

Office of the Secretary, Education

§ 97.123

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260)

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

[56 FR 28012, 28021, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 97.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subject's involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 97.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

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

§ 97.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval

given to the proposed change by the department or agency.

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

§ 97.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

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

§ 97.121 [Reserved]

§ 97.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

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

§ 97.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or

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proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

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

§97.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

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

Subparts B-C [Reserved]

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

SOURCE: 62 FR 63221, Nov. 26, 1997, unless otherwise noted.

§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

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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