Guidance on Designing Undergraduate-Initiated Research Activities (UIRA)

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This document provides guidance to undergraduate investigators and their faculty mentors for human research activities led by the student. This guidance outlines key considerations in the design of such activities. Note: The CPHS strongly recommends that undergraduate researchers should not conduct an independent project involving human participants in which risks to participants are expected to be greater than minimal. Please refer to the document ***Ethical Issues in Undergraduate Research Activities with Human Participants*.**

In addition, before starting any undergraduate-initiated research project, undergraduates are strongly encouraged to complete the online human subjects research CITI training course: http://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, etc.)

b. Consider how voluntary participation will be ensured:

- Researchers should design their studies to minimize the risk of coercion or undue influence, and always emphasize to potential participants that taking part in the project is voluntary. Offering reasonable compensation is entirely acceptable.
- 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?

- Are participants offered **any material inducement to participate**? If participants are paid, what amount and when are they paid? Are gift cards or other forms of compensation to be offered? Is there partial payment for partial completion?
- 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?

c. Vulnerable participants:

NOTE: **Be sure to seek advice before trying to recruit vulnerable participants.**

- Vulnerable participants are individuals who are likely to be susceptible to coercion or undue influence (e.g., students, subordinates, patients). Vulnerable populations also include individuals who cannot give informed consent because of limited autonomy (e.g., children, cognitively impaired, prisoners).
- **CPHS strongly recommends that an undergraduate researcher doing an independent project should not enroll prisoners, pregnant women, or cognitively impaired individuals as target populations.**
- 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.
  - Undergraduates planning research with the following potentially vulnerable populations should first set up a discussion with their faculty advisor and 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;
      - undocumented status; or
      - stigmatized identity.

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 should 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 should 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.

- If so, 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, why have you not chosen that alternative?
- What explanation for the deception or incomplete disclosure do you give to participants following their participation? Will participants be "debriefed" or receive information about the research project following its conclusion? Additional guidance on deception and incomplete disclosure can be found on the CPHS website.
- An undergraduate researcher 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, by email)?
- 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.
- Will recruitment and consent documents be translated into foreign languages? **Children under 18 need to have their parents' permission in order to participate in research.** In addition, they 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:

- Will you use a key or code to identify participants? How will you securely store the information that links codes to identifying information (names, addresses, SSNs)?
- Will the research data be collected and stored in a manner to keep it separate from the information (names, etc.) that uniquely identify participants?
- For online studies, will IP addresses or other potentially identifying information be collected? What host site will be used (e.g., SurveyMonkey, iCommons, etc.)? Will those identifiers be removed from the data? If so, at what point, and if not, why must identifiers be retained?
- Where will data be stored, who has access, and how will it be secured?
- 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? To what uses – research, public performance, archiving – might the data be put in future? Note: You should obtain participants' permission for possible future use of their data. (See sample Media Records Release form on CPHS website).
- If there is a key code connecting participants' data to their identity, when will the link be destroyed? (Include this information during consent process.)

6. Risks:

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

i. **the activities of the research** –surveys, interviews, or activities you ask them to engage in; or

ii. **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. Undergraduate 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:

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 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 could include:
a) having a *compelling and specific justification* for *questions that would elicit risk-inducing information* and *avoiding 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. Undergraduate researchers and faculty advisors are encouraged to review the various guidance documents and other resources provided on the CPHS website: http://cphs.berkeley.edu/.