Overview
The regulation applying to Department of Education funded research is Title 34, Code of Federal Regulations, Part 97, Protection of Human Subjects, which includes Subpart A, Basic Policy, and Subpart D, Additional Protections for Children.

Title 34, Code of Federal Regulations, Part 350, Disability and Rehabilitation Research: Disability and Rehabilitation Research Projects and Centers Program, and Title 34, Code of Federal Regulations, Part 356, Disability and Rehabilitation Research: Research Fellowships, provide additional safeguards in certain research activities funded by the National Institute on Disability and Rehabilitation Research.

34 CFR Parts 350 and 356 impose additional Institutional Review Board membership requirements. For research sponsored by the National Institute on Disability and Rehabilitation Research, when children with disabilities or persons with mental disabilities are purposefully included as research subjects, the Institutional Review Board’s membership must include at least one person who is primarily concerned with the welfare of these research subjects [34 CFR 350.4(c) and 356.3(c)].

Definitions
Definitions of research and human subjects: The regulations define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” It includes activities which meet this definition, whether or not conducted under a program considered "research" for other purposes. [34 CFR 97.102(d)] If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study or the collection of data to test a hypothesis, it is research. The regulations define human subject as "a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information.” [34 CFR 97.102(f)(1) and (2)]

Exempt and nonexempt research: The regulations classify as exempt certain categories of research. Research that is nonexempt is covered by the regulations. The exemptions are found in 34 CFR 97.101(b)

Institutional review boards: The regulations require that all covered research projects be reviewed and approved by an Institutional Review Board before the research takes place. Institutional Review Boards are authorized to approve, request modification in, or disapprove research activities [34 CFR 97.109(a)] and to conduct continuing reviews of the research activities at intervals appropriate to the degree of risk, but not less than once a year [34 CFR 97.109(e)].
Submission Requirements

To be approved, research must satisfy the requirements described in the Human Research Protection Program (HRPP) policies and procedures (see IRB Policy 100 – IRB Review of Research Protocols Involving Human Participants).

Research protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the research, subject recruitment procedures (e.g., advertisements), written information to be provided to the subjects, information about payments and compensation available to subjects, the researcher’s current curriculum vitae and/or other documentation evidencing qualifications, and any other documents that the IRB may require to fulfill its responsibilities.

Permission from the school or school system must be obtained and submitted to the IRB prior to the start of any research and may be requested by the IRB prior to review.

Researchers must provide the IRB with a copy of all surveys and instructional material used in the research. Upon request parents of children\(^1\) involved in the research\(^2\) must be able to inspect these materials.

Review Process

Each legally separate institution that will be conducting nonexempt research under the ED-funded project is subject to the requirement for Assurances and IRB approvals.

The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.

Another ED regulation, The Family Educational Rights and Privacy Act (FERPA), 34 CFR Part 99, allows schools to disclose "student directory information" without consent as long as the school has informed the parents about the directory information and given them the opportunity to opt out of having directory information disclosed.

FERPA does not allow schools to disclose information from student records without parental or student consent if the disclosure does not meet one of several exceptions outlined in the FERPA regulations. Additional information about FERPA is available from the Family Policy Compliance Office at http://www.ed.gov/policy/gen/guid/fpco/index.htm

Additional Requirements

1. Each school at which the research is conducted must provide an assurance that they comply with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).

2. Reporting unanticipated risks in research or serious or continuing noncompliance with the requirements of the Common Rule for the Protection of Human Subjects in Research (34 CFR 97) in studies funded or sponsored by the Department, should be addressed to the Protection of Human Subjects in Research Coordinator. Contact information can be found at: https://www2.ed.gov/policy/fund/guid/humansub/where.html

3. Other specific requirements of the Department of Education (ED) Research can be found in the “Additional Requirements for Department of Education (ED) Research” section in the IRB’s “WORKSHEET: Additional Federal Criteria (HRP-318).”

---

\(^1\) Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

\(^2\) Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.
References

• 34 CFR Part 97, Protection of Human Subjects -also in RTF format (64K)
  Includes Subpart A (Basic Policy) and Subpart D (Additional Protections for Children).

• Research Activities Which May Be Reviewed Through Expedited Review Procedures
  The Department of Education's regulations authorize expedited review procedures for certain
  kinds of research appearing on the list established by the Secretary of Health and Human
  Services.

• Report on: Expedited Review of Social and Behavioral Research Activities
  Issued by the interagency National Science and Technology Council's Social and Behavioral
  Research Working Group of the Human Subjects Research Subcommittee, Committee on
  Science.

• 34 CFR Part 98, the Protection of Pupil Rights Amendment (PPRA)
  PPRA is designed to protect the rights of parents and students in programs that receive funding
  from the Department.

• 34 CFR Part 99, the Family Educational Rights and Privacy Act (FERPA)
  FERPA is designed to protect the privacy of a student's education records at all public elementary
  and secondary schools and virtually all public and private postsecondary institutions.

Revision History
Modified 03/20/2018 (origin)