

Part I Overview Information

Department of Health and Human Services

Participating Organizations

National Institutes of Health (NIH) (www.nih.gov)

Components of Participating Organizations

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

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

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

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

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

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

Title: Meetings, Conferences, and Networks for Research Partnerships to Improve Functional Outcomes (R13)

Announcement Type

New

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

APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.

This FOA must be read in conjunction with the application guidelines included with this announcement in Grants.gov/Apply for Grants (hereafter called Grants.gov/Apply).

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

Program Announcement (PA) Number: PAR-08-207

Apply for Grant Electronically

For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at <http://grants.gov/CustomerSupport>

Catalog of Federal Domestic Assistance Number(s):
93.865, 93.853, 93.389, 93.173, 93.867

Key Dates

Release/Posted Date: July 18, 2008

Opening Date: July 18, 2008 (Earliest date an application may be submitted to Grants.gov)

Letters of Intent Receipt Date(s): Not applicable

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

Application Submission/Receipt Date(s): Standard dates apply, please see <http://grants1.nih.gov/grants/funding/submissionschedule.htm>

AIDS Application Submission/Receipt Date(s): Standard dates apply, please see <http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS>.

Peer Review Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

Council Review Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

Earliest Anticipated Start Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

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

Expiration Date: September 8, 2011

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** This funding opportunity announcement (FOA) solicits Conference Grant (R13/U13) applications from applicant organizations for meetings and networks that will facilitate interdisciplinary research partnership among investigators. The goal is to create opportunities for forming strong and effective multi-disciplinary scientific teams to address basic, translational, or clinical research problems in rehabilitation or management of chronic disease, including mental disorders.
- **Mechanism of Support.** This Funding Opportunity Announcement (FOA) will utilize the R13 grant mechanism
- **Funds Available and Anticipated Number of Awards.** Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the mechanism numbers, quality, duration, and costs of the applications received.

- **Budget and Project Period.** The total project period for an application submitted in response to this funding opportunity may not exceed two years. Direct costs are limited to \$50,000 over an R13 two-year period, with no more than \$25,000 in direct costs allowed in any single year.
- **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 are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.
- **Number of PDs/PIs.** More than one PD/PI (i.e., multiple PDs/PIs) may be designated on the application.
- **Number of Applications.** Applicants may submit more than one application, provided each application is scientifically distinct.
- **Renewals.** At this time, it is not known if competing renewal (formerly ~~“competing continuation”~~) applications will be accepted and/or if this FOA will be reissued.
- **Resubmissions.** Applicants may submit a ~~“resubmission”~~ application, but such application must include an ~~“Introduction”~~ addressing the previous peer review critique (Summary Statement).
- **Application Materials.** See Section IV.1 for application materials.
- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:
 - SF424 (R&R) Application and Electronic Submission Information:
<http://grants.nih.gov/grants/funding/424/index.htm>
 - General information on Electronic Submission of Grant Applications:
<http://era.nih.gov/ElectronicReceipt/>
- **Hearing Impaired.** Telecommunications for the hearing impaired is available at: TTY 301-451-0088.

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

Background

In 2004, the NIH Rehabilitation Coordinating Committee developed a program announcement (PAR-04-077) entitled "Research Partnerships to Improve Functional Outcomes" in order to stimulate multi-disciplinary research into the difficult problems of chronic disease and rehabilitation. The goal of this initiative was to encourage applicants with clinical expertise in rehabilitation or management of chronic disease to partner with scientists outside their fields to develop innovative approaches to problems. Although the announcement did generate a number of responsive applications across a wide scope of research problems, most applicants had significant difficulties in articulating how the expertise of their teams would actually go about addressing their chosen problems. In other words, applicants were successful in recruiting appropriate multi-disciplinary teams, but not in working with them to forge coherent research plans.

Goals

The present FOA attempts to address this problem by supporting meetings and workshops to bring together investigative teams to facilitate the process of developing appropriate research plans. We seek to help investigators who have the same interests in solving particular problems of rehabilitation and chronic disease, including mental disorders, and who have complementary research or clinical expertise and/or resources team up and form partnerships to coordinate, exchange, and disseminate information or to explore or clarify a defined subject, problem or area of knowledge. Proposed workshops and conferences should especially address issues in research methodology, including (but not limited to) selection of appropriate subjects, sample size, subject recruitment, measurement, trial design, and analytic strategies. It is anticipated that these workshops and conferences will help investigators become successful in submitting competitive applications for investigator-initiated research projects in the future.

Scope

The problems of aging and chronic disease articulated in the previous announcement remain as pressing as does the need for collaborative and interdisciplinary basic and clinical investigations to solve them. Applicants should identify a research problem, outline their approach to solving it and the research teams required, and create discussion and networking opportunities that will bring together the expertise needed to develop a competitive research application.

Examples of scientific meetings or networks for addressing research problems responsive to this announcement include, but are not limited to:

Developing and testing the efficacy of symptom-focused or holistic/integrated therapies for high prevalence conditions causing disability, such as low back pain, stroke, hearing

loss, visual loss, and congestive heart failure, as well as for lower prevalence conditions with high levels of co-morbidity, such as spinal cord injury, spina bifida, mental disorders, etc. Randomized clinical trials are especially encouraged.

Determining the extent to which genetic, environmental, social, and psychological factors determine patient responses to specific rehabilitation interventions; developing and testing methods or accommodations for augmenting responses of individuals with risk factors for poor responses.

Investigating the processes, at a molecular level, that lead to formation of muscle and skin contractures that occur due to inactivity and chronic disease; developing and testing the efficacy of targeted interventions based upon these processes.

Determining optimal physical and cognitive exercise patterns and schedules to improve functioning in individuals with specific disabilities ranging from childhood onset disorders, such as muscular dystrophies, cerebral palsy, and autism and other mental disorders to late-life congestive heart failure and sarcopenia.

Application of neuroimaging techniques to permit very early identification of children at risk for cerebral palsy. Application of robotics, virtual reality, and functional neuromuscular stimulation to provide massed practice and fine grained functional measurements for children with motor or sensory deficits from cerebral palsy.

Developing evidence-based algorithms to tailor strategies for rehabilitation based on individual and community characteristics.

Defining the optimal setting(s) and timing of rehabilitation strategies, optimal pain protocols, the role of passive range of motion, and the most cost-effective follow-up for patients undergoing hip and knee replacement surgeries.

Developing algorithms that can be used to match available interventions and technologies to individual patients to optimize functional outcomes; testing the validity of these models for clinical populations in diverse environments.

Developing and evaluating defined rehabilitation interventions based upon detailed biomechanical analyses of the patterns of muscle activation in specific conditions.

Testing methods to promote the dissemination of evidence-based rehabilitative therapies and technologies from the laboratory or clinic to community environments; studies can include foci on family and community issues (including stigma), self-management and advocacy, health-care policy and financial constraints, and cost-effective sustainability.

Testing methods to promote self-care, positive health behaviors, and health management through the use of behavioral, psychosocial, nutritional, and pharmacological strategies.

Developing and testing the efficacy of alternative delivery systems (e.g., telemedicine), providers, and settings for the rehabilitation of patients with specific diseases or conditions, including mental disorders.

Developing innovative engineering approaches that improve outcomes for individuals with acute stroke and other mobility disorders; investigating their cost-effectiveness and feasibility for use in various clinical settings.

Investigating the nature of disability and rehabilitation throughout the lifespan, particularly the special needs of the very young and elders when disability is superimposed on the developmental axis. These investigations may include studies on the interaction of the physiologies of aging and disability as well as studies of motor, sensory, cognitive, and psychosocial functional capability in those with mental disorders.

Evaluating the quality of rehabilitation care in current clinical settings, and linking the rehabilitation and quality of care and specific policies and practices to functional and participatory outcomes.Â Such studies could evaluate the effects of cost constraints on outcomes.

Studying decision making by clinicians, patients and families and impacts on health outcomes including quality of life.

Developing strategies and addressing issues related to increasing research resource and capacity in rehabilitation and disability research, facilitating and coordinating research training, mentoring, and career development in rehabilitation professionals and clinicians.Â Â

Studying methods to improve the integration of rehabilitation services across multiple settings (e.g., hospitals, nursing homes, home care, primary care, etc.) and the coordination with other care received by patients. Such studies could address methods for improving how clinical information is shared as patients move from hospitals to rehabilitation centers, to homes, and back to hospitals, etc., and the impact on outcomes.

Studying priority populations (e.g., women, children, elderly, low income groups; minority groups; individuals with special health care needs, including those with disabilities and those who need chronic care or end-of-life health care) and the identification and reduction of disparities in health care.

Studying methods to improve the measurement of functioning and impairment in people with mental disorders and methods to create novel psychiatric rehabilitation approaches.Â Particularly encouraged are applications of advances in physical impairment and rehabilitation to psychiatric functioning and rehabilitation (and vice versa, where appropriate). Â

Research on the biobehavioral and environmental factors, independent of symptom severity, that contribute to the rehabilitation of those with mental disorders. Â Emphasis

is on potent and modifiable factors associated with social, occupational, or instrumental rehabilitation that could serve as the basis for interventions specifically designed to improve functioning. The broad range of potential contributors to functioning is consistent with an ecological framework in which potential influences include intrapersonal, interpersonal, institutional, community, and public policy factors.

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

Section II. Award Information

1. Mechanism of Support

This Funding Opportunity Announcement (FOA) will use the R13 award mechanism. The applicant will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses "Just-in-Time" information concepts (see SF424 (R&R) Application Guide). It also uses the non-modular budget format (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). Applicants must complete and submit a detailed categorical budget using the Research & Related Budget component.

2. Funds Available

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the Institutes and Centers (ICs) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.

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.

The total project period for an application submitted in response to this funding opportunity may not exceed two years. Direct costs are limited to \$50,000 over an R13 two-year period, with no more than \$25,000 in direct costs allowed in any single year.

NHLBI will limit direct costs of R13 awards to \$10,000.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit an application(s) if your institution/organization has any of the following characteristics:

- Public/State Controlled Institution of Higher Education
- Private Institution of Higher Education
- Nonprofit with 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Nonprofit without 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Small Business
- For-Profit Organization (Other than Small Business)
- State Government
- U.S. Territory or Possession
- Indian/Native American Tribal Government (Federally Recognized)
- Indian/Native American Tribal Government (Other than Federally Recognized)
- Indian/Native American Tribally Designated Organization
- Hispanic-serving Institution
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Regional Organization
- 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 Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

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

The decision of whether to apply for a grant with a single PD/PI or multiple PDs/Pis grant is the responsibility of the investigators and applicant organizations and should be determined by the scientific goals of the project. Applications for grants with multiple

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

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

At this time, it is not known if competing renewal (formerly ~~“recompeting continuation”~~) applications will be accepted and/or if this FOA will be reissued.

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

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

Section IV. Application and Submission Information

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

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

- Grants.gov (<http://www.grants.gov/GetStarted>) and
- eRA Commons (<http://era.nih.gov/ElectronicReceipt/preparing.htm>)

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

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

1) Organizational/Institutional Registration in Grants.gov/Get Started

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

2) Organizational/Institutional Registration in the eRA Commons

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

3) Project Director/Principal Investigator (PD/PI) Registration in the NIH eRA Commons: Refer to the [*NIH eRA Commons System \(COM\) Users Guide*](#).

- The individual(s) designated as PDs/PIs on the application must also be registered in the NIH eRA Commons. In the case of multiple PDs/PIs, all PDs/PIs must be registered **and be assigned the PI role** in the eRA Commons prior to the submission of the application.
- Each PD/PI must hold a PD/PI account in the Commons. Applicants should not share a Commons account for both an Authorized Organization Representative/Signing Official (AOR/SO) role and a PD/PI role; however, if they have both a PD/PI role and an Internet Assisted Review (IAR) role, both roles should exist under one Commons account.
- When multiple PDs/PIs are proposed, all PDs/PIs at the applicant organization must be affiliated with that organization. PDs/PIs located at another institution need not be affiliated with the applicant organization, but must be affiliated with their own organization to be able to access the Commons.

- This registration/affiliation must be done by the AOR/SO or their designee who is already registered in the Commons.

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

Note that if a PD/PI is also an NIH peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

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

1. Request Application Information

Applicants must download the SF424 (R&R) application forms and SF424 (R&R) Application Guide for this FOA through Grants.gov/Apply.

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

For further assistance, contact GrantsInfo: Telephone 301-435-0714, Email: GrantsInfo@nih.gov.

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

2. Content and Form of Application Submission

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

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

The SF424 (R&R) application is comprised of data arranged in separate components. Some components are required, others are optional. The forms package associated with this FOA in [Grants.gov/APPLY](https://www.grants.gov/APPLY) will include all applicable components, required and optional. A completed application in response to this FOA will include the following components:

Required Components:

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

Optional Components:

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

SPECIAL INSTRUCTIONS

SPECIAL INSTRUCTIONS

Applications with Multiple PDs/PIs

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

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

All applications proposing multiple PDs/PIs will be required to include a new section describing the leadership of the proposed conference/meeting.

Multiple PD/PI Leadership Plan: For applications designating multiple PDs/PIs, a new section of the research plan, entitled “Multiple PD/PI Leadership Plan” [Section 14 of the Research Plan Component in the SF424 (R&R)], must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the conference/meeting plan 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 conference/meeting should be delineated for the PDs/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the conference/meeting or individual PDs/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Award (NoA) (see also: [NOT-OD-07-017](#)).

Applications Involving a Single Institution

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

Applications Involving Multiple Institutions

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

3. Submission Dates and Times

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

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

Opening Date: July 18, 2008 (Earliest date an application may be submitted to Grants.gov)

Letters of Intent Receipt Date(s): Not applicable

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

Application Submission/Receipt Date(s): Standard dates apply, please see <http://grants1.nih.gov/grants/funding/submissionschedule.htm>

AIDS Application Submission/Receipt Date(s): Standard dates apply, please see <http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS>.

Peer Review Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

Council Review Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

Earliest Anticipated Start Date(s): Standard dates apply, please see

<http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward>

3.A.1. Letter of Intent

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

3.B. Submitting an Application Electronically to the NIH

To submit an application in response to this FOA, applicants should access this FOA via <http://www.grants.gov/Apply> and follow steps 1-4. Note: Applications must only be submitted electronically. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

3.C. Application Processing

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

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two business days to view the application image.

- If everything is acceptable, no further action is necessary. The application will automatically move forward for processing by the Division of Receipt and Referral, Center for Scientific Review, NIH, after two business days.
- Prior to the submission deadline, the AOR/SO can **Reject** the assembled application and submit a changed/corrected application within the two-day viewing window. This option should be used if the AOR/SO determines that warnings should be addressed. Reminder: warnings do not stop further application processing. If an application submission results in warnings (but no errors) it will automatically move forward after two business days if no action is taken. Please remember that some warnings may not be applicable or may need to be addressed after application submission.
- If the two-day window falls after the submission deadline, the AOR/SO will have the option to **Reject** the application if, due to an eRA Commons or Grants.gov system issue, the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn't transfer correctly during the submission process). The AOR/SO should first

- contact the [eRA Commons Helpdesk](#) to confirm the system error, document the issue, and determine the best course of action. NIH will not penalize the applicant for an eRA Commons or Grants.gov system issue.
- If the AOR/SO chooses to ~~“Reject”~~ the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted, but it will be subject to the [NIH late policy](#) guidelines and may not be accepted. The reason for this delay should be explained in the cover letter attachment.
 - Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two days.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Incomplete applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the [Commons](#). Information related to the assignment of an application to a Scientific Review Group is also in the Commons.Â

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

The NIH will not accept any application in response to this FOA 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. This does not preclude the submission of an application already reviewed with substantial changes, but such application must include an ~~“Introduction”~~ addressing the previous critique. Note such an application is considered a "resubmission" for the SF424 (R&R).

4. Intergovernmental Review

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

5. Funding Restrictions

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

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

initial budget period of a new award.

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

6. Other Submission Requirements and Information

Unlike the "parent" R13 announcement (PA-08-149), advance permission is not required for applications submitted in response to this FOA. Prospective applicants, however, are strongly encouraged to consult with the program contacts listed in Section VII.1., before submitting an application.

The application will be assigned based on NIH Receipt and Referral Guidelines, and other ICs or Offices at NIH could be given dual assignments and have the opportunity to co-fund the conference/meeting with the primary funding IC. Dual assignments can be requested in the Cover Letter of an application.

The following instructions are to be used in conjunction with the SF424 (R&R) Application Guide accompanying the SF424 (R&R) application form:

SF424 (R&R) Cover Component: Enter the title of the scientific conference or scientific meeting on line item 11.

Research and Related Project/Performance Site Locations: Enter the site of the conference or meeting as the Performance Site.

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

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

Research and Related Senior/Key Person: Personnel are defined as the PD(s)/PI(s) and those responsible for the scientific planning and organization of the conference or meeting. Attach biographical sketches for PD(s)/PI(s), Co-Chair, key personnel, and confirmed key speakers.

Organizational DUNS

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

Research and Related Budget: The appropriate staff contacts, listed in Section VII.1., below, for guidance regarding any IC specific budget requirements. Enter the direct costs requested. Provide a narrative justification for each proposed personnel position, including role and proposed level of effort. Include information regarding efforts to obtain funding for this conference/meeting from other sources.

Allowable Costs: Salary (in proportion to the time or effort spent directly on the conference/scientific meeting); rental of necessary equipment; travel and per diem or subsistence allowances; supplies needed for conduct of the meeting (only if received for use during the budget period); conference services; publication costs; funds to help defray registration costs for some select attendees (for example, women, racial/ethnic minorities, persons with disabilities, other individuals who have been traditionally underrepresented in science, graduate students); speakers' fees.

Non-allowable costs: Purchase of equipment; transportation costs exceeding U.S. carrier coach class fares; visas; passports; entertainment; tips; bar charges; personal telephone calls; laundry charges; dues; honoraria or other payments for the purpose of conferring distinction or communicating respect, esteem or admiration; patient care; alterations or renovations; facilities and administrative costs/indirect costs. Refer to the NIH Grants Policy Statement for additional information regarding costs.

PHS 398 Research Plan Component Sections: Submit one attachment, which may not exceed 10 pages, under the Research Design and Methods section (line Item 5). Note that this section will be called ~~Conference Plan~~ in the system-generated Table of Contents. Letters of agreement to participate from key speakers and participants should be attached at line item 16. Do not complete Sections 2-4 and the Human Subjects Sections (Items 6-10) of the PHS 398 Research Plan.

In the ~~Conference Plan~~ section of the application (uploaded as attachment #5), describe the objectives, specific program, and logistical arrangements for the meeting. Describe the format and list the agenda and speakers, including the principal topics to be covered, problems to be addressed, and developments or contributions the conference/meeting might stimulate. Provide a detailed justification for the conference/meeting, including the scientific need, timeliness, and usefulness of the conference/meeting to the scientific community. Describe the composition and role of the organizing committee, and provide the names and credentials of key participants in the conference/meeting, including the basis for their selection and documentation of their agreement to participate.

Describe plans for the appropriate involvement of women, minorities, and persons with disabilities in the planning and implementation of, and participation in, the proposed conference/meeting. Estimate the expected size and composition of the audience, as well as the method of selection. Describe plans for publicizing the conference/meeting to all interested participants and for publishing the proceedings (with the latter possibility not being required). Identify related conferences/meetings held on the subject during the past 3 years [and how the proposed conference/meeting is similar to, and/or different from these, and why it is still necessary and useful]. If this is one of a series of periodic conferences/meetings held by a permanent sponsoring organization, briefly describe and evaluate the last conference/meeting in the series.

Applications requesting multiple years of support must provide the following additional information for each future year requested, in as much detail as possible: meeting topic(s); tentative dates, locations, and participants; and contingency plans for future meetings dependent upon, for example, the outcome of the first year's conference/meeting or developments in the field.

A critical part of the application for NIH support of conferences/meetings is documentation of appropriate representation of women, racial/ethnic minorities, persons with disabilities, and other individuals who have been traditionally underrepresented in science. These individuals must be included in all aspects of planning, organization, and implementation of NIH-sponsored and/or supported conferences/meetings.

Appropriate representation means representation based on the availability of these scientists from these groups known to be working in a particular field of biomedical or behavioral research. If appropriate representation is not apparent, no award will be issued until program staff members are assured of concerted recruitment efforts.

Organizers of scientific conferences/meetings must document compliance with the Guidelines for Inclusion of Women, Minorities, and Persons with Disabilities in Scientific Meetings Supported by the NIH

(<http://grants.nih.gov/grants/funding/r13/index.htm>). This Web site also includes addresses and information for offices at NIH that support conference/meeting activities.

Appendix Materials: The appendix is limited to announcements and reports of previous conferences/meetings under the same sponsorship. No other information or material should be submitted as appendices.

Resource Sharing Plan(s)

The following resource sharing policies do not apply to this FOA:

- Data Sharing Plan. Not Applicable
- Sharing Model Organisms. Not Applicable
- Genome Wide Association Studies (GWAS). Not Applicable

PHS 398 Checklist Component: The checklist is required; however, no information regarding facilities and administrative (F&A) costs (also called indirect costs) should be included as these are not allowable costs for this mechanism.

Section V. Application Review Information

1. Criteria

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

2. Review and Selection Process

Applications submitted for this funding opportunity will be assigned on the basis of established PHS referral guidelines to the ICs for funding consideration.

Applications that are complete will be evaluated for scientific and technical merit by an appropriate scientific review group convened by NICHD in accordance with NIH peer review procedures (<http://grants1.nih.gov/grants/peer/>) using the review criteria below.

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

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

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

- Scientific and technical merit of the proposed conference/scientific meeting as determined by the scientific peer review.
- Availability of funds.
- Relevance of the proposed conference/meeting 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. 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 conference/meeting 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 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.

Significance: Does this conference/scientific meeting 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 endeavors on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the format and agenda for the conference/meeting appropriate for achieving the specified goals? Is the conference/meeting timely for the subject matter? For applications designating multiple PDs/PIs, is the Leadership Plan approach, including the designated roles and responsibilities, governance and organizational structure consistent with and justified by the topics of the conference/meeting and the expertise of each of the PD/PIs?

Innovation: Does the conference/meeting employ novel approaches or methods to fulfill its purpose? Does the conference/scientific meeting draw together appropriate experts who may otherwise not have an opportunity to meet?

Investigators: Is(are) the PD/PI(s) well suited for organizing and fulfilling the goals of this conference/scientific meeting? Are the qualifications and past performance of the PD/PI(s) appropriate, and are they well suited for their described roles in the conference/scientific meeting? Are the key personnel and selected speakers appropriate and well suited for their described roles in the conference/scientific meeting?

Environment: Is the conference/scientific meeting site appropriate? Does the applicant organization have the ability to contribute to the probability of success? Do the proposed meetings, exhibits, interactions, etc., take advantage of unique features of the environment or employ useful collaborative arrangements? Is institutional support evident?

2.A. Additional Review Criterion

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

Appropriate Representation: How well do the plans for inclusion of women, racial/ethnic minorities, persons with disabilities, and other individuals who traditionally have been underrepresented in science provide for their appropriate representation in the planning, organization, and execution of the proposed conference/scientific meeting? See **Inclusion of Women, Minorities and Persons with Disabilities in NIH-Supported Conference Grants:** (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html>).

2.B. Additional Review Consideration

In addition to the above criteria, the following item will be considered, but will not be included in consideration of the priority score:

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed plan.

2.C. Resource Sharing Plan(s)

The following resource sharing policies do not apply to this FOA:

- Data Sharing Plan.Â Not Applicable.
- Sharing Model Organisms.Â Not Applicable.
- Genome Wide Association Studies (GWAS).Â Not Applicable

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/her Summary Statement (written critique) via the NIH eRA [Commons](#).Â

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.

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

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy*

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

3. Reporting

When multiple years are involved, awardees will be required to submit the [Non-Competing 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. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Michael Weinrich, M.D., Director
National Center for Medical Rehabilitation Research
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
National Institutes of Health
6100 Executive Blvd., Room 2A03, MSC 7510
Bethesda, MD 20892-7510*
(Rockville, MD 20852 for courier or express service)
Telephone: (301) 402-4201
Fax: (301) 402-0832
Email: mw287k@nih.gov

Daofen Chen, Ph.D.
Repair and Plasticity Cluster
National Institute of Neurological Disease and Stroke
6001 Executive Blvd, Room 2176, MSC 9523
Bethesda, MD 20892-7510*
(Rockville, MD 20852 for courier or express service)
Telephone: (301) 496.9964
Fax: (301) 480-2424
Email: chenD@mail.nih.gov

Suzanne Goldberg, R.N.
Division of Cardiovascular Diseases
National Heart, Lung and Blood Institute
6701 Rockledge Drive, Room 8154
Bethesda, MD 20892-7956
(Rockville, MD 20852 for courier or express service)
Telephone: (301) 435-0550
Fax: (301) 480-3667
Email: goldbergsh@mail.nih.gov

Donna Mayo, Ph.D.
National Institute of Mental Health
6001 Executive Blvd., Room 6228
Bethesda, MD 20892-9621
(Rockville, MD 20852 for courier or express service)
Telephone: (301) 443-1829
Fax: (301) 443-6000
Email: dmayo@mail.nih.gov

Amy Donahue, Ph.D.
Chief, Hearing and Balance/Vestibular Sciences Branch
NIDCD
6120 Executive Boulevard, EPS Room 400C, MSC 7180
Bethesda, MD 20892-7180
Telephone: (301) 402-3458
Fax: (301) 402-6251
Email: donahuea@nidcd.nih.gov

Michael Oberdorfer, Ph.D.
National Eye Institute
5635 Fishers Lane, Room 1300, MSC 9300
Rockville, MD 20892-9300
Telephone: 301.451-2020
Fax: (301) 402-0528
Email: mdo@mail.nih.gov

2. Peer Review Contacts:

Robert H. Stretch, Ph.D.
Director, Division of Scientific Review
Eunice Kennedy Shriver National Institute of Child Health and Human Development
(NICHD)
6100 Executive Boulevard, Room 5B01, MSC 7510
Bethesda, MD 20892-7510
(Rockville, MD 20852 for courier or express service)
Telephone: 301-496-1485

FAX: 301-402-4104
Email: stretchr@mail.nih.gov

3. Financial or Grants Management Contacts:

Bryan Clark
Grants Management Branch
Eunice Kennedy Shriver National Institute of Child Health and Human Development
(NICHD)
6100 Executive Boulevard, Room 8A01, MSC 7510
Bethesda, MD 20892-7510
(Rockville, MD 20852 for courier or express service)
Telephone: (301) 435-6975
Fax: (301) 402-0915
Email: clarkb1@mail.nih.gov

Christopher Myers
Chief, Grants Management Branch
NIDCD
6120 Executive Blvd, EPS 400C MSC 7180
Bethesda, MD 20892-7180
Telephone: (301) 402-0909
Fax: 301 402 1758
Email: Myersc@mail.nih.gov

William W. Darby
Grants Management Branch
National Eye Institute
5635 Fishers Lane, Suite 1300 MSC 9300
Bethesda, MD 20892
(Rockville, MD 20852 for courier or express service)
Telephone: (301) 451-2020
Fax: (301) 496-9997
Email: darbyw@mail.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 (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (â€œNIH Policy for Data and Safety Monitoring,â€œ *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.

Access to Research Data through the Freedom of Information Act:

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

Sharing of Model Organisms:

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

Inclusion of Women And Minorities in Clinical Research:

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

Inclusion of Children as Participants in Clinical Research:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (<http://grants.nih.gov/grants/funding/children/children.htm>).

Required Education on the Protection of Human Subject Participants:

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

Human Embryonic Stem Cells (hESC):

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

NIH Public Access Policy:

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

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

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

Standards for Privacy of Individually Identifiable Health Information:

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

enforced by the HHS Office for Civil Rights (OCR).

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

URLs in NIH Grant Applications or Appendices:

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

Healthy People 2010:

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

Authority and Regulations:

This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order. 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 Part 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement](#).

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

Loan Repayment Programs:

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