ADMINISTRATIVE COMMUNICATIONS SYSTEM

UNITED STATES DEPARTMENT OF EDUCATION

Office of Management, Executive Office

400 Maryland Avenue; Washington, DC 20202

Transmittal Sheet #:	2004-0017	*Date:*	October 5, 2004
Distribution:	All ED employees	*Distribution Approved:* *Directives Management Officer:*	/s/ Tammy Taylor

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Action: Pen and Ink Changes

Title: Protection of Human Subjects in Research: Extramural Research

Number: OCFO:1-105

Document Changing: OCFO:1-105, *Protection of Human Subjects in Research: Extramural Research*, dated 06/09/2003.

Summary: This directive establishes the responsibilities of Principal Offices and other offices in ED in implementing ED's regulations for the protection of human subjects in extramural research, i.e., research sponsored by ED through a grant, a contract, or the interagency transfer of funds.

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	06/09/2003	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.
2 2	II. IV. C.	A:OCFO:1-104	OCFO:1-104
4	VI. A.	Grants Policy and Oversight Staff (GPOS)	Office of the Chief Financial Officer (OCFO) Grants Policy and Oversight Staff (GPOS)
5	VI. A. 10.	PO/Contracts and Purchasing Operations (CPO)	PO/OCFO's Contracts and Acquisitions Management (CAM)
Several	Several	CPO	CAM

Page	*Section*	*Changed*	*To*
6	VI. B.	Contracts and Purchasing Operations (CPO)	Contracts and Acquisitions Management (CAM)
13	Appendix 2	Appendix 2: Sample PO Notification to GPOS and Request that GPOS Secure Assurances/Pre-Award Certifications	Appendix 2: Sample Principal Office (PO) Notification to Grants Policy and Oversight Staff (GPOS) and Request that GPOS Secure Assurances/Pre-Award Certifications
17	Appendix 3 HS 3, 3a, 2nd bullet	The grantee shall submit the assurance(s) to the Department at the address shown below.	If it does not have an assurance, the grantee shall apply for the Federal Wide Assurance (FWA) from the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services, http://www.hhs.gov/ohrp/assurances/assurances_index.html.
17	Appendix 3 HS 3, 3a, 3rd bullet	The grantee shall ensure that any legally separate institution (not owned or operated by the grantee) that is involved in nonexempt research under this grant submits any required assurance to the Department before it initiates the research activity.	The grantee shall ensure that any legally separate institution (not owned or operated by the grantee) that is involved in nonexempt research under this grant and that does not have an assurance applies for the FWA from OHRP before it initiates the research activity.
18	Contact information	Send the assurances and certifications to: Grants Policy and Oversight Staff U.S. Department of Education Room 3652 ROB-3 7th and D Streets, SW Washington, D.C. 20202	Send the IRB certifications to: Grants Policy and Oversight Staff U.S. Department of Education Room 7062, Potomac Center Plaza 550 12th Street, SW Washington, D.C. 20202-4250 FAX number: 202 245-6271

ADMINISTRATIVE
COMMUNICATIONS SYSTEM
U.S. DEPARTMENT OF EDUCATION

DEPARTMENTAL DIRECTIVE

Distribution:
All Department of Education employees

Approved by: ___/s/ (06/09/2003)_____
William J. Leidinger, Assistant Secretary
Office of Management

Protection of Human Subjects in Research:
Extramural Research

Table of Contents

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

Supersedes ACS directive OCFO:1-105, "Protection of Human Subjects in Research: Extramural Research," dated 06/09/2003.

I. Purpose

This directive establishes the responsibilities of Principal Offices and other Offices of the Department of Education (ED) in implementing the Department's regulations for the protection of human subjects in extramural research, i.e., research sponsored by ED through a grant, a contract, or the interagency transfer of funds.

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. The Department's Ethical Principles and ED Policies Governing Research Involving Human Subjects Conducted or Sponsored by ED are stated in OCFO:1-104, the Department's directive on intramural research, and are attached to this directive as Appendix 1.

III. Applicability

The provisions of this directive apply to research activities involving human subjects sponsored by ED through a grant, a contract, or the interagency transfer of funds, unless waived under 34 CFR 97.101(i).

IV. 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 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 350.4(c) and for the Disability and Rehabilitation Research: Research Fellowships, 34 CFR Part 356, at 356.3(c).

C. Ethical Principles and ED Policies Governing Research Involving Human Subjects Conducted or Sponsored by ED, Part 1 of Departmental Directive OCFO:1-104.

V. 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, it is research.)

B. ***Extramural Research.*** Research sponsored by ED through a grant, a contract, or the interagency transfer of funds.

C. ***Extramural Research Involving Human Subjects.*** Any extramural research activity in which a research investigator 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.

D. ***Covered Research Activity.*** A research activity involving human subjects that is not exempt under the regulations and, therefore, must be reviewed and approved by an Institutional Review Board before it can be initiated.

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

F. ***Institution.*** Any public or private entity or agency, including Federal, state, and other agencies. [1]

G. ***Assurance of Compliance (Assurance).*** 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.)

H. ***Federal Wide Assurance (FWA).*** An Assurance issued by the Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP). The FWA is approved for a three-year period, is valid for multiple research projects, and can be accepted by other Federal agencies. ED accepts the FWAs on file with OHRP, if appropriate, for ED-sponsored research activities, but will issue ED-only assurances, if appropriate. The FWA replaces the former OHRP Multiple Project Assurance (MPA).

I. ***Single Project Assurance (SPA).*** An Assurance that is valid for one specific research project.

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[1] For purposes of this directive, a Local Education Agency (LEA) and its individual schools typically count as one institution. If one or more individual schools in an LEA were to serve as the research sites for covered research under a grant or contract, only one Assurance (defined in Section V. G.) would be required for the research activities at these sites, barring unusual circumstances.

J. ***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.)

K. ***Certification of IRB Review.*** The official notification to ED by an institution, in accordance with the requirements of 34 CFR Part 97, that a research activity involving human subjects covered by the Department's regulations for the Protection of Human Subjects has been reviewed and approved by an IRB, in accordance with an approved assurance.

L. ***Independent Investigator Agreement (Agreement).*** A signed document between a research investigator with no institutional affiliation and an institution. The investigator borrows the institution's IRB for a research project and commits to abide by its decisions. The institution accepts the obligations imposed by the Regulations for the Protection of Human Subjects for the research project.

M. ***Principal Office (PO).*** A major component of ED, including Program and Staff Offices.

VI. Responsibilities

A. Office of the Chief Financial Officer (OCFO) Grants Policy and Oversight Staff (GPOS)

1. Prepares and updates guidance on requirements for grant applicants, contract offerors, grantees and contractors, if research activities involving human subjects are planned at any time during the life of a project under a grant or contract.

2. Serves as technical advisor to the PO on the requirements of the regulations for extramural research activities involving human subjects.

3. Serves as ED liaison with other Federal agency(ies) for matters pertaining to coverage under the regulations, Assurances, and Certifications when activities under a proposed interagency transfer of funds include, or are likely to include, research involving human subjects. Takes appropriate action.

4. Upon request, provides authoritative guidance to the PO in reviewing determinations of offerors that proposed research activities involving human subjects are exempt from coverage under the regulations.

5. Upon request, provides authoritative guidance to the PO in reviewing applicants' responses to item 12 [2] of the ED 424, Application for Federal

[2] Item 12 of the ED 424 asks applicants to indicate if research activities involving human subjects are

Education Assistance, including applicants' determinations that proposed research activities involving human subjects are exempt from coverage under the regulations.

6. Serves as the central point in ED for receiving the PO's formal pre-award notification to GPOS, listing the status of and need for Assurances, Agreements, and IRB Certifications for project(s) proposed for award.

7. Develops the final listing of Assurances, Agreements, and IRB Certifications required before the award can be made.

8. Serves as the central point in ED for receiving, reviewing, negotiating, and approving Assurances and for receiving pre-award IRB Certifications included in the final listing. May delegate to the Principal Office the authority to negotiate the Assurances.

9. Serves as ED liaison with the Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), for matters concerning OHRP Federal Wide Assurances (FWAs). Verifies that FWAs are current and are applicable.

10. Provides formal notification to PO/OCFO's Contracts Acquisitions Management (CAM) when applicant/offeror has complied with all pre-award requirements for Assurances, Agreements, and IRB Certifications.

11. May overrule a PO determination that a research activity is exempt from coverage under the regulations.

12. May put on hold a recommended award for nonexempt research until all pre-award requirements have been met.

13. Provides formal notification to PO/CAM of any post-award requirements for Assurances, Agreements, or IRB Certifications.

14. Develops and maintains a management information system and database to track the status of Assurances, Agreements, and IRB Certifications.

15. Maintains copies of approved Assurances, Agreements, and IRB Certifications, and related documents provided by the grantees/contractors/performance sites. Forwards originals to the PO (grants) or CAM (contracts).

16. Investigates allegations of noncompliance with 34 CFR Part 97 in grants and contracts, forwards findings, and recommends appropriate action, to the appropriate ED official(s).

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planned at any time during the life of the project and, if so, to provide information about these activities.

17. As appropriate, reviews institutions' compliance with the regulations and adherence to their ED-approved Assurances, and provides technical assistance, through site visits and other means.

18. Coordinates the development and delivery of educational materials and training to increase awareness of policies and procedures regarding the protection of human research subjects.

19. Exercises appropriate administrative oversight of PO practices and procedures for the protection of human research subjects in extramural research activities.

B. OCFO Contracts and Acquisitions Management (CAM)

1. Includes appropriate provisions in contract solicitations when a procurement will include, or is likely to include, research activities involving human subjects.

2. Requires receipt of Assurances, Agreements, and IRB certifications in accordance with the requirements of 34 CFR Part 97, this directive, and ED's Ethical Principles and Policies.

3. Forwards the PO's formal pre-award notification to GPOS, listing the status and need for Assurances, Agreements, and Certifications, and the PO's request that GPOS secure the Assurances, Agreements, and Certifications from the offeror.

4. Lifts restrictions to the contract award, upon receipt of notification from GPOS that the offeror has met all pre-award requirements for Assurances, Agreements, and Certifications.

5. Includes appropriate provisions in the contract, including language pertaining to any post-award requirements for IRB Certifications.

6. Maintains the original copies of approved Assurances, Agreements, IRB Certifications, and related documents provided by the winning offeror and others involved in the research activities.

7. Provides appropriate and up-to-date information for the GPOS management information system and database to track the status of Assurances, Agreements, IRB Certifications and other pertinent information.

C. Principal Office (PO)

1. Notifies CAM when a procurement will include, or is likely to include, covered research activities involving human subjects.

2. Ensures that the Contracting Officer's Representative (COR) identifies in the Statement of Work the requirements that will include or are likely to include research activities involving human subjects.

3. Makes a formal request to GPOS, requesting that GPOS take appropriate action when activities under a proposed interagency transfer of funds include, or are likely to include, research activities involving human subjects.

4. Consults with GPOS, as appropriate, in reviewing determinations by an offeror that research activities involving human subjects are exempt from the regulations, i.e., not covered. Contacts the offeror through the CAM, as appropriate, for additional information.

5. Reviews applicants' responses to item 12 of the ED 424, Application for Federal Education Assistance for competitions likely to fund research activities involving human subjects.[3] This review is done when grant applications are included in a recommended slate or earlier, at the option of the PO.

6. Provides GPOS early notification if a slate will include applications for research activities involving human subjects, whether or not these activities are exempt under the regulations.

7. Consults with GPOS, as appropriate, in reviewing applicants' responses to item 12 and in reviewing applicants' determinations that research activities involving human subjects are exempt from the regulations, i.e., not covered.

   When an award is likely to be made for a grant (a grant application is included in an approved slate), contacts the applicant, as necessary, for additional information or clarification about the applicant's responses to item 12.[4]

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[3] The PO should consult with GPOS as necessary to determine if a competition is likely to fund research activities involving human subjects. The ED regulations for the protection of human subjects define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of these regulations, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. 34 CFR 97.102.d.

[4] Examples of situations that require the PO to contact the applicant are: (1) The applicant did not respond to item 12. (2) The applicant indicated in item 12 that research activities involving human subjects are planned during the life of the project but did not include the narrative information about the exemptions or about the nonexempt research activities. (3) The application suggests that research activities involving human subjects are planned even though the applicant indicated in item 12 that no such activities are planned.

8. When a grant or contract award for nonexempt research activities involving human subjects is likely to be made, provides formal pre-award notification[5] to GPOS, listing the status of and need for Assurances, Agreements, and Certifications for the award. (The notification is made through CAM for contracts.) Notification includes a listing of:

    a. institutions that will be engaged in covered research activities and have Assurances;

    b. institutions that will be engaged in covered research activities and need Assurances;

    c. the need for Independent Investigator Agreements;

    d. research activities for which IRB Certifications have been received;

    e. research activities for which IRB Certification must be received before an award can be made;

    f. IRB Certifications needed after the award is made (but before the research activity can be initiated).

9. Makes a formal request to GPOS, requesting that GPOS take appropriate action to contact the applicant or offeror and obtain, review, and negotiate Assurances and Agreements, and to obtain needed pre-award IRB Certifications. (The request is made through CAM for contracts.)

10. Negotiates Assurances, if it has delegated authority from GPOS, and forwards Assurances to GPOS for approval.

11. Makes the grant award upon receipt of notification from GPOS that the applicant has met all pre-award requirements for Assurances and Certifications.

12. Includes appropriate language in the notice of award document pertaining to post-award requirements, e.g., IRB Certifications.[6]

13. In unusual circumstances (e.g., risk of lapsed funds) makes restricted grant award before receipt of notification from GPOS that the applicant has met all pre-award requirements.

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[5] Sample notification is in Appendix 2.

[6] See Appendix 3, Special Grant Terms for the Protection of Human Research Subjects.

Includes language[7] in notice of award document stipulating that Federal funds shall not be expended for research involving human subjects and that no covered research activity will be initiated until the grantee has complied with the requests for Assurances and Certifications.

14. Serves as the central point for receipt of post-award IRB Certifications for projects supported by the PO.

15. Ensures receipt of periodic IRB Certifications (if needed) before making a continuation award.

16. Maintains the original copies of approved Assurances, Agreements, IRB Certifications, and related documents provided by the grantees and others involved in the research activities.

17. Provides appropriate and up-to-date information for the GPOS management information system and database to track the status of Assurances, Agreements, IRB Certifications, and other pertinent information.

[7] See Appendix 3, Special Grant Terms for the Protection of Human Research Subjects.

Appendix 1: Ethical Principles and ED Policies Governing Research Involving Human Subjects Conducted or Supported by ED

(Part 1 of Departmental Directive OCFO:1-104, formerly A:CFO/CIO:1-105)

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.

Appendix 2: Sample Principal Office (PO) Notification to Grants Policy and Oversight Staff (GPOS) and Request that GPOS Secure Assurances/Pre-Award Certifications[8]

TO : Director, Grants Policy and Oversight Staff

FROM : Principal Office [9] :_____

Principal Office Contact Name:_____

Principal Office Contact Phone Number: _____

Name of Applicant or Offeror: _____
_____

ED PR/Award or RFP Number: _____

Project Title: _____

Name, Telephone Number, and e-mail address of Applicant/Offeror Contact:
_____

I. Listing of Pre-Award Documents for this Proposed Award:

A. Institutions that will be engaged in covered research activities under this proposed grant/contract and have Assurances:

i. Institution name:
i.a. Assurance number:

ii. Institution name:
ii.a. Assurance number:

B. Institutions that will be engaged in covered research activities under this proposed grant/contract and need Assurances:

i. Institution name:
ii. Institution name:

[8] GPOS can make changes to this appendix without the need for Departmental clearance.

[9] For contracts, the PO contact sends the notification/request to GPOS through the Contracting Officer.

C. Agreements needed for Independent Investigators (if any)

D. Research activities proposed to be conducted under this grant/contract for which IRB Certifications have been received:

i. Research activity title:
i.a. Name of institution conducting the research:
i.b. Date of IRB approval:

ii. Research activity title:
ii.a. Name of institution conducting the research:
ii.b. Date of IRB approval:

E. Research activities proposed to be conducted under this grant/contract for which IRB Certification must be received before an award can be made:

i. Research activity title:
i.a. Institution name:

ii. Research activity title:
ii.a. Institution name:

F. IRB Certifications needed after the award is made (but before the research activity can be initiated).

i. Research activity title:
i.a. Institution name:

ii. Research activity title:
ii.a. Institution name:

II. Request for GPOS to Secure Assurances/Pre-Award IRB Certifications

We request that GPOS secure the necessary Assurances, Agreements, and pre-award IRB Certifications identified in I.B., I.C. and I.E. above for the research activities involving human subjects proposed to be funded under the above-referenced PR/Award or RFP Number. The activities are covered, i.e., not exempt under the regulations, and must, therefore, be reviewed and approved by an Institutional Review Board before they can be initiated. The applicant's/offeror's application/proposal and human subjects narrative statements are attached.

The projected award date is: _____.

Attachments: /Application/Proposal/Protection of Human Subjects Narrative Statement

Appendix 3: Special Grant Terms for the Protection of Human Research Subjects [10]

HS 1. Continuing Institutional Review Board (IRB) Reviews. *(The Program Office must include this grant term in the award notification for all awards that include nonexempt research activities involving human subjects. (See VI. C. 12. of this directive.))*

This grant includes nonexempt research activities involving human subjects--research that is not exempt under Sections 97.101(b) and 97.401(b) of 34 CFR Part 97, the Department's Regulations for the Protection of Human Subjects. The following grant term applies.

34 CFR Part 97 requires Institutional Review Board (IRB) review, at least once a year, of nonexempt research activities. Whether the IRB review is required more frequently than once a year depends on the degree of risk.

- If an IRB review is required more frequently than once a year, the grantee shall submit the IRB certification to the Program Office immediately following the IRB review except those certifications that coincide with the submission of the Performance Report, which may be submitted with that report.

- If an IRB review is required once a year only, the grantee of a one-year project shall submit the annual certification to the Program Office immediately following the annual IRB review; the grantee of a multi-year project shall submit the annual certification with the Performance Report.

- The grantee shall ensure that the Department receives the required certifications from any legally separate institution (not owned or operated by the grantee) that is involved in nonexempt research under this grant before the institution initiates the research activity.

- The certifications must be submitted to the Program Office at the address shown on attachment B to the Grant Award Notification.

HS 2. Pending Institutional Review Board (IRB) Reviews and Indefinite Activities. *(The Program Office must include this grant term in the award notification when the grantee has met the pre-award requirements, and some IRB certifications are pending and/or the specific research activities are not known at the time of award. (See VI. C. 12. of this directive.))*

This grant includes nonexempt research activities involving human subjects--research that is not exempt under Sections 97.101(b) and 97.401(b) of 34 CFR Part 97, the Department's Regulations for the Protection of Human Subjects. The grantee met the pre-award requirements for assurances and initial Institutional Review Board (IRB) certifications; however, some IRB reviews are pending and/or some research activities are indefinite at the time of award. The following grant term applies.

Under governing regulations, 34 CFR Part 97, Federal funds administered by the Department of Education must not be expended for nonexempt research involving human subjects unless the

[10] GPOS can make changes to this appendix without the need for Departmental clearance.

requirements of the regulations have been met. Under no condition may a grantee or any other institution involved in the research initiate a nonexempt research activity prior to receipt by the Department of a certification that the research has been reviewed and approved by the IRB designated in the assurance of compliance.

- The grantee shall submit the IRB certifications for the research activities identified under one or both of the charts supplied in 2a. and/or 2b. below before the activities are initiated.

- The grantee shall submit the required IRB certifications to the Program Office immediately following review by the IRB.

- The grantee shall ensure that the Department receives the required certifications from any legally separate institution (not owned or operated by the grantee) that is involved in nonexempt research under this grant before the institution initiates the research activity.

- The grantee shall ensure that any legally separate institution (not owned or operated by the grantee) that is involved in nonexempt research under this grant is operating under an approved assurance before it initiates the nonexempt research activity.

- The certifications must be submitted to the Program Office at the address shown on attachment B to the Grant Award Notification.

2a. IRB reviews are pending for the following nonexempt research activities:

Research Activity	Site of Covered Research Activity	Institution Involved in the Research

2b. The specific research activities are not known at the time of award, e.g., the activities remain to be selected [34 CFR 97.118, Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects].

Indefinite Activity (refer to grant application narrative or other narrative)	Institution Involved in Indefinite Activity

HS 3. Assurances and Initial Institutional Review Board (IRB) Certifications. *(The Program Office must include this grant term in the award notification when it makes the grant award before receipt of notification from the Grants Policy and Oversight Staff that the applicant has met all pre-award requirements for Assurances and/or Certifications. (See VI. C. 13. of this directive.))*

This grant includes nonexempt research activities involving human subjects--research that is not exempt under Sections 97.101(b) and 97.401(b) of 34 CFR Part 97, the Department's Regulations for the Protection of Human Subjects. The grant was awarded before the grantee had complied with the pre-award requirements for assurances and/or Institutional Review Board (IRB) certifications. The following grant term applies.

3a. Under governing regulations, 34 CFR Part 97, Federal funds administered by the Department of Education must not be expended for nonexempt research involving human subjects unless the requirements of the regulations have been met. Under no condition may Federal funds be expended for research involving human subjects and under no condition may a grantee or any other institution involved in the research initiate a nonexempt research activity prior to receipt by the Department of a certification that the research has been reviewed and approved by the IRB designated in the assurance of compliance.

- The following institutions are not operating under an approved assurance:

  Name of institution:_____
  Name of institution:_____

- If it does not have an assurance, the grantee shall apply for the Federal Wide Assurance (FWA) from the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services, http://www.hhs.gov/ohrp/assurances/assurances_index.html.

- The grantee shall ensure that any legally separate institution (not owned or operated by the grantee) that is involved in nonexempt research under this grant and that does not have an assurance applies for the FWA from OHRP before it initiates the research activity.

3b. Under no condition may a grantee or any other institution involved in the research initiate nonexempt research prior to receipt by the Department of Education of a certification that the research has been reviewed and approved by the IRB designated in the approved assurance.

- The Department has not received IRB certifications for the activities listed below:

Research activity:

_____

_____

Research activity:

_____

_____

- The grantee shall submit the certifications to the Department at the address or at the FAX number shown below.

- The grantee shall ensure that the Department receives the required certifications from any legally separate institution (not owned or operated by the grantee) that is involved in nonexempt research under this grant before the institution initiates the activity.

Send the IRB certifications to:

Grants Policy and Oversight Staff
U.S. Department of Education
Room 7062, Potomac Center Plaza
550 12th Street, SW
Washington, D.C. 20202-4250

FAX number: 202 245-6271

Attention: Protection of Human Subjects Coordinator