

§ 97.409

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.