

Ethical Issues in Undergraduate Research Activities with Human Participants

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Undergraduate students at the California State University, East Bay are encouraged to become involved in the research life of the University. Capstone courses, the Center for Student Research, and other programs, offer opportunities for students to learn the skills of research and present their results. Frequently, these research projects involve interactions with and/or identifiable data about human beings as participants (or “subjects”).

Some undergraduate-initiated research activities that involve human participants require approval by the Institutional Review Board (IRB) (the federally mandated committee that reviews human subjects research protocols) and, as we discuss at the end of this document; many others do not. Regardless of whether a human subjects research project must be submitted for IRB review, the rights and welfare of the participants involved in the project must be protected.

The first section of this document provides guidance to undergraduate students and their faculty mentors on how to incorporate human subjects protections into undergraduate research activities. This advice applies to all projects, those that receive IRB review and those that are chiefly learning activities. The second section of the document discusses which projects may require review by the IRB.

➤ What are key features of protecting participants in research?

Excellent human subjects protection includes:

1. **Minimizing the risks of research to participants.**
2. **Protecting individuals who are members of a vulnerable group.**
3. **Ensuring that research subjects’ participation is informed and voluntary.**

1. **Minimizing the risks of research**

In all aspects of the research, from recruiting subjects to collecting and storing data to reporting results, risks to research participants should be minimized.

Undergraduate students are strongly encouraged to design their projects so that they are “minimal risk research.” As defined in the federal regulations, ***“minimal risk” means that participants will encounter no harms or discomforts greater than those that are a normal part of their daily lives.*** Faculty mentors/sponsors and research program staff are asked to **guide students in developing minimal risk projects.** *If, in the opinion of the student, faculty sponsor, and/or program advisor, an intended project might be greater than minimal risk, the student or sponsor **must** seek the advice of the IRB Chair.*

What risks can arise in or result from research?

A. Disclosure of identifiable sensitive information: Recording and storing individual-level identifiable information can pose risks if the data are sensitive, in the sense that disclosure could lead to harm for a research participant. Some examples of sensitive data are: information about criminal behavior; information about work-related actions that if known could damage the individual's employment; information that if widely known could engender stigma or shunning; information beyond the very general about the respondent's health (which may be subject to other privacy regulations as well); and information about financial or legal aspects of an individual's life which if publicly known might enable identity theft or fraud. Data can be sensitive in one context and not in another (e.g., certain political opinions are risky under politically repressive regimes).

These types of data only present risks if they are identifiable, that is, if linked to names, Social Security numbers, or other identifiable information, or if recorded using audio or video media (with recognizable voices or faces). To protect research participants, researchers should take steps to minimize the risk of inadvertent disclosure of identifiers and research data. It is also wise to only gather sensitive information if absolutely necessary for the research.

Good research practices include: using password protection (at a minimum) and encryption (preferred) for computer files and digitized audio or video files; using removable storage devices (thumb or flash drives) that are encrypted and password protected; locking filing cabinets where paper files are stored; and quickly transcribing unprotected, taped interviews and notes on paper so they can then be destroyed.

B. Emotional or psychological trauma is a risk when respondents are asked to describe a painful event or a stigmatized identity that they do not usually discuss otherwise. Personal experiences of war, of refugee flight, of being assaulted, or of serious illness or injury are among the many potentially traumatizing topics of interview. One risk-minimizing strategy is to interview individuals who already talk publicly or frequently about a past trauma or a stigmatized identity.

Students with limited experience and training in sensitive interviewing are strongly discouraged from trying to interview research participants about painful topics. Interviewers who do conduct emotionally sensitive interviews should plan to provide subjects with a list of local counseling resources.

C. Potential for other types of greater than minimal risks arise if individuals are asked to do anything that they would not normally do in the course of daily life which could jeopardize (i) their physical safety, (ii) their physical health, (iii) their emotional well-being, (iv) their academic standing, (v) their legal standing, (vi) their financial or employment security, or (vii) their reputation in any context. For example, asking individuals for interviews when engaging in such an interview might put them at risk of retribution for "snitching" (e.g., prostitutes; drug dealers). Other examples include asking participants to engage in unaccustomed physical activity in which they could experience strain or injury; asking them to substantially change their diet over more than a very brief period; asking them to interact socially in unusual ways, to spy on others, or to

deceive others; and so forth.

D. Deception: Avoid deceiving research participants unless clearly necessary and no greater than minimal risk; debrief as soon as possible afterwards. Research that involves actively deceiving participants about research activities presents ethical problems. An undergraduate student whose proposed project includes active deception should work with his/her faculty mentor to ensure that the overall level of risk to participants is minimal and that other IRB requirements for use of deception, e.g., an appropriate debriefing process, are included.

2. Protecting individuals who are members of a vulnerable group

“Vulnerable populations” in IRB parlance are categories of individuals whose capacity to give voluntary informed consent is likely to be impaired in some way. They may not be capable of fully assessing the risks of research participation. They may feel compelled to participate in research because of their relationship to the researcher or because their freedom is curtailed. Fully informed consent may not be possible for them because the consequences of their research participation are unpredictable. Accordingly, federal regulations require heightened scrutiny of research involving vulnerable populations.

Medical research on pregnant women can have unknown consequences for the woman or the fetus. **Research to be conducted with pregnant women as a target group must be submitted for IRB review.** Federally-mandated requirements for such scrutiny will introduce substantial delays in the review process, and could put ultimate approval in jeopardy. **Students are advised to consider a research topic that does not call for interviewing (as a target population) pregnant women.**

Prisoners are vulnerable to coercion and to penalties imposed by the prison system. Research on prisoners also requires the approval of prison or jail authorities. Parolees are an intermediate category almost as vulnerable as prisoners, as they can be re-incarcerated for many activities that are not illegal for non-parolees. **Due to the stringent conditions imposed by federal regulations when doing research with prisoners as subjects, the CSUEB IRB will not approve undergraduate research with prisoners.**

Children are vulnerable because their cognitive and decision-making capacities are still developing. Federal regulations require in almost all cases parental consent (permission) for children to participate in research activities. In many cases, assent from the child will also be required. **Anyone planning research activities with children must be aware of regulations regarding permissible research with children, including obtaining informed parental permission as well as child assent for the research.** In addition, the IRB strongly recommends that undergraduates who plan to interview or interact with children do not include activities or interview questions that could be controversial. **At all times, the interaction must be conducted in a manner that protects the child.**

Other vulnerable populations: Cognitively impaired individuals might not have the intellectual

capacity to consent to research participation. Other groups are vulnerable because any harm that might arise from research would be particularly consequential for them. For example, undocumented residents whose status was revealed outside the research could be deported, a grave risk. Residents in homeless shelters, nursing homes and half way houses have limited autonomy with respect to housing and are vulnerable to the authority of house managers. They, as well as people who have experienced major injury, illness or disability that interferes with the quality of their lives, might be traumatized by unskillful interviewing.

The IRB strongly recommends that an undergraduate student who wishes to study a vulnerable population turn to group spokespeople, group representatives, expert informants, and professionals working with the population if they wish to learn sensitive information about the population. Members of vulnerable groups – excepting those who are identified as spokespeople – should not be asked sensitive questions, by which we mean questions that could re-traumatize them or that, if responses were revealed outside the research, could put respondents at risk.

3. Ensuring that research subjects' participation is informed and voluntary

Undergraduate research activities, even if they do not require IRB review, should include an **informed consent process** that: (a) identifies the researcher; (b) describes what is being requested of the person (i.e., what participation in the project will require); (c) clarifies that he/she does not have to participate; (d) explains any risks or discomforts of the research; (e) explains any potential benefits to the participant, the community, and/or scientific knowledge; and (f) provides contact information for the researcher(s) and for the CSUEB IRB. (The latter contact information should be omitted if the project has not been reviewed by the IRB.) The IRB website has examples of consent documents.

The standard process of informed consent includes a written (signed) document. However, an oral (unsigned) consent process is acceptable for a minimal-risk project not submitted for IRB review, and may be acceptable for an IRB-reviewed project as well, as long as justification for not seeking signed consent is included in the application. When oral consent is used, it is good practice for the researcher to give participants a document for their future reference stating what they were told (i.e., including all the consent elements above).

➤ What undergraduate-initiated research activities need IRB approval?

Cal State East Bay's IRB is obliged to review all projects that are considered human subjects research under the federal regulatory definition of research: *"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."* (45 CFR 46.102(l)).

The IRB considers "a systematic investigation" to be a study or examination that involves a methodical procedure and plan, is theoretically grounded, specifies a focused and well-defined research problem or question, is informed by the empirical findings of others, is analytically robust, and provides a detailed and complete description of data collection methods.

We define “generalizable knowledge” as conclusions, facts, or principles derived from particulars (e.g., individual subjects, medical records) that are applicable to or affect a whole category (members of a class, kind, or group, a field of knowledge, etc.) and enhance scientific or academic understanding. (Note that publication or other dissemination of findings does not in and of itself make the activity human subjects research.)

Although the experience of the IRB has been that nearly all undergraduate research activities do not meet the *federal regulatory* criteria for IRB jurisdiction, the IRB will review any undergraduate human subjects project if the student, faculty advisor, or staff advisor believes the research falls under the regulatory jurisdiction of IRB approval or exemption.

Undergraduate students planning a project with human participants are encouraged to start by referring to the IRB website for information on [Does My Research Require Review](#), and to consult with their faculty sponsor, program staff, or IRB staff to determine if they need IRB approval.

Summary:

1. Some undergraduate-initiated research activities may require IRB review, but most will not. Regardless of whether or not the project requires such review, the rights and welfare of the human participants (subjects) involved in the project must be protected.
2. The IRB strongly recommends that undergraduate students design minimal-risk research activities. Most IRB-approved research at CSUEB is minimal risk research, and undergraduate research should, in general, be minimal risk as well. The standard of minimal risk for research is that it does not expose participants to risks greater than those they are likely to encounter in their daily lives.
3. Special attention should be paid to the potential for risks in research involving certain activities, e.g., disclosure of identifiable sensitive information, interviewing on topics of emotional or psychological trauma, and deception.
4. Undergraduate students who wish to gather information about a vulnerable population should consider interviewing spokespeople and expert informants instead of members of the vulnerable group.
5. Federal law requires that research projects that involve prisoners or pregnant women must receive heightened review scrutiny. Federal regulations also require (with a few exceptions) parental consent (permission) for children to participate in research activities.
6. Undergraduate human subjects research should include a process for informed consent, which can be oral (supplemented by a document) rather than signed. The process should include all the elements of informed consent.

7. Undergraduate human subjects research activities engaged in as part of an educational process usually do not require IRB review, unless the project appears to the student, faculty advisor, or program advisor to fit the regulatory definition of “human subjects research”: “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(l)).

In all cases, undergraduate students undertaking research activities are encouraged to first consult with their faculty advisors/sponsors and program staff, using this document, along with [IRB website resources](#) to develop meaningful and ethical research projects.