

TRAINING FOR A NEW INTERDISCIPLINARY RESEARCH WORKFORCE

RELEASE DATE: December 16, 2003

RFA Number: RFA-RM-04-015

Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATION:

National Institutes of Health (NIH)

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

This RFA is developed as a roadmap initiative. All NIH Institutes and Centers participate in roadmap initiatives.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER(S): 93.849

LETTER OF INTENT RECEIPT DATE: February 10, 2004

APPLICATION RECEIPT DATE: March 10, 2004

THIS RFA CONTAINS THE FOLLOWING INFORMATION

- o Purpose of this RFA
- o Research Objectives
- o Mechanism(s) 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

The purpose of this RFA is to encourage and enable the development of an interdisciplinary workforce by ensuring that undergraduate, pre-doctoral, and postdoctoral students receive the didactic and research experiences necessary to lead and/or engage in integrative and team approaches to solve complex biomedical and health problems. To accomplish this aim, the National Institutes of Health invites applications for developing and implementing novel training programs focused on new interdisciplinary science. These programs will support a variety of new and innovative didactic and research activities designed to provide students with the necessary knowledge and research experience to apply interdisciplinary solutions to complex biomedical and health problems. Applicants are encouraged to build these new training programs around existing institutional research programs, whether formal (e.g., research programs supported by program project, center, or cooperative agreement mechanisms) or informal (e.g., loose networks of collaborating R01 grantees).

RESEARCH OBJECTIVES

The National Institutes of Health (NIH) is engaged in a series of activities collectively known as the “NIH Roadmap” whose goal, in keeping with the NIH mission of uncovering new knowledge about the prevention, detection, diagnosis, and treatment of disease and disability, is to accelerate both the pace of discovery in these key areas and the translation of therapies from bench to bedside. In the course of developing the NIH Roadmap, it has become clear that increasingly, scientific advances are being made at the interfaces of traditional disciplines, and that approaches to science are becoming more integrative. This requires a cooperative effort, typically in the form of investigators from diverse research backgrounds working collectively across traditional disciplinary boundaries to answer scientific questions and achieve specific endpoints. This also requires a workforce capable of crossing disciplinary boundaries and leading and participating in integrative and team approaches to complex biomedical and health problems. Building research teams for the future has therefore emerged as one of the major themes in Roadmap implementation. (Additional information about the NIH Roadmap can be found on the NIH website at: <http://nihroadmap.nih.gov/>)

NIH is particularly interested in developing a new interdisciplinary research workforce. An interdisciplinary approach is distinguished from a multidisciplinary approach in that a multidisciplinary approach brings experts from diverse disciplines to address collectively a common complex problem, each from his or her unique perspective. By contrast, an interdisciplinary approach is what results from the melding of two or more disciplines to create a new (interdisciplinary) science. Biophysics, biostatistics, bioinformatics, bioengineering, social neuroscience, and psychoneuroimmunology are just some examples of existing interdisciplinary sciences. NIH recognizes the value and enormous contributions that existing interdisciplinary approaches have made and are making to our understanding of health, disease, and disability. However, the Roadmap is focused on

developing new interdisciplinary approaches and therefore the necessary interdisciplinary workforce.

NIH is announcing a series of initiatives that will provide investigators with the training to effectively lead and engage in integrative and team approaches to complex biomedical and health problems. These initiatives fall into three categories: programs for long-term interdisciplinary research training; short-term courses and research experiences; and curriculum development. Collectively, the initiatives provide opportunities for integration of disciplines at all stages of investigators' careers, facilitate communication among the disciplines, and support the development of infrastructure to accomplish the building of the workforce for the research teams for the future. Common features of the proposed initiatives include having: comprehensive integrative approaches to solving complex biomedical and health-related problems; developing and implementing new curricula that integrate disparate disciplines; activities that promote cohesiveness among training program participants at all levels (faculty-student, student-student, and faculty-faculty); inclusion of training in the personal and professional skills necessary to lead and participate in multidisciplinary teams; outreach to the under-represented minority community to ensure their participation; monitoring of student progress and outcome; and self-evaluation of the training program.

NIH recognizes that multidisciplinary approaches may be a necessary step in the evolution of interdisciplinary research training, and currently offers many opportunities and mechanisms to support multidisciplinary research training. However, for the purposes of the Roadmap's interdisciplinary research training RFAs, activities that facilitate communication among different disciplines, promote but perhaps do not completely achieve integration of different disciplines in the proposed project period, or propose training in multidisciplinary approaches as a precursor to interdisciplinary research training, are acceptable only if they include a detailed plan with appropriate milestones for achieving the Roadmap goal of developing interdisciplinary research training.

Additional information on initiatives associated with building research teams of the future can be found on the NIH website at <http://nihroadmap.nih.gov/>.

Specific Objectives:

The goal of the initiative described below is to enable the development of a cadre of interdisciplinary research scientists by capitalizing on the infrastructure of existing multidisciplinary and interdisciplinary research programs. This announcement is intended to be broad enough to encourage the building of training programs for students at the undergraduate, pre-doctoral, and/or postdoctoral levels. Applicants may propose programs that target one level of student or a combination of them. All programs are expected to provide to each group of students a comprehensive research

training experience. Special program requirements are outlined below. The choice of scientific areas to target for interdisciplinary research training is left to the applicants and may include any combination of the individual areas encompassed by the NIH mission. Some examples of these include: behavioral sciences, social sciences, molecular biology, mathematics, engineering, chemistry, economics, ethics, computer science, and many others. Programs are expected to combine two or more of these areas and provide a comprehensive research training experience to the students.

NIH strongly encourages potential applicants to discuss their ideas with program staff listed in the Where to Send Inquiries section and to send a letter of intent before submission to ensure that the application will be responsive to the NIH mission and the intent of this RFA.

MECHANISM OF SUPPORT

This RFA will use the new T90 award mechanism, which combines research and NRSA authorities in a single mechanism. (See SUPPLEMENTARY INSTRUCTIONS section for additional information.) Applicants may request a project period of up to five years. As an applicant you will be responsible for planning, directing, and executing the proposed training program. This RFA is part of the NIH Roadmap activities and is a one time solicitation. At the end of the five-year project period, acceptance of applications for competing renewals or for new programs will be at the discretion of individual NIH institutes and centers.

The anticipated award date is 09/30/04.

FUNDS AVAILABLE

The NIH intends to commit approximately \$6,000,000 in FY 2004 to fund approximately 10-12 training programs in response to this RFA. An applicant may request a project period of up five years and a first year budget of \$125,000 total costs for a program focused on undergraduate students and up to \$600,000 total costs for a program focused on pre-doctoral and/or postdoctoral students. Because the nature and scope of the proposed training 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 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 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 Eligible agencies of the Federal government
- o Domestic or foreign institutions/organizations
- o Faith-based or community-based organizations

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

SPECIAL REQUIREMENTS

The NIH recognizes that individual institutions will be positioned to respond in different ways to the opportunities presented in this RFA. However, all programs are expected to provide comprehensive interdisciplinary research training experiences for the students and trainees.

All applications should address the challenges of melding two or more different fields and their associated cultures at the student, faculty, and institutional levels. Successful programs will have addressed the following:

- o Scientific environment - is expected to be strongly collaborative and interdisciplinary. Evidence for this infrastructure may include co-authored publications, collaborative research projects, joint service on dissertation committees, team teaching of courses, and regular interactions in journal clubs or seminar series, among other activities.

- o Curriculum and degree requirements - for undergraduate and pre-doctoral students, both curriculum and degree requirements should avoid extending time to degree; alternatively, a plan for tailoring degree requirements and a description of milestones for accomplishing the plan should be included. For undergraduate and postdoctoral students, specific courses and attendance requirements should be identified.

o Program self-evaluation – the program should determine its baseline with respect to interdisciplinary student training, set measurable goals for itself, and establish milestones and measures of success for achieving them. Applications proposing programs still on the evolutionary path from multidisciplinary to interdisciplinary training should include clear goals and milestones to mark that path and determine progress.

o Institutional commitment – may be indicated via a letter from a high-ranking institutional official that outlines (1) how the proposed program fits within the institution's broader vision with respect to the targeted interdisciplinary area; and (2) how institutional barriers to interdisciplinary research will be or are being addressed; and (3) indicates plans for support of students participating in the training program if the parent grant fails to compete successfully for renewal.

Trainee and faculty attendance at annual meeting – students, trainees and associated faculty supported by the program will be expected to attend a one to two day annual meeting to be held in Bethesda or other suitable location each year. The meeting will highlight the breadth and interdisciplinary nature of the research being conducted and will be a networking node for students, associated faculty, and NIH staff.

Trainee reporting requirements – programs will be required to submit trainee appointment forms for all students supported by the program and to track students who are no longer supported by but are still associated with the program.

In addition, successful applicants will have addressed the following program features:

o Applicant pool – students in the targeted disciplines who have potential for participating in the training program should be clearly identified. The application should also include any recruitment and outreach plans to increase the depth and ethnic diversity of the student pool. Institutions that already have one or more NRSA pre-doctoral or postdoctoral training grants should address how the student pool for the proposed program is distinct from or relates to that for existing training grants.

o Rotations and internships – are highly encouraged and should be of sufficient duration and rigor to ensure that the students produced by this program are at a minimum conversant in the two or more targeted fields and preferably, truly interdisciplinary scientists.

o Mentoring – should be substantively shared by faculty members representing each of the targeted disciplines; formal co-mentoring is strongly encouraged.

o Student interactions – must be of sufficient quantity and quality to ensure that the students and associated faculty develop an internal sense of the identity of their interdisciplinary field and its rewards and challenges. Examples of mechanisms for

fostering program cohesiveness include seminar series with presentations from students, faculty, and invited guests; retreats; and journal clubs.

Leadership and teambuilding skills – will be critical to the future success of the students produced by these programs. Plans should be developed and put in place to help students and interested faculty develop the leadership skills and understanding of the challenges of group dynamics necessary to establish and maintain a genuinely integrated research program.

Responsible conduct of research – plans for training in this area must be included.

Monitoring of students – should be an integral part of the program, with close attention paid to retention in the program and to time to degree (for undergraduate and pre-doctoral students).

Academic and career advice – will be an important factor in the success of these training programs since they will be producing the first generation of students in new interdisciplinary sciences. Students should be apprised of the broad range of career options as well as instructed in how to apply successfully for research funding.

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/research training, peer review, and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Terry Rogers Bishop, Ph.D.
Training and Careers Program Director
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Boulevard, Room 619
Bethesda, MD 20892-5458
Telephone: (301) 594-7726
Fax: (301) 480-3510
Email: tb232j@nih.gov

o Direct your questions about peer review issues to:

Francisco O. Calvo, Ph.D.
Chief, Review Branch
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Boulevard, Room 752
Bethesda, MD 20892-5456
Telephone: (301) 594-8897

Fax: (301) 480-3505
E-mail: fc15y@nih.gov

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

Donna Huggins
Supervisory Grants Management Specialist
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Boulevard, Room 711
Bethesda, MD 20892-5456
Telephone: (301) 594-8848
Fax: (301) 480-3504
E-mail: dh48v@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

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 at the beginning of this document. The letter of intent should be sent to:

Chief, Review Branch
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Boulevard, Rm. 752
Bethesda, MD 20892-5452
(for express/courier service: Bethesda, MD 20817)
Telephone: (301) 594-8897
Fax: (301) 480-3505

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Pay particular attention to

instructions for INSTITUTIONAL NATIONAL RESEARCH SERVICE AWARD (Section V. in the PHS 398 instructions). 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 DUNS number can be obtained by calling (866) 705-5711 or through the web site at <http://www.dunandbradstreet.com/>. The DUNS 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.

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 also available at: <http://grants.nih.gov/grants/funding/phs398/labels.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
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:

Chief, Review Branch
National Institute of Diabetes and Digestive and Kidney Diseases
6707 Democracy Boulevard, Room 752
Bethesda, MD 20892-5452
(for express/courier service: Bethesda, MD 20817)

APPLICATION 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 that 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.

SUPPLEMENTARY INSTRUCTIONS:

Allowable costs:

Two budget pages (NRSA SUBSTITUTE FORM PAGE 4, in PHS 398) will be submitted

to distinguish requested funds for NRSA-qualified and non-NRSA-qualified trainees. Please refer to NRSA Guidelines for eligibility (<http://grants.nih.gov/training/nrsa.htm#policy>). Briefly, NRSA-qualified trainees are either pre-doctoral students or post-doctoral fellows AND either a U.S. citizen or U.S. permanent resident. Non-NRSA-qualified trainees are either college students or non-U.S. students or fellows. Also, applications from foreign institutions will be considered under non-NRSA guidelines. Funds for NRSA-qualified individuals will be for stipends and funds for non-NRSA-qualified individuals will be salaries.

PHS2271 (Statement of Activation) has been approved and shall be used to initiate each trainee or student on the T90 program. Likewise PHS416-7 will be used for termination notices.

Support for students: Under the T90 mechanism, both foreign and domestic students at any level may be supported. However, no student may be supported by the program for more than three years.

Undergraduate students – up to NRSA levels in place at the time of award. To qualify for support by the program, a student must be enrolled full time in a program that will lead to a BS or BA degree.

Pre-doctoral students – up to NRSA levels in place at the time of award. To qualify for support by the program, a student must be enrolled full time in a program that will lead to a Ph.D. or equivalent doctoral degree.

Postdoctoral fellows – up to NRSA levels in place at the time of award. To qualify for support by the program, a fellow must be employed full time.

Training related expenses :

- o Faculty release time - up to 10 percent salary support for the development of courses or curricula for the training program.
- o Travel, supplies – up to \$2,000 for undergraduates; \$3,000 for pre-doctoral students and faculty mentors and program director; and \$5,000 for postdoctoral students - to help defray the cost of attending the annual meeting.

Tuition, Fees, and Health Insurance: The NIH will offset the combined cost of tuition, fees, and health insurance (either self-only or family as appropriate) at the following rate: 100 percent of all costs up to \$3,000 and 60 percent of costs above \$3,000. Costs associated with tuition, fees, and health insurance are allowable only if they are applied consistently to all persons in a similar research training status at the institution regardless of the source of support. A full description of the tuition policy is contained within the Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2001/part_iib_4.htm#_Toc504812072.

Other Trainee Costs: Trainee travel, including attendance at scientific meetings that the institution determines to be necessary to the individual's research training, is an allowable trainee expense. In addition, support for travel to a research training experience away from the institution may be permitted. Research training experiences away from the parent institution must be justified considering the type of opportunities for training available, the manner in which these opportunities differ from and compliment those offered at the parent institution, and the relationship of the proposed experience to the trainee's career stage and goals. This type of research training requires prior approval from the NIH. Letters requesting such training may be submitted to the NIH awarding component at any time during the award period. Under exceptional circumstances, which can include providing accommodations for a trainee with disabilities, it is possible to request institutional costs above the standard rate. Requests for additional trainee costs must be explained in detail and carefully justified in the application. Consultation with NIH program staff in advance of such requests is strongly advised.

Training Related Expenses: Institutional costs of \$2,200 a year per predoctoral trainee and \$3,850 a year per postdoctoral trainee may be requested to defray the costs of other research training related expenses, such as staff salaries, consultant costs, equipment, research supplies, and travel expenses for the training faculty. Training related expenses may be adjusted in future fiscal years.

Facilities and Administrative Costs: A facilities and administrative allowance (indirect cost allowance) based on 8 percent of total allowable direct costs (this excludes amounts for tuition, fees, health insurance, and equipment) may be requested. Applications from state and local government agencies may request full indirect cost reimbursement. Information on Facilities and Administrative Costs is available in the Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2001/part_iib_4.htm#_Toc504812080.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by NIDDK. Incomplete and/or nonresponsive applications will not be reviewed.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NIDDK in accordance with the review criteria stated below. As part of the initial 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 review by an appropriate national advisory council or board.

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, reviewers will be asked to evaluate 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 the following criteria in assigning the application's overall score, weighting them as appropriate for each application.

Program direction:

- o Research and training leadership and experience of the PI
- o Adequacy of the program administration and advisory structure

Participating faculty members:

- o Composition of the faculty (by rank and distribution in different fields and departments)
- o Mechanism and criteria for inclusion of the faculty in the program
- o Publication records
- o Nature and breadth of research in areas pertinent to this announcement
- o Evidence of collaboration and cooperation
- o Experience in the supervision of research training

Training program:

- o Goals of program and rationale for program organization
- o Mechanism for the selection and recruitment of students
- o Mechanism to monitor and guide the students
- o Nature and extent of research opportunities, courses, seminars, etc. in targeted scientific areas

- o Provisions/activities to promote cohesiveness in the program
- o Opportunities for collaboration
- o Integration of the targeted disciplines or adequacy of plans for integration
- o Flexibility for students to take courses, rotations, and mentorships in targeted scientific areas
- o Appropriateness of training experiences for level of student targeted
- o Degree of innovation and potential to impact the research and training culture at the institution

Student pool:

- o Availability of highly qualified candidates (scientific background, academic credentials)
- o Caliber of current (if any) and/or potential students and others identified with the program (may be demonstrated by grades, standardized test scores, publication records, and other means)
- o Publication records of past and current trainees

Research and training environment:

- o Institutional support for the training program
- o Adequacy of plans for student support should the parent grant fail to compete successful for renewal of funding
- o Other sources of training support available
- o Facilities and resources available to the program

Minority recruitment and retention plan:

- o Nature and adequacy of plan

Foreign institutions:

- o Justification of a unique setting or availability of unique resources that are not available in the U.S.

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 subgroups), and children as appropriate for the scientific goals of the research. 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.

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

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: February 10, 2004
Application Receipt Date: March 10, 2004
Peer Review Date: June/July 2004
Council Review: September 2004
Earliest Anticipated Start Date: September 30, 2004

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

- o Scientific merit (as determined by peer review)
- o Availability of funds
- o Programmatic priorities.

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://ohrp.osophs.dhhs.gov/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). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk 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: Starting with the October 1, 2003 receipt date, investigators submitting an NIH application seeking more than \$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 - 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 are 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. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

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://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 proposals for research involving human subjects. You will find this policy announcement 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 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). Those who must comply with the Privacy Rule (classified under the Rule as “covered entities”) must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

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 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 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.

[Return to Volume Index](#)
[Return to NIH Guide Main Index](#)



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