Guidance on Designing Student-Initiated Research Activities (SIRA) with Human Participants

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This document outlines key considerations in the design of human subjects research for student investigators and their faculty mentors. Note: CPHS strongly recommends that such researchers not conduct an independent project involving human participants in which risks to participants are expected to be greater than minimal. As is explained in the final section of this document, "minimal risk research" means that the risks someone faces due to participating in the research are no greater than any they might encounter in their everyday lives. For more information, please refer to the document ***Ethical Issues in Student Research Activities with Human Participants*.**

Before starting any human subjects research project, students must complete the online human subjects research CITI training course: https://cphs.berkeley.edu/training.html - online

1. Participants:

a. Consider participant number and characteristics:

- How many individuals will participate (list maximum sample size)?
- Will all participants be adults? If not, ensure that child assent and parent permission are obtained.
- Are there any specific selection criteria based on age, sex, race/ethnicity, participation in a program, etc.?
- Will you need to utilize or be helped by other institutions -- school, hospital, corporation, or other relevant organization? If so, obtain their permission.

2. Recruitment:

a. Consider how participants will be approached and recruited (e.g., posted flyer; script read by a researcher in person; email invitation; phone call, social media posts, snowball sampling, etc.). See CPHS guidelines on Recruitment.

To better protect privacy considerations, CPHS generally prefers (if feasible) a recruitment method in which potential participants are informed in some way about the research and then make the initial contact with the researcher. Possible methods include posting flyers or social-media posts announcing the study recruitment; approaching strangers physically in a neutral place or electronically via a list serve and inviting them to participate in

research; or asking friends/ contacts to invite their networks to participate, by passing along the study details and researcher contact information. Such approaches are preferable because they remove the social pressure that can arise when a researcher him/herself approaches friends, acquaintances, or friends-of-friends and directly asks them to participate in a study.

b. Consider how you will ensure that everyone's participation is completely voluntary:

- Always emphasize to potential participants that taking part in the project is voluntary.
- Design the study to minimize the risk of coercion or undue influence:
  - Will participants be recruited by someone who might **unduly influence them to participate**? Can this be avoided? How can prospective participants be protected from feeling influenced or compelled to participate when they might not want to?
  - Offering reasonable compensation is entirely acceptable, but **is there a risk that the compensation might be large enough to induce someone to participate when participation might be against their own best interests**? If participants are paid, what amount and when are they paid? Are gift cards or other forms of compensation to be offered?
  - It is important to clarify for yourself and communicate to participants whether compensation will be given only when participation is complete, or whether you will provide partial payment for partial completion, and at what points during the research.

c. Vulnerable participants:

- **Please review the CPHS Ethical Issues guidance document to understand what the CPHS means by "vulnerable" populations and your options and obligations in studying them. Having read that document, be sure to seek advice if you think your proposed participants are vulnerable.**
- Federal regulations identify prisoners and pregnant subjects as vulnerable, and research on either *as a target study group* will trigger additional considerations and requirements. **CPHS strongly recommends that an undergraduate researcher (or other student researcher not subject to IRB review) not enroll prisoners or pregnant subjects as target populations.**
- Among other types of vulnerable participants are individuals who cannot give informed consent because of limited cognition, information or freedom to decline participation (e.g., children, cognitively impaired, prisoners). Specific contexts may make individuals susceptible to coercion or undue influence (e.g., students whose professor asks them to be research participants and will know if they agree; employees whose bosses ask them same of them; patients whose doctors are running a study and personally ask them to participate, and so forth.)
- Restrictions and/or special considerations may also apply where other characteristics render populations vulnerable:

- When recruiting children, both parents and their children must be involved in the recruitment process. Children are not eligible to participate in research without their parents' permission.
- Students planning research with the following potentially vulnerable populations should first set up a discussion with their faculty advisor or an advisor familiar with CPHS procedures and requirements.
    - Adults living in potentially coercive conditions – e.g., nursing home residents, half-way house residents.
    - People who have experienced or now have:
        - major injuries or acute or chronic disease;
        - disabilities that interfere with the quality of their lives;
        - homelessness;
        - significant physical or emotional trauma;
        - undocumented status;
        - stigmatized identity; or
        - involvement in illegal activities.

3. Procedures and Activities:

a. Consider what participants will be asked to do, what will be done to them, or what information will be gathered:

- How frequently and over what time period will interviews, tests, etc., be conducted? Will there be breaks?
- Where will research be conducted? If interviews will be conducted, how will interviewees be made comfortable? What privacy (if any) will be available?
- Are interviews to be audio or video recorded? This must be disclosed ahead of time to participants and their agreement obtained as part of the consent process.
- If recordings will be made, will these recordings be stored? Do you have plans for transcription? Recordings should be destroyed once no longer needed. If you wish to have the option to use recordings in the future, you must tell participants this and obtain their consent.

b. Consider whether the study will involve either active deception or incomplete disclosure that is likely to significantly mislead participants (see FAQ on incomplete disclosure and deception in research).

- If your study will involve deception, please review the discussion of deception in the Ethical Issues guidance document.
- What is the nature of the deception or incomplete disclosure? Is it likely to be significant to participants? If yes, is there another way to conduct the research that would not involve deception or incomplete disclosure, and, if so, choose that alternative instead.
- Will participants receive more information about the research project following its conclusion? If feasible, you should subsequently tell participants that they were deceived or incompletely informed. How will you explain or justify it to them? (You may ask them to not tell others about the deception). Additional guidance on deception and incomplete disclosure can be found on the CPHS website.

- An undergraduate researcher (or other student researcher not subject to IRB review) should not undertake an independent project involving human participants that includes deception or incomplete disclosure that is likely to be upsetting or in some other way harmful to the participants.

4. Informed Consent:

a. Participation in research must always be **informed and voluntary (not coerced or unduly influenced).** These conditions are met through a **consent process.**

b. Points to consider:

- How will you inform participants about your research and then obtain their consent (e.g., orally, in writing, in person, by phone, or online)?
- Will you ask participants to sign a written document – a consent form?
- Whether the consent process includes a signed consent form or not, you should give participants a document that repeats the explanation of the research, identifies you, and provides contact information.
- Consent language should be as simple and straightforward as possible, and appropriate for the level of literacy, education, etc. of the participants. You may use CPHS consent templates and guidance to assist in creating your consent documents. (Be sure to remove CPHS/OPHS contact information from the consent form before use in the field if project is not submitted to CPHS.)
- Will language translation/interpretation be needed? Is there any language barrier that could affect the consent process? If so, be sure to address this and, if needed, make plans for use of translators and translated documents.
- **Children under 18 need to have their parents' permission in order to participate in research.** In addition, the children must themselves be asked to agree ("assent") to participate. Note**:** Examples of assent forms (for children) and permission forms (for their parents) can be found on the CPHS website. (Be sure to remove CPHS/OPHS contact information from assent and permission forms before use in the field if project is not submitted to CPHS).

5. Confidentiality:

a. Consider how confidentiality will be protected. See below for examples of how to best protect confidentiality (for complete information, refer to the CPHS Data Security Guidelines and Matrix). Also, please refer to the Key Researcher Responsibilities provided by Information Security Office for further information.

- Student investigators are strongly discouraged from collecting highly sensitive subject information. However, exceptions may be made on a case-by-case basis. In those instances, student investigators should only collect sensitive or identifiable information that is necessary for their research project. For example, identifiers like student ID numbers and SSNs, financial account information, and protected health information can be used for identity theft and place subjects at high risk. If needed to answer the research question, this data should only be used under direction from a faculty mentor and must be protected appropriately.

- Will you obtain any information that would uniquely identify participants, such as first and last names, physical addresses, email addresses, audiovisual recordings, IP addresses, etc. (see FAQ on what constitutes "identifiable information")? If so, it is vital to have a good way to keep this information secure, and to delete it as quickly as possible.
- Consider creating an anonymized ID (e.g., a random number) for each participant and attaching it to their research data instead of attaching their name or other private information. You would also have a separate file that links the anonymized ID to their name, email address, etc. This is a key-code. It is vital to store a key-code separately from the research data, and to delete it when the research is finished.
- Will research data be destroyed at the end of the study? If not, where and in what format and for how long will the data be stored? (See data retention requirements for various record types). To what uses – research, public performance, archiving – might the data be put in future? Note: You must obtain participants' permission for possible future use of their data. (See sample Media Records Release form).

6. Risks:

a. Think about **possible risks of harm** to participants that might result from:

- **the activities of the research** –surveys, interviews, or activities you ask them to engage in; or
- **inadvertent disclosure** of the data you will collect about participants.

b. Risks can be **psychological or emotional** (e.g., participants are asked to recall or describe unusually troubling aspects of life); **legal** (e.g., participants report their illegal statuses or activities); **social** (e.g., participants are asked to disclose a stigmatized identity, activity or status like poor grades or HIV status and *those data are inadvertently revealed)*; **financial** (participants are asked to invest their own money, or disclose private identity information such as social security numbers or private financial information and *the research data are inadvertently revealed*); and/or **physical (**activity involves strenuous activity, travel, ingestion of substances, etc.).

c. Responsible research requires that risks be **minimized,** be **reasonable** in relation to any benefits that might occur and be **clearly communicated to research participants.**

d. Student researchers should take measures to protect participant privacy (e.g., are questions tailored to the research problem only, so participants are not asked to provide unnecessary information?).

e. Risks no greater than those that research participants would encounter in their everyday lives are considered **minimal risks**. The following examples illustrate risks that are potentially greater than minimal risk and strategies to reduce them so that the research would be minimal risk:

1. Revealing one's personal experiences of domestic violence would not be, for most people, a normal or everyday occurrence. Most people keep this information private. Revealing it could

bring *emotional risks* (if in the recollection and recounting, painful feelings were aroused); *social risks* (if the information were revealed to others); and perhaps *legal risks* (if the individual were a perpetrator or if children were put at risk by the violence, even if the participant were not the perpetrator).

Appropriate risk-reduction strategies to make the research project minimal risk could include:
a) *carefully planning the interview* ahead of time, and obtaining training and advice in *techniques for emotionally sensitive and ethical interviewing*;
b) preparing a list of *appropriate counseling resources* to have ready for participants if needed;
c) designing and rigorously adhering to methods to *protect the confidentiality of data*. Standard methods include *passwords*, *encryption*, and storing research data separately from *a key-code linking personal identifiers (e.g., names) from id codes (e.g., numbers)*.

2. Discussing political organizing and one's political views in a corrupt and violent political environment might be a normal activity for activists, in that they talk to each other, but it still would not be routine for them to engage in such discussions with a researcher. The possible risks could be *reputational* (if their colleagues disapproved of them talking to a researcher, or if the data were inadvertently revealed outside the research); *legal*; and even *physical* (if disclosure might lead to physical reprisals).

Appropriate risk-reduction strategies to make the research project minimal risk could include:
a) *avoiding entirely, or minimizing the use of risk-generating questions*;
b) seeking training in *techniques for ethical interviewing in politically sensitive contexts*;
c) designing and rigorously adhering to methods to *protect the confidentiality of data*, which probably would include *avoiding identifiable information* as far as possible, using *encryption* as well as passwords, *for audio recordings as well as written data*; and, *destroying such information* (e.g., by removing it from computers) as rapidly as possible. Additional data security guidance can be found on the CPHS website.

3. Running a few yards might be a normal physical activity but running to the point of complete exhaustion would not be, for most people, and therefore if it were a research activity, would carry research risks beyond what is encountered in daily life.
Appropriate risk-reduction strategies could include:
a) *recruiting only conditioned athletes,* for whom running to exhaustion might be fairly routine; and/or
b) *requiring a medical exam* ahead of time.

For further information, the CPHS website contains many resources on different topics including, but not limited to, those in this guidance. Student researchers and faculty advisors are encouraged to review the various guidance documents and other resources provided on the CPHS website: https://cphs.berkeley.edu/.