total project period for an application submitted in response to this FOA is seven years. Maximum allowable direct costs for the Research Coordinating Unit per year are \$500,000 in years 1-7.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research coordinating functions 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. PDs/PIs for the clinical trials (see RFA-HL-10-004) must not be the same PDs/PIs for the Research Coordination Unit under this FOA but can come from the same institutions. PDs/PIs time commitments must not be less than 3.6 calendar months (30% effort per year).
- **Number of PDs/PIs.** More than one PD/PI (i.e., multiple PDs/PIs) may be designated on the application. However, the total time commitments by the PDs/PIs must not be less than 3.6 calendar months (30% effort per year).
- **Number of Applications.** Applicants may submit more than one application, provided they are scientifically distinct.
- **Resubmissions.** Resubmission applications are not permitted.
- **Renewals.** Renewal applications are not permitted.
- **Special Date(s).** This FOA uses non-standard due dates. Anticipated Start Dates.
- **Application Materials.** See Section IV.1 for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY 301-451-5936.

Specific Information on Cost limitations

Number of Application Information - this is where it will be noted if only one application from the institution will be accepted.

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Section I. Funding Opportunity Description

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1. Research Objectives

**Purpose**

This funding opportunity announcement (FOA) invites applications from eligible institutions to participate as the Research Coordinating Unit (RCU) for the childhood obesity prevention and treatment research consortium (See [RFA-HL-10-004](#)), which runs in parallel to this FOA. Applicants for the clinical trial will conduct randomized controlled trials that are innovative and that would test innovative interventions to prevent overweight and obesity in youth and to treat existing overweight, obesity and severe obesity in youth.

For the purposes of this FOA, prevention of overweight and obesity is defined as prevention of excess weight in non-overweight youth (primary prevention), as well as prevention of additional weight gain in those already overweight or obese. Treatment is defined as reduction of weight (including weight loss or weight maintenance during linear height growth) in those already overweight, obese or severely obese. Prevention and treatment are considered a continuum. Because of this continuum, communication and collaboration to strengthen the integration between prevention and treatment approaches are needed.

Therefore, the clinical trials (see [RFA-HL-10-004](#)) to be coordinated under this FOA will consist of multi-disciplinary research teams drawn from networks or other collaborative groups that are already established or will be established to conduct high-quality, transdisciplinary research in childhood obesity prevention and treatment. Applicants for this FOA will conduct coordinating functions for the whole program, will foster communication across the studies funded, and will

facilitate the translation of successful interventions into clinical practice and community programs.

## Background

The growing epidemic of childhood obesity requires urgent attention. In 2003-2004, 33.6% of children aged 2 to 19 years were at or above the 85th percentile of body mass index (BMI). The prevalence of overweight or at risk of overweight is particularly high among Mexican American and African American youth 2-19 years of age (37.0% and 35.1%, respectively), and even higher among American Indians (up to 59% in some tribes). Children from families of low socioeconomic status or who live in rural areas are disproportionately affected. Some experts predict that a continuing childhood obesity epidemic may reverse the steady increases in life expectancy substantially because of possible increases in obesity-related cardiovascular deaths.

Observational epidemiologic studies have examined development and consequences of obesity in children and adolescents. Studies such as the Bogalusa Heart Study and the NHLBI Growth and Health Study (NGHS) have measured energy and nutrient intakes, physical activity levels and patterns, psychosocial factors, blood pressure, blood lipids and glucose, fasting insulin and carotid IMT during critical periods of growth. Much has been learned from these studies: obesity during childhood is associated with numerous adverse effects including hypertension, dyslipidemia, left ventricular hypertrophy, atherosclerosis, metabolic syndrome, type 2 diabetes, sleep disorders, and non-alcoholic fatty liver disease as well as psychological effects such as stigmatization, discrimination, depression and emotional trauma. Obesity in childhood substantially increases the risk of being an obese adult; adults who were overweight or obese during childhood have higher risks of developing hypertension, dyslipidemia, metabolic syndrome, diabetes, and coronary heart disease than those who were not overweight or obese during childhood. In addition, these studies have identified important factors associated with development of obesity, such as cultural norms, body image, dietary patterns, and fast-food consumption – information that can be drawn upon to develop overweight and obesity reduction intervention approaches.

A limited number of intervention studies in childhood overweight and obesity prevention and treatment have provided a sound basis, background, and lessons learned for future scientific rigor in childhood overweight and obesity research. A synthesis of current evidence suggests that successful prevention and treatment of childhood overweight and obesity must address multiple etiological factors that shape daily diet and physical activity behaviors. These factors are biological and physiological (e.g., genetic predisposition, appetite and satiety mechanisms and regulation), personal (e.g., physical activity patterns, taste preferences, and dietary composition), environmental (e.g., homes, schools, community, food availability and cost, built environment), as well as societal (e.g., cultural norms, TV advertising of foods, social network) and healthcare-related (e.g., primary care provider and pediatrician).

A recent Cochrane review of 22 obesity prevention intervention studies (including school-based studies such as PATHWAYS, Planet Health, and Project SPARK) identified only two prevention trials where the tested interventions significantly lowered BMI. In the 18 obesity treatment trials from another Cochrane review, the sample sizes were too small to have adequate power to detect

treatment effects, and the studies were not generalizable because the settings were mostly hospital based. Problems in research design and methods were identified for both the prevention and treatment studies, including use of inappropriate statistical methods, small sample sizes that could miss treatment effects, low participation rates that could compromise internal validity, insufficient potency of interventions, limited use of theoretical frameworks to design the intervention, and short duration of studies (a majority less than 12 months). Obesity prevention studies in children have been limited in size and in intervention duration, breadth, and intensity. Obesity treatment trials have been particularly few in number, mostly hospital-based, and have been limited in size, duration, population diversity and in intervention scope and modalities.

Furthermore, intervention designs have not considered the multiple factors associated with overweight and obesity. Although there is strong justification from the observation that multiple factors influence weight (e.g., individual behaviors, peer influences, home, family and school environments, and healthcare settings), there are sparse data on the effectiveness of interventions that are multi-component and intervene on multiple factors that affect body weight. To increase the evidence base for efficacious prevention and treatment methods, research is needed that is rigorous in methodology and builds on previous childhood overweight and obesity research to test promising intervention approaches.

The next generation of research studies should also take advantage of recent advances in our knowledge of environmental influences on energy balance, including physical environments and psychosocial environments such as social networks, and biological factors including genetics, neuroendocrine mechanisms, and appetite regulation. Further, there is a need for adequate methodological rigor that addresses various intervention components including duration and intensity in multiple settings. Data on mediating and moderating variables (e.g., social/peer support and self-efficacy for diet and physical activity behaviors) that are hypothesized as important determinants of changes in behavior are also needed, as is population-based research that intervenes within two or more settings or levels (e.g., individual, community, societal) for childhood overweight and obesity prevention and treatment.

Concerned about the public health burdens, along with a dearth of evidence-based approaches for obesity prevention and treatment, the NHLBI along with other NIH Institutes convened a Working Group to provide recommendations for future research in childhood overweight and obesity prevention and treatment. Attendees included scientists and leaders in clinical trial design, epidemiology, biostatistics, physical activity and nutrition, pediatrics, genetics, and bariatric surgery. The goal was to obtain advice on research priorities to prevent excess weight in youth and to treat obese children and adolescents. The Working Group report is available at <http://www.nhlbi.nih.gov/meetings/workshops/child-obesity/index.htm>. This initiative draws upon these recommendations and those from the literature (e.g., Cochrane reviews) that more successful research will be achieved within a multidisciplinary collaborative framework (e.g., consisting of methodologists, statisticians, pediatricians, nutritionists, physical activity specialists, health-care practitioners, neurobiologists, and geneticists).

## **Program Organization and Coordination**

The clinical trials to be coordinated under this FOA will not use a common study protocol. However, after awards are made and whenever possible, investigators must collaborate to develop and report standardized measures of key common variables, such as height, weight, waist circumference, percent body fat, blood pressure, blood lipids, fasting blood glucose, environmental factors or other characteristics. This FOA strongly encourages the use of common study variables, criteria, and measurement protocols to facilitate meta-analysis of the studies when possible.

### Research Coordinating Unit (RCU)

It is envisioned that data analysis will be mostly conducted by investigators, but coordinating functions will include the following:

Note a separate and specialized research component

investigators, but

### Common measures

- Facilitate the development and collection of common measures. Activities include the following: compile a list of proposed common measures, review relevant literature, assess the advantages and disadvantages for common measures, develop a manual of procedures for data collection, train investigators on data collection and quality control, and facilitate testing of study forms if needed.
- Establish and maintain a computer system needed for data transfer and storage of measures that are common across studies. It is anticipated that security provisions must be implemented to prevent unauthorized access or release of study data.
- Facilitate data transfer and pooling of data from two or more projects for greater statistical power and analyses
- Provide support for analysis of data for manuscripts that are common across studies.

### Meetings

- Compile individual study site's protocols, subject accrual and other documents, and provide relevant reports to NHLBI and Data and Safety Monitoring Board (DSMB).
- Plan, arrange for, and support meetings of the Steering Committee (SC) and its subcommittees and DSMB. Prepare minutes of SC and PRC meetings and distribute to members. Prepare draft minutes of open sessions of DSMB meetings and teleconferences and submit to NHLBI.
- Arrange SC conference calls and bi-annual investigators' meetings.
- Applicants must include funds for DSMB members and RCU staff to attend two biannual face-to-face meetings in the Bethesda/Washington, D.C. Metro area.

Some budgetary information

### Communications

- Develop and maintain a high-availability Web site and email system for group communication and for distribution of study documents, forms and information.
- Facilitate the development of subcommittees and monthly communication among investigators.
- Facilitate sharing of data and development of collaborative manuscripts among awardees.

- Participate in the scientific discussions and implementation of the studies as needed.
- Provide information about the studies to the public including registering and updating the studies on [ClinicalTrials.gov](http://ClinicalTrials.gov).
- Facilitate the dissemination of successful studies, including the preparation of public use files for common measures for archiving and sharing of results.
- Facilitate the submission of manuscripts accepted for publications to PubMed Central according to NIH policy (<http://publicaccess.nih.gov>).

### **Collaboration across studies and with local, state and national agencies**

- Promote collaboration across the studies and among the investigators.
- Establish communications with the scientific community and partnerships with professional agencies, foundations and others as needed.
- Collaborate with NHLBI, including the Division for the Application of Research Discoveries, professional associations and other agencies to promote integration of successful research outcomes into clinical practice and community programs.

### **Evaluation**

- In collaboration with the SC, develop comprehensive metrics for evaluating the program as a whole.

The PD/PI for the clinical trial submitted under FOA [RFA-HL-10-004](#) must not be the same PD/PI for the Research Coordinating Unit. However, the PD/PI for the clinical trial can be from the same institution as the PD/PI for the Research Coordinating Unit.

### **Other Submission Requirements and Information**

#### **Research Plan**

In lieu of a research plan, the following items should be addressed satisfactorily by the applicant:

#### **Evidence of Leadership and Performance Experience:**

The PD/PI should demonstrate leadership and experience in conducting coordinating functions and in monitoring and evaluating trials.

- Promote collaboration across studies and among investigators.
- Provide expert assistance in the development of common measures and in the analysis of data from two or more studies.
- Promote collaboration across studies to identify common measures or constructs and instruments and to standardize procedures for data collection and analysis.
- Establish partnerships with other agencies (e.g., CTSAs, national professional associations and foundations) to leverage resources.
- Harness the skills of staff with various expertises and work collaboratively in building teams and across studies.

Specific information on who can be PIs

### Capacity and Ability to Manage Data and Communications:

- Applicants must indicate in their application their capability to develop manual of operations, common data collection forms, electronic technology, and data management systems.
- Applicants should have experience in developing and maintaining data quality control systems.
- Applicants should provide evidence of data management and program support capabilities by describing the processes for common data collection, management, analysis, data security, privacy protections, and quality control.
- Applicants should propose methods to be employed to facilitate communication between RCU staff and clinical trials investigators as well as with external partners (e.g., professional associations, health and community agencies).

### Academic and Management Capabilities:

- Evidence of scholarship as PI of a Coordinating Center or similar collaborative, or evidence of scholarship in clinical trials, especially those that are cooperative agreements.
- Applicants should demonstrate skills as a manager for an RCU.
- Evidence of scholarship in obesity research.

### Staffing Expertise and Capabilities:

- Applicant must propose an operational structure for coordinating functions at the RCU for four separate clinical trials simultaneously, including lines of responsibility for professional staff at the RCU.
- Applicant must include funds to support one new, young or underrepresented investigator for up to 2 years.
- PD/PI of the RCU must have at least 30% effort, and include full-time data and communications management staff on its team.

### Evidence of Communication Capabilities:

- The RCU is responsible for supporting infrastructure for meetings and teleconferences. Applicant should have experience arranging logistical services for multiple clinical trials, such as assuring meetings (e.g., DSMB, SC meetings) are held and minutes are recorded and communicated to investigators.

### Departmental and/or Institutional Commitment:

- Applicant must demonstrate departmental and/or institutional commitment to participate in research and must provide letters of support from appropriate individuals. Support in areas of secure transfer of data, information technology, equipment, and general support of research, should be described along with evidence of previous research support.
- Applicants are encouraged to describe special or unique strengths that may be relevant to the clinical trial infrastructure and research described in RFA [HL-10-004](#). Examples

Some specific budgetary information

Institutional commitment letters to be included

include participation by the PI or other staff in administrative aspects of clinical research (e.g., IRB, DSMB), and collaborations with CTSA's or other funded research centers.

- Applicants are encouraged to suggest collaboration strategies with CTSA's, local, state, and national agencies or other agencies, and how collaboration would enhance performance, productivity and cost-effectiveness.

Some specific budgetary information

## Other Functions

- Applicants must include funds to support one new/young investigator or investigator from underrepresented racial/ethnic group for up to 2 years. These funds must be included in the general budget and highlighted as such in the budget justification. (For the definition of new investigator, see [http://grants.nih.gov/grants/new\\_investigators/resources.htm#definition](http://grants.nih.gov/grants/new_investigators/resources.htm#definition)).
- Applicant must provide support for data analyses that use common measures across studies and take appropriate leadership in preparation of scientific reports and manuscripts and publication and presentation of findings.
- Application must include a plan for dissemination of research findings, appropriate content of messages to be delivered to widest possible audience, metrics for successful dissemination, appropriate personnel for developing and implementing dissemination activities, willingness to participate in NHLBI Division of Application of Research Discoveries' (DARD's) dissemination and education programs, and a commitment that the Principal Investigator agrees to discuss and finalize the dissemination plan with the Steering Committee and NHLBI Project Office before implementation.
- Application must include a plan to prepare public-use files for archiving and sharing results that include common data according to NIH and NHLBI policies (e.g., NHLBI Limited Access Dataset Program (<http://www.nhlbi.nih.gov/resources/deca/default.htm>)).
- Awardees must agree to the Cooperative Agreement Terms and Conditions of Award in Section VI.2.A.

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

## Section II. Award Information

### 1. Mechanism of Support

Specific type of funding/award mechanism

This funding opportunity will use the NIH Research Project Cooperative Agreement (U01) grant mechanism. The applicant institution's Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

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

This funding opportunity will use a cooperative agreement award mechanism. In the cooperative agreement mechanism, the Project Director/Principal Investigator (PD/PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with NIH staff being substantially involved as a partner with the Principal Investigator, as described under the [Section VI. 2. Administrative Requirements](#), "Cooperative Agreement Terms and Conditions of Award."

## 2. Funds Available

← Funds Available Information

- The participating organizations intend to award up to \$5.25 million over seven years (FY2010-2016) under this FOA. Awards issued under this FOA are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.
- It is anticipated that one Research Coordinating Unit (RCU) award will be made under this FOA.
- Budgets for direct costs of up to \$500,000 per year and a project duration of up to seven years may be requested for a maximum of \$3.5 million direct costs over a seven year project period.

Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Facilities and administrative costs requested by consortium participants are not included in the direct cost limitation, see [NOT-OD-05-004](#).

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

## Section III. Eligibility Information

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### 1. Eligible Applicants

#### 1.A. Eligible Institutions

The following organizations/institutions are eligible to apply:

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)

- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- For-Profit Organizations (Other than Small Businesses)
- State Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribally Designated Organizations
- U.S. Territory or Possession
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Regional Organizations
- Others: Eligible Agencies of the Federal Government
- Faith-based or Community-based Organizations

## 1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI 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.

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

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

The PD/PI must have the necessary expertise to lead this effort. He or she must be an experienced investigator, be able to lead a collaborative effort, and must nurture existing and ongoing partnerships.

## 2. Cost Sharing or Matching

Review for any cost sharing requirements

This program does not require cost sharing as defined in the current *NIH Grants Policy Statement*. However, third party in-kind matching contributions could be proposed to promote participation of a diverse group of multidisciplinary teams and to encourage partnerships with agencies. Applicants who propose matching or in-kind financial contributions will be held to the requirement financially and must provide evidence (*e.g.*, letter of support) of such contribution.

### 3. Other-Special Eligibility Criteria

**Resubmissions.** Applicants are not permitted to submit a resubmission application in response to this FOA.

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

**Number of Applications.** Applicants may submit more than one application, provided each application is scientifically distinct and from different principal investigators.

Awards for a Clinical/Field Center and a Research Coordinating Unit (RCU) will not be made to the same Principal Investigator to ensure that pooled data analyses and data acquisition are performed independently.

An institution may submit an application for both a RCU and a Clinical/Field Center but each must have a different PI/PD.

## 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](mailto:GrantsInfo@nih.gov).

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

### 2. Content and Form of Application Submission

PAPER  
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.

## SPECIAL INSTRUCTIONS

### Applications with Multiple PDs/PIs

Specific Face Page Requirement on PHS398 form



When multiple PD/PIs are proposed, use the Face Page-Continued page to provide items 3a – 3h for all PD/PIs. NIH requires one PD/PI be designated as the “contact PD/PI” for all communications between the PD/PIs and the agency. The contact PD/PI must meet all eligibility requirements for PD/PI status in the same way as other PD/PIs, but has no special roles or responsibilities within the project team beyond those mentioned above. The contact PD/PI may be changed during the project period. The contact PD/PI should be listed in block 3 of Form Page 1 (the Face Page), with all additional PD/PIs listed on Form Page 1-Continued. When inserting the name of the PD/PI in the header of each application page, use the name of the “Contact PD/PI, et. al.” The contact PD/PI must be from the applicant organization if PD/PIs are from more than one institution.

All individuals designated as PD/PI must be registered in the eRA Commons and must be assigned the PD/PI role in that system (other roles such as SO or IAR will not give the PD/PI the appropriate access to the application records). Each PD/PI must include their respective eRA Commons ID in the eRA Commons User Name field.

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

Multiple PD/PI Leadership Plan: For applications designating multiple PDs/PIs, a new section of the research plan, entitled “Multiple PD/PI Leadership Plan” must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, and should include communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and other collaborators. The PDs/PIs must devote at least 3.6 calendar months/year (not less than 30% effort/year) to the study.

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

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 ([Section IV.3.A](#)). Submission times N/A.

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

Letters of Intent Receipt Date: September 8, 2009


Application Receipt Date: October 6, 2009

Peer Review Date: March 2010

Council Review Date: May 2010

Earliest Anticipated Start Date: July 2010

Letter of Intent  
Information



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

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

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

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

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

The letter of intent should be sent to:


Chief, Review Branch  
Division of Extramural Research Activities  
National Heart, Lung, and Blood Institute  
6701 Rockledge Drive  
Room 7214, MSC 7924  
Bethesda, MD 20892-7924 (Express zip: 20817)  
Telephone: (301) 435-0270  
FAX: (301) 480-0730  
Email: [nhlbchiefreviewbranch@nhlbi.nih.gov](mailto:nhlbchiefreviewbranch@nhlbi.nih.gov)

#### 3.B. Sending an Application to the NIH

Applications must be prepared using the 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

Specific Mailing  
Instructions for the  
RFA



Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)  
Bethesda, MD 20817 (for express/courier service; non-USPS service)

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

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

Chief, Review Branch  
Division of Extramural Research Activities  
National Heart, Lung, and Blood Institute  
6701 Rockledge Drive  
Room 7214, MSC 7924  
Bethesda, MD 20892-7924 (Express zip: 20817)  
Telephone: (301) 435-0270  
FAX: (301) 480-0730  
Email: [nhlbchiefreviewbranch@nhlbi.nih.gov](mailto:nhlbchiefreviewbranch@nhlbi.nih.gov)

ADDITIONAL  
MAILING  
INSTRUCTIONS!!!



### 3.C. Application Processing

Applications must be **received on or before the application receipt date**) described above ([Section IV.3.A.](#)). If an application is received after that date, the application may be delayed in the review process or not reviewed. Upon receipt, applications will be evaluated for completeness by the CSR and for responsiveness by the reviewing Institute. Incomplete and/or 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 review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

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

### 4. Intergovernmental Review

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

### 5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at [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 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 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](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part6.htm).)

**6. Other Submission Requirements and Information**

Specific Budgetary Information

- There will be two Steering Committee meetings in Bethesda, MD; therefore, the budget should include funds for travel for two two-day trips to the Bethesda/Washington, D.C. Metro area for the Research Coordinating Unit PI and at least one other staff member, as well as the costs associated with the meetings. Travel for the Research Center PIs and other staff will be included in the Research Center grants.
- Applicants are required to participate in monthly steering committee conference calls and should include their time for this effort in their budget. The principal investigators from each research team, the Research Coordinating Unit principal investigator and the

NIH staff will comprise the committee. The committee will establish policies and procedures for the RFA program such as approaches to coordinate common measures, monitor development of new investigators, and support for ancillary studies.

- Time commitment for this FOA for the PD/PI must not be less than 3.6 calendar months
- (30% effort). The PD/PI must plan for at least this level of effort in his or her budget.

Additional information or answers to questions on submission requirements are at:

<http://www.funding/inits/faq-hl-10-004andhl-10-005.htm>

**For cooperative agreements**, awardees must agree to the “Cooperative Agreement Terms and Conditions of Award” in Section VI.2.A "Award Administration Information."

Research Plan Page Limitations

The research plan may not exceed 25-pages.

Note: Appendix  
on CDS ONLY!

## 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](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

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 National Heart, Lung, and Blood Institute (NHLBI) 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 NHLBI Advisory 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
- Multidisciplinary and diverse team of investigators

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

**Overall Impact.** Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

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

**Significance.** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims

change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Does the applicant address the importance of performing coordinating functions in order to enhance the value of the research programs as indicated in the FOA under Program Organization and Coordination?

**Investigator(s).** Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Does the PD/PI devote enough time (at least 3.6 calendar months or 30% effort) for the research? Does the applicant have prior experience in performing coordinating functions and/or expertise in obesity research?

**Innovation.** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

**Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed? Are the proposed approaches appropriate for facilitating coordination among both obesity prevention and treatment research projects? Are the proposed coordination strategies adequate? Does the applicant propose adequate plans to facilitate the development of common measures, training of investigative staff in data collection, testing of study forms, transfer and pooling of data, and analysis of common data across the studies? Does the applicant propose plans for developing partnerships with national, state or local agencies (e.g., to leverage resources, disseminate study findings)? Does the applicant provide plans to evaluate progress of the program as a whole (e.g., **comprehensive metrics**)?

**Environment.** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

**Additional Review Criteria.** As applicable for the project proposed, reviewers will consider **the following additional items in the determination of scientific and technical merit.**

***Protections for Human Subjects.*** For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

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

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

***Vertebrate Animals.*** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

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

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

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

***Select Agent Research.*** Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

***Resource Sharing Plans.*** Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan ([http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)); 2)

Sharing Model Organisms (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>); and 3) Genome Wide Association Studies (GWAS) (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>).

### 3. Anticipated Announcement and Award Dates

Award date information

Earliest Anticipated Announcement and Award Date: June/July 2010.

## Section VI. Award Administration Information

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### 1. Award Notices

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

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

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

The FOA uses the cooperative agreement (U01) grant mechanism.

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](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](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.

## 2.A. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when state and local governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined below.

### 2. A.1. Awardee Rights and Responsibilities

The awardee (s) will have the primary and lead responsibilities for the project as a whole, including, for example, research design and protocol development, participant recruitment and follow-up, data collection, quality control, interim data and safety monitoring, final data analysis and interpretation, preparation of publications, as well as collaboration with other awardees, and with assistance from the NIH Project Scientists.

Study investigators are encouraged to publish and to release publicly and disseminate results and other products of the study, in accordance with study protocols and governance. Within three years of the end of the period of NIH support for the project, data not previously released and other study materials or products not previously distributed are to be made available to individuals who are not study investigators, provided such release is consistent with the study protocol and governance and with 2.A.2, paragraph 3 below. In addition, study investigators must establish a plan for making data sets and materials available to the scientific community and to the NIH immediately upon completion of the three year period following the end of the period of NIH support.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current HHS, PHS, and NIH policies.

### 2. A.2. NIH Responsibilities

The NIH Project Scientists have substantial scientific and/or programmatic involvement during

conduct of this activity, through scientific and technical assistance, advice and coordination above and beyond the levels required normally for program stewardship of grants, as described below:

The NIH Project Scientist will serve on the Steering committee; he/she or other NIH scientists may serve on other study committees, when appropriate. The NIH Project Scientist (and other NIH scientists) may work with awardees on issues coming before the Steering Committee and DSMB, and, as appropriate, other committees, e.g., recruitment, intervention, follow-up, quality control, adherence to protocol, assessment of problems affecting the study and possible changes in protocol, interim data and safety monitoring, final data analysis and interpretation, preparation of publications, and development of solutions to major problems such as insufficient participant enrollment.

The NIH reserves the right to phase-out or curtail the study (or an individual award) in the event of (a) failure to develop or implement a mutually agreeable collaborative protocol, (b) substantial shortfall in participant recruitment, follow-up, data reporting, or quality control, (c) major breach of the protocol, major change in scope, or substantive changes in the agreed-upon protocol with which NIH cannot concur, (d) attainment of a major study endpoint before schedule with persuasive statistical significance, or (e) human subject ethical issues that may dictate a premature termination.

Partnerships with community agencies, clinics, industry are encouraged in this FOA and may be advantageous and appropriate.

Additionally, an agency program official or IC program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice. The assigned program director may also serve as an NIH Project Scientist.

#### 2.A.3. Collaborative Responsibilities

Budget Note: 2 individuals (at minimum) to attend the Steering Committee Meetings.

A Steering Committee, composed of the principal investigator(s) of each field site, the principal investigator of the Research Coordinating Unit, and the NIH Project Scientists will be the main governing board of the study and will have primary responsibility for facilitating the conduct and monitoring of studies, and reporting study results. The Steering Committee will establish subcommittees, and members of the Steering Committee including the Project Scientist will serve on subcommittees as they deem appropriate.

Awardee(s) agree to the governance of the study through a Steering Committee. Steering Committee voting membership shall consist of the principal investigators (i.e., cooperative agreement awardees) including a Chairperson selected by the Steering Committee, and the principal investigator from the Research Coordinating Unit, and the NIH Project Scientist.

Meetings of the Steering Committee will ordinarily be held by telephone conference call or face-to-face in the Bethesda/Washington, D.C. Metro Area.

Budget Note

Each full member of the Steering Committee will have one vote. Awardee members of the Steering Committee will be required to accept and implement policies approved by the Steering Committee.

A Data and Safety Monitoring Board will be appointed by the Director, NHLBI, to provide overall monitoring of interim data and safety issues; the Steering Committee will nominate members for this Board but the final decision on membership will be made by the NHLBI. Meetings of the Data and Safety Monitoring Board will ordinarily be held in Bethesda/Washington, D.C. Metro Area. An NIH scientist other than the NIH Project Scientist shall serve as Executive Secretary to the Board. An independent Protocol Review Committee, established by the NIH, will provide peer review for each protocol. Because the Board serves as an independent group advisory to the NHLBI, study investigators will not communicate with Board members regarding study issues, except as authorized by the Board's Executive Secretary.

Each awardee designs and implements his/her own protocol and analyzes own data. However, for analysis of data that are common for all studies, collaborative protocols (e.g., manuscripts from two or more sites), and governance policies will call for the continued submission of data centrally to the Coordinating Unit for a collaborative database; the submittal of copies of the collaborative datasets to the RCU upon completion of the study; procedures for data analysis, reporting and publication; and procedures to protect and ensure the privacy of medical and genetic data and records of individuals. The NIH Project Scientist, on behalf of the NIH, will have the same access, privileges and responsibilities regarding the collaborative data as the other members of the Steering Committee.

Awardee members of the Steering Committee will be required to accept and implement policies approved by the Steering Committee.

#### 2.A.4. Arbitration Process

Any disagreements that may arise in scientific or programmatic matters (within the scope of the award) between award recipients and the NIH may be brought to arbitration. An Arbitration Panel composed of three members will be convened. It will have three members: a designee of the Steering Committee chosen without NIH staff voting, one NIH designee, and a third designee with expertise in the relevant area who is chosen by the other two; in the case of individual disagreement, the first member may be chosen by the individual awardee. This special arbitration procedure in no way affects the awardee's right to appeal an adverse action that is otherwise appealable in accordance with PHS regulations 42 CFR Part 50, Subpart D and HHS regulations 45 CFR Part 16.

Procedures for resolving disagreements between grantee and the Steering Committee (e.g., policies related to collaborative activities (e.g., use of common measures) will be resolved through a similar arbitration panel.

### 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

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

### 1. Scientific/Research Contacts:

Charlotte A. Pratt, PhD, RD  
Program Director  
Division of Prevention and Population Sciences  
National Heart, Lung, and Blood Institute  
6701 Rockledge Drive  
MSC 7936, Room 10118  
Bethesda, MD 20892  
Tel.: (301) 435-0382  
Fax: (301) 480-5158  
E-mail: [prattc@nhlbi.nih.gov](mailto:prattc@nhlbi.nih.gov)

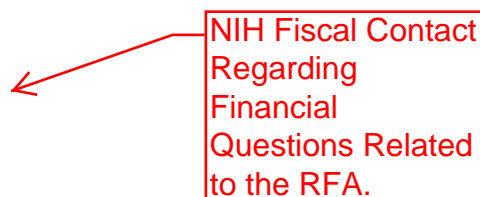
### 2. Peer Review Contacts:

Chief, Review Branch  
Division of Extramural Research Activities  
National Heart, Lung, and Blood Institute  
6701 Rockledge Drive, Room 7214, MSC 7924  
Bethesda, MD 20892-7924 (Express zip: 20817)  
Telephone: (301) 435-0270  
Fax: (301) 480-0730  
Email: [nhlbchiefreviewbranch@nhlbi.nih.gov](mailto:nhlbchiefreviewbranch@nhlbi.nih.gov)

### 3. Financial or Grants Management Contacts:

Ms. Kim Stanton  
Grants Operations Branch  
National Heart, Lung, and Blood Institute  
Rockledge II, Room 7167  
6701 Rockledge Drive  
Bethesda, MD 20892

NIH Fiscal Contact  
Regarding  
Financial  
Questions Related  
to the RFA.



Telephone: (301) 435-0159

FAX: (301) 480-1948

Email: [stantonk@mail.nih.gov](mailto:stantonk@mail.nih.gov)

## Section VIII. Other Information

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### 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](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/>

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

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

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

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see [http://grants.nih.gov/grants/policy/model\\_organism/index.htm](http://grants.nih.gov/grants/policy/model_organism/index.htm)). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement [http://grants.nih.gov/grants/policy/nihgps\\_2003/index.htm](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.

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

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the

health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm). The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the 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/) (<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 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>.

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