

16.0 Research Conducted by the Department of Education

Additional regulatory considerations are required for human research that is funded by the U.S. Department of Education (ED), and/or is conducted in institutions that receive ED funding.

For research funded by the National Institute on Disability and Rehabilitation Research, when an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these research participants. 34 CFR 350.4(c) and 356.3(c)

16.1 FERPA

The Family Educational Rights and Privacy Act (FERPA) of 1974 (as amended) is a federal law that sets forth requirements for the protection of privacy of students' educational records. This policy addresses the applicability of FERPA to human subject research reviewed by the Pennington Biomedical Research Center Institutional Review Board (IRB).

16.2 FERPA Definitions

Directory information: means information contained in an education record of a student that would not generally be considered harmful or an invasion of privacy if disclosed.

- a) Directory information includes, but is not limited to, the student's name; address; telephone listing; electronic mail address; photograph; date and place of birth; major field of study; grade level; enrollment status (e.g., undergraduate or graduate, full-time or part-time); dates of attendance; participation in officially recognized activities and sports; weight and height of members of athletic teams; degrees, honors and awards received; and the most recent educational agency or institution attended.
- b) Directory information does not include a student's
 1. Social security number; or
 2. Student identification (ID) number, except as provided in paragraph (c) of this section.
- c) Directory information includes a student ID number, user ID, or other unique personal identifier used by the student for purposes of accessing or communicating in electronic systems, but only if the identifier cannot be used to gain access to education records except when used in conjunction with one or more factors that authenticate the user's identity, such as a personal

identification number (PIN), password, or other factor known or possessed only by the authorized user.

Disclosure: means to permit access to or the release, transfer, or other communication of personally identifiable information contained in education records by any means, including oral, written, or electronic means, to any party except the party identified as the party that provided or created the record.

Education records:

- a) The term means those records that are:
 1. Directly related to a student; and
 2. Maintained by an educational agency or institution or by a party acting for the agency or institution.
- b) The term does not include:
 1. Records that are kept in the sole possession of the maker, are used only as a personal memory aid, and are not accessible or revealed to any other person except a temporary substitute for the maker of the record.
 2. Records of the law enforcement unit of an educational agency or institution, subject to the provisions of 99.8.
 3. Records relating to an individual who is employed by an educational agency or institution, that:
 - Are made and maintained in the normal course of business;
 - Relate exclusively to the individual in that individual's capacity as an employee; and
 - Are not available for use for any other purpose.
 - Records relating to an individual in attendance at the agency or institution who is employed as a result of his or her status as a student are education records and not excepted under this definition.
 4. Records on a student who is 18 years of age or older, or is attending an institution of postsecondary education, that are:
 - Made or maintained by a physician, psychiatrist, psychologist, or other recognized professional or paraprofessional acting in his or her professional capacity or assisting in a paraprofessional capacity;
 - Made, maintained, or used only in connection with treatment of the student; and
 - Disclosed only to individuals providing the treatment. For the purpose of this definition, "treatment" does not include remedial

educational activities or activities that are part of the program of instruction at the agency or institution; and

5. Records created or received by an educational agency or institution after an individual is no longer a student in attendance and that are not directly related to the individual's attendance as a student.
6. Grades on peer-graded papers before they are collected and recorded by a teacher.

Educational agency or institution means any public or private agency or institution to which this part applies under 99.1(a).

Eligible student means a student who has reached 18 years of age or is attending an institution of postsecondary education.

Parent means a parent of a student and includes a natural parent, a guardian, or an individual acting as a parent in the absence of a parent or a guardian.

Personally Identifiable Information. The term includes, but is not limited to:

- a) The student's name;
- b) The name of the student's parent or other family members;
- c) The address of the student or student's family;
- d) A personal identifier, such as the student's social security number, student number, or biometric record

16.3 FERPA Policy

FERPA applies to educational agencies or institutions to which funds have been made available under any program administered by the Secretary of the U.S. Department of Education if the institution provides educational services or instruction to students and is authorized to direct and control public elementary, secondary, or post-secondary educational institutions. 34 CFR 99.1(a). Funds include those provided to the institution by grant, cooperative agreement, contract, subgrant, or subcontract or if funds are provided to the students attending the institution. If there is a question about the applicability of FERPA to an educational institution, 34 CFR 99.1 should be reviewed.

The education records protected by FERPA are those records that directly related to a student and are maintained by an educational agency or institution or by a party acting for the agency or institution. 34 CFR 99.3. When FERPA is applicable, consent from the parent or student is required in order for the educational institution to disclose the education record or the disclosure must meet an exception criteria found in 34 CFR

99.31. Such disclosures may be requested to obtain student records as part of a human subject research study.

The disclosure must be to an institution (Pennington Biomedical Research Center) conducting studies for, or on behalf of, educational agencies or institutions to:

- a. Develop, validate, or administer predictive tests;
- b. Administer student aid programs; or
- c. Improve instruction

Unless the request meets an exception in 34 CFR 99.31, signed and dated written consent must be obtained from the parent or eligible student before the educational institution discloses the personally identifiable information. 34 CFR 99.30(a). Written consent must include the following elements (34 CFR 99.30(b)):

- a. Specify the records that may be disclosed
- b. State the purpose of the disclosure; and
- c. Identify the party or class of parties to whom the disclosure may be made

If the request involves an exception to parental permission or student consent, the request must meet an exception provided in 34 CFR 99.31(a). The exceptions relevant to research include 34 CFR 99.31(a)(6) or 34 CFR 99.31(11).

- a. The following requirements apply to this exception:

The exception under 34 CFR 99.31(11) permits educational institutions or agencies to release "directory information" from students without consent so long as the conditions under 34 CFR 99.37 are met. A researcher may receive directory information from an educational institution without student or parental consent as required by FERPA. If a student's social security number or other non-directory information is used alone or combined with other data elements to identify or help identify the student or the student's records, informed consent must be obtained. 34 CFR 99.37(d)

- 1) In order for the student records to be disclosed, the researcher on behalf of Pennington Biomedical Research Center, must enter into a written agreement with the educational agency or institution. The written agreement must contain the following elements (34 CFR 99.31(6)(ii)(C)):
 - a. Specifies the purpose, scope, and duration of the study or studies and the information to be disclosed
 - b. Requires the organization to use personally identifiable information from education records only to meet the purpose or purposes of the study as stated in the written agreement
 - c. Requires the organization to conduct the study in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization with legitimate interests

- d. Requires the organization to destroy or return to the educational agency or institution all personally identifiable information when the information is no longer needed for the purposes for which the study was conducted and specifies the time period in which the information must be returned or destroyed
- 2) Once the information is disclosed to the researchers, the limitations outlined in the written agreement on use of the student data must be followed. 34 CFR 99.31(6)(ii).

16.4 Protections of Pupil Rights Amendment (PPRA)

PPRA affords parents certain rights regarding the conduct of surveys, collection and use of information for marketing purposes, and certain physical exams. These include the right to:

- Consent before students are submit to a survey that concerns one or more of the following protected areas (“protected information survey”) if the survey is funded in whole or in part by a program of the U.S. Department of Education (ED)
 1. Political affiliations or beliefs of the student or student’s parent;
 2. Mental or psychological problems of the student or student’s family;
 3. Sex behavior or attitudes;
 4. Illegal, anti-social, self-incriminating, or demeaning behavior;
 5. Critical appraisals of others with whom respondents have close family relationships;
 6. Legally recognized privileged relationships, such as with lawyers, doctors, or ministers;
 7. Religious practices, affiliations, or beliefs of the student or parents; or
 8. Income, other than as required by law to determine program eligibility.
- Receive notice and an opportunity to opt a student out of
 1. Any other protected information survey, regardless of funding;
 2. Any non-emergency, invasive physical exam or screening required as a condition of attendance, administered by the school or its agent, and not necessary to protect the immediate health and safety of a student, except for hearing, vision, or scoliosis screenings, or any physical exam or screening permitted or required under State law; and
 3. Activities involving collection, disclosure, or use of personal information obtained from students for marketing or to sell or otherwise distribute the information to others.
- Inspect upon request and before administration or use
 1. Protected information surveys of students;

2. Instruments used to collect personal information from students for any of the above marketing, sales, or other distribution purposes; and
3. Instructional material used as part of the educational curriculum.

These rights transfer from the parents to a student who is 18 years old or an emancipated minor under State law.

16.4.1 Investigator Responsibilities

Investigators must provide an assurance letter from each school in which the research will be conducted stating that the school complies with the Family Educational Rights and Privacy Act (FERPA) and the Protections of Pupil Rights Amendment (PPRA).

Investigators must provide a copy of all surveys and instructional material used in the research. Parents of children involved in the research must be able to inspect these materials upon request within a reasonable amount of time.

Investigators must ensure 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.

16.5 IRB Review of Department of Education Research

Requests for use in research must be submitted to the IRB. The IRB will evaluate such requests, including any exceptions to parental permission and student consent, for compliance with FERPA and PPRA requirements.

- a. An educational agency or institution may disclose education records or information from education records without consent if the disclosure is after the removal of all personally identifiable information, provided that the educational agency/institution (or other party that received the information or education records) has made a reasonable determination that a student's identity is not personally identifiable, whether through single or multiple releases, and taking into account other reasonably available information.