

**Occupational and Environmental Health Education and Research Center at the University
of Illinois at Chicago School of Public Health (Illinois ERC)**

**Pilot Projects Research Training Program
Grants Policy Statement Regarding Ethical Conduct in Research**

2009-2010

Human Subjects

The Illinois ERC requires that applicants for funding from us follow the U.S. Department of Health and Human Services (HHS) regulations for protection of human subjects involved in HHS-funded research.

The HHS requirements are presented here. These requirements were taken from NIH Grants Policy Statement, Part II: Terms and Conditions of NIH Grant Awards-Part 2 of 7.

HHS regulations for the protection of human subjects, at 45 CFR Part 46, implement section 491(a) of the PHS Act and provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by NIH or other HHS components. They stipulate that the applicant/grantee, whether domestic or foreign, is responsible for safeguarding the rights and welfare of human subjects involved in NIH grant-supported research activities. Subpart A of the HHS regulations constitutes the Federal policy (common rule) for the protection of human subjects.

Applicant organizations proposing to involve human subjects in research must file (or have previously filed) a written Assurance of Compliance with the Office for Human Research Protections, HHS (OHRP) setting forth the commitment of the organization to establish appropriate policies and procedures for the protection of human subjects. Affiliated organizations or organizations that will serve as other performance sites for the grant-supported research must also file an Assurance. OHRP is responsible for approving the Assurance, which may be a Multiple Project Assurance (MPA), a Single Project Assurance (SPA), or other type of Assurance, as appropriate. OHRP may also negotiate an Inter-Institutional Amendment if employees of an organization with an MPA routinely conduct their grant-supported research at an affiliated institution, thereby avoiding the need for an SPA for each separate project performed at such sites.

NIH will not award any grant for research involving human subjects unless the organization is operating under an approved Assurance and, if operating under an MPA, provides certification, as part of its application, that an appropriate Institutional Review Board (IRB) has, within 12 months of the budget period start date, reviewed and approved the proposed activity in accordance with the regulatory requirements. SPA organizations must provide certification of IRB approval to OHRP as part of the SPA. In addition, no human subjects may be involved in research at an affiliated institution prior to approval by OHRP of an applicable Assurance for that organization. If an MPA organization submits an application with the knowledge that human subjects may be involved within the project period, but definite plans are not set forth in the application, the research activity must be reviewed and approved by an IRB and a certification submitted to NIH before human subjects may be involved in covered research activities supported by the award.

No individual may receive NIH grant funds for covered research involving human subjects unless the individual is affiliated with or sponsored by an organization that assumes responsibility for the research under an applicable written Assurance or the individual makes other arrangements with OHRP.

For purposes of this public policy requirement, the definitions at 45 CFR 46.102 apply. A "human subject" is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. The regulations extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR 46.

"Research" is defined as "systematic investigation designed to develop or contribute to generalizable knowledge." Unless an activity is "exempt" (see 45 CFR 46.101), any activity meeting the regulatory definition of "research" constitutes research for purposes of applying the regulations, even if supported by a grant that might have as its overall purpose an activity that is not primarily research. (For example, some training programs may include research activities.) OHRP should also be consulted if there is any question concerning the classification of research as exempt or nonexempt.

The Illinois ERC will not award any grant for research involving human subjects unless the organization demonstrates compliance with the above HHS requirements. No individual may receive grant funds from the Illinois ERC for covered research involving human subjects unless the individual is affiliated with or sponsored by an organization that assumes responsibility for the research under an applicable written Assurance or the individual makes other arrangements with OHRP.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved with or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Inclusion Of Women And Minorities In Research Involving Human Subjects

It is the policy of the CDC and NIH, as well as the Illinois ERC, to ensure that individuals of both sexes and the various racial and ethnic groups will be included in supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

Inclusion Of Children As Participants In Research Involving Human Subjects

It is the policy of NIH and the Illinois ERC that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, including research conducted and supported by the Illinois ERC, 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>

Animal Subjects

If the proposed project involves research on animal subjects, compliance with the "PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions" is required. An applicant (as well as each subcontractor or cooperating institution that has immediate responsibility for animal subjects) proposing to use vertebrate animals in CDC and NIH supported activities, including those supported by the Illinois ERC, must file (or have on file) the Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health. The applicant must provide in the application the assurance of compliance number and evidence of review and approval (including the date of the most recent approval) by the Institutional Care and Use Committee (IACUC).

Lobbying Restrictions

Applicants should be aware of restrictions on the use of HHS funds, including awards by the Illinois ERC, for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their sub-tier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition no part of PHS appropriated funds (including funds from the Illinois ERC), shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Prohibition on use Of CDC Funds for Certain Gun Control Activities

The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, specifies that: "None of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention may be used to advocate or promote gun control. Anti-Lobbying Act requirements prohibit lobbying Congress with appropriated Federal monies. Specifically, this Act prohibits the use of Federal funds for direct or indirect

communications intended or designed to influence a Member of Congress with regard to specific Federal legislation. This prohibition includes the funding and assistance of public grassroots campaigns intended or designed to influence Members of Congress with regard to specific legislation or appropriation by Congress. In addition to the restrictions in the Anti-Lobbying Act, CDC interprets the new language in the CDC's Appropriations Act to mean that CDC's funds may not be spent on political action or other activities designed to affect the passage of specific Federal, State, or local legislation intended to restrict or control the purchase or use of firearms.