

Best Practices for Educational Research Involving Minors as Subjects

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Intended audience: Student researchers in graduate programs at Saint Mary's University of Minnesota and their faculty research advisors

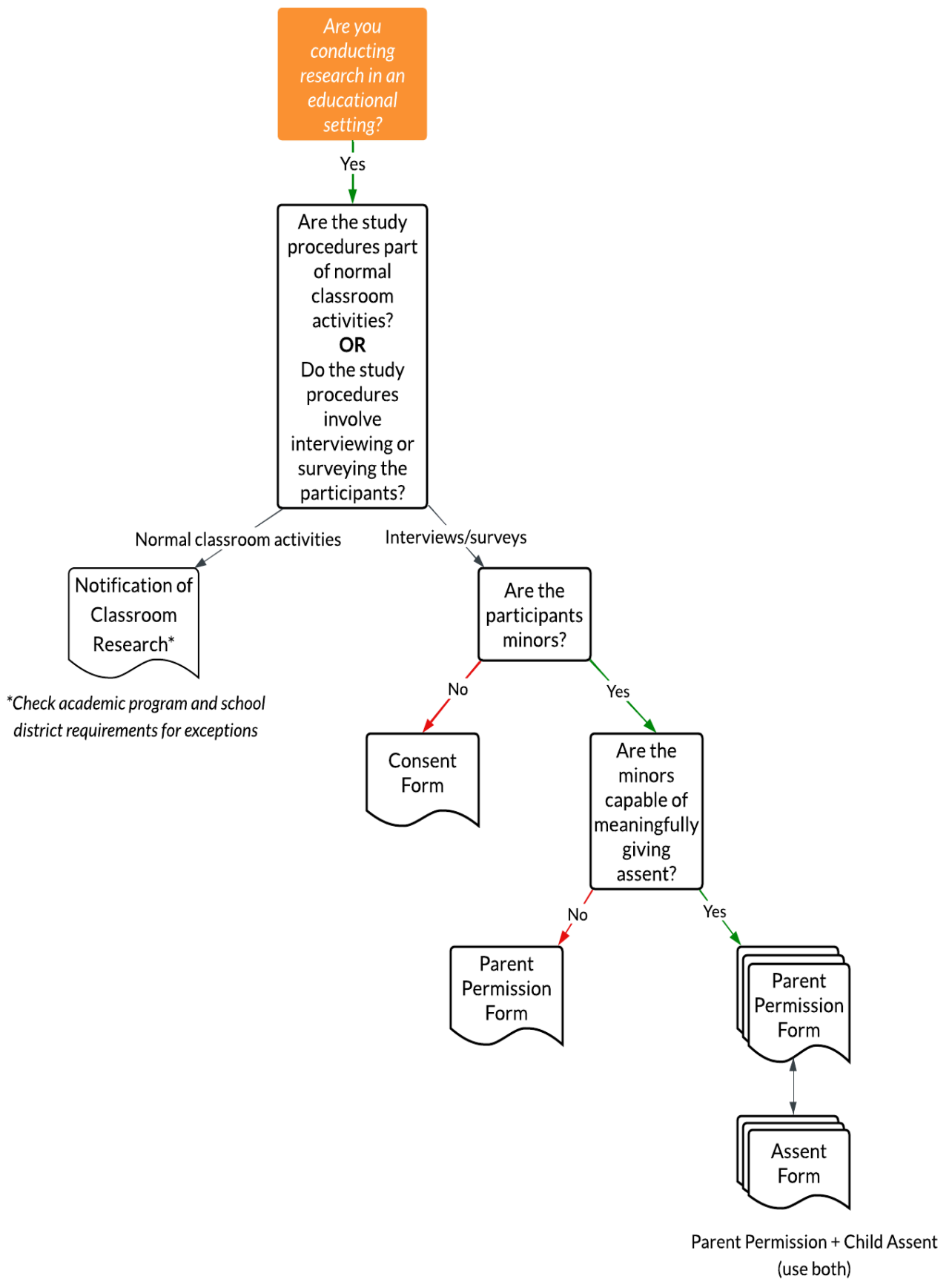
Overview

1. Complete the CITI training before beginning your application. The training gives a good background to the field of research ethics and the regulatory requirements.
2. Understand why youth are considered a “vulnerable population” by regulatory agencies
3. Understand situational vulnerabilities common to education research, such as the teacher’s position of authority in the classroom or the effects of peer pressure.
4. One of the main goals of ethical research is to answer the research question with as little risk to the human subjects as possible, and to minimize risks that cannot be avoided. Risk can be present in the study design, the procedures, the topic, or in certain situations.
 - a. Study design - Some study designs present risk in an educational setting. For example, if the goal is to conduct one-on-one interviews about a sensitive topic, it may be very difficult to discreetly remove a child from their scheduled class or activity without drawing the attention of others. The child’s right to privacy would be difficult to maintain if others knew of their involvement in a study about a particular sensitive topic.
5. Know that some topics that are sensitive in nature require a more robust consent process with the child’s parent(s) or guardian(s).

Frequently Asked Questions

What do I use for obtaining consent? What do I include in my application?

The short answer: If the study is a normal classroom activity, you can usually use a Notification of Classroom Research. If the study involves a survey or interview of the child, or something not part of a normal classroom activity, you will need to use a Parent Permission form and an Assent form if appropriate.



What is a Notification of Classroom Research?

This is a way of waiving the need for consent documentation, because you are not requesting a signature by the parent or guardian. You are simply informing them that a normal classroom assignment or activity will be used as data for research. Parent(s)/guardian(s) can then choose to opt their child out of the data collection, so that the child still participates in the normal classroom activity, but their results will not be used as data. This is best for research studies that do not involve any interviews or surveys with the child (instead you are observing classroom behavior or using results from tests/worksheets).

Note that some school districts require a signed parent permission form instead. Check the requirements for your research site and consult your Faculty Research Advisor if this is an option for your academic program.

What are “Normal Classroom Activities”?

Some educational practices meet the criteria for Exempt IRB review, even when they involve minors as subjects. Normal classroom activities refers to research conducted in established or commonly accepted educational settings, that specifically involve education practices not likely to impact students’ opportunity to learn required content or assessment of educators who provide instruction. **This includes most research on regular and special education instructional strategies, instructional techniques, curricula, or classroom management methods.**

Survey, interview, or focus group research involving minors **do not** qualify for exemption under 45 CFR 46.104(d). Observation of public behavior research involving minors may be determined as exempt if the investigator does not participate in the activities being observed. Survey, interview, focus group, and some types of observation research involving minors are Expedited categories and require review by two IRB Board Members.

What is an Assent form?

Because children are minors, they cannot give consent, but they can give assent, which means they indicate a willingness to participate. In research involving surveys or interviews with children, it is important to seek assent. **Assent is not a signature on a page, but an ongoing process throughout the research.** The Assent Form templates are meant to help you develop a way to document that process. The goal is to enable the child to give assent in a way that is meaningful. That might mean you read the form out loud to them, ask questions to make sure they understand what will happen, and check in throughout the study to see if they’ve changed their mind. Be sure to explain how you plan to engage in an assent process on the application. If a written Assent Form is useful for the age and capacity of the child, use it. If not, explain why. If you determine that the children do not

have the capacity to meaningfully give assent, explain how you came to that decision on your application.

What is a Parent Permission Form?

This form is almost identical to the Consent Form, except that it is intended for the parent or guardian of a participant. They give permission for their child to participate, and then the child gives assent.

If the subjects are all students in my own class, what do I submit for recruitment documentation?

- If you are using a Notification of Classroom Research, that functions as both your recruitment material and your consent documentation. Explain on the application form why you do not have a separate recruitment letter.
- Same goes for a Parent Permission Form. If you're not using a recruitment letter in addition to the Parent Permission Form, just explain why.

Do I need to submit a Research Cooperation Agreement (RCA) or an IRB Authorization Agreement? What's the difference?

If you are recruiting participants through a school, club, organization, or group, you need to show you have the proper permission to do so. If there is another IRB involved (common when recruiting from another college or university) you would use an Authorization Agreement. If you are recruiting from a school district, they might have a research office, but probably not a formal IRB. In that case, use an RCA.

Note that when you fill out the RCA, there are three checkboxes that describe different permissions the school/organization can grant you. Not all apply to every study. Be sure to read each one and select only those that apply to your project. For example, if you are doing a survey and don't plan to use any archival data (grades, attendance records, etc.), don't select the checkbox for archival data usage. The checkboxes should help you explain to the organization what your study involves and what they are agreeing to let you do.

If I need my school district's approval, why do I also need the IRB's approval?

An IRB makes sure the studies that involve human subjects are done ethically. The school district gives permission for you to conduct that study using their students. Both are necessary for conducting academic research responsibly.

Why does the application ask about potential benefits to the participants? How do I answer that question?

- In most social-behavioral research, there are no direct benefits to the participants. Your answer to this question should be consistent with a statement on the consent form about benefits to the participants.
- In medical research, a test group may receive treatment for a disease while the control group does not. In those situations, the IRB needs to know how you will ethically distribute the benefits to the participants.
- If you are studying a behavioral intervention or teaching method, you cannot guarantee that the subjects will be better off than if you did not do the study. It's important to remind potential participants in the consent form that they will not benefit from the study, in order to avoid the risk of therapeutic misconception.

If you have any questions about IRB processes, applications, forms, documents, etc. please don't hesitate to reach out to the IRB Coordinator or an IRB member. We can help answer questions while you're working on your application, even before you submit.

Website:

<https://irb.smumn.edu/>

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