

SAN JOSE STATE UNIVERSITY
HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD
Students as Research Subjects – A Guide to IRB Protocol Considerations

If you will be conducting research with students as research participants, your IRB application should provide the following basic information where prompted:

- A rationale for recruiting students as research participants that demonstrates that students are the logical choice for answering the research questions (e.g., the research is related to student issues, academics, curriculum, instructional strategies, instructional techniques, classroom management methods, or program evaluation). If a study topic does not necessitate the recruitment of students specifically, then researchers should recruit from the general population. Students may be included as part of the general population, but they should not be singled out for recruitment.
- Whether you are a university faculty member, a teacher in a primary school setting (perhaps yourself a student working on a degree program at SJSU), an administrator, or other service provider in the education setting and:

* Information about your specific role(s) at the school or institution,

* Whether or not you intend recruit students who are enrolled in your courses/classes or students to whom you provide direct services. If you want to recruit students whom you teach or directly serve, the IRB application must provide a strong justification for pursuing an approach where there is an interpersonal conflict of interest. A clear explanation about why the research questions cannot be answered any other way needs to be provided. In addition, you must provide a strategy for mitigating an interpersonal conflict of interest.

Strategies for Minimizing Interpersonal Conflict of Interest

If you plan on recruiting students whom you teach or directly serve, the application may not state that there is no interpersonal conflict of interest. When the subject pool is the researcher's own class or client roster, participants are often recruited out of convenience, and there may be more benefit to the researcher than to the participants. Past history and a continuing relationship with students can also bias a researcher and affect whether or not free informed consent and assent can truly be achieved.

The protocol application must address your dual role and the resulting power imbalance. A description of the tangible measures that will be used to mitigate the conflict of interest needs to be provided where prompted. A tangible strategy is not merely stating that participation is voluntary and will not affect course grades or other services to which students are entitled.

The following options are available to mitigate interpersonal conflicts of interest:

- Ensure that data collection is anonymous and that you would not be able to trace individual responses. This option is not feasible if the class or client roster is small and if the responses provide enough contextual info that could result in the identification of students. As well, this option is not feasible if you wish to access FERPA-protected data for which written consent is required. See the heading Secondary Data below for more information about FERPA requirements.
- Ask a neutral third party not involved in the research to recruit students and collect consent and assent forms (if applicable) on your behalf. The third party may also need to collect the data if doing so could result in the identification of participants (e.g., interviews); the data would then either be de-identified by the third party, if possible, or provided to you after a grade in the course has been assigned or after the students are no longer under your supervision if de-identification is not possible.
- Conduct the study in another course not taught by you.
- Conduct recruitment, consent, and data collection after grades have been assigned.

Addressing Inequitable Subject Selection and Stigmatization

Every effort should be made to recruit students who would most benefit from participation in the study. This must be balanced by an equal effort to avoid singling out students from their classmates, especially in primary and secondary education settings where students may not have a choice about which classes they are enrolled in. The following three examples outline some problematic subject selection strategies that have been presented in IRB protocols in the past as well as some alternative strategies that can be employed.

- Research targeting specific groups of students in a specific class. Concerns are raised when investigators target a specific sub group of students in a class in a way that could cause stigmatization (e.g., low performing students, minority students). You can't isolate students within a class based on their race, ethnicity, gender, or academic performance.

Alternative: invite all students to participate (after obtaining parental consent if students are minors) and design data instruments with screening criteria built in, so that your target group is evaluated in the analysis stage and not during the recruitment stage.

Alternative: Keep the decision to participate private by handing out materials to all students – some of which may include the research instruments, some of which may include alternative activities.

- Cherry picking a representative sample from a group of eligible participants to be subjects of the research. This practice lends itself to researcher bias and does not yield generalizable

results. If the research questions are broad, but the sample size is too small, conclusions can only be made about those particular subjects.

Alternative: invite all students to participate and allow for a control group, if feasible, to support conclusions and eliminate alternate explanations for results.

- Research that withholds educational benefits to students who do not participate. You cannot apply an intervention to a small group of students who agree to participate in the research if the intervention could benefit all students.

Alternative: either apply the intervention to all students who stand to benefit or ensure that the intervention will be applied to the rest of the group after the research is concluded.

What Does Research Participation Mean in a Classroom Setting?

When conducting research in a class setting, the IRB protocol needs to make a distinction between required classroom work and research. Data cannot be used for research without consent¹, even if students are required to complete the class assignments and curriculum. From the beginning, the research methods described in your protocol should clearly delineate between school-driven versus investigator-driven research and between normal educational practices and special, research-specific interventions. Your protocol should explain whether the planned activities were designed by the school or department and would occur regardless of whether the research takes place or whether the planned activities are designed by the study team to be done exclusively as part of the research.

Normal educational practices. If you plan on investigating the effectiveness of normal educational practices such as instructional strategies, instructional techniques, curricula, or classroom management methods, the research summary in your IRB application needs to explain the difference between choosing and not choosing to participate in the research. This information should also be communicated in the consent and assent documents and procedures. For example, if the research entails analyzing class assignments that students are

¹ The term “consent” is used here to denote permission from:

1. Students who are 18+ years old,
2. College students even if they may not be 18 years old,
3. Parents or legal guardians of non-college students who are minors.

The term “assent” is used to denote permission from minors. For most research, parental permission is required for the participation of minors in research. At SJSU, we do not require permission from parents when college students are approached to provide consent for their participation in school-based research. In other settings where parental permission is required, it must be sought before seeking assent from the minor. Assent is only required when the subjects are capable of providing it. This means that the investigator must explain the research to the minor in an age appropriate and developmentally appropriate manner and obtain the minor’s affirmative agreement to participate in the research.

required to complete, the consent/assent language should indicate that all students are required to do the work but that the research team will only analyze the work from those students from whom consent/assent has been obtained.

The burden of demonstrating whether an activity is part of normal educational practices is on the researcher. If a proposed research project appears to place participants at risk or has no precedent in previous, published research, the IRB will likely question the “normalcy” of the activity. For this reason, you should be prepared with a brief literature review that provides enough background information for the IRB to determine whether the proposed work falls within what is typical in the context of a specific classroom setting. What is considered to be normal in one classroom may not be in another. For example, curriculum and interventions for special education students in the primary or secondary school setting are tailored to each student, so normal classroom activities in a special education environment are student-specific in a way that they would not be in a general education environment. Be prepared to provide the contextual information about the school environment in which you intend to conduct your research in your IRB protocol – do not assume that IRB members will automatically know this.

Special, research-specific interventions. If you plan on conducting a special investigation or intervention that goes beyond assessing normal classroom practices, the consent and assent language must explain what those who choose not to participate will be doing in the meantime. An alternate assignment or activity may need to be designed, and non-participating students cannot be singled out by either their peers or their teacher (see above sections on interpersonal conflict of interest and stigmatization). The research must be designed so that neither the participating group nor the non-participating group forego any educational benefits as a result of their choices. That is, participating students should not be made to devote time to the research at the expense of their learning or in a way that is disruptive to the classroom environment, and non-participating students should not be excluded from the potential educational benefits that might be provided by an intervention. In the former instance, you should consider setting aside non-classroom time for participating students to complete research tasks, or come up with a research design that keeps information about who is and who is not participating private. In the latter case, when students might stand to benefit from the intervention but may not want to participate in the research, you can offer to apply the intervention to all students after the research is concluded.

Secondary Data

The IRB has oversight over the access and use of secondary data that contain identifying information. In most cases, consent and assent are also required for the use of individually identifying secondary data even if the school has given you permission to access the data. If

you have access to school data as part of your job function, this does not automatically mean that you may access the data for research purposes.

School records are protected under the Family Educational Rights and Privacy Act (FERPA), and there is no statute of limitations on the privacy of uniquely identifying student records. FERPA still applies to students' records even if they have graduated or are no longer enrolled at the school. FERPA may also apply to counseling and medical records. Teachers and administrators cannot be asked to share information about specific students without the student's and parent's consent.

FERPA allows IRBs to waive the need for consent in certain narrow circumstances. The FERPA studies exception can be used if the disclosure of individually identifying information from student education records is for, or on behalf of, an educational agency or institution in order to:

1. Develop, validate, or administer predictive tests;
2. Administer student aid programs; or,
3. Improve Instruction.

The IRB application must clearly demonstrate that one of the FERPA study exceptions applies if you wish to waive the informed consent requirement.

School permission alone is only acceptable if it confirms that the research team will not access FERPA-protected records or the school will provide you with data from which all of the identifying information has already been removed and you are not affiliated with the school in a manner that allows you to have access to the records.

In your protocol materials, please also avoid false claims about anonymity. If a researcher has access to individual student data and if he/she knows who participated in the research and who did not participate, the subjects are not anonymous. Efforts should be made to maintain confidentiality – such as through the use of pseudonyms – but anonymity cannot be guaranteed. Do not use the word “anonymous” in your protocol submission if it does not apply.

Observations in the Classroom

If the classroom environment will be observed, the IRB application must provide details about what information the research team wishes to gather from the observations and how the observations will help to answer the research questions. The IRB often receives educational research submissions that contain vague language about classroom observations. A rationale, justification, and details must be provided in order for proposed observations to be approved. In addition to explaining the nature of the observations, the IRB application must also explain

who will conduct observations, when they will occur and how frequently they will occur, whether or not any information that could identify individual students will be recorded, and what data elements will be recorded. You may wish to create an observation intake sheet to record specific data elements to be gathered from observations.

Audio and Video Recording in the Classroom

If the classroom environment will be recorded, an explanation should be provided in both the IRB application and on the consent form about why the recordings are needed to carry out the research. A video-recording may be able to catch more than what a teacher could observe. In a primary or secondary school setting, the teacher/researcher role can become conflated when recordings capture behavior that may require disciplinary action on the part of the teacher but that may not be relevant to the research. The teacher's role may interfere with the researcher's promise that participation will not negatively impact the student. The protocol should explain how such situations will be handled. As with individually identifying secondary data, video recordings by default are not anonymous. The protocol should explain how recordings will be handled in a classroom where some students may have provided consent/assent for participation in the research and some have not. If the purpose of the recording is to focus on the teacher and not the students, this needs to be outlined in detail, including the procedures for ensuring that students will not be video recorded. The protocol application should also explain who will have access to recordings, whether or not they will be disseminated, how long the recordings will be kept, where they will be stored, and when and how they will be destroyed.

Extra Credit as an Incentive for Participation in Research

The decision about whether or not to participate in research should not affect a student's grade in a course. For this reason, extra credit may only be offered as an incentive for participation in research if an alternative, equivalent form of extra credit is offered for those students who want to obtain extra credit but who do not want to participate in research. In a college setting many institutions, including SJSU, use Sona Systems for advertising studies and credit management for college student subject pools. At SJSU, the College of Business and the department of Psychology use Sona Systems; this tool is not available to all researchers. Where there is no system in place, researchers must describe the alternative extra credit in their IRB application. In addition, all researchers offering extra credit must specify the amount. For example, Sona allows assignment of credit hours in 15 minute increments. Researchers should not offer extra credit from differing instructors unless they can guarantee all students will receive the same amount and that an alternative is available. Unless you are using a tool such as Sona to mask the identity of students, extra credit may not be a feasible option if you are trying to maintain anonymity of subjects.

Validity of Data Instruments

The data instruments selected should be age and developmentally appropriate if they will be distributed to students in primary or secondary education settings and should be relevant to the research questions posed in the IRB application. While the selection of data instruments pertains to research design, if the instruments are too complex or cannot possibly answer the research questions posed, the IRB may request that they be revised or replaced. Inappropriate data instruments can contribute to additional risks for participants; at best the research can be a waste of the subjects' time and, at worst, the research may lead to false conclusions that affect student learning. It is important that your instruments are not only reliable and well-established, but that they are designed to address the issue that you are studying and that you use them as they are designed for the specific research context.