

Part I Overview Information

Department of Health and Human Services

Participating Organization

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

Components of Participating Organization

National Institute of Biomedical Imaging and Bioengineering (NIBIB) (<http://www.nibib.nih.gov/>)

National Institute on Aging (NIA) (<http://www.nia.nih.gov/>)

National Institute of Arthritis and Musculoskeletal and Skin Disorders (NIAMS) (<http://www.niams.nih.gov/>)

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

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (<http://www2.niddk.nih.gov/>)

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

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

Title: Innovation in Molecular Imaging Probes (R01)

Announcement Type

New

Program Announcement (PA) Number: PAR-09-016

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](http://Grants.gov/ApplyforGrants) (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](#).

Note: Electronic application submission is required for this FOA. The new Adobe versions of the application forms are not yet available.

Please check back in December to download the application package. See Notice [NOT-OD-08-117](#).

Catalog of Federal Domestic Assistance Number(s)

93.286, 93.866, 93.846, 93.865, 93.847, 93.242, 93.853

Key Dates

Release/Posted Date: November 18, 2008

Opening Date: December 22, 2008 (Earliest date an application may be submitted to Grants.gov)

Letters of Intent Receipt Date(s): December 22, 2008; April 21, 2008; August 21, 2009; December 21, 2010; April 21, 2010; August 21, 2010; December 21, 2011; April 20, 2011; August 21, 2011

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): January 22, 2009; May 21, 2009; September 21, 2009; January 21, 2010; May 21,

2010; September 21, 2010; January 21, 2011; May 20, 2011; September 21, 2011

Peer Review Date(s): July 2009, November 2009, March 2010, July 2010, November 2010, March 2011, July 2011, November 2011, March 2012

Council Review Date(s): October 2009, January 2010, May 2010, October 2010, January 2011, May 2011, October 2011, January 2012, May 2012

Earliest Anticipated Start Date(s): December 2009, April 2010, July 2010, December 2010, April 2011, July 2011, December 2011, April 2012, July 2012

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

Expiration Date: September 22, 2011

Due Dates for E.O. 12372

Not Applicable

Additional Overview Content

Executive Summary

- **Purpose** This FOA is issued by the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health. This FOA is a follow up of a previous Roadmap RFA ([RM-04-021](#) "Innovation in Molecular Imaging Probes"). The purpose of this initiative is to encourage the development of novel molecular imaging approaches that can detect and image specific molecular activities in vivo, and have the potential for clinical applications. Novel molecular imaging approaches developed through this initiative can focus on one (or both) of the following long-term translational goals: (1) imaging the characteristic markers, and function, of normal cells in control human subjects and patients, and (2) imaging the characteristic markers, and biochemical or physiological abnormalities, of disease cells in patients. Potential abnormalities that could provide early markers for disease include (but are not restricted to): inflammation, fibrosis, immune cell activation, altered signal transduction pathways, altered gene expression pathways, and altered post-translational modification of proteins. This initiative solicits applications that explore innovative "high-impact" approaches, rather than incremental technology development that is already supported by current NIH programs.
- **Mechanism of Support.** This FOA will utilize the NIH Research Project Grant (R01) award mechanism with a 12 page limit for the research plan.
- **Funds Available and Anticipated Number of Awards.** Awards issued under this FOA are contingent upon the availability of funds. The total amount awarded and the number of grants will depend upon the quality, duration and costs of the applications received.
- **Budget and Project Period.** 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.
- **Application Research Plan Component Length:** The R01 application Research Plan component of the PHS398 (Items 2-5) may not exceed 12 pages, including tables, graphs, figures, diagrams, and charts (see http://grants.nih.gov/grants/funding/funding_program.htm).
- **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 submit more than one application, provided that each application is scientifically distinct.
- **Resubmissions.** Applicants may submit a resubmission application, but such application must include an Introduction addressing the previous peer review critique (Summary Statement). Unfunded applications previously submitted to RFA RM-04-021 must apply as a new application.
- **Renewals.** Applicants may submit a renewal application.
- **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.

- **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 are available at: TTY 301-451-5936.

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

Background

Molecular imaging is an emerging research area aimed at imaging specific molecular signatures - particularly those that are key targets in disease processes. Unlike anatomical imaging, molecular imaging displays the biochemical or physiological abnormalities underlying disease, rather than the structural consequences of these abnormalities.

Potential clinical applications of molecular imaging have been widely recognized at recent workshops and meetings sponsored by the NIH and other organizations. However, the poor sensitivity and specificity of current molecular imaging approaches is a major road-block for clinical applications. The purpose of this initiative is to encourage the development of novel molecular imaging approaches that can detect and image specific molecular activities in vivo, and have the potential for clinical applications.

Novel molecular imaging approaches developed through this initiative can focus on one (or both) of the following long-term translational goals:

- (1) imaging the characteristic markers, and function, of normal cells in control human subjects and patients, and
- (2) imaging the characteristic markers, and biochemical or physiological abnormalities, of disease cells in patients.

This initiative solicits applications that explore innovative "high-impact" approaches, rather than incremental technology development that is already supported by current NIH programs. A team approach is encouraged, and chemists, physicists and engineers who are new to the NIH are strongly encouraged to participate in this program.

Novel molecular imaging technologies developed in response to this PAR may initially involve in vitro or animal studies. While human or clinical applications do not need to be undertaken during the period of this grant, the results from the PAR should eventually have broad applications to medical research and clinical care.

The National Institute on Aging (NIA) is interested in supporting novel molecular imaging approaches that can detect, measure, and image specific molecular and biological processes that change in the cardiovascular, musculoskeletal, immune and nervous system with age and age-related disease, particularly Alzheimer's disease. Examples include protein misfolding and aggregation, mitochondrial function, reactive oxygen species, signaling pathways, tissue stem cells, and inflammatory processes.

The National Institute of Mental Health (NIMH) is interested in supporting novel molecular imaging approaches that can

provide markers relevant to mental illness, particularly for revealing neural circuits or aberrant neural development.

The National Institute of Neurological Disorders and Stroke (NINDS) is interested in funding the development of novel molecular imaging probes with the potential to cross the blood-brain barrier and visualize neurodegeneration or other CNS abnormalities (i.e., glial activation, protein misfolding) or monitor therapy of CNS disorders.

Research Objectives

The objectives of this initiative are:

- Development of highly specific molecular imaging probes using novel concepts (e.g., “multivalent” designs).
- Development of highly sensitive molecular imaging probes using novel “amplification” methods.
- Development of novel molecular imaging instrumentation that can be applied to clinical applications.
- Development of novel molecular imaging probes that target a wide range of “normal” cells. Potential examples include (but are not restricted to):
 - Quantitating and characterizing viable pancreatic beta cells in type-1 diabetes patients
 - Discriminating brown fat mass and metabolic activity from metabolism in surrounding tissue
 - Identifying non-invasive signatures of neuronal plasticity and/or remodeling
 - Identifying circuits of interconnected neurons, particularly in the human nervous system.
- Development of novel molecular imaging probes that target fundamental biological conditions or processes that might provide early markers for a wide range of diseases. Potential biological conditions or processes that could provide early markers for disease include (but are not restricted to):
 - Inflammation
 - Fibrosis
 - Activation of immune cells and migration to specific targets
 - Alterations in signal transduction pathways (e.g., G-protein-coupled receptor pathways and receptor tyrosine kinase pathways)
 - Alterations in gene expression pathways
 - Post-translational modifications of proteins

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 NIH Research Project Grant 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 as well as the non-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) should use the PHS398 Modular Budget component.

U.S. applicants requesting more than \$250,000 in annual direct costs and all foreign applicants must complete and submit budget requests 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 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](#).

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)
- Small Businesses
- For-Profit Organizations (Other than Small Businesses)
- State Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribally Designated Organizations
- U.S. Territory or Possession
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- Regional Organizations
- Non-domestic (non-U.S.) Entities (Foreign Organizations)

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.

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

Applicants may submit a competing renewal (formally “competing continuation”) if the proposed research is a logical progression of a currently funded NIH R01 grant. Applicants who did not receive funding may submit a “resubmission” application, but such application must include an “Introduction” (1 page maximum) addressing the previous peer review critique (Summary Statement).

Applicants may submit more than one application in response to this FOA, provided that 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, 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.

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
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 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 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 his/her designee who is already registered in the Commons.

Both the PD(s)/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 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 and in accordance with the SF424 (R&R) Application Guide

for this FOA through [Grants.gov/Apply](https://grants.gov/apply).

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](https://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

Foreign Organizations (Non-domestic [non-U.S.] Entities)

NIH policies concerning grants to foreign (non-U.S.) organizations can be found in the NIH Grants Policy Statement at: http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part12.htm#_Toc54600260.

Applications from Foreign organizations must:

- Request budgets in U.S. dollars;
- Prepare detailed budgets for all applications (that is, complete the Research & Related Budget component of the SF424 (R&R) application forms – not the PHS398 Modular Budget component)(see [NOT-OD-06-096](#));
- Not include any charge-back of customs and import fees;
- Comply with the format specifications, which are based upon a standard U.S. paper size of 8.5” x 11” within each PDF;
- If appropriate, request funds for up to 8% Facilities and Administrative (F&A) costs (excluding equipment) (see [NOT-OD-01-028](#), March 29, 2001);
- Comply with Federal/NIH policies on human subjects, animals, and biohazards; and
- Comply with Federal/NIH biosafety and biosecurity regulations (see [Section VI.2](#), “Administrative and National Policy Requirements”)

Proposed research should provide special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States (U.S.) or that augment existing U.S. resources.

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

Multiple PD/PI Leadership Plan: For applications designating multiple PDs/PIs, a new section of the research plan, entitled "Multiple PD/PI Leadership Plan" [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 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

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.

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: December 22, 2008 (Earliest date an application may be submitted to Grants.gov)

Letter of Intent Receipt Date(s): December 22, 2008; April 21, 2008; August 21, 2009; December 21, 2010; April 21, 2010; August 21, 2010; December 21, 2011; April 20, 2011; August 21, 2011

Application Submission/Receipt Date(s): January 22, 2009; May 21, 2009; September 21, 2009; January 21, 2010; May 21, 2010; September 21, 2010; January 21, 2011; May 20, 2011; September 21, 2011
Peer Review Date(s): July 2009, November 2009, March 2010, July 2010, November 2010, March 2011, July 2011, November 2011, March 2012
Council Review Date(s): October 2009, January 2010, May 2010, October 2010, January 2011, May 2011, October 2011, January 2012, May 2012
Earliest Anticipated Start Date(s): December 2009, April 2010, July 2010, December 2010, April 2011, July 2011, December 2011, April 2012, July 2012
Additional Information To Be Available Date (Activation Date): Not Applicable
Expiration Date: September 22, 2011

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:

Yantian Zhang, PhD
Program Director
Division of Applied Science and Technology
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Blvd, Suite 200
Bethesda, MD 20892-5477
Telephone: (301) 402-1373
Fax: (301) 480-1614
Email: y Zhang@mail.nih.gov

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.**

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 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.

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 weekdays (Monday – Friday, excluding Federal holidays) to view the application image to determine if any further action is necessary.

- 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, 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 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](#). 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 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. However, the NIH will accept a resubmission application, but such application must include an Introduction addressing the critique from the previous review.

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 or renewal award if such costs: 1) are necessary to conduct the project, and 2) would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or renewal award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH either to make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part6.htm.

6. Other Submission Requirements and Information.

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 Plan Component Sections

Items 2-5 of the PHS398 Research Plan component are **limited to 12 pages**. While each section of the Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to better monitor formatting requirements such as page limits. 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.

All application instructions outlined in the SF424 (R&R) Application Guide are to be followed, incorporating "Just-in-Time" information concepts.

Specific Instructions for Applications Requesting \$500,000 (direct costs) or More per Year

Applicants requesting \$500,000 or more in direct costs for any year (excluding consortium F&A costs) must carry out the following steps:

- 1) Contact the IC program staff at least 6 weeks before submitting the application, i.e., as plans are being developed for the study;
- 2) Obtain agreement from the IC staff that the IC will accept the application for consideration for award; and,
- 3) Include a cover letter with the application that identifies the staff member and IC who agreed to accept assignment of the application.

This policy applies to all new, renewal, revision, or resubmission applications. See [NOT-OD-02-004](#), October 16, 2001.

Appendix Materials

Applicants **must** follow the specific instructions on Appendix materials as described in the SF424 (R&R) Application Guide (See <http://grants.nih.gov/grants/funding/424/index.htm>).

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

Resource Sharing Plan(s)

NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value 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*: Investigators seeking \$500,000 or more in direct costs in any year 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 in which the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms and related resources, or state appropriate reasons why such sharing is restricted or not possible (see [Sharing Model Organisms Policy](#), and [NIH Guide NOT-OD-04-042](#).)

(c) *Genome-Wide Association Studies (GWAS)*: Regardless of the amount requested, applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. A genome-wide association study is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (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 \(NOT-OD-07-088\)](#) and <http://grants.nih.gov/grants/gwas/>.

Foreign Applications (Non-domestic [non-U.S.] Entities)

Indicate how the proposed project has specific relevance to the mission and objectives of the NIH/IC and has the potential for significantly advancing the health sciences in the United States.

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 the **Center for Scientific Review** in accordance with NIH peer review procedures (<http://grants1.nih.gov/grants/peer/>) using the review criteria stated below.

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

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned a priority score;
- Receive a written critique; 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 project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

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

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Is the emphasis on the development of novel molecular imaging approaches and tools, rather than on a hypothesis-driven study of a particular disease? Will the proposed novel molecular imaging tools and approaches have a high-impact on advancing knowledge of a fundamental biological condition/process, disease mechanism, or clinical application?

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

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice or address a critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area? Does the application explore innovative approaches rather than incremental technology development?

Investigators: Are the PD/PIs and other key personnel appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level(s) of the principal investigator(s) and other researchers? Do the PD/PIs and investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Do(es) the scientific environment(s) in which the work will be done contribute to the probability of success? Do

the proposed studies benefit from unique features of the scientific environment(s), or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

2.A. Additional Review Criteria

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

Resubmission Applications: Are the responses to comments from the previous scientific review group adequate? Are the improvements in the resubmission application appropriate?

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. See the “Human Subjects Sections” of the PHS398 Research Plan component of the SF424 (R&R).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated. See the “Human Subjects Sections” of the PHS398 Research Plan component of the SF424 (R&R).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the adequacy of the plans for their care and use will be assessed. See the “Other Research Plan Sections” of the PHS398 Research Plan component of the SF424 (R&R).

Biohazards: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

2.B. Additional Review Considerations

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

Applications from Foreign Organizations: Whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources will be assessed.

2.C. Resource Sharing Plan(s)

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

- Data Sharing Plan. [http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm]
- Sharing Model Organisms. [<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>]
- Genome Wide Association Studies (GWAS). [<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>]

3. Anticipated Announcement and Award Dates

Not Applicable

Section VI. Award Administration Information

1. Award Notices

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

3. Reporting

Awardees are encouraged to report any scientific highlights, publications, patents, and products resulted from the awards directly to the scientific program staff of the funding agency.

When multiple years are involved, 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):

Yantian Zhang, PhD
Program Director
Division of Applied Science and Technology
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Blvd, Suite 200

Bethesda, MD 20892-5477
Telephone: (301) 402-1373
Fax: (301) 480-1614
Email: yzhang@mail.nih.gov

Bradley C. Wise, PhD
Program Director, Fundamental Neuroscience
Division of Neuroscience
National Institute on Aging
7201 Wisconsin Avenue, Suite 350
Bethesda, MD 20892-9205
Telephone: (301) 496-9350
Fax: (301) 496-1494
Email: wiseb@nia.nih.gov

Gayle Lester, PhD
Program Director, Osteoarthritis Initiative and Diagnostic Imaging
Musculoskeletal Diseases Branch
National Institute of Arthritis and Metabolic Diseases
6701 Democracy Blvd; Suite 800
Bethesda, MD 29892-4872
Telephone: (301) 594-3511
Fax: (301) 480-4543
Email: lester1@mail.nih.gov

Gilman Grave, MD
Acting Director, Center for Research for Mothers and Children
National Institute of Child Health and Human Development
6100 Executive Blvd; Room 4B-05
Bethesda, MD 20892-7510
Telephone: (301) 496-5593
Fax: (301) 480-9791
Email: graveg@mail.nih.gov

Maren R. Laughlin, PhD
Senior Advisor for Integrative Metabolism
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Blvd, Room 787, MSC-5460
Bethesda, MD 20892-5460
Telephone: (301) 595-8802
Fax: (301) 480-0475
Email: maren.laughlin@nih.gov

Michelle Freund, PhD
Chief, Molecular Biotechnology Program
Division of Neuroscience and Basic Behavior Science
National Institute of Mental Health
6001 Executive Boulevard, Room 7202, MSC 9645
Bethesda, MD 20892-9645
Telephone: (301) 443-1815
Fax: (301) 443-1731
Email: freundm@mail.nih.gov

Ursula Utz, MBA, PhD
Program Director
National Institute of Neurological Diseases and Stroke
6001 Executive Blvd, Room 2134
Bethesda, MD 20892-9521
Telephone: (301) 496-1321
Fax: (301) 480-2424
Email: utzu@mail.nih.gov

2. Peer Review Contact(s):

Not Applicable

3. Financial/Grants Management Contact(s):

Angela Eldridge
Grants Management Specialist
Office of Grants Management
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Blvd. Suite 900
Bethesda, MD 20892
Telephone: (301) 451-4793
Fax: (301) 451-5735
Email: ae49k@nih.gov

Linda Whipp
Grants Management Office
National Institute on Aging
7201 Wisconsin Avenue, Suite 2N212
Bethesda, MD 20892-7731
Telephone: (301) 402-7731
Email: whipl@nia.nih.gov

Victoria Carper, MPA
Division of Extramural Activities
National Institute of Mental Health
6001 Executive Boulevard, Room 6118, MSC 9608
Bethesda, MD 20892-9608
Telephone (301) 443-3858
Email: carpervictoria@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 ("NIH Policy for Data and Safety Monitoring," *NIH Guide for Grants and Contracts*, <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

Sharing Research Data:

Investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing). Investigators should seek guidance from their institutions, on issues related to institutional policies and local institutional review board (IRB) rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Policy for Genome-Wide Association Studies (GWAS):

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

Sharing of Model Organisms:

NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh-Dole Act (see the [NIH Grants Policy Statement](#). 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. 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-02-005.html>. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (<http://escr.nih.gov/>). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

NIH Public Access Policy Requirement:

In accordance with the NIH Public Access Policy, *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/>.

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