Ethical Issues in Student-Initiated Research Activities (SIRA) with Human Participants

Undergraduate and graduate students at the University of California at Berkeley are encouraged to become deeply involved in the research life of the University. Frequently, these research projects involve interactions with and/or identifiable data about human beings as participants (or "subjects").

Some student-initiated research activities (SIRA) 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, 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 and graduate students and their faculty mentors on how to incorporate human subjects protections into student research activities. This advice applies to all SIRA projects, those that receive IRB review and those that are not. The second section of this document discusses which SIRA projects may require review by the Committee for Protection of Human Subjects (CPHS), which is UC Berkeley's 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.

All 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 are strongly recommended to seek the advice of an OPHS staff member, as they may need to consult with a CPHS 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 (see the FAQ for what constitutes "identifiable information"), 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 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 files (such as recorded interviews or paper notes) so the unprotected documentation can then be destroyed. (See CPHS Guidelines on Data Security.)

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. Possible examples of research presenting such risks include:
- interviewing workers in an illicit industry (sex workers; drug dealers) in a location where being interviewed might make them appear to others as "snitching";
- asking individuals to engage in unaccustomed strenuous activity, or to change their diets (over more than a very brief period), both of which could lead to injury or ill-health for them;
- asking individuals to interact socially in unusual ways, to spy on others, or to deceive others.
This list is illustrative, not comprehensive; each activity included in a research project should be assessed imaginatively both individually and collectively for the risks it might present to participants.

D. Deception: Research that involves actively deceiving participants about research activities presents ethical problems. Deception is acceptable only where it is necessary to achieve the research goals, and it is acceptable only in minimal-risk research. It should never be part of any research that presents greater-than-minimal risk. If deception is used, participants should be debriefed if feasible, and as soon as possible after the research activity. A student whose proposed project includes active deception should ensure that the overall level of risk to participants is minimal, that it is not used more than absolutely necessary for the research, and that, where feasible, an appropriate debriefing

process is included. (See CPHS Guidelines on Deception and Incomplete Disclosure in Research.) Note that there is a difference between deception and incomplete disclosure (See FAQ on Incomplete Disclosure and Deception in Research). In both cases, consider whether the deception and/or incomplete disclosure will or will not matter to the participant if or when they were to find out.

2. Specific considerations for protecting potentially vulnerable individuals

"Vulnerable populations" in IRB parlance are categories of individuals whose capacity to give consent that is both fully voluntary and fully informed 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 will not be possible for certain individuals when the consequences of their research participation are unpredictable and possibly risky.

We discuss below the options available to a researcher seeking to study a group whose decision-making capacity (to consent) is somehow constrained. We start with the two groups specifically identified as "vulnerable" in the federal regulations that govern human-subjects research: children and 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[1] 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**. (See CPHS guidelines on Children in Research and Child Assent and Parent Permission.)

CPHS strongly recommends that students 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.**

Prisoners are vulnerable to coercion and to penalties imposed by the prison system. Research on prisoners will also require 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. **Students are advised to consider a research topic that does not call for interviewing (as a target population) prisoners or parolees.** (See CPHS guidelines on Prisoners as Research Participants.

Other populations are potentially vulnerable even if not specifically listed in the regulations. Cognitively impaired individuals might not have the intellectual capacity to consent to research participation. Medically vulnerable individuals with serious chronic or acute illness or injury may also have impaired decision making due to the severity of their impairment. If they are hospitalized or in a nursing home, they have less daily freedom than most.

[1] "Assent", meaning agreement, is the term used for "consent" given by a research participant who is not legally able to consent for themselves because they are not legal adults, or because they are so cognitively or medically impaired as to require a guardian or legal proxy.

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. Residents in homeless shelters, nursing homes and halfway 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.

Research on pregnant subjects as a target group (i.e., not subjects who are part of a randomly-selected group of subjects and happen to be pregnant) can have unknown consequences for the subject or the fetus. For this reason, the federal regulations governing human subjects research include additional protections and requirements for research involving pregnant subjects. Targeting pregnant people as research subjects will pose substantial delays in the IRB review process, and may introduce concerns from reviewers that the researcher did not anticipate, given the complexity of protecting the wellbeing of pregnant subjects and fetuses. **Accordingly, students are advised to not consider a research topic that calls for targeting pregnant people as a subject population.** (See CPHS guidelines on Research with Pregnant Women, Fetuses, and Neonates.)

CPHS strongly recommends that a 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 research respondents at risk.

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

Participation in research should always be informed and voluntary. These principles of human subject research participation are accomplished, in part, by the informed consent process. For research eligible for review at the exempt level, and research that will not be reviewed at all, OPHS does not review consent materials, but recommends that researchers provide participants with (a) the identity (and, unless it would create problems, the affiliation) of the researcher; (b) a clear description of what is being requested of the person (i.e., what participation in the project will require) and how data will be used in the future; (c) a clear statement to the potential research subject that they do not have to participate; (d) contact information for questions about the research; and (e) the CPHS protocol ID number.

For research that requires review at the non-exempt level, consent forms must be included with the non-exempt application. The CPHS website has many informed consent resources, including guidance documents and template consent forms that offer suggested language to present required information. **See CPHS guidance on Informed Consent**.)

For research activities that do not require review, best practices would follow the same suggestions as for exempt research (refer to the FAQ on informed consent in exempt level research).

Although the standard process of informed consent includes a written (signed) document, an oral (unsigned) consent process is acceptable, and may be superior, for minimal-risk projects. 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). Researchers

applying for non-exempt IRB approval must include a justification for not seeking signed consent in the application.

- **What student-initiated research activities (SIRA) need IRB approval?**

UC Berkeley's IRB (CPHS) 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)).

CPHS 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 CPHS has been that many undergraduate research activities do not meet the *federal regulatory* criteria necessary for IRB jurisdiction, CPHS will review any project if the student, faculty advisor, or staff advisor believes the research falls under the regulatory jurisdiction of IRB approval or exemption.

Students planning a project with human participants are encouraged to start by referring to the CPHS website for information on What Needs CPHS/OPHS Review, and to consult with their faculty sponsor, program staff, or OPHS staff to determine if they need IRB approval.

Summary:

1. Some student-initiated research activities (SIRA) may require IRB/CPHS review, others may 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. CPHS strongly recommends that students design minimal-risk research activities. Most IRB-approved research at UC Berkeley is minimal risk research, and SIRA 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 human subjects research projects that are focused on prisoners or pregnant subjects must receive heightened review scrutiny. Federal regulations also require (with a few exceptions) parental consent (permission) for children to participate in research activities.

6. All human subjects research should include a process for informed consent, which can be oral (typically supplemented by a document) rather than signed. The process should include all the elements of informed consent.

7. Student human subjects research activities engaged in as part of an educational process usually do not require IRB (CPHS) review, unless the project appears to the student, faculty advisor, or program advisor to fit the regulatory definition of "human subjects research," where "research" is "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, students undertaking research activities are encouraged to first consult with their faculty advisors/sponsors and program staff, using **this document**, along with Guidance on Designing Student-Initiated Research Activities with Human Participants, and ample **CPHS website resources** to develop meaningful and ethical research projects.