

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

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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))

PART 98—STUDENT RIGHTS IN RESEARCH, EXPERIMENTAL PROGRAMS, AND TESTING

Sec.

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AUTHORITY: Sec. 514(a) of Pub. L. 93-380, 88 Stat. 574 (20 U.S.C. 1232h(a)); sec. 1250 of Pub. L. 95-561, 92 Stat. 2355-2356 (20 U.S.C. 1232h(b)); and sec. 408(a)(1) of Pub. L. 90-247, 88 Stat. 559-560, as amended (20 U.S.C. 1221e-3(a)(1)); sec. 414(a) of Pub. L. 96-88, 93 Stat. 685 (20 U.S.C. 3474(a)), unless otherwise noted.

SOURCE: 49 FR 35321, Sept. 6, 1984, unless otherwise noted.

§ 98.1 Applicability of part.

This part applies to any program administered by the Secretary of Education that:

(a)(1) Was transferred to the Department by the Department of Education Organization Act (DEOA); and

(2) Was administered by the Education Division of the Department of Health, Education, and Welfare on the day before the effective date of the DEOA; or

(b) Was enacted after the effective date of the DEOA, unless the law enacting the new Federal program has the effect of making section 439 of the General Education Provisions Act inapplicable.

(c) The following chart lists the funded programs to which part 98 does not apply as of February 16, 1984.

Name of program	Authorizing statute	Implementing regulations
1. High School Equivalency Program and College Assistance Migrant Program.	Section 418A of the Higher Education Act of 1965 as amended by the Education Amendments of 1980 (Pub. L. 96-374) 20 U.S.C. 1070d-2).	part 206.
2. Programs administered by the Commissioner of the Rehabilitative Services Administration.	The Rehabilitation Act of 1973 as amended by Pub. L. 95-602 (29 U.S.C. 700, et seq.).	parts 351-356, 361, 362, 365, 366, 369-375, 378, 379, 385-390, and 395.
3. College housing	Title IV of the Housing Act of 1950 as amended (12 U.S.C. 1749, et seq.).	part 614.