

INNOVATION IN MOLECULAR IMAGING PROBES

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Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATION:

The National Institutes of Health (NIH)

(<http://www.nih.gov/>)

This RFA is developed as an NIH Roadmap initiative <http://nihroadmap.nih.gov>. All NIH Institutes and Centers participate in Roadmap initiatives. This RFA will be administered by the National Institute of Biomedical Imaging and Bioengineering on behalf of the NIH.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBERS: 93.286

LETTER OF INTENT RECEIPT DATE: September 22, 2004

APPLICATION RECEIPT DATE: October 22, 2004

THIS RFA CONTAINS THE FOLLOWING INFORMATION:

- o Purpose of this RFA
- o Research Objectives
- o Mechanism of Support
- o Funds Available
- o Eligible Institutions
- o Individuals Eligible to Become Principal Investigators
- o Special Requirements
- o Where to Send Inquiries
- o Letter of Intent
- o Submitting an Application
- o Supplementary Instructions
- o Peer Review Process
- o Review Criteria
- o Receipt and Review Schedule
- o Award Criteria
- o Required Federal Citations

PURPOSE OF THIS RFA

This Request for Applications (RFA) is part of the Molecular Libraries and Imaging (MLI) Initiative of the NIH Roadmap. Molecular imaging has the potential to monitor both normal and abnormal biochemical and physiological parameters in individual patients. A major road-block to clinical application of molecular imaging is the poor sensitivity, specificity and spatial localization of current imaging probes. The purpose of this RFA is to encourage the development of new probes that will achieve one or two orders of magnitude (i.e., a factor of 10 to 100) improvement in the ability to detect and image specific molecular events in vivo, and also have potential for clinical applications.

This RFA solicits pilot and feasibility studies that explore novel and untested “high-risk” approaches to achieve this goal, 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.

RESEARCH OBJECTIVES

Background

Current methods for imaging humans provide predominantly anatomical information, or functional information at a macroscopic level. Molecular imaging is an emerging research area aimed at extending existing or novel methods to image specific molecular pathways in vivo, particularly those that are key targets in disease processes. Unlike anatomical imaging, molecular imaging displays biochemical and physiological abnormalities underlying disease, rather than the structural consequences of these abnormalities.

Potential clinical applications of molecular imaging include:

- o monitoring cell therapies by tracking the survival, movement, engraftment and differentiation of injected or implanted cells and tissues
- o monitoring gene therapies by reporting on gene expression and cellular function
- o precise localization of tumors within organs, and detection of precancerous cells
- o detection and tracking of bacteria and viruses throughout their infectious cycles in cells, tissues and organs; monitoring of cellular responses to infection
- o tracking of circulating cells in the vasculature and tissues
- o following the movement of cells in tissue injury and repair, inflammation, and metastasis
- o imaging of cellular functions in organs and tissues by detecting trafficking and transport, adhesion and migration, differentiation, neurogenesis, cell cycle progression, stress responses and apoptosis
- o detection of microenvironments contributing to pathology and monitoring of responses to injury, oxidative stress and hypoxia
- o imaging of action potentials, membrane polarization, channel activity, synaptic

transmission. Neurochemical imaging
o imaging intracellular molecular processes, intermolecular interactions, and signal transduction pathways.

Molecular imaging approaches are not used to their full potential in humans, either in research or clinical environments. One reason is the poor sensitivity, specificity and spatial localization of molecular probes that can be used in humans. Another reason is the relatively poor signal-to-noise and spatial resolution of most human molecular imaging techniques. A third reason could be toxicity of the molecular probe. Potential clinical applications of molecular imaging have, however, been widely recognized at recent workshops and meetings sponsored by the NIH and other agencies, and the development of molecular imaging approaches that can be used in clinical environments is an important goal of the NIH Roadmap process.

Scope of Research

Contrast in molecular imaging is generated or enhanced by molecular probes—reagents that are targeted to specific intracellular or extracellular molecules and either produce or alter signals that are detected by imaging devices. Imaging of molecular probes in individual cells or small groups of cells in vivo will require contrast that is orders of magnitude better than current capabilities. Responses to this RFA should propose long-term strategies to achieve one or two orders of magnitude improvement in the ability to detect and image specific molecular events in humans. These improvements should result primarily from increases in the sensitivity and specificity of molecular probes, but could also include related improvements that result from increases in the signal-to-noise or spatial resolution of human molecular imaging devices.

Applications that propose only to improve the signal-to-noise or spatial resolution of molecular imaging devices will be considered non-responsive.

Novel molecular imaging probes developed in applications submitted to this RFA should have a clear path to future clinical applications. However, clinical research need not be undertaken during the period of this grant.

This RFA is specifically intended for innovative research of unproven feasibility, and will support projects that explore chemical and physical phenomena that may ultimately lead to new molecular imaging probes. Investigators are encouraged to work closely with biologists and clinicians in order to address potential issues of toxicity and delivery that could complicate the clinical utility of new molecular imaging probes.

Novel molecular probes or imaging techniques that result from this RFA should eventually have broad applications to medical research and clinical care.

MECHANISM OF SUPPORT

This RFA will use the R21 mechanism. As an applicant you will be solely responsible for planning, directing, and executing the proposed project. This RFA is a one-time solicitation. Future unsolicited, competing-continuing applications based on this project will compete with all investigator-initiated applications and will be reviewed according to the customary peer review procedures. The earliest anticipated award date is July 1, 2005. Applications that are not funded in the competition described in this RFA may be resubmitted as NEW investigator-initiated applications using the standard receipt dates for NEW applications described in the instructions to the PHS 398 application.

This RFA uses just-in-time concepts. It also uses the modular budgeting as well as the non-modular budgeting 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. Otherwise follow the instructions for non-modular budget research grant applications. 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.

FUNDS AVAILABLE

The NIH intends to commit approximately \$3.3 million in FY 2005 to fund about seven new grants in response to this RFA. An applicant may request a project period of up to four years and a budget for direct costs of up to \$300,000 per year. Indirect costs associated with consortia or subcontracts will not be considered as part of the \$300,000 direct cost limit.

Although the financial plans of the NIH provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

ELIGIBLE INSTITUTIONS

You may submit an application if your institution is domestic and has any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories
- o Units of State and local governments
- o Eligible agencies of the Federal Government
- o Faith-based or community-based organizations
- o Foreign institutions are not eligible to apply.

Applications from foreign institutions will not be accepted; however, participating collaborators at foreign institutions may be included through sub-contracts.

We welcome public-private partnerships, since academia and industry may have the complementary capabilities needed for development and commercialization of new technologies.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

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 under-represented racial and ethnic groups, as well as individuals with disabilities, are always encouraged to apply for NIH programs.

SPECIAL REQUIREMENTS

Sharing of Results. All research resources (e.g., methods, tools, materials) and information (e.g. IND filing information) developed in these projects are expected to be made readily available to the scientific community for non-profit research purposes. Applications should include a sharing plan that includes criteria, mechanisms, and timetables by which all the resources and information developed in the course of the project will be shared. Sharing plans must be in accord with the NIH Grants Policy Statement (<http://grants.nih.gov/grants/policy/nihgps/>) and the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999 (http://ott.od.nih.gov/NewPages/RTguide_final.html and <http://ott.od.nih.gov/NewPages/64FR72090.pdf>). Applicants are invited to utilize NIH supported repositories to make reagents widely available to the scientific community. The adequacy of the proposed sharing plan will be considered by NIH staff prior to award. The proposed sharing plan, after negotiation with the applicant when necessary, will be made a condition of the award.

Grantees Meetings: Principal Investigators are expected to attend an annual meeting, most likely in the Bethesda, MD region, organized by NIH. Investigators must include travel to this meeting as part of the budget request and state a willingness to participate in this meeting.

WHERE TO SEND INQUIRIES

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

- o Direct your questions about scientific/research issues to:

Alan McLaughlin, Ph.D.
Division of Applied Science and technology
National Institute of Biomedical Imaging and Bioengineering
Building: Two Democracy Plaza, Room: 232
6707 Democracy Boulevard
Bethesda, MD 20892-5469
Telephone: (301) 496-9321
FAX: (301) 480-4973
Email: mclaugal@mail.nih.gov

Linda Brady
Neuropharmacology and Drug Discovery/Clinical Therapeutics Program
Division of Neuroscience and Basic Behavioral Science
National Institute of Mental Health
6001 Executive Boulevard, Room 7185
Bethesda, MD 20892-9641
Telephone: (301) 443-5288
Fax: (301) 402-4740
Email: lbrady@mail.nih.gov

Denis Buxton
Heart Research Program
Division of Heart and Vascular Diseases
National Heart, Lung and Blood Institute
6701 Rockledge Drive, Suite 9044
Bethesda, MD 20892-7940
Telephone: (301) 435-0516
Fax: (301) 480-1454
Email: buxtond@mail.nih.gov

Daofen Chen
Channels, Synapses, and Circuits Research
National Institute of Neurological Disorders and Stroke
NIH Neuroscience Center, Room 2131
6001 Executive Boulevard
Bethesda, MD 20892-9523
Telephone: (301) 496-1917
Fax: (301) 402-1501
Email: Daofen.chen@nih.gov

James Deatherage
Cell Biology Branch
Division of Cell Biology and Biophysics
National Institute of General Medical Sciences
45 Center Drive, Room 2AS.13J
Bethesda, MD 20892-6200

Telephone: (301) 594-3828
Fax: (301) 480-2004
Email: deatherj@nigms.nih.gov

Eleni Kousvelari
Center for Biotechnology and Innovation
National Institute of Dental and Craniofacial Research
Building 45, Room 4AN 18A
Bethesda, MD 20892
Telephone: (301) 594-2427
Fax: (301) 480-8318
Email: kousvelarie@mail.nih.gov

Maren Laughlin
Metabolism Program
Division of Diabetes, Endocrinology and Metabolic Diseases
6707 Democracy Boulevard, Room 6101
Bethesda, MD 20892-5460
Telephone: (301) 594-8802
Fax: (301) (301) 480-3503
Email: laughlinm@mail.nih.gov

Abraham Levy
Division of Biomedical Technology Research and Research Resources
National Center for Research Resources
6701 Democracy Boulevard, Room 970
Bethesda, MD 20892-4874
Telephone: (301) 435-0777
Fax: (301) 480-3659
Email: levyabra@mail.nih.gov

Bradley Ozenberger
Division of Extramural Research
National Human Genome Research Institute
5635 Fishers Lane, Suite 4076
Bethesda, MD 20892-9305
Telephone: (301) 451-4735
Fax: (301) 480-9305
Email: bozenger@mail.nih.gov

o Direct your questions about peer review issues to:

David T. George, Ph.D.
Office of Scientific Review
National Institute of Biomedical Imaging and Bioengineering
Building: Two Democracy Plaza, Suite: 920, Room: 956

6707 Democracy Boulevard
Bethesda, MD 20892-5469
Bethesda, MD 20817 for express/courier service
Telephone: (301) 496-8633
FAX: (301) 480-0675
Email: georged@nih.gov

o Direct your questions about financial or grants management matters to:

Nancy Curling
National Institute of Biomedical Imaging and Bioengineering
Building: Two Democracy Plaza, Suite: 920
6707 Democracy Boulevard
Bethesda, MD, 20892-5469
Telephone: (301) 496-8633
FAX: (301) 480-4974
Email: curlingn@mail.nih.gov

LETTER OF INTENT

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

- o Descriptive title of the proposed research
- o Name, address, and telephone number of the Principal Investigator
- o Names of other key personnel
- o Participating Institutions
- o Number and title of this RFA.

A letter of intent is not required, is not binding, and does not enter into the review of a subsequent application. However, the information 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 at the beginning of this document, and should be sent to Dr. David T. George at the address listed under WHERE TO SEND INQUIRIES.

SUBMITTING AN APPLICATION

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. The PHS 398 document is 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.

SUPPLEMENTARY INSTRUCTIONS: All PHS 398 requirements should be followed, with the exception of items affected by the following instructions:

- o The total page limit for the Research Plan (items a – d) may not exceed a total of 15 pages. Items e-g (human subjects/vertebrate animals/sharing plan) do not count against the page limit.

- o Preliminary data (published or unpublished) are not required, but may be included if available. However, preliminary data should be kept to a minimum, and will not be a major criterion for review. More emphasis will be placed on development of the proposed strategy based on the combined insight, knowledge and experience of the research group.

- o The only allowable items in the Appendix are original photographs or color images, provided that a photocopy (may be reduced in size) is also included within the 15-page limit of Items a-d of the research plan. No photographs or color images may be included in the appendix that are not also represented within the Research Plan. Publications, manuscripts, abstracts, patents, or other printed materials are not permitted and, if present, will not be forwarded to the review panel.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS: Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular grant format. The modular grant 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. 5/2002) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step instructions for preparing modular grants. Additional information on modular grants is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is available at <http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to Dr. David T. George at the address listed under WHERE TO SEND INQUIRIES.

APPLICATIONS PROCESSING: Applications must be received on or before the application receipt date listed in the heading of this RFA. If an application is received after this date, it will be returned to the applicant without review.

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

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

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by NIBIB and the Roadmap project team. Incomplete and/or non-responsive applications will not be reviewed.

Applications that are complete and responsive to this RFA will be evaluated for scientific and technical merit by an appropriate peer-review group convened by NIBIB in accordance with the review criteria stated below. As part of the merit review, all applications will:

- o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score
- o Receive a written critique
- o Receive a second level of review by National Institute of Biomedical Imaging and Bioengineering Advisory Council.

REVIEW CRITERIA

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 the 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:

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

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.

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 concept, 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?

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.

o Since this RFA invites innovative research applications of unproven feasibility, the “Significance” and “Innovation” review criteria are especially important and should be emphasized.

o Preliminary data are optional and will not be a major criterion at review. Greater emphasis will be placed on the proposed strategy based on the combined insight, knowledge and experience of the research group, and on the potential impact of the proposed research.

o Applicants need not have publications in the immediate research topics proposed in the application, but should have a record of accomplishment in relevant research areas to show they are capable of carrying out the proposed work.

o Applicants should address the stated goal of developing new probes that will achieve one to two orders of magnitude improvement in the ability to detect and image specific molecular events in vivo, and also have potential for clinical applications.

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 criteria included in the section on Federal Citations, below).

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and sub-groups), 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 Inclusion Criteria in the sections on Federal Citations, below).

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL REVIEW CONSIDERATIONS

SHARING RESEARCH DATA: All applications must include a data sharing plan (see “SPECIAL REQUIREMENTS” section). The adequacy of the data sharing plan will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or priority score.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research will be assessed.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: September 22, 2004

Application Receipt Date: October 22, 2004

Peer Review Date: March 2005
Council Review: May 2005
Earliest Anticipated Start Date: July 1, 2005

AWARD CRITERIA

Award criteria that will be used to make decisions include:

- o Scientific merit (as determined by peer review)
- o Level of innovation
- o Relevance to program priorities and roadmap priorities
- o Availability of funds

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTIONS: Federal regulations (45CF46) 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 to be gained. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

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 – Amended, October, 2001”, published in the NIH Guide for Grants and Contracts on October 9, 2001 (<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.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects 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 that is available at <http://www.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 subjects participants for all investigators submitting NIH proposals for research involving human subjects. This policy announcement can be found in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, 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 hESC’s can be found at <http://stemcells.nih.gov/index.asp> and at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-005.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 RFA 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 the question “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: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URL’s) 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 RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of “Healthy People 2010” at <http://www.healthypeople.gov>.

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 of 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.

[Return to Volume Index](#)

[Return to NIH Guide Main Index](#)



Department of Health
and Human Services



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