

RESEARCH PARTNERSHIPS FOR IMPROVING FUNCTIONAL OUTCOMES

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Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATIONS:

National Institutes of Health (NIH)

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

Agency for Healthcare Research and Quality (AHRQ)

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

COMPONENTS OF PARTICIPATING ORGANIZATIONS:

National Institute of Child Health and Human Development (NICHD)

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

National Cancer Institute (NCI)

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

National Eye Institute (NEI)

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

National Heart, Lung, and Blood Institute (NHLBI)

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

National Institute on Aging (NIA)

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

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

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

National Institute on Deafness and Other Communication Disorders (NIDCD)

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

National Institute of Neurological Disorders and Stroke (NINDS)

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

National Institute of Nursing Research (NINR)

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

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THIS PA CONTAINS THE FOLLOWING INFORMATION

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PURPOSE OF THIS PA

Participating Institutes and Centers (ICs) of the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ) invite applications for R01 awards to support Research Partnerships for Improving Functional Outcomes (RPIFO) for basic, applied, and translational multi-disciplinary research that addresses important biological, behavioral, medical, and/or psychosocial research problems related to rehabilitation or health maintenance of individuals with acute or chronic disease. In the context of this program, a “partnership” is a multi-disciplinary research team that applies an integrative, systems approach to develop knowledge and/or methods to improve functioning, promote health, and increase participation in community life. The partnership must include appropriate individuals with clinical expertise related to rehabilitation in combination with biomedical, psychosocial-behavioral, engineering, epidemiological, and/or health services researchers. The Principal Investigator (PI) also serves as the project manager and must be capable of leading the proposed research and partnership. An RPIFO may propose outcomes-directed, developmental, discovery-driven, translational or hypothesis-driven research at universities, national laboratories, medical or nursing schools, large or small businesses, or other public and private entities or combinations of these entities. It is expected that an RPIFO will have a well-defined, public health-related goal that can be assessed based on objective milestones.

RESEARCH OBJECTIVES

Background

An increasing proportion of the nation's health care expenditures is devoted to the care of individuals with chronic diseases and disorders, many of whom experience significant declines in their abilities to perform activities of daily living and participation in community life. Effective solutions for rehabilitation of these individuals have the potential to significantly improve the nation's utilization of increasingly constrained health care resources. Rehabilitation is by its very nature a multi-disciplinary activity.

Solving many of the complex research problems in rehabilitation will require a multi-disciplinary approach that extends well beyond the traditional professional boundaries of rehabilitation, and incorporate interdisciplinary collaborations of investigators with broad-ranging technical, clinical, and research expertise. In addition, new, emerging technologies and resources that allow us to attack difficult, large-scale problems are becoming available from diverse technical and biomedical fields and cross the boundaries of many scientific disciplines represented throughout academia, laboratories, and industry.

Recognizing the importance of rehabilitation to all areas of medical care, Congress mandated the establishment of the NIH Rehabilitation Coordinating Committee in 1990. This committee has been active in organizing trans-NIH and trans-agency conferences to highlight issues in rehabilitation and establish research priorities. Abstracts of presentations from the most recent conference, "Physical Disabilities through the Lifespan," are available at <http://www.nichd.nih.gov/about/ncmrr/ncmrr.htm>.

A major recommendation of the conferees at the "Physical Disabilities through the Lifespan" conference is for NIH to develop a new mechanism to allow investigators to address difficult research problems in rehabilitation requiring multi-disciplinary teams. The NIH Rehabilitation Coordinating Committee has developed the current Program Announcement in an attempt to meet this need.

Additionally, the NIH and AHRQ, as part of the U.S. Department of Health and Human Services, have been charged under Executive Order 13217, "The New Freedom Initiative," to help promote the full participation of individuals with disabilities in all areas of society. This Program Announcement is also designed to address the charge from this Executive Order. Researchers who are interested in the community integration of people with severe psychiatric disorders are encouraged to see PA 03-144 (<http://grants.nih.gov/grants/guide/pa-files/PA-03-144.html>).

Research Scope

The objective of this Program Announcement is to encourage basic, applied, and translational research directed towards improving the health of individuals with acute or chronic diseases who may benefit from rehabilitation. Examples of such research encouraged by the NIH include, but are not limited to:

- o Develop and test the efficacy of symptom-focused or holistic/integrated therapies for high prevalence conditions causing disability, such as low back pain, stroke, hearing loss, visual loss, and congestive heart failure, as well as for lower prevalence conditions with high levels of comorbidity, such as spinal cord injury, spina bifida, etc. Randomized clinical trials are especially encouraged. Applicants interested in proposing clinical trials that are of potential interest to the National Institute of Neurological Disorders and Stroke (NINDS) should contact the clinical trial group at NINDS (http://www.ninds.nih.gov/funding/clinical_trials/clinical_research.htm) prior to submitting a formal application.

o Determine the extent to which genetic, environmental, social, and psychological factors determine patient responses to specific rehabilitation interventions; develop and test methods or accommodations for augmenting responses of individuals with risk factors for poor responses.

o Investigate the processes, at a molecular level, that lead to formation of muscle and skin contractures that occur due to inactivity and chronic disease; develop and test the efficacy of targeted interventions based upon these processes. Applicants interested in submitting applications of potential interest to the National Institute of Arthritis and Musculoskeletal Disorders (NIAMS) should refer to the notices for applicants http://www.niams.nih.gov/rtac/funding/grants/notice/not_ar_03_004.pdf prior to submitting a formal application.

o Determine optimal physical and cognitive exercise patterns and schedules to improve functioning in individuals with specific disabilities ranging from inherited childhood disorders, such as muscular dystrophies, to late-life congestive heart failure and sarcopenia.

o Define the optimal setting(s) and timing of rehabilitation strategies, optimal pain protocols, the role of passive range of motion, and the most cost-effective follow-up for patients undergoing hip and knee replacement surgeries.

o Develop algorithms that can be used to match available interventions and technologies to individual patients to optimize functional outcomes; test the validity of these models for clinical populations in diverse environments.

o Using biomechanical modeling, develop and evaluate defined rehabilitation interventions based upon detailed biomechanical analyses of the patterns of muscle activation in specific conditions.

o Test methods to promote the dissemination of evidence-based rehabilitative therapies and technologies from the laboratory or clinic to community environments; studies can include foci on family and community issues (including stigma), self-management and advocacy, health-care policy and financial constraints, and cost-effective sustainability.

o Test methods to promote self-care, positive health behaviors, and health management through the use of behavioral, psychosocial, nutritional, and pharmacological strategies.

o Develop and test the efficacy of alternative delivery systems (e.g., telemedicine), providers, and settings for the rehabilitation of patients with specific diseases or conditions.

o Develop innovative engineering approaches that improve outcomes for individuals with acute stroke and other mobility disorders; investigate their cost-effectiveness and feasibility for use in various clinical settings.

- o Investigate the nature of disability and rehabilitation throughout the lifespan, particularly the special needs of the very young and elders when disability is superimposed on the developmental axis. These investigations may include studies on the interaction of the physiologies of aging and disability as well as studies of motor, sensory, cognitive, and psychosocial functional capability.
- o Studies that evaluate the quality of rehabilitation care in current clinical settings, and link the rehabilitation and quality of care and specific policies and practices to functional and participatory outcomes. Such studies could evaluate the effects of cost constraints on outcomes.
- o Studies related to the impact of reimbursement changes associated with rehabilitation since the Balanced Budget Act of 1997 and the impact of prospective payment on rehabilitation cost and outcomes.
- o Studies that include quality of life outcomes for rehabilitating patients and families; studies that address cost-effectiveness and how health care teams make clinical decisions, and how patients and their families are involved in these decisions.
- o Studies investigating methods to improve the integration of rehabilitation services across multiple settings (e.g., hospitals, nursing homes, home care, primary care, etc.) and the coordination with other care received by patients. Such studies could address methods for improving how clinical information is shared as patients move from hospitals to rehabilitation centers, to homes, and back to hospitals, etc., and the impact on outcomes.
- o Studies that target priority populations (e.g., women, children, elderly, low income groups; minority groups; individuals with special health care needs, including those with disabilities and those who need chronic care or end-of-life health care) and the identification and reduction of disparities in health care.

MECHANISM OF SUPPORT

This PA will use the NIH Research Project Grant (R01) award mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The initial period of support of an RPIFO award may be up to five years.

This PA uses just-in-time concepts. It also uses the modular 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 format. Otherwise follow the instructions for non-modular research grant applications. Please note that applications assigned to AHRQ will be required to submit a nonmodular budget after the initial submission. This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2001/part_I_1.htm.

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 national laboratories
- o Units of State and local governments
- 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 his/her 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.

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity answer questions from potential applicants. Inquiries may fall into two areas: scientific/research and financial or grants management issues:

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

Michael Weinrich, M.D., Director
National Center for Medical Rehabilitation Research
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 2A03, MSC 7510
Bethesda, MD 20892-7510
Rockville, MD 20852 (for express/courier service)
Telephone: (301) 402-4201
FAX: (301) 402-0832
Email: mw287k@nih.gov

Noreen M. Aziz, M.D., Ph.D., M.P.H.
Program Director, Office of Cancer Survivorship
Division of Cancer Control & Population Sciences
National Cancer Institute
6130 Executive Boulevard, Room 4090, MSC 7340
Bethesda, MD 20892-7340
Rockville, MD 20852 (for express/courier service)

Telephone: (301)-496-0598
FAX: (301)-594-5070
Email: na45f@nih.gov

Michael D. Oberdorfer, Ph.D.
Division of Extramural Research
National Eye Institute
6120 Executive Boulevard, Suite 350, MSC 7164
Bethesda, MD 20892-7164
Rockville, MD 20852 (for express/courier service)
Telephone: (301) 451-2020
FAX: (301) 402-0528
Email: mdo@nei.nih.gov

Suzanne Goldberg, R.N., M.S.N.
Clinical and Molecular Medicine Program
Division of Heart and Vascular Diseases
National Heart, Lung and Blood Institute
6701 Rockledge Drive, Room 9174, MSC 7940
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Bethesda, MD 20817(for express/courier service)
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FAX: (301) 480-1336
Email: goldbergsh@mail.nih.gov

Sidney M. Stahl, Ph.D.
Chief, Individual Behavioral Processes Branch
Behavioral and Social Research Program
National Institute on Aging
7201 Wisconsin Avenue, 533, MSC 9205
Bethesda, MD 20892-9205
Telephone: (301) 402-4156
FAX: (301) 402-0051
Email: Sidney_Stahl@nih.gov

James S. Panagis, M.D., M.P.H.
Orthopaedics Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872
Telephone: (301) 594-5055
Email: jp149d@nih.gov

Amy M. Donahue, Ph.D.
Division of Scientific Programs
National Institute on Deafness and Other Communication Disorders

6120 Executive Boulevard, Room 400C, MSC 7180
Bethesda, MD 20892-7180
Telephone: (301) 402-3458
FAX: (301) 402-6251
Email: donahuea@nidcd.nih.gov

Daofen Chen, Ph.D.
Program Director, Channels, Synapses, and Circuits
National Institute of Neurological Disorders and Stroke
6001 Executive Boulevard, Room 2131, MSC 9523
Bethesda, MD 20892-9523
Telephone: (301) 496-1917
FAX: (301) 402-1501
Email: dc342b@nih.gov

Kathy Mann Koepke, Ph.D.
Program Director
National Institute of Nursing Research
6701 Democracy Boulevard, Suite 710, MSC 4870
Bethesda, MD 20892-4870
Telephone: (301) 496-9623
FAX: (301) 480-8260
Email: KoepkeK@mail.nih.gov

Rosalyn Correa-de-Araujo, M.D., M.Sc., Ph.D.
Senior Advisor on Women's Health
Office of Extramural Research, Education, and Priority Populations
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850
Telephone: (301) 427-1550
FAX: (301) 427-1651
Email: rcorrea@ahrq.gov

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

Mr. Chris Robey
Lead Grants Management Specialist
Grants Management Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard, 8A17, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 435-6975
FAX: (301) 402-0915
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6120 Executive Boulevard, Room 234, MSC 7150
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National Heart, Lung and Blood Institute
6701 Rockledge Drive, Room 7164, MSC 7926
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FAX: (301) 480-3310
Email: landerc@nhlbi.nih.gov

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7201 Wisconsin Avenue, Suite 2N212, MSC 9025
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George 'Skip' Moyer
Grants Management Specialist
Agency for Healthcare Research and Quality
OPART/GM
540 Gaither Road
Rockville, MD 20850
Telephone: (301) 427-1452
FAX: (301) 427-1462
Email: smoyer@ahrq.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 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.

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

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. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

SPECIFIC INSTRUCTIONS FOR APPLICATIONS REQUESTING \$500,000 OR MORE PER YEAR: Applications requesting \$500,000 or more in direct costs for any year must include a cover letter identifying the NIH staff member within one of NIH institutes or centers who has agreed to accept assignment of the application.

Applicants requesting more than \$500,000 must carry out the following steps:

- 1) Contact the IC program staff at least six weeks before submitting the application, i.e., as you are developing plans for the study;
- 2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,
- 3) Identify, in a cover letter sent with the application, the staff member and IC who agreed to accept assignment of the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and Contracts, October 19, 2001 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

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

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

APPLICATION PROCESSING: Applications must be received on or before the receipt dates listed on the first page of this announcement.

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

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

PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>) will evaluate applications for scientific and technical merit.

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

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

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

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. The application does not need to be strong in all categories to be judged likely to have major

scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

SIGNIFICANCE: If the specific aims of the RPIFO are achieved, will they provide significant advances in the selected area of rehabilitation research? Is the research likely to have a significant impact on other areas of research? Will the technological advances have a significant impact on human health?

APPROACH: Are the RPIFO rehabilitation, scientific, and clinical approaches and methods adequately developed, well-integrated, and appropriate to the aims of the project? Does the application address potential problem areas and consider alternative strategies? Is a timetable with adequate research milestones proposed? Are appropriate specifications and evaluation procedures provided for assessing progress? Is the proposed partnership adequate for the research? Is there evidence that the partnership will be effectively managed by the PI or project manager? Is the partnership strategy well-planned and documented? Is there evidence that the partners from academia or industry can work together effectively, have an impact on achieving the research goals, and disseminate the treatments, interventions, therapies and technologies developed (including through commercialization)? Is the plan for sharing or disseminating the developments of this proposal adequate? Is the plan for technology transfer involving each partnering organization adequate? Does the application describe arrangements that facilitate the fruitful participation of a partner at a distant site? If partnership with industry or small business is included, does this positively affect the research goals and technology dissemination?

INNOVATION: Does the RPIFO propose new approaches, explore new research paradigms, or represent new concepts that combine rehabilitation, physical, psychosocial, behavioral, engineering, and clinical sciences? Will the proposed approaches or concepts solve current compelling public health problems in novel ways?

INVESTIGATOR: Is the PI capable of coordinating and managing the proposed RPIFO? Are the investigators (partners) appropriately trained in their disciplines and capable of conducting the proposed interdisciplinary work?

ENVIRONMENT: Does the scientific, clinical, and technological environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements within the partnership? Is there evidence of institutional support? Does the partnership create potential opportunities to foster trans-disciplinary communication and training across traditional scientific and clinical boundaries?

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

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See 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 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 CONSIDERATIONS

SHARING RESEARCH DATA: Applicants requesting more than \$500,000 in direct costs in any year of the proposed research are expected to 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.

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

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- o Scientific merit of the proposed project as determined by peer review
- o Availability of funds
- o Relevance to program 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 \$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 PRIORITY POPULATIONS: The Healthcare Research and Quality Act of 1999 (see <http://www.ahrq.gov/hrqa99a.htm>) reauthorized the AHRQ and directed the Agency, in carrying out its mission, to conduct and support research and evaluations, and to support demonstration projects, with respect to the delivery of health care in inner-city and rural areas (including frontier areas); and health care for priority populations,

which include low income groups; minority groups; women; children; the elderly; and individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care. To implement this directive, AHRQ published a notice in the NIH Guide on February 28, 2003, establishing a new Agency policy on the Inclusion of Priority Populations in health services research (see <http://grants.nih.gov/grants/guide/notice-files/NOT-HS-03-010.html>). Applicants under this PA who seek funding from AHRQ should address the requirements of including priority populations as specified in the Notice.

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 PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at <http://www.cfda.gov/> and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the

Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at <http://grants.nih.gov/grants/policy/policy.htm>.

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

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