ADMINISTRATIVE COMMUNICATIONS SYSTEM

UNITED STATES DEPARTMENT OF EDUCATION

Office of Management, Executive Office

400 Maryland Avenue; Washington, DC 20202

Transmittal Sheet #:	2004-0018	*Date:*	October 5, 2004
Distribution:	All ED employees	*Distribution Approved:* *Directives Management Officer:*	/s/ Tammy Taylor

Action: Pen and Ink Changes

Title: Protection of Human Subjects in Research: Intramural Research

Number: OCFO:1-104

Document Changing: OCFO:1-104, *Protection of Human Subjects in Research: Intramural Research*, dated 08/18/1998.

Summary: This directive establishes: 1) ED's principles and policies in its responsibilities for protecting the rights and welfare of human subjects of research in accordance with Title 34, Code of Federal Regulations, Part 97, Protection of Human Subjects; 2) the responsibilities of Principal Offices, other ED Offices, and the ED Institutional Review Board (IRB) in intramural research involving human subjects; and 3) the ED IRB and its membership.

Pen and Ink Changes: The following pen and ink changes have been made to reflect reorganizations throughout the Department.

Page	*Section*	*Changed*	*To*
1-18	Date	08/18/1998	10/05/2004
1	Superseding Information	Information described above	Information described above
1	Contact information	For technical questions regarding this directive, please contact Helene Deramond via e-mail or on 202-260-5353	For technical questions regarding this directive, please contact Helene Deramond via e-mail or on 202-245-6154.
6	Part 2, II. A. 2. ii.	Grants Policy and Oversight Staff	Grants Policy and Oversight Staff, Office of the Chief Financial Officer
8-10	Several	Office of the Chief Financial & Chief Information Officer	Office of the Chief Financial Officer

ADMINISTRATIVE
COMMUNICATIONS SYSTEM
U.S. DEPARTMENT OF EDUCATION

DEPARTMENTAL DIRECTIVE

Distribution: All ACS Manual Holders Approved by: /s/ (08/18/98)
Richard W. Riley, Secretary

The Protection of Human Subjects in Research: Ethical Principles and ED Policies, Intramural Research Involving Human Subjects, and the ED Institutional Review Board

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For technical questions regarding this directive, please contact Helene Deramond via e-mail or on 202-245-6154.

Supersedes OCFO:1-104 “The Protection of Human Subjects in Research: Ethical Principles and ED Policies, Intramural Research Involving Human Subjects, and the ED Institutional Review Board” dated 08/18/1998.

I. Purpose

This directive establishes: 1) the Department of Education's (ED's) principles and policies in its responsibilities for protecting the rights and welfare of human subjects of research in accordance with Title 34, Code of Federal Regulations, Part 97, Protection of Human Subjects; 2) the responsibilities of Principal Offices, other ED Offices, and the ED Institutional Review Board (IRB) in intramural research involving human subjects; and 3) the ED IRB and its membership.

II. Policy

It is the Department's policy to protect the rights and welfare of human subjects of research in research activities covered by the Department's regulations for the protection of human subjects. Any conflict between this directive and the controlling authority listed in Paragraph III of this directive must be resolved in favor of the controlling authority.

III. Controlling Authorities

This directive implements policies of the Federal government and the Department of Education for the protection of human research subjects, as follows:

A. The Federal Policy for the Protection of Human Subjects which was published as a Common Rule in the Federal Register on June 18, 1991, is codified at 34 CFR Part 97, Protection of Human Subjects, and was amended December 28, 1997, to add Subpart D, Additional ED Protections for Children who are the Subjects in Research; [See 62 FR 63221 et seq., November 26, 1997, for these amendments]

B. The Department of Education's program regulations for the Disability and Rehabilitation Research Projects and Centers Program, 34 CFR Part 350, at 34 CFR 350.4(c) and for the Disability and Rehabilitation Research: Research Fellowships, 34 CFR Part 356, at 34 CFR 356.3(c);

C. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was published in the Federal Register, on April 18, 1979;

D. The Secretary of Education's August 17, 1992, decision memorandum, Implementing the Common Rule for Protection of Human Subjects, which approved the establishment of an ED Institutional Review Board (IRB) [Copy on file in the Grants Policy and Oversight Staff]; and

E. The November 10, 1997, memorandum from the Chief Financial & Chief Information Officer to the Director, Grants Policy and Oversight Staff, which assigned the responsibility for the Protection of Human Subjects function to the Grants Policy and Oversight Staff. [Copy on file in the Grants Policy and Oversight Staff]

IV. Definitions

The following definitions apply to this directive:

A. ***Research.*** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study or the collection of data to test a hypothesis, it is research.)

B. ***Intramural Research Involving Human Subjects.*** Any research activity in which an ED employee obtains information about a human subject through his/her intervention or interaction with the human subject or obtains identifiable private information about a human subject.

C. ***Cooperative Research.*** A research activity under a contract or cooperative agreement awarded by ED in which an ED research investigator(s) is engaged.

D. ***Research Investigator.*** An individual who conducts research.

E. ***Assurance of Compliance.*** A document executed by an individual authorized to act for the institution and to assure that the institution will comply with the obligations imposed by the Regulations for the Protection of Human Subjects. (See 34 CFR 97.103.)

F. ***Institutional Review Board (IRB).*** A formally constituted group of individuals responsible for reviewing the research for a given institution for the purpose of ensuring that there are adequate protections to safeguard the rights and welfare of human subjects of research. (See 34 CFR 97.103 and 97.107.)

G. ***Funding Organization.*** An organization, e.g., a Principal Office, or institution that provides financial support for a research activity.

H. ***Common Rule for the Protection of Human Subjects.*** The Federal Policy for the Protection of Human Subjects adopted as a Common Rule by 17 Federal agencies.

Part 1 - Ethical Principles and ED Policies Governing Research Involving Human Subjects Conducted or Sponsored By ED

I. Applicability

A. 1. Part 1 of this directive applies to all research involving human subjects and all other activities which even in part involve that research, regardless of whether the research is otherwise subject to Federal regulation, as specified in subparagraph 2 of this Paragraph A, unless review of the research is:

i. exempted under 34 CFR 97.101(b);
ii. exempted if children are research subjects under 97.101(b) as amended by 97.401(b);
iii. waived under 34 CFR 97.101(i); or
iv. subject to other review as noted in I.B.2. of Part 1 of this directive.

2. Research is subject to Part 1 of this directive if:

i. the research is sponsored by ED; or
ii. the research is conducted by or under the direction of any employee or agent of ED in connection with ED responsibilities; or
iii. the research is conducted by or under the direction of any employee or agent of ED using any property or facility of ED; or
iv. the research involves the use of ED's nonpublic information to identify or contact human research subjects or prospective subjects.

B. 1. ED recognizes that it and ED research investigators bear full responsibility for the performance of all intramural research, including responsibility for complying with Federal, state and local laws as they may apply to such research.

2. If ED intramural research also involves research at other institutions, those institutions bear responsibility for that research, subject to oversight by the funding organization and any other organization with which they have an approved assurance of compliance covering the research.

II. Ethical Principles

ED is guided by the ethical principles regarding all research involving human subjects as set forth in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, and as specified below.

A. ED recognizes the principles of respect for persons, beneficence (including minimization of risks and maximization of benefits) and justice as stated in the Belmont Report, and will apply these principles in all research covered by this directive.
B. ED acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects.

III. ED Policies

A. ED acknowledges its responsibility for complying fully with the requirements of 34 CFR Part 97 and, as appropriate, 34 CFR Parts 350 and 356.

B. Except for research exempted under 34 CFR 97.101(b) or, if children are research subjects, 97.101 (b) as amended by 97.401(b), or waived under 34 CFR 97.101(i), all research covered by this directive and proposed to be conducted or sponsored by ED will be reviewed and approved by an Institutional Review Board (IRB) operating under an approved Assurance of Compliance. ED will not permit the involvement of human subjects in research until an IRB has reviewed and approved the research protocol and its provisions for ensuring the protection of the research subjects, including where appropriate, the obtaining of informed consent, the assent of children and the permission of their parents or guardians, or, if authorized under CFR Part 97, Subpart D, permission of their parents or guardians without the assent of the children.

C. ED recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence, such as children, persons with disabilities, or economically or educationally disadvantaged persons and shall ensure that appropriate safeguards exist to protect vulnerable subjects.

D. ED shall take steps to ensure that the Principal Offices and ED research investigators conducting research involving human subjects are aware of and knowledgeable about the ethical principles and policies governing research involving human subjects.

E. ED encourages and promotes constructive communication among Principal Office staff, research administrators, research investigators, human subjects and other relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

F. ED will exercise appropriate administrative overview over research projects at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

G. If an ED employee engages in Cooperative Research with another agency or institution, ED will enter into an agreement specifying the responsibilities of ED and the other agency(ies) or institution(s) in the review of that research which is subject to the Common Rule for the Protection of Human Subjects.

Part 2 - Intramural Research Involving Human Subjects: Responsibilities for Compliance with 34 CFR Part 97

I. Applicability

Except for research waived under 34 CFR 97.101(i), Part 2 of this directive is applicable to all intramural research projects involving human subjects. Part 2 applies to intramural research sponsored by one Principal Office and conducted by staff of another Principal Office as well as research both sponsored and conducted by the same Principal Office.

II. Responsibilities

A. Principal Office and Research Investigators

1. The Principal Office(s) and its research investigator(s) shall comply with the requirements of 34 CFR Part 97 for intramural research activities involving human subjects they propose to conduct.

2. i. The Principal Office(s) and its research investigator(s) shall make a determination as to whether research they propose to conduct will involve human subjects as defined in 34 CFR 97.102.

   ii. When it is not clear whether the research involves human subjects as defined in 34 CFR 97.102, the research investigator(s) shall seek assistance from the Grants Policy and Oversight Staff, Office of the Chief Financial Officer.

3. The Principal Office(s)/its research investigator(s) shall make a preliminary determination of whether a research activity involving human subjects they propose to conduct is exempt from coverage under 34 CFR 97.101(b) or, if children are research subjects, 97.101(b) as amended by 97.401(b).

4. i. The research investigator(s) shall prepare a proposal giving a complete description of the proposed research, including any research proposed to be exempt.

   ii. The research investigator(s) shall include samples of proposed informed consent forms with the proposal, procedures for obtaining informed consent, any alternative procedures when the subjects are not capable of giving informed consent, and procedures for soliciting the assent of children and the permission of their parents or guardians, or, if authorized under 34 CFR Part 97, Subpart D, permission of their parents or guardians without the assent of the children.

   iii. The Principal Office(s) and its research investigator(s) shall submit all research proposals for intramural research involving human subjects to the Grants Policy and Oversight Staff, as specified in separately published guidance.

5. The research investigator(s) shall submit a supplement to an original proposal when: 1) the research investigator(s) propose to involve human subjects and the original research proposal had only indefinite plans for the involvement of human subjects, or 2) the research investigator(s) propose to involve human subjects, and the research proposal previously had no plans for the involvement of human subjects, or 3) the research investigator(s) propose to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the ED Institutional Review Board (IRB).

6. The research investigator(s) shall comply with all IRB decisions, conditions, and requirements for all research activities subject to their purview and not otherwise waived under 34 CFR 97.101(i).

7. The research investigator(s) shall comply with the requirements for obtaining and documenting informed consent in accordance with 34 CFR 97.116 and 34 CFR 97.117, or assent of children and/or the permission of parents or guardians in accordance with Part 97, Subpart D, Additional ED Protections for Children who are Subjects in Research.

8. The research investigator(s) shall acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this directive and 34 CFR Part 97.

9. The research investigator(s) shall report promptly to the IRB proposed changes in a research activity approved by the IRB, and the changes shall not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subjects. The research investigator(s) shall report promptly to the IRB changes made without IRB review and approval in order to eliminate apparent immediate hazards to the subjects.

10. The research investigator(s) shall report promptly to the IRB any unanticipated problems involving risks to subjects and others.

B. ED Institutional Review Board

1. Before human subjects may be involved in research subject to Part 2 of this directive, the IRB must approve the research. The IRB may require modification of proposed research before approving the research or may disapprove the research.

2. The IRB shall comply fully with the requirements of 34 CFR Part 97 in the performance of its duties.

3. The IRB shall develop and, in accordance with 34 CFR 97.103(b)(4), shall follow written procedures for:

   i. conducting its initial and continuing review of research and for reporting its findings and actions to the research investigator(s) and the Principal

Office(s);

ii. determining which projects require review more often than annually and which projects need verification from sources other than the research investigator(s) that no material changes have occurred since the previous IRB review; and

iii. ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

4. The IRB shall comply fully with the requirements of all applicable Federal policies and guidelines, including those concerning confidentiality of information about human subjects, the protection of pupil rights, and the protection of family educational rights and privacy. (See 34 CFR Parts 98 and 99, respectively.)

C. Office of the Chief Financial Officer

1. The Office of the Chief Financial Officer shall provide both meeting space for the IRB and sufficient staff to support the IRB's review and record keeping duties for the research activities specified in this directive.

2. The Chief Financial Officer shall take steps to ensure that the IRB membership for the research activities specified in this Directive satisfy the compositional requirements of 34 CFR 97.107.

D. Office of the Chief Financial Officer, Grants Policy and Oversight Staff

1. The Director of the Grants Policy and Oversight Staff is responsible for oversight of IRB functions.

2. The Director of the Grants Policy and Oversight Staff is the institutional official responsible for oversight of compliance with 34 CFR Part 97.

3. The Grants Policy and Oversight Staff shall receive from the research investigator(s) through their Principal Office(s), all intramural research proposals which involve human subjects.

4. The Director, Grants Policy and Oversight Staff, or his/her designee, is responsible for reviewing the preliminary determination of exempt status and for making the final determination of exemption from coverage under 34 CFR 97.101(b) or, if children are research subjects, 97.101(b) as amended by 97.401(b). He/she may request the assistance of the IRB chair in making the determination.

5. The Grants Policy and Oversight Staff shall forward all research proposals involving human subjects to the IRB for review.

6. The Grants Policy and Oversight Staff is responsible for developing and issuing written administrative procedures and guidance for the Principal Offices and ED research investigators for preparing and submitting to the Grants Policy and Oversight Staff research proposals for research projects involving human subjects.

Part 3 - The ED Institutional Review Board

I. Establishment

The ED IRB is established to safeguard the rights and welfare of human subjects of research in intramural research projects, in accordance with 34 CFR Part 97, Protection of Human Subjects.

The IRB chair and the IRB members are appointed by the Chief Financial Officer.

. The ED IRB functions and operates in accordance with the requirements in 34 CFR 97.108, IRB functions and operations.

The IRB documents its decisions and retain such records as prescribed by 34 CFR 97.115.

II. Membership

A. The ED IRB must satisfy the compositional requirements of 34 CFR 97.107.

B. The IRB may not have a member participate in the IRB's initial or continuing review of any project in which a member has a conflicting interest, except to provide information requested by the IRB.

C. The IRB may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond, or in addition to, that which is available on the IRB. In addition, a Senior Attorney from the Office of the General Counsel serves as counsel to the IRB. These individuals may not vote on any matter before the IRB.

D. The names and qualifications of the members of the ED IRB are provided in the IRB roster that is maintained by the Grants Policy and Oversight Staff, Office of the Chief Financial Officer.