DEPARTMENT OF EDUCATION

34 CFR Part 97

RIN 1880–AA75

Protection of Human Subjects

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the Department's regulations governing the protection of human research subjects to add special protections for children who are involved as subjects of research. These amendments to the Department's regulations are needed to secure additional protections for children who are involved as subjects of research. The regulations will, for research involving children as subjects, remove exemptions for certain kinds of research, modify the informed consent provisions, and further limit the risks to which children may be made vulnerable. These amendments will make the Department's policy regarding the protection of children as research subjects consistent with the regulations of the Department of Health and Human Services and the Federal Policy for the Protection of Children as practiced by other research agencies of the Federal government.

EFFECTIVE DATE: These regulations take effect December 26, 1997.

FOR FURTHER INFORMATION CONTACT: Kent H. Hannaman, U.S. Department of Education, 600 Independence Avenue, SW., Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651. *Telephone:* (202) 708–5207. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

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SUPPLEMENTARY INFORMATION: The Secretary adopts for the Department of Education regulations that are already in effect for research supported or conducted by the Department of Health and Human Services (DHHS), Subpart D—Additional DHHS Protections for Children Involved as Subjects in Research (Subpart D). These regulations contain provisions specifically designed to protect children who are involved in research as subjects. Children are involved as subjects of important research that will benefit the Nation's children. Balancing the importance of this research with the needs of children, the Secretary is adding these protections because the research activities supported by the Department often include children, and the Department has a particular interest in protecting the welfare of children.

The Common Rule, in which the Department of Education is a participant, currently only includes Subpart A of the DHHS rule. To ensure that the protections in Subpart D apply to research subjects who are children, the Secretary adopts Subpart D, applying it to research programs of the Department.

On May 22, 1997, the Secretary proposed to add Subpart D through a notice of proposed rulemaking (NPRM) published in the **Federal Register** (62 FR 28156–28159). In the preamble to that NPRM, the Secretary discussed the current government-wide and Department of Education policy, the additional protections provided by these regulations, the additional costs and administrative burdens, alternative policy mechanisms, and additional protections for children as education research subjects other than the protections in these regulations.

There are no differences between the proposed regulations and these final regulations.

Analysis of Public Comment

In response to the Secretary's invitation in the NPRM, three parties submitted comments on the proposed regulations. Two commenters were from associations representing affected communities, and one commenter was an individual at an institution of higher education. Two of the commenters expressed support for the protections and the consistency of these protections with policies of other Federal agencies. An analysis of the other comments follow.

Comment: One commenter expressed concern over whether the regulations were sufficiently clear about the need to provide potential research subjects with specific information about their involvement in proposed research activities.

Discussion: The Secretary agrees that potential research subjects must have appropriate information about a specific research activity in order to give informed consent to participate. Subpart A of the existing regulations protecting human research subjects requires, as part of the provisions concerning informed consent, that potential research subjects be given information including the purpose of the particular research activity, the specific procedures to be followed, and the risks and benefits to the subject. Because existing regulations cover this subject, Subpart D, as proposed in the NPRM, has not been changed.

Changes: None.

Comment: One commenter recommended that the regulations include guidance stating that research project descriptions include information about what safeguards will be put into place in order to respond to anticipated risks that actually occur.

Discussion: Information about safeguards for anticipated risks in research is important both for the review and approval of research activities and for the informed consent of potential research subjects. Subpart A of the existing regulations for the protection of human research subjects calls for information about available medical treatment in cases of injury as part of the informed consent process for research involving more than minimal risks. This information should be made available to any potential human research subject, not just children who are potential research subjects. Because existing regulations cover this subject, Subpart D, as proposed in the NPRM, has not been changed.

Changes: None.

Paperwork Reduction Act of 1995

These final regulations have been examined under the Paperwork Reduction Act of 1995 and have been found to contain no additional information collection requirements.

Assessment of Educational Impact

In the NPRM the Secretary requested comments on whether the proposed regulations would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the NPRM and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

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Note: The official version of this document is the document published in the **Federal Register**.

List of Subjects in 34 CFR Part 97

Human subjects, Reporting and recordkeeping requirements, Research.

(Catalog of Federal Domestic Assistance Number does not apply)

Dated: November 18, 1997.

Richard W. Riley,

Secretary of Education.

The Secretary amends Part 97 of Title 34 of the Code of Federal Regulations as follows:

PART 97—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for Part 97 is revised to read as follows:

Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; 42 U.S.C. 300v–1(b).

2. Sections 97.101 through 97.124 are designated as Subpart A—Federal Policy for the Protection of Human Subjects (Basic ED Policy for Protection of Human Research Subjects) and Subparts B and C are reserved.

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3. Sections 97.101, 97.102, 97.103, and 97.107 through 97.124 are amended by adding authority citations to read as follows:

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

4. A new Subpart D containing §§ 97.401 through 97.409 is added to read as follows:

Subpart D—Additional ED Protections for Children Who are Subjects in Research

Subpart D—Additional ED Protections for Children Who Are Subjects in Research

§ 97.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects conducted or supported by the Department of Education.

(1) This subpart applies to research conducted by Department employees.

(2) This subpart applies to research conducted or supported by the Department of Education outside the United States, but in appropriate circumstances the Secretary may, under § 97.101(i), waive the applicability of some or all of the requirements of the regulations in this subpart for that research.

(b) Exemptions in § 97.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption in § 97.101(b)(2) regarding educational tests is also applicable to this subpart. The exemption in § 97.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator or investigators do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in § 97.101(c) through (i) are applicable to this subpart.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b)).

§ 97.402 Definitions.

The definitions in § 97.102 apply to this subpart. In addition, the following definitions also apply to this subpart:

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b)).

§ 97.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research that satisfies the conditions of all applicable sections of this subpart.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b)).

§ 97.404 Research not involving greater than minimal risk.

ED conducts or funds research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

§ 97.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

ED conducts or funds research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that—

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

§ 97.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

ED conducts or funds research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not

likely to contribute to the well-being of the subject, only if the IRB finds that—

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

§ 97.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

ED conducts or funds research that the IRB does not believe meets the requirements of § 97.404, § 97.405, or § 97.406 only if—

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either that—

(1) The research in fact satisfies the conditions of § 97.404, § 97.405, or § 97.406, as applicable; or

(2)(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles; and

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

§ 97.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, if in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even if the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 97.116.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 97.116, that adequate provisions are made for soliciting the permission of each child's parent(s) or guardian(s). If parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 97.404 or § 97.405. If research is covered by §§ 97.406 and 97.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or if only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 97.116, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism depends upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians must be documented in accordance with and to the extent required by § 97.117.

(e) If the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

§ 97.409 Wards.

(a) Children who are wards of the State or any other agency, institution, or entity may be included in research approved under § 97.406 or § 97.407 only if that research is—

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or *in loco parentis.* One individual may serve as advocate for more than one child. The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator or investigators, or the guardian organization.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; and 42 U.S.C. 300v–1(b))

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