Part I Overview Information

Department of Health and Human Services

Participating Organizations
National Institutes of Health (NIH), (http://www.nih.gov)

Components of Participating Organizations
National Center on Minority Health and Health Disparities (NCMHD), (http://www.ncmhd.nih.gov)

Title: NCMHD Health Disparities Research on Minority and Underserved Populations (R01)

Announcement Type
This is a reissue of RFA-MD-09-004.

Request for Applications (RFA) Number: RFA-MD-10-003

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 (4) weeks prior to the grant submission date. See Section IV.

Catalog of Federal Domestic Assistance Number(s)
93.307

Key Dates
Release/Posted Date: December 10, 2009
Opening Date: January 26, 2010 (Earliest date an application may be submitted to Grants.gov)
Letters of Intent Receipt Date(s): January 26, 2010
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 Due Date(s): February 26, 2010
Peer Review Date(s): June-July 2010
Council Review Date(s): August 2010
Earliest Anticipated Start Date(s): September 2010
Additional Information To Be Available Date (Activation Date): Not Applicable
Expiration Date: February 27, 2010
Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** The overarching goal of this FOA is to solicit innovative research addressing elements that eliminates health disparities. Research focused on disease and/or conditions that disproportionately affect racial/ethnic minorities is a growing field and has been employed lately in understanding dynamics contributing to health disparities. Funding for this FOA will support investigators who propose to conduct health disparities research using its principles to improve health inequities. The research should take into account the characteristics of health systems and health seeking behaviors that propagate disparities. The focus of targeted research population is diverse. It includes ethnic racial minorities, medically underserved and vulnerable populations, and rural and low-income populations. Several approaches could be used when designing programs; specific interventions may include but are not limited to biological, behavioral change strategies, lifestyle factors, environmental, social and structural barriers, economics, institutional and cultural, family influences, delivery system interventions, medical procedures and regimens (including alternative therapy), medical and assistive devices and technologies.

- **Mechanism of Support.** This FOA will utilize the NIH Research Project Grant (R01) award mechanism.

- **Funds Available and Anticipated Number of Awards.** NCMHD has designated approximately $1.9 million in total costs to fund 5 or more awards in FY10, contingent upon the submission of sufficient number of scientifically meritorious applications.

- **Budget and Project Period.** An applicant may request a budget of direct costs up to $250,000 per year and a project period of up to five years. In addition, Facilities and Administrative (F&A) costs will be provided at the applicant organization’s negotiated rates. F&A costs requested by consortium participants are not included in the direct costs limitation (see NOT-OD-05-004).

- **Application Research Strategy Length:** The R01 application Research Strategy section may not exceed 12 pages, including tables, graphs, figures, diagrams, and charts. See Table of Page Limits.

- **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/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

- **Number of PDs/PIs.** More than one PD/PI (i.e., multiple PDs/PIs) may be designated on the application.

- **Number of Applications.** Applicants may only submit only one application in response to this FOA.

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

- **Renewals.** Renewals are not permitted in response to this FOA.

- **Special Date(s).** This FOA uses non-standard due dates. See Receipt, Review and Anticipated Start Dates.

- **Application Materials.** See Section IV.1 for application materials. All applications, including resubmission, revision and renewal, submitted for due dates January 25, 2010 and beyond, must utilize the current forms and instructions.

- **General Information.** For general information on SF424 (R&R) Application and Electronic Submission, see these Web sites:

- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (301) 451-5936

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1. Research Objectives

NCMHD has undertaken a number of efforts to eliminate health disparities among populations who have been heavily burdened with preventable and/or treatable diseases. These populations include African Americans, Hispanics, American Indians, Alaska Natives, Asian Americans, Native Hawaiians, Pacific Islanders and medically underserved populations (i.e., socio-economically disadvantaged individuals and those in rural areas). Given the changes in healthcare intervention and introduction of dynamic regimens over the past two decades, data clearly indicates improved overall health of the nation. Despite this trend, medically underserved vulnerable populations have not benefited. Studies have shown that these populations have shorter life expectancies in disease entities such as cardiovascular, all cancers (including breast, prostate and cervical), infant mortality, birth defects, asthma, diabetes, stroke, sexually transmitted diseases, mental illness and obesity. Research conducted has also indicated that eliminating these racial inequalities can lead to improved health status of U.S. population in general.

Health disparities continue to grow among vulnerable populations in urban and rural settings at alarming rates. It is important to keep in perspective that racial and ethnic groups who bear the brunt of health disparities are heterogeneous. Each group may carry a specific disease burden. Evidence shows that African Americans have the highest age-adjusted all-causes of disease rates than all races/ethnicities and the highest age-adjusted death rate for heart disease, cancer, diabetes, and HIV/AIDS. The incidence rates for both liver and stomach cancers are substantially higher among Asian Americans/Pacific Islanders than any other minority population. Further, health disparities also exist within different geographic regions of the United States, in particular, the Mississippi Delta, Appalachia, the U.S.-Mexico border region, and tribal communities. Cervical cancer mortality and diabetes-related death rates are higher than average among Hispanic/Latino women than non-Hispanic white women living on the Texas-Mexico border. Disease burden associated with mental disorders also falls disproportionately on ethnic minority populations; Native American and Alaska Natives not only suffer from higher rates of depression but this population also experience higher rates of suicide.

Recent evidence-based studies suggest that bridging health disparities gap has improved health conditions in the nation as a whole but has not equalized outcomes for health disparities populations. Further studies have shed light on various factors that are associated with the existence of health disparities. However, in order to enhance the trajectory for eliminating health disparities, new research models must be created. Hypothesis driven research is needed on proactive strategies in making strides for curtailing health disparities and designing effective methods that facilitate parity in health status for vulnerable Americans and other underserved populations.

The NCMHD leads the federal effort at the National Institutes of Health in stimulating a portfolio of new research that promote studies with high efficacy in determining the relative characteristics and/or methods contributing to favorable health outcomes. Various institutions have used numerous models suggesting favorable health outcomes but documentation on their comparable effectiveness is rather limited. This new initiative seeks to assess the extent to which health disparities research principles orchestrated in various settings can contribute to measurable and sustained improvements in health equity among the populations carrying the burden of health disparities.

The expectation of this FOA is for applicants to conduct health disparities studies that assesses comprehensive array of social and/or health-related systems methods/interventions, which are rigorous and well grounded in appropriate theoretical framework. Applicants will design their own intervention strategies and outcome measures. The research strategies should be expected to contribute to the fundamental understanding of health disparities and to answer associated questions relevant to program’s success. Applicants should be concrete in describing how their results would translate into eliminating health disparities and ensure that knowledge generated can be replicated.

Illustrative examples are as follows, but not limited to:

- Determine the relative characteristics of research intervention that contribute to favorable health outcomes
- Assess the effectiveness of comparable interventions in improving appropriate use of health systems that would make a difference in eliminating health disparities
• Determine the extent to which cultural influence or competence on behalf of the healthcare professional is advantageous to eliminating health disparities
• Determine the extent to which social and structural factors interface in propagating disease entities
• Determine the extent to which structural barriers (e.g.) are implicated in non-compliance of some regimens
• What concepts (including faith-based) are comprehensive enough to cater to the needs of health disparities population; thus eliminating health disparities
• What aspects of health system’s organizational composition (e.g. service delivery, convenience of location, hours of operation, availability of on-site ancillary services) that make a difference in curtailing health disparities
• Determine the level of “Real” or “Imagined” fears about one’s experience of disapproval by health provider, family and peers that keep people away from needed health services
• The use of effective strategies to minimize human barriers in an effort to eliminate health disparities
• What innovative models allow for fair societal representation in decision-making with respect to health equity and create and maintain a socially inclusive framework for policy-making

Investigators who conduct original and innovative social, behavioral, clinical, population based research or any aspects of determinants of health that is directed toward improving general health outcomes, eliminating Health Disparities, or both are invited to apply to this opportunity. Investigators at all career stages and those who have conducted Health Disparities Research as participants in the NIH loan repayment program (LRP) are encouraged to apply. New investigators including LRP recipients may refer to the following website and Notice for guidance.  

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

Section II. Award Information

1. Mechanism of Support

This FOA will use the R01 award mechanism. The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses “Just-in-Time” information concepts (see SF424 (R&R) Application Guide). It also uses the modular budget formats (see http://grants.nih.gov/grants/funding/modular/modular.htm). Specifically, a U.S. organization submitting an application with direct costs in each year of $250,000 or less (excluding consortium Facilities and Administrative [F&A] costs) must use the PHS398 Modular Budget component.

2. Funds Available

The total funds available in FY 2010 to support applications submitted in response to this FOA are approximately $1.9 million including grantees’ and consortium participants’ associated Facilities and Administrative (F&A) costs. The requested amount for individual awards may not exceed $250,000 Direct Costs per year for up to five years. It anticipated that 5 or more awards would be made in FY 2010.

Future year amounts will depend on annual appropriations.

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 IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds.

Facilities and Administrative (F&A) 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

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)

Foreign Organizations (Non-domestic [non-US] entities) are not eligible for this FOA.

1.B. Eligible Individuals

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

All investigators who conduct original and innovative social, behavioral, clinical, population based research or any aspects of determinants of health that is directed toward improving minority health, eliminating Health Disparities, or both are invited to apply to this opportunity.

Investigators at all career stages and those who have conducted Health Disparities Research as participants in the NIH loan repayment program (LRP) are encouraged to apply. New investigators including LRP recipients may refer to the following website and Notice for guidance. [http://grants1.nih.gov/grants/new_investigators/index.htm](http://grants1.nih.gov/grants/new_investigators/index.htm)

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](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](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. 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

Number of Applications. Applicants may not submit more than one application in response to this FOA.

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

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

Section IV. Application and Submission Information

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

Registration:

Appropriate registrations with Grants.gov and eRA Commons must be completed on or before the due date in order to successfully submit an application. 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 with both Grants.gov and the Commons. All registrations must be complete by the submission deadline for the application to be considered “on-time” (see 3.C.1 for more information about on-time submission).

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

- Grants.gov (http://www.grants.gov/applicants/get_registered.jsp) and
- eRA Commons (http://era.nih.gov/ElectronicReceipt/preparing.htm)

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

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

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

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

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

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

- The individual(s) designated as PDs/PIs on the application must be registered also in the NIH eRA Commons. In the case of multiple PDs/PIs, all PDs/PIs must be registered **and be assigned the PI role** in the eRA Commons prior to the submission of the application.
- Each PD/PI must hold a 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 NIH 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 the organization. PDs/PIs located at another institution need not be affiliated with the applicant organization, but must be affiliated with their own organization to be able to access the Commons.
- This registration/affiliation must be done by the AOR/SO or his/her designee who is already registered in the Commons.

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

**Note:** The registration process is not sequential. Applicants should begin the registration processes for both Grants.gov and eRA Commons as soon as their organization has obtained a DUNS number. Only one DUNS number is required and the same DUNS number must be referenced when completing Grants.gov registration, eRA Commons registration and the SF424 (R&R) forms.

### 1. Request Application Information

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

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

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

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

### 2. Content and Form of Application Submission

Prepare all applications using the SF424 (R&R) application forms for this FOA through Grants.gov/Apply and in accordance with the SF424 (R&R) Application Guide. ([http://grants.nih.gov/grants/funding/424/index.htm](http://grants.nih.gov/grants/funding/424/index.htm)).
The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to NIH. Some fields within the SF424 (R&R) application components, although not marked as mandatory, are 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 has several components. Some components are required, others are optional. The forms package associated with this FOA in Grants.gov/APPLY includes all applicable components, required and optional. A completed application in response to this FOA includes the data in the following components:

**Required Components:**
- SF424 (R&R) (Cover component)
- Research & Related Project/Performance Site Locations
- Research & Related Other Project Information
- Research & Related Senior/Key Person
- PHS398 Cover Page Supplement
- PHS398 Research Plan
- PHS398 Checklist
- PHS398 Modular Budget or Research & Related Budget, as appropriate (See Section IV.6., “Special Instructions,” regarding appropriate required budget component.)

**Optional Components:**
- PHS398 Cover Letter File
- Research & Related Subaward Budget Attachment(s) Form

**SPECIAL INSTRUCTIONS**

**Applications with Multiple PDs/PIs**

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

Information for the Contact PD/PI should be entered on 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.

**Multiple PD/PI Leadership Plan:** For applications designating multiple PDs/PIs, the Research Plan section, “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.

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

**Applications Involving a Single Institution**
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.

When submitting a modular budget, the prime institution completes the PHS398 Modular Budget component only. Information concerning the consortium/subcontract budget is provided in the budget justification. Separate budgets for each consortium/subcontract grantee are not required when using the Modular budget format. See Section 5.4 of the Application Guide for further instruction regarding the use of the PHS398 Modular Budget component.

3. Submission Dates and Times

See Section IV.3.A, for details.

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

Opening Date: January 26, 2010 (Earliest date an application may be submitted to Grants.gov)
Letters of Intent Receipt Date(s): January 26, 2010
Application Due Date(s): February 26, 2010
Peer Review Date(s): June-July 2010
Council Review Date(s): August 2010
Earliest Anticipated Start Date(s): September 2010

3.A.1. Letter of Intent

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

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

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

Prabha Atreya, PhD
Chief, Office of Scientific Review
Division of Extramural Activities and Scientific Programs
National Center on Minority Health & Health Disparities
National Institutes of Health
6707 Democracy Blvd., Suite 800, MSC 5465
Bethesda, MD 20892-5465
Telephone: (301) 594-8696


12/11/2009
3.B. Submitting an Application Electronically to the NIH

To submit an application in response to this FOA, applicants should access this FOA via http://www.grants.gov/applicants/apply_for_grants.jsp and follow Steps 1-4. Note: Applications must only be submitted electronically. PAPER APPLICATIONS WILL NOT BE ACCEPTED. All attachments must be provided to NIH in PDF format, filenames must be included with no spaces or special characters, and a .pdf extension must be used.

In order to expedite the review, applicants are requested to notify the NCMHD Referral Office by email atreyapr@mail.nih.gov when the application has been submitted. Please include the FOA number and title, PD/PI name, and title of the application.

3.C. Application Processing

3.C.1 Submitting On-Time

Applications may be submitted on or after the opening date and must be successfully received by Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization) on the application due date(s). (See Section IV.3.A. for all dates.) If an application is not submitted by the due date(s) and time, the application may be delayed in the review process or not reviewed. All applications must meet the following criteria to be considered “on-time”:

- All registrations must be complete prior to the submission deadline
- The application must receive a Grants.gov tracking number and timestamp (or eRA help desk ticket confirming a system issue preventing submission) by 5:00 p.m. local time on the submission deadline date.
- Any system identified errors/warnings must be corrected and the submission process completed within the “error correction window.”

Please visit http://era.nih.gov/electronicReceipt/app_help.htm for detailed information on what to do if Grants.gov or eRA system issues threaten your ability to submit on time.

Submission to Grants.gov is not the last step – applicants must follow their application through to the eRA Commons to check for errors and warnings and view their assembled application!

3.C.2 Two Day Window to Correct eRA Identified Errors/Warnings

Once an application package has been successfully submitted through Grants.gov, NIH provides applicants a two day error correction window to correct any eRA identified errors or warnings before a final assembled application is created in the eRA Commons. The standard error correction window is two (2) business days, beginning the day after the submission deadline and excluding weekends and standard federal holidays. All errors must be corrected to successfully complete the submission process. Warnings will not prevent the application from completing the submission process.

Please note that the following caveats apply:

- Initial application submission must be “on-time.”
- The AOR/Institutions is expected to enforce that application changes made within the error correction window are restricted to those necessary to address system-identified errors/warnings. NIH may reject any application that includes additional changes.
- Proof of “on-time” submission (e.g., Grants.gov timestamp and tracking number) and description of all changes made within the window must be documented in the PHS 398 Cover Letter component of the application.

3.C.3 Viewing an Application in the eRA Commons

Once any eRA identified errors have been addressed and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two weekdays (Monday – Friday, excluding Federal holidays) to view the assembled application before it automatically moves forward to NIH for further processing.

- If everything is acceptable, no further action is necessary. The application will automatically move forward to the Division of Receipt and Referral in the Center for Scientific Review for processing after two weekdays, excluding Federal holidays.
- Prior to the submission deadline, the AOR/SO can “Reject” the assembled application and submit a changed/corrected application within the two-day viewing window. This option should be used if it is determined that some part of the application was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to “Reject” the application and submit a Changed/Corrected application. In these cases, please contact the eRA Help Desk to ensure that the issues are addressed and corrected. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12 of the SF 424 (R&R) application guide, including the requirement for cover letters on late applications. The “Reject” feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two weekdays if no action is taken. Some warnings may need to be addressed later in the process.
- If the two-day window falls after the submission deadline, the AOR/SO will have the option to “Reject” the application if, due to an eRA Commons or Grants.gov system issue, the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn’t transfer correctly during the submission process). The AOR/SO should first contact the eRA Commons Helpdesk to confirm the system error, document the issue, and determine the best course of action. NIH will not penalize the applicant for an eRA Commons or Grants.gov system issue.
- If the AOR/SO chooses to “Reject” the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted, but it will be subject to the NIH 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 weekdays.

Upon receipt, applications will be evaluated for completeness by the CSR and responsiveness by the IC. Incomplete and non-responsive applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the Commons. The submitting AOR/SO receives the Grants.gov acknowledgments. The AOR/SO and the PI receive Commons acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

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

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an “Introduction” describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

4. Intergovernmental Review

This initiative is not subject to intergovernmental review.

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: 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 the NIH Grants Policy Statement).

6. Other Submission Requirements

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

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

Organizational DUNS

The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see “Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.”

PHS398 Research Strategy Component Sections

All application instructions outlined in the SF424 (R&R) Application Guide are to be followed, incorporating "Just-in-Time" information concepts, and with the following additional requirements:

- Introduction (required for a resubmission or revision application) is limited to 1 page.
- Specific Aims is limited to 1 page.
- Research Strategy, including tables, graphs, figures, diagrams, and charts are limited to 12 pages. See Table of Page Limits.

Budget Component

U.S. applicants submitting an application with direct costs in each year of $250,000 or less (excluding consortium Facilities and Administrative [F&A] costs) must use the PHS398 Modular Budget component.

U.S. applicants requesting more than $250,000 in annual direct costs must complete and submit budget requests using the Research & Related Budget component.

Appendix Materials

Applicants must follow the specific instructions on Appendix materials as described in the SF424 (R&R) Application Guide.
Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. If the final data/resources are not amenable to sharing, this must be explained in the Resource Sharing section of the application (see http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm.)

(a) Data Sharing Plan: Regardless of the amount requested, 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 NOT-OD-04-042.)

(c) Genome-Wide Association Studies (GWAS): Regardless of the amount requested, applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. A genome-wide association study is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (e.g., blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (go to NOT-OD-07-088, and http://grants.nih.gov/grants/gwas/.)

Section V. Application Review Information

1. Criteria

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

2. Review and Selection Process

Review Process

Applications that are complete and responsive to this FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NCMHD 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 an impact/priority score;
- Receive a written critique; and
- Receive a second level of review by NCMHD Advisory Council

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/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

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

**Significance.** Does the project address an important problem or a critical barrier to progress in the field? 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 proposed have adequate potential for favorably impacting the fields of minority health and health disparities research?

**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? Is the work proposed appropriate to the experience level of the PD/PI and other researchers?

**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? Does the application present unique characteristics that would make a difference in health disparities?

**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? For applicants designating multiple PDs/PIs, is the leadership approach, including the designated roles and responsibilities, governance, and organizational structure, consistent with and justified by the aims of the project and the expertise of each of the PDs/PIs?

**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? Is there evidence of institutional/organizational support?

**Additional Review Criteria**

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

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

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

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

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/priority score.

Select Agents 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).


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.

Selection Process

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

- Scientific merit of the proposed project as determined by peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
3. Anticipated Announcement and Award Dates

Not Applicable.

Section VI. Award Administration Information

1. Award Notices

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

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

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."

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.

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.

3. Reporting

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the NIH Grants Policy Statement.

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

Section VII. Agency Contacts

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

1. Scientific/Research Contact(s):
Robert Nettey, MD  
Health Scientist Administrator  
Division of Extramural Activities and Scientific Programs  
National Institutes of Health  
6707 Democracy Blvd., Suite 800, MSC 5465  
Bethesda, MD 20892-5465  
Telephone: (301) 496-3996  
Fax: (301) 480-4049  
Email: netteyr@mail.nih.gov

2. Peer Review Contact(s):

Prabha Atreya, PhD  
Chief, Office of Scientific Review  
Division of Extramural Activities and Scientific Programs  
National Center on Minority Health & Health Disparities  
National Institutes of Health  
6707 Democracy Blvd., Suite 800, MSC 5465  
Bethesda, MD 20892-5465  
Telephone: (301) 594-8696  
Fax: (301) 480-4049  
Email: atreyapr@mail.nih.gov

3. Financial/Grants Management Contact(s):

Priscilla Grant, JD, CRA  
Chief, Grants Management Officer  
National Center on Minority Health and Health Disparities  
National Institutes of Health  
6707 Democracy Blvd, Suite 800, MSC 5465  
Bethesda, MD 20892-5465  
Telephone: (301) 594-8412  
Fax: (301) 480-4049  
Email: grantp@mail.nih.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:

Human Subjects Protection:
Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).
**Data and Safety Monitoring Plan:**
Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants ("NIH Policy for Data and Safety Monitoring," NIH Guide for Grants and Contracts, [http://grants.nih.gov/grants/guide/notice-files/not98-084.html](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 institutional review board (IRB) rules, as well as local, State and Federal laws and regulations, including the Privacy Rule.

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

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

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

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

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

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

Human Embryonic Stem Cells (hESC):
Criteria for Federal funding of research on hESCs can be found at [http://stemcells.nih.gov/index.asp] and at [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-116.html]. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding ([http://escr.nih.gov/]). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research.

NIH Public Access Policy Requirement:
In accordance with the NIH Public Access Policy, investigators funded by the NIH must submit or have submitted for them to the National Library of Medicine’s PubMed Central (see [http://www.pubmedcentral.nih.gov/]), an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. The NIH Public Access Policy is available at [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html]. For more information, see the Public Access webpage at [http://publicaccess.nih.gov/].

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

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

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

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

Authority and Regulations:
This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372. Awards are made under 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/.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

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