

HUMAN SUBJECTS RESEARCH ENHANCEMENTS PROGRAM (HSREP)

RELEASE DATE: May 22, 2003

RFA: OD-03-007

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.nia.nih.gov/>)

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 General Medical Sciences (NIGMS)

(<http://www.nigms.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/>)

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER(S): 93.393, 93.394, 93.395, 93.396, 93.399, 93.307, 93.308, 93.333, 93.371, 93.389, 93.306, 93.867, 93.172, 93.233, 93.837, 93.838, 93.839, 93.866, 93.273, 93.855, 93.856, 93.846, 93.864, 93.929, 93.279, 93.173, 93.121, 93.847, 93.848, 93.849, 93.113, 93.114, 93.115, 93.242, 93.309, 93.859, 93.862, 93.821, 93.853, 93.361

APPLICATION RECEIPT DATE: July 11, 2003

THIS RFA CONTAINS THE FOLLOWING INFORMATION

- o Purpose of this RFA
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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 limited solicitation made available to the grantees funded under the first RFA ([OD-02-003](#)) as a recompetition for an additional, final, one-year award.

HOWEVER, FOR THIS SOLICITATION, THE NIH REQUIRES APPLICANTS TO COLLABORATE WITH OTHER INSTITUTIONS CONDUCTING HUMAN SUBJECTS RESEARCH AND ARE NOT CURRENTLY FUNDED UNDER THIS PROGRAM, TO SHARE EDUCATIONAL RESOURCES, COMPUTER TECHNOLOGIES, BEST PRACTICES, ETC. 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 Development of infrastructure/technology for computer tracking of human subjects protocols, secure records retention, electronic protocol submission, and the like;
- o Purchase of equipment to facilitate IRB activities, such as teleconferencing or computer support;
- o Implementation of minor renovations to allow for confidential and secure data storage systems for all stages of research;
- o Development of means to coordinate the activities of IRBs that allow for the approval of consent forms used in multiple institutions;
- o Development of 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.

Applications must include plans for reaching out to other institutions that conduct human subjects research but do not receive HSREP support.

Note: Institutions with a General Clinical Research Center (GCRC) should endeavor to coordinate the activities proposed in HSREP with the activities of the Research Subject Advocate (RSA). However, funds from HSREP 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-year limited competition for the current grantees. The anticipated award date is September 30, 2003. 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 only those new activities that can be encompassed in this one-year award, and/or activities that are continuations or expansions of their first-year S07 programs. Institutions are expected to have explicit plans for how they will continue any innovations after the end of the award. This RFA uses just-in-time concepts, but not modular budgets.

FUNDS AVAILABLE

The participating ICs intend to commit approximately \$25M in FY 2003 to fund current HSREP grantee institutions that re-compete successfully for an additional, final year. The specific number of applications to be funded as well as the amount awarded for each will depend on the merit of the applications received.

ELIGIBLE INSTITUTIONS

Current grantees under the Human Subjects Research Enhancements Program who are eligible to receive support under this program are listed in the following URL:

http://grants.nih.gov/grants/policy/hsrea/hsrea_list.htm.

The dollar limits set for the previous competition (\$250K, \$150K, or \$100K, depending on the tier) are the dollar limits set for this recompetition. Applicants may refer to the previous NIH Guide announcement

(<http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-02-003.html>) to remind them of those dollar limits.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

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

SPECIAL REQUIREMENTS

Applicants must include in the application their plan for reaching out to other institutions, not already receiving support from the HSREP, that conduct human subjects research. This plan should detail, for example, how initiatives will be shared with these other institutions.

APPLICATIONS NOT INCLUDING SUCH PLANS WILL BE RETURNED TO THE APPLICANT AS BEING NON-RESPONSIVE TO THIS RFA.

The final reports submitted by the grantees at the end of the award period 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 description of what was accomplished, but also the methodology for development of those programs, and 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.

o Direct inquiries to:

L. Tony Beck, Ph.D.
Division of Clinical Research
National Center for Research Resources
National Institutes of Health
One Democracy Plaza
6701 Democracy Blvd., Room 916
Bethesda, MD 20892-4874
(20817 Zip Code for courier deliveries)
(301) 435-0805; FAX: (301) 480-3661
e-mail: beckl@mail.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, e-mail: GrantsInfo@nih.gov.

An application from a single institution is limited to 5 pages instead of the usual 25. (Those current awardees who are funded as 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 TWO 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, THREE 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 reviewed by NIH staff for adherence to program guidelines and cost allowability. To allow for this review, 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. A second level review will be done by the NCRR National Advisory Council.

RECEIPT AND REVIEW SCHEDULE

Application Receipt Date: July 11, 2003

Review Date: August/September 2003

Council Review: September 2003

Earliest Anticipated Start Date: September 30, 2003

AWARD CRITERIA

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

- o Responsiveness to this RFA
- 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 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.

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