

MULTIDISCIPLINARY CLINICAL RESEARCH CENTERS

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Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATION:

National Institutes of Health (NIH)

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

COMPONENT OF PARTICIPATING ORGANIZATION:

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

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

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER (S): 93.846

LETTER OF INTENT RECEIPT DATE: January 24, 2005

APPLICATION RECEIPT DATE: February 24, 2005

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 National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites new and renewal applications for Multidisciplinary Clinical Research Centers (MCRCs) in arthritis and/or musculoskeletal disorders and/or skin diseases. Each MCRC will be organized around a methodology core and will be expected to include a minimum of three highly meritorious projects encompassing clinical research drawing from different disciplines. The methodology core will be the foundation of the center, providing key support for development and implementation of clinical projects. Each project must address a critical issue that directly involves prevention, assessment and/or outcomes for patients with one or more of the many chronic diseases within the mission of the NIAMS.

RESEARCH OBJECTIVES

The goals of the MCRC program are to prevent disease and to assess and improve outcomes for patients with arthritis and other rheumatic diseases; musculoskeletal disorders including orthopaedic disorders, bone diseases and muscle diseases; and skin diseases. For a comprehensive listing of the disease areas covered in the NIAMS extramural programs, please see <http://www.niams.nih.gov/rtac/funding/faq.htm>

o Any given MCRC will not be expected to include all disease areas defined above or all clinical approaches included in the NIH definition of clinical research. An MCRC can focus on one or more disease areas, e.g. arthritis or skin diseases, but should not focus on just one disease, e.g. osteoarthritis or psoriasis. Two or more clinical approaches (patient-oriented research, epidemiologic and behavioral studies, outcomes research and health services research) must be encompassed by the projects supported in the MCRC.

o Each MCRC will define its research base, goals for promoting clinical research utilizing that research base, and how multidisciplinary research will be promoted. The interaction with a General Clinical Research Center (GCRC), if present, must be documented.

o An MCRC is not a mechanism to support a large or complex clinical trial, but proof of concept trials may be appropriate. In addition, research on animals and animal models should not be proposed in the MCRC application.

The key elements of an MCRC will include:

1. a Center Director, Associate Director and an executive committee with outstanding credentials for promoting clinical research;
2. a research base that encompasses diseases/disorders within the NIAMS mission and provides professional and patient resources for developing clinical projects using more than one clinical research approach;

3. a methodology core that will play a key role in the design and implementation of ALL projects supported through the center; and
4. a minimum of three highly meritorious clinical research projects that utilize the methodology core and encompass one or more disease areas, e.g. arthritis or skin diseases, but not just one disease, e.g. osteoarthritis or psoriasis, within the NIAMS mission.

Optional elements of an MCRC are (a) one development and feasibility project supported by the methodology core and lasting no more than three years and (b) other core(s) supportive of two or more of the proposed projects.

The Director of the MCRC, aided by an Associate Director, an executive committee and the methodology core, is expected to provide leadership to focus all research projects on clinically relevant issues to improve patient outcomes and to assure a rigorous research approach. The proposed director must document this leadership with examples of the ability to network with colleagues from clinical and other areas of biomedical research. Plans for data sharing must be described in the Administrative Core.

A methodology core is a required component of the MCRC and must serve all projects proposed in the center. The core should have sufficient professional personnel to provide an interactive leadership role not only in supporting the projects within the MCRC, but also promoting rigorous methodologic and biostatistical support for the research base. The methodology core should also provide oversight plans for data safety and monitoring issues. Other cores supporting two or more of the research projects proposed may be requested.

A minimum of three highly meritorious clinical research projects, each with a focus to prevent disease or to assess and/or improve outcomes for patients, must be present in an MCRC. Each project will define the patient problem under study and the anticipated improvement in assessment and/or outcome for the patient that might be realized through this project. The projects must represent two or more general areas of clinical research.

An optional component in an MCRC is one development and feasibility project lasting no more than three years and with a budget of \$20,000 - \$50,000 a year. The goal of the development and feasibility project should be to gather preliminary data or to develop a resource for a future study.

MECHANISM OF SUPPORT

This RFA will use the NIH P60 award mechanism. As an applicant you will be solely responsible for planning, directing, and executing the proposed project. This RFA is the first of three yearly RFAs planned. The earliest anticipated award date in response to this RFA is January 1, 2006.

This RFA uses just-in-time concepts. The instructions for non-modular budget

research grant applications should be followed. 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

NIAMS intends to commit approximately \$3.6 million in FY 2006 to fund 3 new and/or competitive continuation applications in response to this RFA. An applicant may request a project period of up to 5 years and a budget for direct costs of up to \$800,000 per year (excluding F&A costs of subcontracts). Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the NIAMS provides 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(s) if your domestic institution has any of the following characteristics

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities or hospitals
- o Units of State and local governments
- o Eligible agencies of the Federal government

- o Foreign institutions are not eligible to apply.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are 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 Director and Associate Director should budget for an annual two-day meeting with NIAMS staff and other MCRC directors.

All applications will be expected to address data sharing as indicated at http://grants.nih.gov/grants/policy/data_sharing. Therefore, the Administrative Core should include a plan for data sharing from the center projects or state why this is not possible.

Each project must discuss recruitment and retention of patients, clinical expertise and facilities needed, and a data safety and monitoring plan. It is not anticipated that a Data

Safety and Monitoring Board will be required for oversight of an MCRC study because multi-site or complex clinical trials are generally not appropriate for the MCRC mechanism. However, if the patient population is at some significant risk, a Data Safety and Monitoring Board should be proposed. For most studies, an independent Safety Officer, not affiliated with the institution, will be appropriate. The methodology core should detail support for the data safety and monitoring issues for the projects proposed. NIAMS has developed guidelines for data safety and monitoring plans: <http://www.niams.nih.gov/rtac/clinical/index.htm>. If the application is funded, the investigators will be expected to provide detailed methods of operating procedures, patient consent forms, and updated data and safety monitoring plans.

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:

Charisee Lamar, Ph.D., M.P.H.
Multidisciplinary Centers and Diversity Programs
National Institute of Arthritis and Musculoskeletal and Skin Diseases
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872
Telephone: (301)594-5052
FAX: 301-480-4543
Email: lamarc@mail.nih.gov

o Direct your questions about peer review issues to:

Tommy Broadwater, Ph.D.
Chief, Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872
Telephone: (301) 594-4952
FAX: (301) 402-2406
Email: broadwat@mail.nih.gov

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

Melinda Nelson
Chief, Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872

Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: nelsonm@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

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 NIAMS 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:

Charisee Lamar, Ph.D., M.P.H.
Multidisciplinary Centers and Diversity Programs
National Institute of Arthritis and Musculoskeletal and Skin Diseases
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872
Telephone: (301)594-5052
FAX: 301-480-4543
Email: lamarc@mail.nih.gov

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 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.

SUPPLEMENTARY INSTRUCTIONS:

Guidelines are available for the MCRC program at

http://www.niams.nih.gov/rtac/funding/grants/centers_programs.htm#P60.

These guidelines are intended to assist the applicant in assembling an application in a manner to facilitate an optimal review of the complex topics covered in the application.

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, 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:

Tommy Broadwater, Ph.D.
Chief, Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872
Telephone: (301) 594-4952
FAX: (301) 402-2406
Email: broadwat@mail.nih.gov

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.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by NIAMS. Applications that are not complete or not responsive to the RFA will be returned to the applicant.

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 NIAMS 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 the National Arthritis and Musculoskeletal and Skin Diseases 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 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. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that 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.

Each project and core (including the administrative unit) will be individually reviewed for scientific merit and a rating assigned by committee consensus. Merit ratings will also be provided for other center elements, i.e. qualifications of the center leadership, the research base, the institutional environment and resources. If a competitive renewal is being sought, the progress during the previous funding period will also be evaluated. To be funded, there must be a highly meritorious methodology core and at least three highly meritorious projects (not including the developmental/feasibility project, if any).

Review Criteria for MCRC Leadership:

Do the Director and Associate Director have the leadership and research qualifications to lead a Center? Does the leadership team (Director, Associate Director, and executive committee) have the collective expertise to assure focused development and implementation of high quality and meaningful clinical research projects?

Review Criteria for Research Base:

Is there a substantial productive and funded research base? Is the research base sufficiently broad to foster new multidisciplinary research? Is there a definition of who will be a Center investigator and what this designation might mean?

Review Criteria for Institutional Base:

Is there evidence of a supportive institutional environment for the proposed MCRC? Will the MCRC add an important multidisciplinary element to the institutional environment? Does the proposed MCRC utilize available resources well? Is there support and commitment from the institutional authorities?

Review Criterion for Applications Seeking Competitive Renewal:

Does the progress report reflect significant accomplishments? Has any work been published or are publications likely?

Review Criteria for Administrative Unit:

1. Do the proposed MCRC Director, Associate Director and executive committee have the collective expertise and leadership to identify and focus research projects on clinically relevant issues?

2. Is the management proposed appropriate for scientific administration as well as fiscal administration, procurement, property and personnel management, planning, budgeting, etc.?

3. Is there a plan for establishment and maintenance of internal communication and cooperation among the MCRC investigators, core leaders and executive committee? Are there plans for outside review and input?

4. Is there scientific and administrative leadership, commitment and ability, and adequate time commitment of the MCRC Director and Associate Director for the effective management of the MCRC program?

5. Is there documentation of institutional support for the MCRC by the parent institution?

6. Is a plan for data sharing included?

Review Criteria for Methodology Core:

1. Does the methodology core serve all projects proposed in the Center (mandatory)? Have issues relating to data and safety monitoring been addressed? Is there a plan describing teaching services for the research base?
2. Are the services offered appropriate and of high quality, especially for the projects directly supported? How is cost reimbursement proposed?
3. Will the core likely promote multidisciplinary research? Are unique services offered? Is there a plan for prioritizing services to the research base?
4. Are the qualifications of the professional and support personnel appropriate? Is there a plan for interactive leadership of the methodology core and the proposed projects?
5. Are the facilities and equipment adequate? Is there institutional commitment to the core?

Review Criteria for Other Cores:

1. Will the core have utility to at least two of the MCRC projects?
2. Are the services of high quality? Are there procedures for quality control? Is the core cost effective?
3. Do the services offered best fit within a core structure? If this is an add-on to a preexisting core, what is the benefit to the Center over direct purchase of services from the existing core? If the core offers new services that may be used by non-MCRC projects, how will the non-MCRC projects purchase these services from the core?
4. Are the personnel appropriate?
5. Are the facilities and equipment adequate? Is there institutional commitment to the core?

Review Criteria for Research Projects:

Significance: Does this project address an important clinical issue, especially one not well studied? Is it likely that the research may have a clinically important impact? Will these studies influence 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 investigator acknowledge potential problem areas and consider alternative tactics? Does the project utilize the multidisciplinary resources of the Center, especially the Methodology Core? Is a data safety and monitoring plan included, if appropriate?

Innovation: Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies? (The quality of the idea or the extent to which the research will advance theory or practice should outweigh an emphasis on technical excellence.)

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 collaborators?

Environment: Does the scientific environment of the Center contribute to the probability of success? Do the proposed experiments take advantage of unique features of the Center and employ useful collaborative arrangements?

Review Criteria for Development and Feasibility Project (Optional):

Significance: Does this project address an important problem? If the aims of the application are achieved, will the work be the basis for a full research proposal?

Approach: Does the project utilize the expertise of the methodology core? Does the investigator acknowledge potential problem areas and consider alternative tactics? Does the project utilize the multidisciplinary resources of the MCRC?

Innovation: Does the project employ sound concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies? (The quality of the idea or the extent to which the research will advance theory or practice should outweigh an emphasis on technical excellence.)

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 collaborators?

Environment: Does the scientific environment of the Center contribute to the probability of success? Do the proposed experiments take advantage of unique features of the Center and employ useful collaborative arrangements?

After the review of the individual components of the application, an application may be judged non-competitive and not scored, or may be assigned an overall priority score. This score will reflect not only the individual quality of the projects, cores, and administration, but also how the proposed MCRC will bring together all these elements in a workable unit. The overall score may be higher or lower than the average of the descriptors based on the assessment of whether the whole is greater than the sum of its parts. The overall priority score will reflect:

1. The scientific excellence of the Center's research base as well as the relevance and interrelationship of these separately funded research projects

to the goals of the Center and the likelihood for meaningful collaboration among Center investigators. The application must convey how the proposed Center will enhance significantly the established research base of the host institution.

2. The overall environment for a Center. This includes the institutional commitment to the program, including lines of accountability regarding management of the Center, the institution's partnership with the Center, and the institutional commitment to individuals responsible for conducting essential Center functions. This also includes the academic environment and resources in which the activities will be conducted, e.g., the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and schools.

3. The overall priority score assigned to the application will also reflect how well the policies regarding (a) the inclusion of women, minorities and children in study populations, (b) the protection of human subjects from research risks, (c) sharing research data, and (d) the budget have been addressed.

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).

ADDITIONAL REVIEW CONSIDERATIONS

SHARING RESEARCH DATA

Applicants requesting \$500,000 or more in direct costs in any year of the proposed research must include a data-sharing plan in their application. 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 priority score. All applications will be expected to address data sharing as indicated at

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

This discussion is to be included in the Administrative Core.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The total direct cost cannot exceed \$800,000(excluding F&A costs of subcontracts).

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: January 24, 2005

Application Receipt Date: February 24, 2005

Peer Review Date: June 2005

Council Review: October 2005

Earliest Anticipated Start Date: January 1, 2006

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://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). 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: 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 - 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://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 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 “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. 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



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