

This Program Announcement expires on December 31, 2004, unless reissued.

## SHORT-TERM COURSES IN RESEARCH ETHICS

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National Institutes of Health

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

Centers for Disease Control and Prevention

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

Agency for Healthcare Research and Quality

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

Application Receipt Dates: March 12, 2002; March 12, 2003; March 12, 2004

## PURPOSE

The National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Agency for Health and Research Quality (AHRQ) invite applications for grants to develop, conduct, evaluate, and disseminate short-term courses on ethical issues in research, particularly those involving human participants. Courses should improve the skills of biomedical, behavioral, nursing, social science, and public health researchers in identifying and addressing the ethical, legal, and social implications of their research, especially when human participants are involved.

## 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 Program Announcement (PA), Short-Term Courses in Research Ethics, is related to all priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople/>.

## ELIGIBILITY

Applications may be submitted by domestic for-profit and non-profit, public and private organizations, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Racial and ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

## MECHANISM OF SUPPORT

This PA will use the NIH Continuing Education Training Grant (T15) award mechanism, which funds institutions to establish or expand programs of continuing professional education. Research ethics courses may be of any duration as long as they are consistent with the goals of the proposed program. For organizations wanting to teach research ethics courses, such courses should be offered at least once a year. Courses can be developed for the Internet, video, or other formats.

Responsibility for the planning, direction, and execution of the proposed curriculum will be solely that of the applicant.

Applicants may request up to three years of support. Allowable costs include personnel, supplies, travel and per diem for faculty, and other costs, such as printing, telephone, audio-visuals, postage, recruitment materials, and computer software. In addition, travel and per diem funds for those attending courses developed by grantees are appropriate when necessary. However, it is expected that courses will be partially supported through registration fees paid for by the attendees. Attendees may be recruited locally (at the grantee institution), regionally, or nationally. The facilities and administration rate for T15 awards is eight percent.

## RESEARCH OBJECTIVES

### Background

Advances in preventing and controlling human diseases require dedicated scientists and volunteers who participate in human experimentation. Medical advances must be made through a productive and respectful partnership between researchers and research participants.

The vast majority of collaborations between research participants and scientists in biomedical, behavioral, nursing, social science, and public health research that have led to important advances in health care and life expectancy, and an improvement in the quality of life, have

occurred through such a partnership. At the same time, there have been some highly visible cases of serious lapses in the ethical conduct of research involving human participants. Examples such as the Tuskegee Syphilis Study, the Willowbrook State School experiments, and the Cold War radiation experiments remind the public and researchers alike that protection of participants must be of the highest priority. Balancing the dual goals of scientific advances and ethical acceptability is the responsibility of investigators who design, conduct, analyze, and disseminate the results of research.

Although researchers must have an understanding of ethical issues that pertain to research, most are presented with few opportunities to obtain and develop this knowledge. Academic training through specialized curricula related to research ethics can provide a key learning opportunity in this area; this program announcement is one step in this direction.

### Research Objectives and Scope

The objective of this grant program is to support the development, conduct, and evaluation of short-term courses on ethical issues in research, particularly research involving human participants. The courses should improve the skills of biomedical, behavioral, nursing, social science, and public health researchers in identifying and addressing the ethical, legal, and social implications of their research, especially research involving human participants. The long-term objective is to increase the number of researchers who have both awareness and skills in the ethical aspects of such research. Further, applicants are encouraged to propose innovative programs with new approaches to the teaching and learning of research ethics.

There are many topics in research ethics that can benefit from the short course approach. The following are examples that could be of value; they are not inclusive:

- o Practical problems arising in the design and conduct of research, using case studies that illustrate problems faced by investigators.
  
- o Issues in handling the needs of specific populations participating in research, including women or minorities; populations with special needs, such as pregnant women, children, prisoners, or persons who may be mentally or physically challenged; or those whose capacity to make decisions freely is not clear. Applicants should discuss their expertise and competency to study racial and ethnic minority groups. Curricula must reflect understanding of cultural values, beliefs, and practices.

- o International issues in research ethics, including those arising in the conduct of clinical trials in the developing world.
- o Theoretical approaches to understanding ethical, legal, and social issues. These might include the principle-based approach, risk/benefit assessments, informed consent process, privacy and confidentiality, and methods to recognize and respond to vulnerability of human participants.
- o Issues arising in the context of institutional review board (IRB) review; for example, training for IRB members in both traditional areas of protocol review and areas such as genetic epidemiology, the use of stored tissue, and the needs of special populations.

All courses should be developed to meet the needs of junior or senior biomedical and behavioral researchers. Each individual area of the application should be addressed in sufficient depth to show how it significantly improves the attendees' skills in addressing the ethical, legal, and social implications of research.

In both developing and teaching courses, grantees are encouraged to take an interdisciplinary approach and involve biomedical, behavioral, nursing, social science, and public health investigators experienced in addressing research ethics as well as scientists and scholars in ethics, philosophy, law or other relevant fields. It is important for one or more of the scientists involved in the proposed program to actually have recognized expertise in the field of research ethics.

Applicants to this program will be required to disseminate their educational materials widely. Applicants should describe what specific mechanisms they will employ for dissemination. In the case of internet-based materials, applicants are encouraged to submit plans on how these materials will be advertised and made available to the appropriate communities and evaluated for effectiveness.

Applications from institutions seeking to implement a program with a large target population of researchers are encouraged to apply. Although others are eligible to apply, priority will be given to those applications reaching a broad audience.

Grantees should also address plans to include attendees from groups currently underrepresented in the field of research ethics.

Proposals for courses should include clear plans for evaluating the effectiveness of the course(s) in terms of attendees' perceptions of the material and conduct of the course. Importantly, there must be plans for assessing the longer-term impact, as measured by attendees' subsequent activities or responsibilities in their institutions in the areas of research bioethics. For example, assessments might address whether course participants are assuming more leadership responsibility in research bioethics as shown by membership on ethics review committees, IRBs, and other such groups.

## SPECIAL REQUIREMENTS

The participating agencies will organize a bi-annual meeting of course developers and course instructors to exchange information about effective approaches to teaching research ethics and sharing course materials. The applicant should include a request for funds to support the travel of the principal investigator and a small number of other course participants to the Washington, DC, area to attend this meeting.

## INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

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 biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are 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 research involving human subjects should read the UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html>); a complete copy of the updated Guidelines are available at [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_update.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm): The revisions relate to NIH defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to 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) all investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

## INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH 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 was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

## 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. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

## 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](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.

## APPLICATION PROCEDURES

The PHS 398 research grant application instructions and forms (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> are to be used in applying for these grants. This version of the PHS 398 is available in an interactive, searchable PDF format. For further assistance contact GrantsInfo, Telephone 301/435-0714, Email: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov).

Applicants planning to submit an investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended/revised version of the preceding grant application types requesting \$500,000 or more in direct costs for any year are advised that he or she must contact the Institute or Center (IC) program staff before submitting the application, i.e., as plans for the study are being developed. Furthermore, the application must obtain agreement from the IC staff that the IC will accept the application for consideration for award. Finally, the applicant must identify, in a cover letter sent with the application, the staff member and Institute or Center who agreed to accept assignment of the application. This policy requires an applicant to obtain agreement for acceptance of both any such application and any such subsequent amendment. Refer to the NIH Guide for Grants and Contracts, March 20, 1998 at <http://grants.nih.gov/grants/guide/notice-files/not98-030.html>

Applicants should employ the forms and format for Institutional National Research Service Award, described in section V of Form PHS 398. However, because section V provides instructions for submitting a traditional training grant (T32) and the present T15 mechanism is considerably different, applicants are encouraged to modify the format appropriately. In addition, applicants should use the budget format for research grants (section I, pages DD and EE), for the present T15 application.

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

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)

## REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications will be evaluated for scientific and technical merit by an appropriate scientific review group convened in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

### Review Criteria

The review criteria for the Short-term Courses in Research Ethics will include:

- o Need for the course and its potential effectiveness in training researchers in awareness of the ethical issues associated with research.
- o Quality of the course content and adequacy of the syllabus.
- o Training, experience, and competence of the faculty in the ethical issues applicable to this program.
- o Criteria for selecting trainees and for awarding scholarships, for publicizing the availability of the course to the target audience of active researchers, and plans to reach out to underrepresented investigators.
- o Plans for evaluating the effectiveness and the extent of dissemination of the course.
- o Plans for disseminating curricula to a broad audience.
- o Adequacy and availability of any necessary institutional facilities, such as the library and computer resources.

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

- o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.
  
- o The reasonableness of the proposed budget and duration in relation to the proposed research
  
- o The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

#### 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.

#### INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Inquiries regarding programmatic issues may be directed to:

Lawrence Friedman, M.D.  
National Heart, Lung, and Blood Institute  
Building 31, Room 5A03  
Bethesda, MD 20892-2482  
Telephone: (301) 496-9899  
FAX: (301) 402-1056  
Email: [lawrence\\_friedman@nih.gov](mailto:lawrence_friedman@nih.gov)

Direct inquiries regarding fiscal matters to:

Suzanne White  
National Heart, Lung, and Blood Institute  
6701 Rockledge Drive, Room 7154

Bethesda, MD 20817-7926  
Telephone: (301) 435-0171  
FAX: (301) 480-3310  
Email: [whitesa@nhlbi.nih.gov](mailto:whitesa@nhlbi.nih.gov)

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.837. 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 and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-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, and 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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