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))

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

Sec.
98.1 Applicability of part.
98.2 Definitions.
98.3 Access to instructional material used in a research or experimentation program.
98.4 Protection of students' privacy in examination, testing, or treatment.
98.5 Information and investigation office.
98.6 Reports.
98.7 Filing a complaint.
98.8 Notice of the complaint.
98.9 Investigation and findings.
98.10 Enforcement of the findings.

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