



Title:	Research in Educational Settings		
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1 Research in educational settings

Research conducted in established or commonly accepted educational settings that involve normal educational practices as well as research involving the use of educational tests, survey procedures, interview procedures, or the observation of public behavior is eligible for exemption from the Common Rule. However, such research sometimes raises special concerns to which the IRB must be especially attentive. One example of such a concern is the “two-hat” problem in which a researcher is also an instructor with potential coercive power or undue influence over students who are also potential research subjects. Such a situation does not automatically disqualify a project from exemption, but the IRB should be cognizant of the problems such an arrangement might create. Furthermore, even if the research is exempt, the investigator has an ethical obligation to ensure that students’ rights and welfare are respected. When educational institutions become engaged in the actual conduct of research, they are required to file an assurance in accordance with 45 CFR 46.103(a).

2 Student Research

See SOP 4601 Trainee or Student Projects Involving Human Subjects Research

3 Oral History

A decision whether oral history or other activities solely consisting of open ended qualitative type interviews are subject to the policies and regulations outlined in an institution's FWA and DHHS regulations for the protection of human research subjects (45 CFR 46) is based on the prospective intent of the investigator and the definition of "research" under DHHS regulations at 45 CFR 46.102(d): "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Specifically, for the purposes of this policy, the evaluation of such activities hinges upon whether:

The activity involves a prospective research plan that incorporates data collection, including qualitative data, and data analysis to answer a research question; and

The activity is designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

In order to be subject to the UNC-Chapel Hill human research protections policies, the activity must meet both of the above standards. This determination will be made according to the procedures described in Section 5 above.

General principles for evaluating Oral History activities:

1. Oral history activities, such as open ended interviews, that ONLY document a specific historical event or the experiences of individuals without intent to draw conclusions or generalize findings do not constitute "research" as defined by DHHS regulations 45 CFR 46.

Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the video tape does not intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.

2. Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) would constitute "research" as defined by DHHS regulations at 45 CFR 46.

Example: An open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings.

3. Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Because the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR 46, the creation of such an archive would constitute research under 45 CFR 46.

Example: Open ended interviews are conducted with surviving Negro League Baseball players to create an archive for future research. The creation of such an archive would constitute research under 45 CFR part 46 because the intent is to collect data for future research.

Investigators are advised to consult with the IRB Office regarding whether their oral history project requires IRB review.

3.1 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 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, it must:

- 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.

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 conducting the study. That agreement must:

- specify the purpose, scope and duration of the study or studies and the information to be disclosed;
- require that the organization use personally identifiable information from education records only to meet the purpose or purposes of the study as spelled out in the agreement;
- 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.

More generally, information from education records may be released without the student's or parent's consent where the information released is de-identified. Even if a student's name or other common identifiers (e.g., date of birth, address) have been removed, the educational institution must still consider whether a reasonable person in the community could use the released information to identify a student with reasonable certainty. If so, then the information does not qualify as "de-identified" and may not be released without a valid consent.

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).

Questions about FERPA and permissible uses of education records may be directed to the Office of University Counsel.

3.2 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.

3.2.1 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.