Office for Protection of Human Subjects | Tips for Efficient Approval

Plan ahead – Many researchers are on set schedules for their research and theses. Plan in advance to allow enough time for the review cycle. Depending on variables such as the complexity of the study, completeness of the submission, etc., the review cycle may take up to *eight weeks or longer at the expedited level*.

Seek feedback from colleagues – Student researchers should work with their faculty advisors closely for mentoring, drafting, and other assistance with the research protocol. Obtain a copy of an approved protocol from a colleague to see commonly used language.

Complete/comprehensive informed consent process – Researchers should ensure that the consent documents are clear and concise and use language that is understandable to the subject. See the Informed Consent Guidelines, Consent Builder, and templates on our website: http://cphs.berkeley.edu/informedconsent.html

Clearly describe study procedures – Remember that the reviewer needs to be able to put him/herself in the shoes of the subject, so provide sufficient detail. The protocol should include how long each procedure will take, frequency, and estimated total time commitment for the subject to participate in the study.

Confidentiality - *Privacy* refers to the individuals' right to control access to themselves. On the other hand, *confidentiality* refers to how private information provided by individuals will be protected by the researcher from release. Describing how the confidentiality of research information will be maintained is an important element of the protocol & consent process.

Anonymous data collection – *Anonymous* data collection means that no identifiable information (e.g., name, address, student ID number, email, phone number, etc.) is connected to the data either directly or through a coding system, *at any point in the study*. Therefore, even if the identifiers are separated from the data immediately after collection, the study would not be considered anonymous. In addition to videotapes and photographs, audio recordings are considered to be identifiable; therefore any data collection that involves audio recordings, video recordings, or photographs of subjects would not be considered anonymous. It is also possible that multiple pieces of information, none of which are identifiable on their own, may uniquely identify a person when brought together; in this case, the data would be identifiable and would not be considered anonymous. *Follow security requirements for identifiable data* (see: http://cphs.berkeley.edu/datasecurity.pdf).

Risks/discomforts from study participation– Remember to include both the possible risks *and* discomforts from participation in the study. With all studies that involve the collection of private identifiable information, there is a chance that confidentiality could be compromised. However, researchers should also keep in mind that some procedures, including surveys and lab experiments with deception might cause some type of discomfort (whether physical or emotional). When making a risk assessment, the Committee takes into account both probability and magnitude of harm, so researchers should address both of these factors in the protocol.

Student Guide (http://cphs.berkeley.edu/student.html) - Student Researchers will find this helpful; it contains an overview of the submittal/review process and links to other key resources on the CPHS website.

Guidance Documents (http://cphs.berkeley.edu/guideline.html) **-** Guidance is available on specific topics, including what requires CPHS/OPHS review, deception in research, subject recruitment, data security, etc.

eProtocol Quick Guides: http://cphs.berkeley.edu/eprotocol_guides.html

How to create a protocol: http://cphs.berkeley.edu/eprotocolguide/investigator/create.pdf
How to check for completeness: http://cphs.berkeley.edu/eprotocolguide/investigator/check.pdf
How to submit a protocol: http://cphs.berkeley.edu/eprotocolguide/investigator/submit.pdf
How to respond to comments: http://cphs.berkeley.edu/eprotocolguide/investigator/comments.pdf

Questions?

Call our office*: 510-642-7461. We answer the phone during the following hours: 8:30am – 12pm, 1pm – 4:30pm, M-F.

Schedule an appointment in advance to meet with an OPHS Staff Analyst during business hours at 2150 Shattuck Ave., Suite 300. (Use the email below)

Website: http://cphs.berkeley.edu/ (use the search box)

Email: ophs@berkeley.edu

*If you have already submitted an application, contact your assigned panel manager.

Commonly Requested Revisions:

Include maximum total sample size. If unsure, over-estimate.

- Include recruitment details specific to the proposed study, and copies of all recruitment scripts.
- Include copies of all data collection materials.
- Include interview questions. At minimum, include topics to be explored during the interview.
- If obtaining consent online, choose the "Unsigned Consent" type. Be sure to complete all text boxes.
- Include a PDF copy of the Student Investigator's CITI completion report. Complete the *human research curriculum* - Group 1 (bio-medical) or Group 2 (social-behavioral) for Research Investigators and Key Personnel.
- Provide thorough but concise answers. Only include information relevant to the question posed.
- When responding to comments, be sure to make the applicable revisions to the protocol information. Be sure to click the "submit to IRB" button to submit your responses and revisions.
- Include anticipated benefit to individual subjects and to research/society in the protocol and the consent form(s). If there are no direct benefits to subjects, this should be stated.
- Make sure information is consistent between study procedures and the consent form.
- Template Text for Adverse Events and Reporting Section in section 13F (biomedical)/11C (social behavioral) of eProtocol: "Any unanticipated problem or adverse event (as defined in the CPHS Policies & Procedures) will be reported to the Director, Research Subject Protection, as soon as possible (by fax, mail/delivery, phone, or email), and within seven (7) calendar days of the Principal Investigator learning of the incident. The Principal Investigator will submit a written incident report (via eProtocol), within fourteen (14) days of learning of the incident."
- If obtaining existing secondary data, attach a data collection form in eProtocol.