

EXEMPTION CATEGORY 1 EDUCATIONAL RESEARCH <u>45 CFR 46.104(D)(1)</u>



- ▶ This exemption covers research conducted in established educational settings and involving normal educational practices, so long as the research is not likely to adversely affect students' opportunity to learn required content or the assessment of educators who provide instruction.
- ► This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- ► <u>Letter of support</u> from the school
- Qualifies for a waiver of documentation of consent unless FERPA applies
- Use of an <u>Informational sheet</u> is allowed

Exemption Category 1 Educational Research 45 CFR 46.104(d)(1)

- I. Research **must** be conducted in an established or commonly accepted educational setting
- a. schools and colleges, any place where educational activities regularly take place, including an after-school program, workplace, library, or a museum.
- II. The research **must** involve normal educational practices only
- b. regular and special educational instruction strategies
- c. effectiveness of or the comparison among accepted instructional techniques, curricula, or classroom management methods
- III. The research *can not* collect info, beyond basic demographics, of students, families, or teachers, such as mental health, personal beliefs or opinions beyond those associated with the curriculum or learning
- IV. The research **can not** affect students' opportunity to learn, i.e., take time or attention away from normal instruction
- V. The research **can not** affect the assessment of the educators who provide instruction, i.e., take time or attention away from normal instruction

EXEMPTION CATEGORY 2 SURVEYS, INTERVIEWS, EDUCATIONAL TESTS, OR OBSERVATION 45 CFR 46.104(D)(2)

- This exemption covers research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)
- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation (and the identity of the participants can be readily ascertained);
- Does not include children under 18, best used for research enrolling adult students, teachers/faculty, or adult family members
- ▶ Requires a Letter of support from the school
- Qualifies for a waiver of documentation of consent
- ▶ Use of an Informational sheet is allowed



Qualitative Research Protocol

Can be used for research with children under 18 in a school

Common research interventions: interviews, focus groups, questionnaires, classroom observation, collection of class records or artifacts

Generally, requires assent from children and consent from one parent

<u>Letter of support</u> from the school

Potential risks tend to be minor – breach of confidentiality

Should not be used if quantitative methods are included (use Human Subjects Protocol instead; may involve mixed methods)

Parental Consent

All expedited research conducted in a public school with children under age 18 will require at least one parent to sign a consent form.

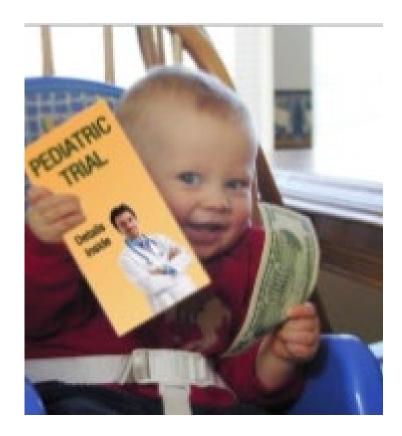
Use the <u>Behavioral & Social Science Consent Form</u> template, edited to focus on study purpose, procedures, risks, benefits, and confidentiality of the minor participant

Strongly recommended all researchers take our local IRB Education:

<u>UVM Consent Process & Documentation Training</u>
<u>Module</u>

Child Assent

- ▶ A child's affirmative agreement (verbally or written) to participate in research obtained in conjunction with consent from the child's parent(s) or legally authorized representative.
- ► Written research assent at UVM is typically conducted with children 11 17.
- ➤ Verbal assent should be documented for children under 11 (if capable, accounting for the ages, maturity, and psychological state of the children involved).
- Assent can be waived if the IRB finds the capability of some, or all the children is so limited that they cannot be reasonably consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.
- ► Consent of the parent/guardian is always a requirement.



Child Assent Process

The process of asking a child to participate in research should be carefully planned and implemented, using ageappropriate language and methods, for any child who is considered capable of understanding and providing assent.

The IRB has 2 <u>child assent templates</u> for researchers to use.

What is the research about?

Why is the child being invited to participate in the study?

List procedures the child will be expected to take part in

Include any potential risks and/or discomforts to the child

Are there potential benefits to the child or society?

Inform the child they may withdraw at any time without negative consequences

Invite them to ask questions about the research

Consent Process Documentation

The process of administering a consent for research should be documented using *an additional form* from the consent!

Especially important when consenting vulnerable populations such as children under 18

Documents: correct consent version was used, correct assent process was used for the age of the child, appropriate parent/legal guardian provided consent, consent was obtained prior to research activities, all questions were answered, additional special circumstances, optional activities, and notes

The IRB has 2 <u>Consent Process Documentation templates</u> available for researchers.

MODIFY TO FIT YOUR STUDY CONSENT PROCESS

(remove or edit all sections in red that are not applicable, including removing this header)

Informed Consent & HIPAA Authorization Process Documentation

on the participant (check all that apply): a Sheet/Consent Form with the anybody they believe could help them ed the consent form. any research-related procedures. participant have, any special

Possible additional information to collect during the consent process if approved in the protocol (modify above as needed):

Children in State Custody

- The Vermont Department of Children and Families (DCF) is the legally authorized agency able to grant permission for participation in research for children in their custody.
- The decision of whether to grant permission for research is made on a case-by-case basis by DCF and consent is provided by an appropriate representative of DCF.
- If a child has begun research procedures with the consent of a parent but is subsequently placed in the custody of DCF while undergoing research interventions, consent must be sought again from the appointed advocate for the child at DCF in order to continue participation in the research.
- Researchers should work with classroom teachers and school administration to ensure consent is obtain properly.



A FEDERAL LAW ADMINISTERED BY THE U.S. DEPARTMENT OF EDUCATION; 34 CFR PART 99, WHICH PROTECTS THE PRIVACY OF STUDENT EDUCATION RECORDS, INCLUDING FOR RESEARCH

Accessing Educational Records for Research -Complying with FERPA

The law applies to all educational agencies and institutions that receive federal funding.

Student education records are considered confidential and may not be released without written consent from the student (and parent/legal guardian if required) unless disclosure is permitted through one of the FERPA signed consent exceptions.

Education records include any record containing personally identifiable information (PII) directly related to the student. PII is not limited to name but may include indirect identifiers as well.

What is considered Educational Records?

Education records include:

Education records do not include:

- graded papers or exams
- transcripts
- attendance or disciplinary records
- class rosters or student demographics
- notes from a conversation with a student
- computer screens displaying student information
- emails containing information about a student

- sole possession (lap drawer) records
- peer graded papers
- online forums (e.g., Oncourse/Canvas chats)
- law enforcement unit records
- employment records (unless employment is based on student status)
- medical records
- alumni records

Signed Consent Requirements Under FERPA

Requires student consent (if age 18 or over) or parental permission and assent from the student (if under 18)

Consent form must:

- ✓ Specify the records to be disclosed;
- ✓ State the purpose of the disclosure;
- ✓ Identify the party to whom the disclosure is to be made;
- ✓ Include a dated student (+/- parent) signature.





Protecting Student Privacy

U.S. DEPARTMENT OF EDUCATION

A Service of the Privacy Technical Assistance Center and the Student Privacy Policy Office

PPRA - THE LAW (34 CFR PART 98) REQUIRES THAT SCHOOLS OBTAIN WRITTEN CONSENT FROM PARENTS BEFORE MINOR STUDENTS PARTICIPATE IN ANY U.S. DEPARTMENT OF EDUCATION FUNDED SURVEY, ANALYSIS, OR EVALUATION THAT REVEALS SENSITIVE INFORMATION

Applicability and Requirements of PPRA

Schools must obtain written consent from parents before minor students participate in any U.S. Department of Education funded survey, analysis, or evaluation that reveals information concerning the following areas:

Political affiliations;

Mental and psychological problems potentially embarrassing to the student and his/her family;

Sex behavior and attitudes;

Illegal, anti-social, selfincriminating and 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*; or Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program.)

Note: Parental permission for the students to participate cannot be waived.



UVM Educational Protocols

Exemption Category 1 Educational Research

<u>45 CFR</u> 46.104(d)(1) "Black Homeschooling in the United States" PI - Cee Carter, Ph.D.

- research aims to understand homeschooling education as an alternative learning space and to examine curricula, learning settings, and assessment practices of Black homeschoolers - so research question is about normal educational practices
- participants are parent homeschoolers (no minors)
- ► internally funded
- ▶ interviews + photo solicitation + collection of curricular resources (lesson plans, curricular maps, examples of completed student work, etc.)
- ► Even though parent homeschoolers are given the option to provide completed student records/classwork, FERPA doesn't apply because they are not an "educational agency or institution that receives federal funding."
- ► Information Sheet with verbal consent, Waiver of Documentation of Consent

Exemption Category 2 Educational Research

<u>45 CFR</u> 46.104(d)(2) "Survey of Collaborative and Resilience-Oriented Practitioners" PI – Kristabel Stark, Ph.D.

- ➤ Does not qualify for Exempt 1 because research question is about the students, not normal educational practices
- ► US Department of Education funded
- ▶ PPRA doesn't apply. Could argue surveys are about "mental and psychological problems potentially embarrassing to the student" with questions about resilience like "I tend to take a long time to get over setbacks in my life." However, the law applies to the rights of parents of minor students and this enrolls adult students.
- Surveys (collected for program eval, obtaining consent to use for research) about adult students' skills and knowledge
- ► Adult consent PI obtaining signatures for tracking purposes, no Waiver of Documentation requested (but would have met the criteria for approval)

Expedited,

Qualitative Research

45 CFR 46.110

"Encuentros: Constructing Racial Identity at Home and School" PI – Eliana Castro, Ph.D.

- internally funded
- participants are minor students and their families (including adults and minors), and teachers
- classroom observation + task-elicitation interviews + focus groups + collection of artifacts
- ► research taking place at a public school receiving federal funding, so FERPA would apply if identifiable school records are collected
- child assent/parental permission for child observation, interviews, and artifacts
- adult consent for teacher participation and parent/adult family member interviews

PI Guidance & Education Materials

- ► <u>PI Checklist for New Studies</u> A list of questions for researchers to consider while working your way through the IRB submission process
- <u>UVM IRB Templates</u> Protocol, consent and data management forms required for review
- ► <u>UVM Policy & Procedures</u> search this document to access federal and local research regulations and polices that may affect your research. CRTL F on the page
- ► <u>Guidance Materials Required for UVMClick</u>
 <u>Submissions</u> Outlines the materials investigators should assemble and include with their applications for IRB review or Determination of Exemption
- ▶ <u>UVMClick User Guides</u> Step-by-step directions on how to submit and navigate the Click software platform for protocol submission to the IRB.