

Ancillary Studies to the Ad Neuroimaging Initiative

PA Number: PA-04-158

Part I Overview Information

Department of Health and Human Services

Participating Organization

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

Components of Participating Organizations

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

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

Announcement Type:

New

Catalog of Federal Domestic Assistance Number(s):93.866 ,
93.286.

Key Dates

Release Date:September 20, 2004

Application Receipt Dates: October 1, February 1, June 1 (a month later for amended applications)

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

Peer Review Date: February/March, June/July, October/November

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

Council Review Date: May/June, September/October, January/February.

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

Earliest Anticipated Start Date: July 1, December 1, April 1

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

Expiration Date: November 1, 2007, unless reissued.

Due Dates for E.O. 12372 Not Applicable

Executive Summary

This PA invites research grant applications for ancillary studies to the Alzheimer's Disease Neuroimaging Initiative (ADNI), a multi-site, longitudinal, prospective, naturalistic study of normal cognitive aging, mild cognitive impairment (MCI), and early Alzheimer's disease (AD). The ADNI will collect, process, and store serial blood, CSF, and urine samples in the three groups for analyses for potential biomarkers of disease progression, including genomic, proteomic, and metabolomic markers that can be correlated with clinical, neuropsychological, and imaging data. Immortalized cell lines will also be established. The ancillary studies may propose and measure potential biomarkers, or offer new approaches to analyzing the dataset (e.g., image processing techniques, statistical analysis), or

develop parallel neuroimaging studies with a different sample but with a subset of the measures used in the ADNI protocol, or propose autopsy studies.

- Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the mechanism (R03, R21, R01) numbers, quality, duration, and costs of the applications received.
- This PA uses the NIH R01, R03 and R21 mechanisms and is open to for profit and not for profit organizations, public or private, including eligible agencies of local, state and federal governments. Domestic or foreign institutions may apply.
- Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs. Individual principal investigators may submit more than one application provided that the applications are substantively different from each other.
- The application form is available at: <http://grants1.nih.gov/grants/funding/phs398/phs398.html>

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The purpose of this PA is to invite research grant applications for ancillary studies to the Alzheimer's Disease Neuroimaging Initiative (ADNI). The purpose of the ADNI is to develop a multi-site, longitudinal, prospective, naturalistic study of normal cognitive aging, mild cognitive impairment (MCI), and early Alzheimer's disease (AD) as a public domain research resource to facilitate the scientific evaluation of neuroimaging (magnetic resonance imaging [MRI], positron emission tomography [PET]), and other biomarkers for the onset and progression of MCI and AD. The ADNI will collect, process, and store serial blood, CSF, and urine samples in the three groups of subjects for analyses for potential biomarkers of disease progression, including genomic, proteomic, and metabolomic markers that can be correlated with clinical, neuropsychological, and imaging data. Immortalized cell lines will also be established.

The ADNI will also establish methodologies for the multi-site collection, quality assurance/quality control, and distribution/sharing of neuroimaging and other biological data, in conjunction with clinical and neuro-psychological data.

The period of support for the ADNI will be five years, beginning September, 2004, with recruitment anticipated to start in March, 2005.

Advances in the understanding of the pathophysiology and genetics of AD are providing opportunities for developing disease-modifying therapies. A number of neuroimaging technologies and biological substances in the blood and cerebrospinal fluid (CSF) now appear to have considerable potential for measuring onset and progression in this disease (Jack, C.R., et al., *Neurology* 60:253-60, 2003; Alexander, G.E., et al., *Am J Psychiatry* 159:738-45, Frank, R.A., et al., *Neurobiology of Aging* 24:521-36, 2003).

During the ADNI (see RFA AG-04-005, <http://grants1.nih.gov/grants/guide/rfa-files/RFA-AG-04-005.html>), a group of cognitively normal older subjects will be studied in order to document changes in neuropsychological, imaging, and biochemical parameters that occur with normal aging. This will allow comparison with the changes occurring in the MCI and early AD groups.

This PA encourages applications for research to conduct ancillary studies to the ADNI, including but not limited to:

1. Studies for measurement of potential biomarkers in samples of biological fluids, as well as genomic, proteomic, metabolomic, etc. analyses.
2. Studies of data processing and analysis that use the imaging, clinical, neuropsychological, and/or biological measures, singly or in combination, collected during the ADNI. Innovative approaches to analyzing the dataset are encouraged, in, for example, the areas of image processing techniques, statistical analysis, heterogeneous data integration, informatics, and database methods.
3. Neuroimaging studies, although not using the enrolled participants of the ADNI, as there is concern about the burden of procedures being asked of them now, and for their retention in the study. A suggestion is the proposal of parallel studies, using techniques such as magnetic resonance spectroscopy, functional MRI, diffusion-tensor imaging, that can be harmonized across multiple sites and imaging platforms etc. Participants in such parallel studies could complete all, or a portion of the clinical, neuropsychological, and imaging studies, and biological sampling, completed by the primary enrollees of the ADNI. Clinical sites for the ADNI would need to complete enrollment of their assigned number of subjects for the ADNI, before enrolling subjects for such an ancillary study.
4. Autopsy follow-up studies.

In addition, this PA encourages applications to National Institute of Biomedical Imaging and Bioengineering (NIBIB) for ancillary studies, applied to AD as a clinical model, which might also be applied to other organ systems and diseases. These might include but are not limited to:

5. Develop novel imaging and analysis methods, that take advantage of the ADNI database, that may improve the sensitivity and specificity for the early diagnosis of disease, such as Alzheimer's Disease. Ideally, imaging and analysis methods should be independent of the imaging platform and clinical site (i.e., methods that can be integrated across different commercial platforms and data collection sites.)
6. Develop novel image processing or change analysis methods that may improve the sensitivity and specificity for the early diagnosis of AD. Image processing and change analysis methods would ideally be independent of the imaging systems. Standardized methods that include validation and performance measures of software. NIBIB is also interested in the creation and design of databases that contain validated images and associated data, which permit objective methods for training and testing the relative performance of different image and data processing algorithms.

Section II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the NIH RO1, RO3, and R21 award mechanisms. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project. Application instructions for the R03, NIH Small Research Grant, program are provided in the program announcement: <http://grants1.nih.gov/grants/guide/pa-files/PA-03-108.html>. Instructions for the R21, NIH Exploratory/Developmental Research Grant, program are provided in the program announcement: <http://grants1.nih.gov/grants/guide/pa-files/PA-03-107.html>.

This funding opportunity uses just-in-time concepts. It also uses the modular as well as the non-modular budget formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular budget format described in the PHS 398 application instructions. Otherwise follow the instructions for non-modular research grant applications.

2. Funds Available

For Small Grant (R03) awards, you may request a project period of up to two years and a budget for direct costs of up to two \$25,000 modules or \$50,000 per year. See <http://grants1.nih.gov/grants/guide/pa-files/PA-03-108.html>. For Exploratory/Developmental Grant (R21) awards, you may request a project period of up to two years with a combined budget for direct costs of up to \$275,000 for the two year period. For example, you may request \$100,000 in the first year and \$175,000 in the second year. Normally, no more than \$200,000 may be requested in any single year. See <http://grants1.nih.gov/grants/guide/pa-files/PA-03-107.html>.

For R01 awards you may request up to five years of support with costs appropriately tailored to the proposed work. Although no limit is set on R01 requested costs you should follow the instructions in Section IV. 6. Other Submission Requirements if you anticipate that the budget will exceed \$500,000 in direct costs in any year.

Fiscal and administrative costs on subcontracts are not included in the direct cost limitations described above, see [NOT-OD-04-040](#).

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the mechanism (R03, R21 or R01), numbers, quality, duration, and costs of the applications received. Although the financial plans of NIA and NIBIB provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

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

- For-profit or non-profit
- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Units of State government
- Units of local government
- Eligible agencies of the Federal government
- Domestic or foreign institutions/organizations

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

2. Cost Sharing

This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part2.htm.

3. Other-Special Eligibility Criteria

None

Section IV. Application Submission Instructions

1. Address to Request Application Information

The PHS 398 application instructions are available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

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

2. Content and Form of Application Submission

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dunandbradstreet.com>. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

See Section VI.2 Administrative and National Policy Requirements for additional information.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

3. Submission Dates

Applications must be mailed on or before the receipt date described at <http://grants1.nih.gov/grants/funding/submissionschedule.htm>.

3.A. Receipt, Review and Anticipated Start Dates

Application Receipt Dates: October 1, February 1, June 1 (a month later for amended applications)
<http://grants1.nih.gov/grants/funding/submissionschedule.htm>
Peer Review Date: February/March, June/July, October/November
<http://grants1.nih.gov/grants/funding/submissionschedule.htm>
Council Review Date: May/June, September/October, January/February
<http://grants1.nih.gov/grants/funding/submissionschedule.htm>
Earliest Anticipated Start Date: July 1, December 1, April 1
<http://grants1.nih.gov/grants/funding/submissionschedule.htm>

3.A.1. Letter of Intent

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

3.B. Sending an Application to the NIH

Applications must be prepared using the PHS 398 research grant application instructions and forms as described above. Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health

6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

3.C. Application Processing

Applications must be sent on or before the application receipt dates described above (Section IV.3.A.) and at <http://grants.nih.gov/grants/dates.htm>.

The NIH will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of a substantial revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

4. Intergovernmental Review

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

5. Funding Restrictions

All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm> (See also Section VI.3. Award Criteria)

6. Other Submission Requirements

Applications that involve direct access to ADNI subjects are subject to approval by the ADNI Steering Committee. A Resource Allocation Review Committee, composed of experts not directly involved with the ADNI and selected by the Steering Committee, will review applications for the use of biological specimens, and oversee their allocation and distribution.

For applications that involve direct access to ADNI subjects you should state your willingness and ability to cooperate with the ADNI clinical sites, coordinating centers, and NIA staff in all design, data collection, management, and distribution functions.

NIA and NIBIB require you to provide documentation at the time of grant application submission that you have received approval from the ADNI Steering Committee to conduct the proposed ancillary study. Therefore, investigators considering submitting applications must first contact the ADNI principal investigator to determine if the research plan is feasible.

As noted in the ADNI RFA (<http://grants1.nih.gov/grants/guide/rfa-files/RFA-AG-04-005.html>), data from the ADNI will be made publicly available on a periodic basis. Investigators supported under this PA are asked to follow the same practice. For example, public access to data would encourage the development of more standardized methods for evaluation of the relative performance of software tools employed in longitudinal studies.

Specific Instructions for Modular Grant applications.

Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular budget format. The modular budget format simplifies the preparation of the budget in these applications by

limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular budgets. Additional information on modular budgets is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

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 must carry out the following steps:

1. Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;
2. Obtain agreement from the IC staff that the IC will accept your 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 investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

Plan for Sharing Research Data

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.

All applicants must include a **plan** for sharing research data in their application. The data sharing policy is available at http://grants.nih.gov/grants/policy/data_sharing. All investigators responding to this funding opportunity should include a description of how final research data will be shared, or explain why data sharing is not possible.

The reasonableness of the data sharing **plan** or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing **plan** into the determination of scientific merit or the priority score.

Sharing Research Resources

NIH policy requires that grant award recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication. NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm and http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part7.htm#_Toc54600131. Investigators responding to this funding opportunity should include a **plan** for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report. (PHS 2590). See Section VI.3. Award Criteria.

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 to the ICs on the basis of established PHS referral guidelines. Appropriate scientific review groups convened in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>) will evaluate applications for scientific and technical merit.

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

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

3. Merit Review Criteria

Applications submitted in response to a funding opportunity will compete for available funds with all other recommended applications.

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. The scientific review group will address and consider each of these criteria in assigning the application's overall score, weighting them as appropriate for each application.

- Significance
- Approach
- Innovation
- Investigator
- Environment
- Additional Review Criteria

The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high 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 be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

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

Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

3.A. Additional Review Criteria:

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

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 also Section VIII - Other Information.

Inclusion of Women, and Minorities in Research: The adequacy of plans to include subjects from both genders, and all racial and ethnic groups (and subgroups), 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 also Section VIII-Other Information.

3.B. Additional Review Considerations

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

3.C. Sharing Research Data

Data Sharing Plan: The reasonableness of the data sharing **plan** or the rationale for not sharing research data **will** be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The presence of a data sharing **plan** will be part of the terms and conditions of the award. The funding organization will be responsible for monitoring the data sharing policy.

3.D. Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication. NIH Grants Policy Statement <http://grants.nih.gov/grants/policy/nihgps> and http://ott.od.nih.gov/newpages/rtguide_final.html. Investigators responding to this funding opportunity should include a sharing research resources **plan** addressing how unique research resources will be shared or explain why sharing is not possible

The adequacy of the resources sharing **plan** will be considered by Program staff of the funding organization when making recommendations about funding applications. Program staff may negotiate modifications of the data and resource sharing **plans** with the Principal Investigator before recommending funding of an application. The final version of the data and resource sharing **plans** negotiated by both will become a condition of the award of the grant. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report. (PHS 2590). See Section VI.3. Award Criteria.

Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the Principal Investigator will also receive a written critique called a Summary Statement.

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
http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part4.htm

A formal notification in the form of a Notice of award will be provided to the applicant organization. The notice of award signed by the grants management officer is the authorizing document.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA (Notice of Grant Award) are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

NGAs are sent via e-mail to the office of the Administrative Official named in item 12 on the Face Page of the PHS 398 (rev. 5/2001) application form.

2. Administrative and National Policy Requirements

All NIH Grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the notice of grant award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General
http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm.

2.A. Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Award Criteria

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance to program priorities

4. Reporting

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually:
<http://grants.nih.gov/grants/funding/2590/2590.htm> and financial statements as required in the NIH Grants Policy Statement.

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 two areas: scientific/research and financial or grants management issues:

1. Scientific/Research Contacts:

Direct questions related to NIA interests and issues to:

Susan Molchan, M.D.
Program Director, Alzheimer's Disease Clinical Trials
Neuroscience and Neuropsychology of Aging Program
National Institute on Aging
Gateway Bldg., Suite 350
7201 Wisconsin Ave.
Bethesda, MD 20892-9205
Telephone:(301)496-9350; FAX:(301)496-1494
Email: molchans@mail.nih.gov

Direct questions related to NIBIB interests and issues to:

John W. Haller, PhD
Division of Applied Science and Technology
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Blvd, Suite 200
Bethesda, MD, 20892-2077
Telephone: 301-451-4780
Email: hallerj@amil.nih.gov

2. Financial or Grants Management Contacts:

Deborah Stauffer
Grants Management Officer
National Institute on Aging
7201 Wisconsin Avenue, Suite 2N-212
Bethesda, Maryland 20892-9205
Express Mail Zip Code: 20814
Telephone: 301/496-1472; FAX: 301/402-3672
E-mail: stauffed@nia.nih.gov

Angela Eldridge
Grants Management Officer
National Institute of Biomedical Imaging and Bioengineering
6707 Democracy Blvd, Suite 900
Bethesda, MD, 20892-2077
Telephone: 301-451-4782
Email: aeldridg@amil.nih.gov

Section VIII. Other Information

Required Federal Citations

Human Subjects Protection:

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks,

the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.

Data and Safety Monitoring Plan:

Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity, and dose-finding studies (phase I); efficacy studies (Phase II) efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <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, local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Inclusion of Women And Minorities in Clinical Research:

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines is available at

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

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 (see <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.

Public 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 public 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 PA 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.

Standards for Privacy of Individually Identifiable Health Information:

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

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

URLs in NIH Grant Applications or Appendices:

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA 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 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

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

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Department of Health
and Human Services



National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892