

HUMAN SUBJECTS RESEARCH ENHANCEMENTS PROGRAM

RELEASE DATE: March 5, 2002

RFA: OD-02-003

APPLICATION RECEIPT DATE: May 7, 2002

National Cancer Institute (NCI)

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

National Center for Complementary and Alternative Medicine (NCCAM)

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

National Center on Minority Health and Health Disparities (NCMHD)

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

National Center for Research Resources (NCRR)

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

National Eye Institute (NEI)

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

National Heart, Lung, and Blood Institute (NHLBI)

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

National Human Genome Research Institute (NHGRI)

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

National Institute on Aging (NIA)

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

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

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

National Institute of Allergy and Infectious Diseases (NIAID)

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

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

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

National institute of Child Health and Human Development (NICHD)

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

National Institute on Deafness and Other Communication Disorders (NIDCD)

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

National Institute of Dental and Craniofacial Research (NIDCR)

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

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

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

National Institute on Drug Abuse (NIDA)

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

National Institute of Environmental Health Sciences (NIEHS)

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

National Institute of Mental Health (NIMH)

<http://www.nimh.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>)

THIS RFA CONTAINS THE FOLLOWING INFORMATION

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

PURPOSE OF THIS RFA

The purpose of this initiative is to provide short-term interim support for institutional activities that will strengthen oversight of human subjects research at institutions that receive significant NIH support for clinical research. While there is considerable flexibility in the types of activities that could be supported under this program, it is important that these enhance the protection of research subjects by means that will be sustained by the institution after the award period ends.

This is a one-time solicitation; it is not anticipated that this RFA will be reissued. While all NIH components supporting clinical research are providing support for this program, it will be administered by the National Center for Research Resources.

RESEARCH OBJECTIVES

Background

The conduct of research on human subjects has come under increasing scrutiny in recent years, and as a consequence, has become the focus of increasing demands for oversight, enhanced protections, and increased education for those conducting the research. Institutions are now aware of the need to ensure greater patient protections, to promote patients' rights and understanding of the research they are part of, and to train their investigative teams in the ethical as well as scientific aspects of human subjects research. However, the added procedures and safeguards create a burden for institutions in providing adequate resources.

Scope of the Activity

Applicants must detail the types of activities they plan to undertake. The following is a list of possible activities, but applicants are not limited to these, and it is not intended that an applicant would be engaged in all of these activities. However, applicants may wish to use these as an indicator of the types of activities that could be proposed:

- o Development of educational initiatives for investigators, administrators and IRB members in the safe and ethical conduct of clinical research
- o Creation of tracking systems for monitoring and coordinating adverse event reporting, including expenses for site monitoring
- o Infrastructure/technology development for computer tracking of human subjects protocols, secure records retention, electronic protocol submission, and the like
- o Equipment to facilitate IRB activities, such as teleconferencing or computer support
- o Minor renovations to allow for confidential and secure data storage systems for all stages of research

- o Means to coordinate the activities of IRBs that allow for the approval of consent forms used in multiple institutions

- o Systems for coordinating activities of multiple IRBs when participating in multi-center clinical trials

- o Development of Phase I/II data and safety monitoring plans, tracking systems, educational initiatives, etc.

- o Development of tools for strengthening continuing reviews

- o Development of tools to link compliance, IRB and other (e.g., DSMB) processes to strengthen the overall protection of human research subjects.

Note: Institutions with a GCRC may wish to relate the activities proposed in this application to the activities of the Research Subject Advocate (RSA). However, funds from this program may only be used to support non-GCRC activities of the RSA's effort.)

MECHANISM OF SUPPORT

This RFA will use the NIH S07 award mechanism. As an applicant you will be solely responsible for planning, directing, and executing the proposed project. This RFA is a one-time solicitation. The anticipated award date is September 1, 2002. Awards are for direct costs only; i.e., F&A costs will not be provided. The duration of support will be one year. It is expected that institutions will propose activities that can be encompassed in a one-year award, and/or that they will have explicit plans for how they will continue any innovations after the end of the award. This RFA uses just-in-time concepts.

FUNDS AVAILABLE

The participating ICs intend to commit approximately \$28.5M in FY 2002 to fund up to 174 grants in response to this RFA. The specific number to be funded as well as the amount awarded for each will depend on the merit and scope of the applications received. For direct costs allowed to be requested, see "ELIGIBLE INSTITUTIONS" below.

ELIGIBLE INSTITUTIONS

Institutions eligible to receive support under this program are listed in Appendices 1, 2, and 3. From among all NIH grantee organizations, 174 institutions were found to account for approximately 90% of NIH's total support of clinical research. These 174 institutions were further stratified, by relative amounts of NIH clinical research grant support received in FY 2000, into 3 groups. The first group of institutions (Appendix 1) receives the greatest amount of support; each institution in this group is eligible to request up to \$250K. Institutions listed in Appendix 2 are eligible to request up to \$150K. Institutions listed in Appendix 3 are eligible to request up to \$100K. Two or more of these 174 institutions may submit applications as consortia, with increased requested budgets (described further under "SUPPLEMENTAL INSTRUCTIONS" below). Furthermore, other institutions that receive lesser levels of NIH support for clinical research are encouraged to partner with any of the named 174 institutions in collaborative efforts that can benefit both. In this way, all institutions that conduct NIH-supported clinical research may benefit from this unique initiative.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

The Principal Investigator (PI) should be an appropriately high-level institutional official, such as a Vice Provost for Research or Dean of the Medical School.

SPECIAL REQUIREMENTS

A meeting of grantees in the Washington DC area will be held after completion of these awards, to share information about successful strategies. For this meeting, funds should be budgeted for travel by the PI and/or other relevant individual with significant day-to-day involvement in the activities performed under this award. Grantees should use their expanded authorities to extend the grant in order to charge meeting travel costs.

The final report will be used to provide insights for the NIH to share with other institutions regarding promising approaches to strengthening the systems of protections for research subjects. The final report should include not only a reporting of what was accomplished, but also an evaluation of their potential usefulness, impact and feasibility for other institutions.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants.

Direct inquiries to:

Anthony Demsey, Ph.D.
Senior Advisor for Policy
Office of Extramural Research
Building 1, Room 154
Bethesda, MD 20892
Telephone: (301) 496-5127
FAX: (301) 402-3469
Email: demseya@od.nih.gov

SUBMITTING AN APPLICATION

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

SUPPLEMENTAL INSTRUCTIONS: Eligible institutions, and the maximum amount that each may request from this program, are found in the Appendices. The application may request the full amount in direct costs allowable, although institutions have the discretion to request less should they not have plans/need for the entire amount allowable.

In addition, two or more eligible institutions may choose to submit a single application under a consortium arrangement. Under consortium agreements, the award will be made to a single grantee with a single PI, and the proposed collaborations between/among the participating institutions must be detailed in the grant application. Such an arrangement may be appropriate when the collaborating institutions are proposing large-scale projects of broad applicability. In such cases, the amount that may be requested in the application is the sum of the amounts allowable for each institution as listed in the Appendices. As stated above under "ELIGIBLE INSTITUTIONS," institutions not listed among the 174 in the appendices are encouraged to develop partnerships with any of those 174 institutions; however in such cases, no additional funds will be available for the award.

An application from a single institution is limited to 5 pages instead of the usual 25. Applications from consortia are limited to 10 pages.

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/label-bk.pdf>.

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

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

At the time of submission, two additional copies of the application must be sent to the individual listed under "WHERE TO SEND INQUIRIES."

APPLICATION PROCESSING: Applications must be received by 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.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by NIH staff. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated, by NIH staff with the addition of outside expertise as needed, for adherence to program guidelines and cost allowability. To allow for this evaluation, the application should include specific details as to how the institution will make use of the funds received under this program by drawing from the

examples listed under "Scope of the Activity" above, and/or by proposing other similar initiatives, and by relating these activities to those already ongoing at the institution. As part of the initial merit review, all applications will receive a written summary of the review and a second level review by the NCRR or other appropriate National Advisory Council or Board.

RECEIPT AND REVIEW SCHEDULE

Application Receipt Date: May 7, 2002

Review Date: June/July 2002

Council Review: September 2002

Earliest Anticipated Start Date: September 1, 2002

AWARD CRITERIA

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

- o Merit (as determined by staff/peer review)
- o Availability of funds

Requests that propose lasting enhancements to the quality assurance capacities of the institution and its investigators to support and monitor the use and safety of human subjects in clinical research, as well as applications that include consortia arrangements or participation of other institutions that are not among the named 174, are encouraged.

REQUIRED FEDERAL CITATIONS

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.health.gov/healthypeople/>.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance No. 93.337, and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at <http://grants.nih.gov/grants/policy/policy.htm> and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

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.

APPENDICES

Appendix 1

BAYLOR COLLEGE OF MEDICINE
BOSTON UNIVERSITY
BRIGHAM AND WOMEN'S HOSPITAL
CASE WESTERN RESERVE UNIVERSITY
COLUMBIA UNIVERSITY
CORNELL UNIVERSITY
CTRC RESEARCH FOUNDATION
DANA-FARBER CANCER INSTITUTE
DUKE UNIVERSITY
EMORY UNIVERSITY
FRED HUTCHINSON CANCER RESEARCH CENTER
HARVARD UNIVERSITY
INDIANA UNIVERSITY
JOHNS HOPKINS UNIVERSITY
MASSACHUSETTS GENERAL HOSPITAL
MAYO CLINIC ROCHESTER

MOUNT SINAI SCHOOL OF MEDICINE OF NYU
NEW YORK STATE PSYCHIATRIC INSTITUTE
NEW YORK UNIVERSITY
NORTHWESTERN UNIVERSITY
OREGON HEALTH SCIENCES UNIVERSITY
SLOAN-KETTERING INSTITUTE FOR CANCER RES
SOCIAL AND SCIENTIFIC SYSTEMS
STANFORD UNIVERSITY
UNIVERSITY OF ALABAMA AT BIRMINGHAM
UNIVERSITY OF ARIZONA
UNIVERSITY OF CALIFORNIA LOS ANGELES
UNIVERSITY OF CALIFORNIA SAN DIEGO
UNIVERSITY OF CALIFORNIA SAN FRANCISCO
UNIVERSITY OF CHICAGO
UNIVERSITY OF COLORADO HLTH SCIENCES CTR
UNIVERSITY OF IOWA
UNIVERSITY OF MIAMI CORAL GABLES
UNIVERSITY OF MICHIGAN
UNIVERSITY OF MINNESOTA
UNIVERSITY OF NORTH CAROLINA CHAPEL HILL
UNIVERSITY OF PENNSYLVANIA
UNIVERSITY OF PITTSBURGH
UNIVERSITY OF ROCHESTER
UNIVERSITY OF SOUTHERN CALIFORNIA
UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON
UNIVERSITY OF TEXAS MD ANDERSON CAN CTR
UNIVERSITY OF TEXAS SW MED CTR/DALLAS
UNIVERSITY OF UTAH
UNIVERSITY OF WASHINGTON
UNIVERSITY OF WISCONSIN MADISON
VANDERBILT UNIVERSITY
WAKE FOREST UNIVERSITY
WASHINGTON UNIVERSITY
YALE UNIVERSITY

AMERICAN COLLEGE OF RADIOLOGY
BETH ISRAEL DEACONESS MEDICAL CENTER
BOSTON MEDICAL CENTER
BROWN UNIVERSITY
CENTER FOR HEALTH STUDIES
CHILDREN'S HOSPITAL (BOSTON)
CHILDREN'S HOSPITAL MED CTR (CINCINNATI)
CHILDREN'S HOSPITAL OF PHILADELPHIA
CITY OF HOPE NATIONAL MEDICAL CENTER
DARTMOUTH COLLEGE
FOX CHASE CANCER CENTER
FRONTIER SCIENCE & TECH RESEARCH FDN, INC
GEORGETOWN UNIVERSITY
GLAXOSMITHKLINE PHARMACEUTICAL
HARBOR-UCLA RESEARCH & EDUC INST
KAISER FOUNDATION RESEARCH INSTITUTE
MASSACHUSETTS INSTITUTE OF TECHNOLOGY
MC LEAN HOSPITAL (BELMONT, MA)
MEDICAL COLLEGE OF WISCONSIN
MEDICAL UNIVERSITY OF SOUTH CAROLINA
MIRIAM HOSPITAL
MONTEFIORE MEDICAL CENTER (BRONX, NY)
NATIONAL DEVELOPMENT & RES INSTITUTES
NATIONAL JEWISH MEDICAL & RES CTR
NEW ENGLAND MEDICAL CENTER HOSPITALS
NEW ENGLAND RESEARCH INSTITUTES, INC.
NORTHERN CALIFORNIA INSTITUTE RES & EDUC
NSABP FOUNDATION, INC.
OHIO STATE UNIVERSITY
OREGON RESEARCH INSTITUTE
PENNSYLVANIA STATE UNIVERSITY
RAND CORPORATION
RESEARCH TRIANGLE INSTITUTE
ROCKEFELLER UNIVERSITY
RUSH-PRESBYTERIAN-ST LUKES MEDICAL CTR
SCRIPPS RESEARCH INSTITUTE
ST. JUDE CHILDREN'S RESEARCH HOSPITAL

ST. LUKE'S-ROOSEVELT INST FOR HLTH SCIS
STATE UNIVERSITY NEW YORK STONY BROOK
STATE UNIVERSITY OF NEW YORK AT BUFFALO
SUNY DOWNSTATE MEDICAL CENTER
THOMAS JEFFERSON UNIVERSITY
TULANE UNIVERSITY OF LOUISIANA
UNIV OF MED/DENT NJ NEWARK
UNIVERSITY OF ARKANSAS
UNIVERSITY OF CALIFORNIA BERKELEY
UNIVERSITY OF CALIFORNIA DAVIS
UNIVERSITY OF CALIFORNIA IRVINE
UNIVERSITY OF CINCINNATI
UNIVERSITY OF CONNECTICUT
UNIVERSITY OF FLORIDA
UNIVERSITY OF HAWAII AT MANOA
UNIVERSITY OF ILLINOIS AT CHICAGO
UNIVERSITY OF KANSAS
UNIVERSITY OF KENTUCKY
UNIVERSITY OF MARYLAND BALT PROF SCHOOL
UNIVERSITY OF MASSACHUSETTS MEDICAL SCH
UNIVERSITY OF NEW MEXICO
UNIVERSITY OF PUERTO RICO
UNIVERSITY OF TENNESSEE AT MEMPHIS
UNIVERSITY OF TEXAS HLTH SCI CTR SAN ANT
UNIVERSITY OF TEXAS MEDICAL BR GALVESTON
UNIVERSITY OF VERMONT & ST AGRIC COLLEGE
UNIVERSITY OF VIRGINIA
VIRGINIA COMMONWEALTH UNIVERSITY
WAYNE STATE UNIVERSITY
YESHIVA UNIVERSITY

Appendix 3

AMC CANCER RESEARCH CENTER
AMERICAN COLLEGE OF OB AND GYN
AMERICAN COLLEGE OF SURGEONS
AMERICAN HEALTH FOUNDATION

ARIZONA STATE UNIVERSITY
BETH ISRAEL MEDICAL CTR (NEW YORK)
CEDARS-SINAI MEDICAL CENTER
CHARLES R. DREW UNIVERSITY OF MED & SCI
CHILDREN'S HOSPITAL LOS ANGELES
CHILDREN'S HOSPITAL OF PITTSBURGH
CHILDREN'S MEMORIAL HOSPITAL (CHICAGO)
CLEVELAND CLINIC FOUNDATION
FAMILY HEALTH INTERNATIONAL
FORSYTH INSTITUTE
FRIENDS RESEARCH INSTITUTE, INC.
GARDEN ST CNCR CTR/CTR MOL MED & IMMUNOL
GEORGE WASHINGTON UNIVERSITY
GEORGIA STATE UNIVERSITY
HOWARD UNIVERSITY
IOWA STATE UNIVERSITY OF SCIENCE & TECH
JOHN WAYNE CANCER INSTITUTE
JOSLIN DIABETES CENTER
LONG ISLAND JEWISH MEDICAL CENTER
LOYOLA UNIVERSITY OF CHICAGO
MAGEE-WOMEN'S HOSPITAL
MCP HAHNEMANN UNIVERSITYMEDICAL COLLEGE OF GEORGIA
MEHARRY MEDICAL COLLEGE
NORTH SHORE UNIVERSITY HOSPITAL
OKLAHOMA MEDICAL RESEARCH FOUNDATION
OREGON SOCIAL LEARNING CENTER, INC.
PACIFIC INSTITUTE FOR RES AND EVALUATION
PRINCETON UNIVERSITY
PUBLIC HEALTH INSTITUTE
PURDUE UNIVERSITY
RHODE ISLAND HOSPITAL (PROVIDENCE, RI)
ROSWELL PARK CANCER INSTITUTE CORP
RUTGERS THE STATE UNIVERSITY OF NJ
SAN DIEGO STATE UNIVERSITY
SOUTH AFRICAN MEDICAL RESEARCH COUNCIL
ST. LOUIS UNIVERSITY
TEMPLE UNIVERSITY

TUFTS UNIVERSITY MEDFORD
UNIVERSITY OF CALIF-LAWRENC BERKELEY LAB
UNIVERSITY OF COLORADO AT BOULDER
UNIVERSITY OF GEORGIA
UNIVERSITY OF LOUISVILLE
UNIVERSITY OF MARYLAND COLLEGE PK CAMPUS
UNIVERSITY OF MISSOURI
UNIVERSITY OF NEBRASKA MEDICAL CENTER
UNIVERSITY OF OKLAHOMA
UNIVERSITY OF RHODE ISLAND
UNIVERSITY OF SOUTH CAROLINA
UNIVERSITY OF SOUTH FLORIDA
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