

RESEARCH ON ETHICAL ISSUES IN HUMAN STUDIES

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P.T.

National Cancer Institute  
National Heart, Lung, and Blood Institute  
National Human Genome Research Institute  
National Institute on Aging  
National Institute on Alcohol Abuse and Alcoholism  
National Institute of Allergy and Infectious Diseases  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
National Institute of Child Health and Human Development  
National Institute of Dental and Craniofacial Research  
National Institute of Diabetes and Digestive and Kidney Diseases  
National Institute on Drug Abuse  
National Institute of Environmental Health Sciences  
National Institute of General Medical Sciences  
National Institute of Mental Health  
National Institute of Neurological Disorders and Stroke  
National Institute of Nursing Research  
Centers for Disease Control and Prevention  
Fogarty International Center  
National Center for Complementary and Alternative Medicine  
National Center for Research Resources  
Office of Research on Women's Health

Application receipt dates: June 1, October 1, February 1

THIS PROGRAM ANNOUNCEMENT (PA) USES "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS.

THE PA INCLUDES DETAILED MODIFICATIONS TO STANDARD APPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING AN APPLICATION IN RESPONSE TO THIS PA.

## PURPOSE

The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention invite research grant applications (R01) for support to conduct research on ethical issues that arise with research involving human participants.

The sponsoring organizations are jointly offering this Program Announcement (PA). Although this PA applies to several agencies, it will be administered according to National Institutes of Health (NIH) policies and procedures. This PA is one of the steps the NIH is taking to develop an on-going, multi-agency, comprehensive program in research ethics. Other steps include the "Short-Term Courses in Research Ethics" (T15), PA-99-051 (<http://www.nih.gov/grants/guide/pa-files/PA-99-051.html>), and the "Mentored Scientist Development Award in Research Ethics" (K01), PA-99-050 (<http://www.nih.gov/grants/guide/pa-files/PA-99-050.html>), both published in the NIH Guide for Grants and Contracts, January 22, 1999 and, for those particularly interested in genetic research ethics, "Ethical, Legal, and Social Implications of Human Genetics Research," PA-96-042 (<http://www.nih.gov/grants/guide/pa-files/PA-96-042.html>), published April 26, 1996.

## HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS led national activity for setting priority areas. This PA, Research on Ethical Issues in Human Studies, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2000" at <http://www.crisny.org/health/us/health7.html>.

## ELIGIBILITY REQUIREMENTS

Applications may be submitted by any domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, research institutions, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

## MECHANISM OF SUPPORT

This PA will use the NIH individual research project grant (R01) award mechanism. However, specific application instructions have been modified to reflect "MODULAR GRANT" and "JUST-IN-TIME" streamlining efforts. The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. Complete and detailed instructions and information on Modular Grants can be found at <http://www.nih.gov/grants/funding/modular/modular.htm>.

Applications will request direct costs in \$25,000 modules, up to a total direct cost of \$250,000 per year for three to five years. A typical modular grant application will request the same number of modules in each year. Grants that include a request for more than \$250,000 in direct costs will use the usual application process. The cost of equipment and Consortium/Contractual agreements is included in the budget limitation. Application budgets will be simplified. Detailed categorical budget information will not be submitted with the application; budget form pages of the application kits will not be used. Instead, total direct costs requested for each year will be presented. Information, in narrative form, will be provided only for Personnel and, when applicable, for Consortium/Contractual Costs. See section on APPLICATION PROCEDURES below.

There will be no routine escalation for future years. In determining the total for each budget year, applicants should first consider the direct cost of the entire project period. Well-justified modular increments or decrements in the total direct costs for any year of the project that reflect substantial changes in expected future activities may be requested. For example, purchase of major equipment in the first year may justify a higher overall budget in the first, but not in succeeding years.

Other Support pages of the PHS 398 will not be submitted with the application.

Information on research projects ongoing or completed during the last three years of the principal investigator and key personnel will be provided as part of the "Biographical Sketch." This information will include the specific aims, overall goals and responsibilities, and should include Federal and non-Federal support. This information will be used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project.

Following peer review, information about Other Research Support will be requested by NIH from the applicant for applications being considered for award.

Additional budget information will be requested only under special circumstances.

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

## RESEARCH OBJECTIVES

This is a promising time for research because the prospect for advancing generalizable knowledge is so great. These advances, however, stretch our ethical limits, generate new dilemmas, and demand constant vigilance to ensure that researchers do not jeopardize the rights and welfare of their research participants.

Because of the rapid advances and complexity of the research enterprise, more empirical work is needed to guide researchers and Institutional Review Board (IRB) members towards selecting optimal ways that promote appropriate protections for research participants. Few studies, for example, have been conducted on how best to provide information about a study's methods and procedures to improve participants' comprehension, the effect of different recruitment strategies on retention of study participants, methods to assess the risk/benefit calculus, or the effects investigator characteristics and behavior have on levels of recruitment, retention, and withdrawal.

Furthermore, the importance or consequences of the myriad aspects of the research process on research participants, researchers, and IRB members need to be investigated. Of interest are topics including: (1) the identity of the sponsor of the study and the appearance of conflict of interests; (2) purposes for which the research is being conducted; (3) the study's methods that might include perilous procedures or interventions; (4) inducements to participate and the relative risks and benefits (including medical, financial, legal, and social) of deciding to consent to or refuse participation; (5) ensuring justice in the selection of participants as well as in the conduct of the research; (6) consequences for the participant as well as for the integrity of the research study when the participant withdraws from a study; (7) privacy and confidentiality and when there might be exceptions to either or both; (8) planned and possible future use of collected tissues or cells (e.g., blood, cell cultures, DNA, saliva, skin, organs, and tumor biopsies); and (9) planned and future uses of data collected from a completed study.

This PA is designed to encourage empirical studies that are expected to fill many gaps in our knowledge and understanding of the complex ethical issues that arise when involving human participants in research. The PA does not solicit essays, editorials, literature or historical reviews of science, conferences, or speculative, theoretical, or policy analyses. Research may or may not

be linked to a particular disease, disorder, or population. Applicants are encouraged to link to the Institutes' or Centers' home pages to learn more about their specific interests.

The focus can be on potential, current, or former research participants, investigators, and/or institutional review boards (IRBs). Possible research topics are listed below in no order of priority. This list of topics should not be considered exhaustive and the selection of topic by the applicant need not be limited to those provided below.

- o Evaluate the cognitive ability required to comprehend, appreciate, and reason in order to consent to specific experimental procedures and risks (e.g., a placebo controlled trial, phase I study, sham surgery, pain inducement, symptom- provocation or exacerbation study, stored tissue repository); to differentiate between research and standard treatment (e.g., therapeutic misconception); and to distinguish between discretionary and obligatory activities (e.g., quid pro quo add-on studies or wrap-around studies).

- o Develop and test new means of sustaining autonomy to be used in situations of declining or loss of capacity; means can include current yet untested advance directives for research, and consent programs for organ donation (e.g., durable power of attorney, proxy, legally authorized representative) and especially novel and innovative approaches.

- o Investigate how potential participants weigh risks and benefits e.g., what factors would lead individuals to participate in studies that present significant risk with little or no prospect of direct benefit.

- o Develop and evaluate the concept and working definition of "community" in the context of research. Identify optimal ways in which: (1) a community could be consulted when considered the sampling frame of a research protocol; (2) researchers can determine who represents the interests of a community and how to obtain input from community representatives; (3) researchers can minimize group harms that may result as a consequence of the study. For example, how does "community" apply when a waiver of consent has been granted to conduct emergency research\* and the consent process includes setting up and assessing community consultation and consent process strategies or programs [\* References: "Informed Consent Requirements in Emergency Research," OPRR Reports, No. 97-01, Oct. 31, 1996 available on the web at the following URL address:

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/hcdc97-01.htm>]; Also: "Protection of Human Subjects: Informed Consent and Waiver of Informed Consent Requirements in Certain

Emergency Research; Final Rules" in the Federal Register of October 2, 1996 (Vol. 61, 51498-51531)].

- o Apply existing knowledge from cognitive, behavioral, social, and educational fields to develop practical, reliable, valid, and efficient methods and instruments for assessing capacity to comprehend, appreciate and/or reason in a research setting, especially when individuals with cognitive, psychiatric, and developmental disorders are involved; the focus should be on functional abilities rather than on clinical diagnosis.

- o Research the determining factors and consequences for:

- (1) participation (e.g., the impact of escalating monetary incentives on potential subjects from varied socioeconomic groups to determine the threshold for interest and consent, perception of fairness, and coercion to remain in the study);

- (2) retention and satisfaction in research (e.g., altruism, wanting to help family members or future generations, free care, research burden, adverse events, researcher behavior);

- (3) participant withdrawal (e.g., for the participant, the researcher, and the integrity of the research study).

- o Research the definition, measurement, and understanding of social harms that might be associated with research participation (e.g., discrimination by insurance companies or employers that results from participation in HIV/AIDS or drug abuse studies, vaccine research, or genetic research using identifiable tissue samples; novel re-contact or opt-out strategies and certificates of confidentiality could be considered).

- o Identify and develop ways to address special issues related to research and medical records (e.g., allowing participants access to their research records, protection of privacy and confidentiality while providing a mechanism for future notification of unanticipated benefits or risks resulting from study participation).

- o Research the ethical issues within the context of a specific disease/disorder, or a group of diseases/disorders, or identified vulnerable populations (e.g., by age, gender, economic status, race/ethnicity/culture).

- o Research the challenges in the ethical design and conduct of cross-cultural studies, especially research conducted in low- and middle- income nations. Topics for investigation could include: translating ethical procedures to local environments such as risk/benefit assessment, informed consent, privacy and confidentiality, and appropriate material inducements; considerations arising

from the methodological design and conduct of cross-cultural protocols, such as placebo control and randomization; community involvement at different levels of study design, conduct and recruitment; and broader issues of "distributive justice" including clinical obligations to the study participants and allocation of intellectual property and other benefits.

o Develop and evaluate best practice outcome measures for IRBs to use in monitoring protocol review (e.g., extent of sponsors contributing funds to cover costs of protocol review, recruitment and signing bonuses); the on-going consent process (e.g., consent monitor, Research Intermediary); and conduct of the study (e.g., number and type of procedural reviews, aggregation of adverse events, measures to reduce exposure to unwarranted risk, data safety and monitoring boards, educational strategies).

#### ANNUAL MEETINGS AND COLLABORATION

Successful applicants will be asked to participate in yearly meetings to report progress, discuss problems, and share information related to the conduct of their grants. Previous experience with meetings of this kind has shown that they can provide an opportunity for grantees to work collaboratively with other investigators on various issues, which might include common core instruments, joint publication, sharing of protocols and data, or other avenues of collaboration that may arise. Meetings may be held in the Washington, D.C. area, in conjunction with a professional meeting [e.g., PRIM&R/ARENA (Public Responsibility in Medicine and Research/Applied Research Ethics National Association Conferences)], or another mutually agreed upon site. It is recommended that costs associated with attendance of the principal investigator and one collaborator at these meetings be included as part of the budget proposal.

#### 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 subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided 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 "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide

for Grants and Contracts, Vol. 23, No. 11, March 18, 1994 available on the web at the following URL address: <http://grants.nih.gov/grants/guide/notice-files/not94-100.html>.

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

It is the policy of the 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://www.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.

## APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev.4/98) and will be accepted at the standard application deadlines as indicated in the application kit. Application kits are available at most institutional offices of sponsored research, or may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301-435-0714, email: [Grantsinfo@od.nih.gov](mailto:Grantsinfo@od.nih.gov). Applications are also available on the World Wide Web at: <http://www.nih.gov/grants/forms.htm>

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 and Center (IC) program staff before submitting the application, i.e., as plans for the study are being developed. Furthermore, the applicant 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 who, and the Institute or Center that, 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.

<http://www.nih.gov/grants/guide/notice-files/not98-030.html>).

## BUDGET INSTRUCTIONS

For applications requesting \$250,000 or less, the total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below:

### PHS 398

- o FACE PAGE- Item 2 should be completed as noted above. Items 7a and 7b should be completed to indicate Modular Direct Costs (in \$25,000 increments up to a maximum of \$250,000) and Total Costs [Modular Direct plus Facilities and Administrative (F&A) costs] for the initial budget period. Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

- o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398 (rev 4/98). It is not required and will not be accepted at the time of application.

- o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget tables on page 5 of the PHS 398 (rev. 4/98) Form. It is not required and will not be accepted with the application.

- o NARRATIVE BUDGET JUSTIFICATION - Use a Modular Grant Budget Narrative page. (See <http://www.nih.gov/grants/funding/modular/modular.htm> for sample pages.)

At the top of the page, enter the total direct costs requested for each year.

- o Under Personnel, list key project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest \$1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project. Indicate whether the collaborating

institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount.

Provide an additional narrative budget justification for any variation in the number of modules requested.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at:

<http://www.nih.gov/grants/funding/modular/modular.htm>

- Complete the educational block at the top of the form page;
- List current position(s) and then previous positions;
- List selected peer-reviewed publications, with full citations;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years.

o CHECKLIST - This page should be completed and submitted with the application.

If the F&A rate agreement has been established, indicate the type of agreement and the date. It is important to identify all exclusions that were used in the calculation of the F&A costs for the initial budget period and all future budget years.

o The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

**APPLICATIONS NOT CONFORMING TO THESE GUIDELINES WILL BE CONSIDERED UNRESPONSIVE TO THIS PA AND WILL BE RETURNED WITHOUT FURTHER REVIEW.**

The PA title and number must be typed on item 2 of the face page of the application form, and the "YES" box must be marked.

Submit a signed, typewritten original of the application 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)

The Center for Scientific Review (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 substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

#### 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 goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1) Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

2) Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3) Innovation. Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

4) Investigator. Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

5) Environment. Does the scientific 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? Is there evidence of institutional or other support that will contribute to the success of the research?

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

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review
- o Availability of funds
- o Program priority

## INQUIRIES

Written and telephone inquiries are encouraged. Additional information, including sample budget narratives and biographical sketch, may be found at this site:

{<http://www.nih.gov/grants/funding/modular/modular.htm>}. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding general programmatic issues to:

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Senior Advisor for Biomedical Ethics  
Office of Extramural Research  
1 Center Drive, Room 144, MSC 0152  
Bethesda, MD 20892-0152  
Telephone: (301) 496-1414  
FAX: (301) 402-7062  
Email: [rfisch@nih.gov](mailto:rfisch@nih.gov)

Programmatic inquiries related to a specific Institute or Center may be directed as follows:

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31 Center Drive, Room 3A44, MSC-2440  
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## AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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