
Yale University Institutional Review Boards Guidance

310 GD.1 Research Conducted in Schools

Overview

Research conducted in schools raises a distinct set of concerns with regards to proper treatment of research participants. In addition to the usual requirements of IRB review, an investigator who intends to conduct research in a school needs to be aware of these issues when designing a research study. The guidance below describes some of the more common issues which have come to the attention of the IRB. The IRB is available to assist investigators in determining what issues are likely to arise in a particular study.

Student Concerns

Special caution must be taken when recruiting students. In most cases they are minors and by definition require special protection under 45CFR46 Subpart D. When recruiting in schools, investigators also must be sensitive to the influences of peer pressure and the desire to please teachers and parents. Studies performed in schools require special attention to consent and confidentiality.

Consent and Assent

Participants in school studies are likely to be minors and thus not able to give legally effective consent. The minimum age at which an individual can consent to research participation varies from state to state and may be distinct from other consent statutes such as ability to consent to medical treatment. The laws of the state in which the study is conducted are the ones to be followed. In Connecticut, only subjects over the age of 18 can legally consent to participate in research. Written parental consent is required for all participants under the age of 18 except in rare cases as determined by the IRB.

Despite their inability to legally consent, ethical standards require that the autonomy of minors be respected by requesting assent to participate. Assent is similar to consent although the information provided to gain assent must be tailored to the intellectual capacity of the children. For example, a form similar to the parental consent form may be appropriate for high school seniors whereas a less detailed verbal description may be most appropriate with kindergartners. Non-therapeutic research can only proceed when both the parent and the child have agreed to take part in the study.

Limits to Confidentiality

Most studies promise confidentiality of the student's responses. When this promise is made, it is absolute. The only instances in which it can be breached involve state-mandated reporting requirements (abuse, some infectious diseases, etc.), prevention of harm to the participant or others, and subpoena. The promise of confidentiality is to the student and their parent or legally-authorized representative. Thus, in cases where there is a need to intervene, it is not considered a breach of confidentiality to contact the parents. The one exception would be circumstances in which it would be more damaging to the child for the parents to be informed, such as instances of child abuse. In which case, it may be prudent to consult the child first. These limitations of confidentiality must be conveyed to the students, including under what circumstances their parents would be informed of their responses.

Providing information about an individual participant to anyone other than the student and parent/guardian is considered to be a breach of confidentiality. This includes providing individually identifiable information to the schools, whether or not it is in the student's best interest. Although the school is often thought of as a partner in the research, they are nonetheless not privileged to see the individually identifiable data.

If the information to be collected in the study includes criminal activity (drug use/sale, violence to others), and it can not be collected anonymously, then the investigator may need to apply for a Certificate of Confidentiality from the DHHS. This document protects the data from subpoena, and thus removes the risk of use in criminal proceedings. Receipt of a Certificate of Confidentiality does not alleviate legal or

ethical requirements to report child abuse. It should be noted that even in cases where a Certificate of Confidentiality is not presumed to be needed, access to research data may be sought via subpoena. For example, one can imagine that the child's responses could be of value in the context of a custody dispute. Although the likelihood of a litigant wanting to look at your data are low, it remains a possibility. Thus, it is always in the best interest of the participants to have all of their information coded and the code destroyed upon completion of data collection.

School Concerns

One could argue that the concerns of the school are not within the purview of the IRB as a school is not a "subject" since it is not a "living individual." Nor is the school part of the research team since they will not be involved in the design and conduct of the research. However, since a school study can not, by definition, be conducted without the approval of the school, sensitivity to their concerns will facilitate your ability to complete the proposed data collection and produce valid results.

The primary function of a school is to educate students. Involvement in a research study will necessarily compete for the limited time that a school has to perform its primary function. The moment an investigator enters a school, the education function of the school has been disrupted. Such disruption will only be tolerated by the school if it anticipates receiving some benefit from participation. In agreeing to participate and to allow access to its students, the school must weigh the disruption of the study against the expected benefits. To do so, the school must be fully informed about the details of the study, much like the requirement for an individual participant's informed consent. It is imperative that the investigator clearly describes the roles of all parties, the risks and benefits of the study, as well as the purpose and procedures of the study.

Define who is responsible for what. There is a broad spectrum of the intrusiveness of a study. At one extreme are observational studies in which the investigator is interested in discreet observation and thus only approval to enter the schools is needed. Purely observational studies would not require parental consent, although the school may require that the parents are informed of the research.

Most common, however, are studies in which the data is collected interactively on school grounds during the school day. The responsibility of the schools may include distribution and collection of parental consent documents. The testing session itself may occur during normal classroom time, either with the class being testing *en masse* or by individuals being excused from the class to meet with the investigator. When the data is collected *en masse*, it is frequently the responsibility of the school to determine appropriate alternate activities for those students who decline to participate. It should be noted, however, that in some cases it is preferable to have a "filler" activity for the non-participants. In this way, the confidentiality of those who chose not to participate can be respected by allowing the appearance of participation in front of their peers and teachers while completing an unrelated task.

In defining the roles of the research team and the schools, the research personnel who will be on site should be identified to the school along with their qualifications and role. The school should be forewarned about who will be present in the schools, when they will be present and in what capacity. This includes undergraduates on the project as well as graduate students and postdoctoral fellows. To facilitate the school's ability to monitor who is present in their facility, the IRB recommends that all research personnel wear a visible form of identification which indicates their name and their affiliation with the research project.

Define benefits to the school: As noted, schools are only willing to relinquish classroom time if they feel that the benefits of the study are worthwhile. A realistic description of the benefits for the school should include not only what benefits will be provided but also what the limitations of these benefits are. For example, the types of reports which will be provided to the schools must be outlined—will there be information specific to an individual school or to schools in general? Are there circumstances in which the study will be terminated early and thus reports not be provided? This latter instance must be addressed if a study commences prior to securing adequate funding. The IRB recommends that the school be provided with a timeline showing when the data will be collected and when the school can expect to see any promised reports or other benefits.

Define disclosure risks: Public schools in particular have legal and moral requirements which they must fulfill to ensure the safety of their students. For example, school personnel in Connecticut are mandated to report suspected child abuse to state authorities. Such reports are frequently followed by an investigation by DCF and have the potential to have a child removed from the home. The threshold of required reporting is low and schools are put into a difficult situation when informed of suspected abuse of an identified student.

Another area where the school would be expected to act include threats to student safety. Information suggesting that a student may harm another student or him/herself would require the school to further assess the threat. Should the threat be substantiated, the school would be expected to mitigate the situation. Although it would be difficult to identify all situations in which a response would be necessary, investigators should be prepared when the study queries about depression, possession of weapons, or threatening behavior, either directly or indirectly.

To protect the school from having to implement its mandated procedures, it is generally better for the investigator to take responsibility for information uncovered in a study and present the school with generalized results. Any reporting should be done by the investigator directly to the relevant authorities. Note that many reporting requirements are defined by each individual state. Investigators are urged to be aware of what they as researchers would be legally required to report, as well as what they as individuals may feel ethically required to report. In cases where it would be absolutely necessary to inform the school, the school and the participants must be informed from the start that this would be a potential risk involved in the study. This risk must be stated clearly and in writing, including what types of actions the school would be required to take and whether or not the information would become part of the student's school record. The IRB urges investigator to discuss reporting expectations with the school personnel prior to the initiation of a study.

Define other site specific risks: Each school is a unique environment about which the school personnel are experts. Measures, which are of little concern in one school, may be of great concern in another, based on the local culture. It is essential that investigators provide school administrators with a full set of the measures to be used so that they may assess the likelihood of problems for their school. The school should be asked if the measures are appropriate for their students and if any problems can be anticipated during or after the research procedure. Note that highly sensitive topics may promote discussion of these issues by the students during the remainder of the school day. Depending on the nature of the issues, the school may want to be prepared for any subsequent repercussions arising from the research participation. Hence, the school must be aware of what measures will be administered when.

Define appropriate contacts: Communication is essential to maintaining rapport with the schools. Note only does the school need to be informed as to who they should contact with questions and concerns, but also, the investigator will need to know who the appropriate contacts are for various aspects of the study. The individual with authority to allow access to the students is usually different from the person who should be contacted about the logistics of data collection. In any case, these individuals should be defined up front to facilitate future communication.

Obtaining approval to work in the schools is a multi-step process. In the end, written approval should come from the highest level. In public schools this may be the superintendent. For private schools, the headmaster may be the appropriate official. This individual will be required to sign a letter indicating that they agree to allow access and have been shown all the required materials. To facilitate this process, the IRB will provide the investigator with a study specific checklist which is to be attached to the letter. This checklist will indicate all the relevant measures and responsibilities inherent in participation.

Schools as Research Partners

Occasionally, the study will call for the school to play an active role in the design and/or conduct of the research. Once the school moves beyond merely providing access, it is considered to be "engaged in research" and must meet additional requirements under the regulations. In particular, the school would be required to file an assurance with OHRP, indicating their plans to comply with 45 CFR 46. The IRB will

assist in determining when such an assurance is needed and how the school can comply with this requirement.

Adverse Event Reporting

Occasionally, there will be problems during data collection. Whether or not these problems were anticipated, they constitute an adverse event and must be reported to the IRB. Problems can range from complaints or distress of a participant to identification of participants at risk of harm. Note that an “adverse event” is viewed from either the participants or the researcher’s point of view. Whether or not the event is expected, if there is an outcome which is detrimental to the participant or perceived as detrimental, then an adverse event has occurred. If the event requires investigator intervention or alteration of procedures then the event must be reported within 5 working days. Otherwise, the events may be reported annually via the renewal application. Note that the IRB has experience in ways to handle adverse events and is available to assist the investigator determine the appropriate course of action.

Exempt Studies

45 CFR 46 exempts “research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.” Thus, studies which focus on improving the educational experience of the students are not covered by the regulations. Yale policy, however, requires that the exempt status always be determined by the IRB. Please see Guidance on Exempt Research for additional information.

FERPA and PPRA

Schools that receive funding from the US Department of Education are required to comply with the Family Educational Rights and Privacy Act (FERPA, 34CFR49) as well as the Protection of Pupil Rights Amendment (PPRA, 34CFR98). Under FERPA, schools may not release identified student academic information without authorization from the student (if over 18) or parent/guardian. PPRA requires that consent be obtained for any surveys involving sensitive information and that such surveys be available for review by parents prior to their administration to students. Investigators are reminded to take these regulations into account when planning research involving schools.

Checklist of Requirements for School Studies

Information to be provided to school officials:

- ✓ Full copy of protocol including all measures
- ✓ Logistics of data collection—when and where
 - Estimation of intrusiveness
 - Length of individual sessions
 - Length of entire study
- ✓ Handling of students who do not consent to participate. Who will be responsible for alternate activities?
- ✓ Listing of all research personnel, their roles on the project and qualifications
- ✓ Anticipated benefits to the school including timing and certainty of delivery
- ✓ Any risks of the study
 - Possible disruptions to school both during and after data collection
 - Identification of students at risk of harm
 - Identification of other reportable information
- ✓ Any responsibilities of the school—collecting consents, monitoring, interventions, etc.
- ✓ What, if any, individual student information will be provided to the school and if none, so state

- ✓ Ability to withdraw participation or request an individual measure be withdrawn. If school can not participate without inclusion of all measures, so state.
- ✓ Contact information for the Principal Investigator and HSC

Items to be ascertained from the schools

- ✓ Appropriate contact(s) for day to day issues
- ✓ Authorized official for the school
- ✓ Assessment of local context and related issues which the investigator must be sensitive to
- ✓ Appropriateness of study measures for the local population

Information to be provided to parents/guardians and students:

- ✓ Description of the study and clear statement that this is research
- ✓ Confidentiality of responses
 - What information will be shared with school
 - What information would be reported to other authorities
 - What information will be shared with parent and/or student
- ✓ Ability to decline/withdraw
 - Both parent and child can withdraw individually
 - Impact of study on students who decline to participate
- ✓ Duration of study
- ✓ Risks of participation
- ✓ Benefits
- ✓ Contact information for PI and IRB

Information to be provided to IRB, in addition to standard requirements:

- ✓ Listing of all research personnel, their roles/responsibilities, and qualifications
- ✓ Approval of the study by appropriate school official
- ✓ Description of procedures for mitigating consequences of adverse events
- ✓ Availability of appropriate level of funding for duration of project
- ✓ Assurance that full scope of study is within PI's area of expertise and if not, provide signed agreement from appropriately trained collaborator
- ✓ Continuing review items
 - Adverse event reporting
 - Reporting of all adverse events whether or not they were anticipated
 - Reporting of any complaints about the study
 - Reporting of any difficulties encountered by the investigator or participants
 - Copies of any new measures/procedures
 - Justification for addition
 - Description of how change will effect the risks and benefits of the study
 - Description of how new measure will be administered
 - Approval of the school for additional measure
 - Description of any changes in procedures from initial submission including revised measures with changes highlighted
 - Copies of all correspondence with school including relevant letters, reports, and e-mails

Template School Agreement

Agreement to Participate in a Research Study

As the authorized official of _____ school, I am agreeing to the participation of _____ school in the study entitled “_____” under the direction of Professor _____.

I have been given a full description of the project and have reviewed the following items and discussed their appropriateness with Professor _____:

- Measure 1
- Measure 2
- Listing of all research personnel who will be working in the schools

I understand that school personnel will be asked to perform the following functions:

- Distribution and collection of parental consent forms
- Providing alternate activities for those students who decline to participate

I understand I will be provided with a report on the outcome of the study within X months of completion as well as annual progress reports. The school system will also receive _____ as a thank-you gift for our participation.

I understand that I will not be provided with any information which individually identifies students and their responses except in cases where the student is found to pose a risk of harm to another student. I understand that the investigator will take responsibility for any other findings which require follow-up with the student, their parents or appropriate state authorities.

I understand that I may withdraw the school's participation at any time or prohibit the inclusion of any of the measures listed above.

If I have any questions about this research study I may contact Professor _____ at 432-_____.

If I have any concerns about the conduct of this study I can contact the Human Subjects Committee at 203-436-3650, human.subjects@yale.edu.

Name authorized official: _____

Title: _____

Phone: _____

Signature _____

Alternate school contact for routine study administration issues: _____

Title: _____

Phone: _____