DEPARTMENT OF EDUCATION

34 CFR Part 97

RIN 1880–AA75

Protection of Human Subjects

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend 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 proposed regulations would, 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.

DATES: Comments must be received on or before July 21, 1997.

ADDRESSES: All comments concerning these proposed regulations should be addressed to Kent H. Hannaman, Attention: Protection of Human Subjects in Research, U.S. Department of Education, Seventh and D Streets, S.W., Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651. Comments may also be sent through the Internet to (Human__Subjects@ed.gov).

FOR FURTHER INFORMATION CONTACT: Ivor Pritchard, U.S. Department of Education, 555 New Jersey Avenue, N.W., Washington, D.C. 20208–5573. Telephone: (202) 219–2231. 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.

SUPPLEMENTARY INFORMATION: The Secretary proposes to adopt 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 believes that these protections should be added because the research activities supported by the Department often include children, and the Department has a particular interest in protecting the welfare of children.

Current Government-Wide and ED Policy

The Federal Policy requires institutions receiving support from Federal agencies or offices for research activities involving human subjects to assure that covered research activities will be reviewed by an Institutional Review Board (IRB). The purpose of the IRB review is to ensure that persons not involved in carrying out the research activities determine that adequate provisions have been made to protect the research subjects involved in the proposed activities. The adequacy of the protections is judged by the IRB, which consists of qualified individuals at the institutions where the research takes place, and by other individuals in the local community who are familiar with the research population and with local community standards.

Additional Protections Afforded by Subpart D

The amendments regarding children substantially modify the Federal Policy in three ways. First, they remove an exemption from IRB review of research involving surveys, interviews, or observation of public behavior if the research investigators interact with subjects who are children. Second, they modify the procedures for obtaining informed consent from research subjects who are children, by including procedures for proxy consent by the parent or guardian, and assent by the children themselves. Third, they limit the kind of risks to which children may be made vulnerable during the research activity, if the child's participation in the research contains no prospects of benefits to the individual child. IRBs are charged with the responsibility of ensuring that these modifications are included in research activities taking place at their institutions, or sponsored by their institutions, whenever children are involved as subjects.

The Secretary believes that adopting Subpart D protections through rulemaking is an important part of meeting the Department's obligation to fully implement the Federal Policy. Children are a primary focus of the Department's mission and activities, and protections designed specifically for children serving as research subjects are appropriate. With the Subpart D protections, children involved as research subjects would have more protections than they would have if Subpart D is not adopted, and the Secretary believes that there is good reason to protect children in this manner. In addition, the adoption of the Subpart D protections would make the Department's policy more consistent with that of DHHS and certain other Federal agencies and offices, which was the original intent of the Common Rule.

The Secretary considered but rejected implementing Subpart D on a case-by-case basis as a matter of policy without formal rulemaking. The effect of the case-by-case approach would be to make Subpart D application a matter of negotiation between the Department and some institutions receiving support for relevant research activities. It would be more costly, burdensome, and confusing for researchers and institutions requesting Department support and for the Department's own administration of the Federal Policy. It would also increase the possibility that sponsored research projects would not be fully reviewed for appropriate protections.

The Secretary recognizes that this action will produce some additional costs and administrative burdens. More resources will be expended inside and outside the Government to ensure that children who are research subjects are protected. More research protocols will be reviewed by Institutional Review Boards, the protocols will have to meet higher standards for approval with respect to the potential benefits to the individual subjects where the research poses more than minimal risk, and parental consent and a child's assent will be required when it otherwise would not be. It is not possible to provide an accurate estimate of the additional costs. The Secretary, however, believes that the important benefits of providing consistent protections for children as research subjects outweigh the burden of additional administrative costs.

The Secretary also recognizes that some additional protections for children as education research subjects exist even if Subpart D is not adopted. The applicability of DHHS multiple project assurances [1] at some three hundred

[1] DHHS issues multiple project assurances to some institutions. A multiple project assurance is an agreement between DHHS and an institution that sets forth the institution's commitment to employ the basic ethical principles of ''The Ethical Principles and Guidelines for the Protection of

institutions means that education research supported by those institutions is already regulated by Subpart D. The Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. 1232h) and the Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. 1232g) both provide some protections. However, the safeguards provided by the PPRA and the FERPA are enforced retrospectively, after infractions have occurred. In contrast, these regulations assure compliance before research is initiated. Therefore, the Secretary believes that adoption of Subpart D is important to ensure the highest degree of protection for children as human research subjects.

Executive Order 12866

Assessment of Costs and Benefits

These proposed regulations have been reviewed in accordance with Executive Order 12866. Under the terms of the order, the Secretary has assessed the potential costs and benefits of this regulatory action.

The potential costs associated with the proposed regulations are those resulting from statutory requirements and those determined by the Secretary as necessary for administering the Department's programs effectively and efficiently. As stated under the heading Paperwork Reduction Act of 1995 in this preamble, this proposed rule contains no paperwork burdens.

In assessing the potential costs and benefits—both quantitative and qualitative—of these proposed regulations, the Secretary has determined that the benefits of the proposed regulations justify the costs.

The Secretary has also determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

To assist the Department in complying with the specific requirements of Executive Order 12866, the Secretary invites comment on whether there may be further opportunities to reduce any potential costs or increase potential benefits resulting from these proposed regulations without impeding the effective and efficient administration of the program.

Summary of Potential Costs and Benefits

The potential costs and benefits of these proposed regulations are discussed elsewhere in this preamble under the heading Additional Protections Afforded by Subpart D.

Clarity of the Regulations

Executive Order 12866 requires each agency to write regulations that are easy to understand.

The Secretary invites comments on how to make these proposed regulations easier to understand, including answers to questions such as the following: (1) Are the requirements in the proposed regulations clearly stated? (2) Do the regulations contain technical terms or other wording that interferes with their clarity? (3) Does the format of the regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity? Would the regulations be easier to understand if they were divided into more (but shorter) sections? (A ''section'' is preceded by the symbol ''§'' and a numbered heading; for example, § 97.401 *To what do these regulations apply?*) (4) Is the description of the regulations in the **SUPPLEMENTARY INFORMATION** section of this preamble helpful in understanding the regulations? How could this description be more helpful in making the regulations easier to understand? (5) What else could the Department do to make the regulations easier to understand?

A copy of any comments that concern how the Department could make these proposed regulations easier to understand should be sent to Stanley M. Cohen, Regulations Quality Officer, U.S. Department of Education, 600 Independence Avenue, S.W. (Room 5121, FB–10B), Washington, D.C. 20202–2241.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities. For the most part, these revisions are adopted to effect greater consistency in the protection of children as human research subjects. The proposed revisions would not have a significant impact on the entities affected. The applicability of Department of Health and Human Services multiple project assurances at some three hundred institutions means that education research supported at those institutions is already regulated by Subpart D. The institutions that do not have multiple project assurances with DHHS should find the consistent approach to safeguarding children as research subjects a workable approach to increased protections.

Paperwork Reduction Act of 1995

These proposed regulations have been examined under the Paperwork Reduction Act of 1995 and have been found to contain no additional information collection requirements. (The recordkeeping requirements of Subpart A, for which DHHS has received OMB approval on behalf of affected agencies, encompass recordkeeping requirements of Subpart D.)

Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 5624, Regional Office Building 3, 7th and D Streets, S.W., Washington, D.C., between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

Assessment of Educational Impact

The Secretary particularly requests comments on whether the proposed regulations in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 97

Human subjects, Reporting and recordkeeping Research, requirements.

(Catalog of Federal Domestic Assistance Number does not apply.)

Dated: February 18, 1997.

Richard W. Riley,

Secretary of Education.

The Secretary proposes to amend 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; and 42 U.S.C. 300v–1(b).

§§ 97.101, 97.102, 97.103, 97.104, 97.107, 97.108, 97.109, 97.110, 97.111, 97.112, 97.113, 97.114, 97.115, 97.116, 97.117, 97.118, 97.119, 97.120, 97.121, 97.122, 97.123, 97.124 [Redesignated as Subpart A]

Subpart B—[Reserved]

Subpart C—[Reserved]

2. Sections 97.101 through 97.124 are designated as ''Subpart A—Federal

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Human Subjects of Research'', known as the Belmont Report, and to comply with DHHS regulations for the protection of human subjects. The assurances are issued for a five-year period and are approved for Federal-wide use. Institutions with DHHS-approved multiple project assurances must abide by the provisions of Title 45 CFR Part 46 Subpart D.

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

Sec.

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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