Research Subject to the US Department of Education Regulations

The following special considerations apply to all research involving human subjects supported or conducted by the U.S. Department of Education. These considerations are in addition to those found in 45 CFR 46 Subparts A-D.

- All instructional material—including teachers' manuals, films, tapes, or other supplementary instructional material—which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in such research.

- 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.

- 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.

1.1 Research Subject to the Family Educational Rights and Privacy Act (FERPA)

The Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records. The term “education records” includes any information that directly relates to a student and is maintained by an educational institution. In general, FERPA provides that, with certain exceptions, information from a student’s education records may not be released to others, including those within the same educational institution, without the student’s or parent’s prior written consent. If the student is over 18 or enrolled in college, the student must give the consent. If the student is under 18 and not enrolled in college, the consent must come from his or her parent. For a FERPA consent to be effective, the researcher obtain written consent from each individual whose records will be accessed for research purposes. This can be embedded in the consent form and must include the following:

- Be in writing;
- Signed and dated by the student or parent (as applicable);
- Specify the records that may be disclosed;
- State the purpose of the disclosure; and
• Identify the party to whom the records may be released.

Otherwise the Office of the University Registrar is required to approve access to student records for research purposes.

Notably, FERPA does not apply to schools that do not receive funds under a program of the U.S. Department of Education (e.g., certain private or parochial schools).

Note that health records pertaining to students, which are created and maintained by an educational institution (e.g., Campus Health Services; school nurses) are covered by FERPA rather than the Health Insurance Portability and Accountability Act (HIPAA). Accordingly, educational institutions must observe the restrictions and requirements of FERPA, including obtaining a valid FERPA consent (described above) or meeting a relevant exception (described below), before such records may be released.

In the research context, information from education records may be released, without the student’s or parent’s consent, to organizations conducting studies for, or on behalf of, educational agencies or institutions, but only if the study is:

1. for developing, validating, or administering [academic] predictive tests;
2. to administer student aid programs; or
3. to improve instruction.

In order to qualify for this exception, the study must be conducted in such a way that parents and students may not be personally identified by anyone other than those working on the study, and the identifying information must be destroyed when it is no longer needed for the study’s purposes. If the study at issue involves the University’s data, there must be a written agreement between the University and the organization (e.g., school district or post-secondary institution) conducting the study. That agreement must:

• Specify the purpose, scope and duration of the study or studies and the information to be disclosed;
• The determination of the exception;
• Require that the organization use personally identifiable information from education records only to meet the purpose or purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information;
• The information to be disclosed;
• Require the organization to conduct the study in such a way that there is no personal identification of parents and students by anyone other than representatives of the organization who have legitimate interests;
• Require the organization to return to the University or destroy the personally identifiable information when it is no longer needed for purposes of the study; and
• Specify the time period within which the organization must either return or destroy the personally identifiable information.

Education records may be released without consent under FERPA if all personally identifiable information has been removed including:

• Student’s name and other direct personal identifiers, such as the student’s social security number or student number.

• Indirect identifiers, such as the name of the student’s parent or other family members; the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable; date and place of birth and mother’s maiden name.

• Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.

• Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

Directory information publicly maintained by an educational institution may also be released without the student’s or parent’s consent, provided that the student or parent (as applicable) has not opted out of directory information disclosures. Researchers must check to confirm that a student has not opted out before accessing or disclosing directory information absent written consent. Researchers can verify whether a student has opted out of directory information disclosures by checking the relevant, publicly-available directory (e.g., the University’s online directory) or asking the appropriate administrative office of the educational institution (e.g., the Office of the University Registrar).

OTHERWISE, you must submit a request to the provost office as follows:

The Office of the University Registrar is required to approve access to student records for research purposes. Please submit via email a pdf copy of your IRB application to the Assistant Provost and University Registrar

You may create a pdf copy of your IRB application by clicking on the PDF icon in the upper right corner of the Application Status screen.

After you have received approval from the Office of the University Registrar, please attach it to your IRB application.
DO NOT begin human subject interaction until the IRB has reviewed your application and made an NHSR determination, Exempted it from review, or given an Approval (i.e., do not begin the consent process -- even if it is requested by the provost office -- until you receive you final IRB letter).

Questions about FERPA and permissible uses of education records may UNC-Chapel Hill HRPP SOPs be directed to the Office of University Counsel.

1.2 Research Subject to the Protection of Pupil Rights Amendment

In order to comply with the Protection of Pupil Rights Amendment (34 CFR 98.4), the following must be in place as applicable, and the investigator must document for the IRB that for research projects directly funded by the U.S. Department of Education, no student will be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:

- Political affiliations or beliefs of the student or the student's parent.
- Mental or psychological problems of the student or the student's family.
- Sex behavior or attitudes.
- Illegal, anti-social, self-incriminating, or demeaning behavior. Critical appraisals of other individuals with whom respondents have close family relationships.
- Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
- Religious practices, affiliations, or beliefs of the student or student's parent.
- Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

*Prior consent* means prior consent of the student, if the student is an adult or emancipated minor; or prior written consent of the parent or guardian, if the student is an unemancipated minor.

1.2.1 Research Conducted in a School Receiving U.S. Department of Education Funding (34 CFR 98, 99)

For research not directly funded by the U.S. Department of Education but conducted in a school that receives funding from the U.S. Department of Education, the research protocol must include provisions, as applicable, to ensure:

- The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student. Such access must be made available within a reasonable period of time after the request is made by the parent.
• The protection of student privacy and data confidentiality in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items):
  • Political affiliations or beliefs of the student or the student’s parent.
  • Mental or psychological problems of the student or the student’s family.
  • Sex behavior or attitudes.
  • Illegal, anti-social, self-incriminating, or demeaning behavior.
  • Critical appraisals of other individuals with whom respondents have close family relationships.
  • Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
  • Religious practices, affiliations, or beliefs of the student or the student’s parent.
  • Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

• The right of a parent of a student to have reasonable access to inspect any instructional material used as part of the educational curriculum for the student. The procedures for granting such a request must be described.

• The school has adopted a policy in conjunction with parents regarding:
  • Administration of physical examinations or screenings that the school or agency may administer to a student.
    • The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.
  • The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.
  • Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

• Research Funded by the National Institute on Disability and Rehabilitation Research (34 CFR 350.4(c)(2))

When research is funded by the National Institute on Disability and Rehabilitation Research and the 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.