Office for Protection of Human Subjects | Tips for Efficient Approval

Plan ahead

- Are you on a set schedule for your research and/or thesis? Plan accordingly. The CPHS review cycle for new non-exempt applications generally takes six to eight weeks. For exempt applications, the review cycle generally takes four to six weeks. Note that these are *estimates only* and that reviews may take longer depending upon variables such as the complexity of the study, submission completeness, volume of applications to CPHS at any given time, etc.

Seek feedback from faculty advisor/colleagues

- Work with your faculty advisor for assistance with the research protocol, especially for study design.
- Obtain a copy of an approved protocol from a colleague to see commonly-used language.
- If the Principal Investigator of an existing CPHS-approved study agrees--and your study design is similar--the eProtocol cloning feature could be used. (The clone would be edited/adapted and then submitted for CPHS approval in the usual manner.)

Subject recruitment - privacy considerations (see CPHS recruitment guidelines)

- Recruitment materials (e.g., flyers) should include researcher contact information so that potentially-interested subjects, rather than the researcher, may make the first contact.
- Typically recruitment is not carried out by the UCB researcher receiving a list with names and contact information for potential subjects. Instead, the point person forwards information about the study (e.g, study flyer) to those individuals leaving them free to contact the researcher directly if interested.
- The first two bullets provide examples of recruitment methods that avoid invading subjects' privacy. Researchers who wish to propose alternative methods, such as the "snowballing" method whereby the researcher, rather than the subject makes the first contact, should provide adequate justification in their eProtocol applications.

Clearly describe study procedures and subject time commitment involved

- Procedures should be described in sufficient detail. The CPHS reviewer needs to know exactly what subjects will be asked to do.
- Include in the protocol the number of planned contacts with each subject (e.g., initial interview and two possible follow-ups), how long each procedure will take, and an overall time estimate for the subject's participation in the study.

Complete/comprehensive informed consent process

- Consent documents should be written using clear, concise lay language at an appropriate reading level (e.g., at no more than an 8th grade reading level for most adult subjects). The use of scientific and medical terms should be avoided. The use of bullets when describing procedures is highly recommended.

- Before creating consent documents, read the CPHS Informed Consent Guidelines. Then, view the templates available on the CPHS website (see http://cphs.berkeley.edu/informedconsent.html) or use the ConsentBuilder software (see http://cphs.berkeley.edu/consentbuilder.html) to create and download consent document(s) customized for your study.

- When consenting subjects into a study within a group context (e.g., in a classroom, for a focus group), the procedures should provide for each subject to meet one-on-one with a researcher to ask questions and consent privately. Be sure to adequately address and describe these issues within the protocol.

Confidentiality and Privacy

- *Confidentiality* pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure. Examples of minimizing the likelihood of a breach of confidentiality include sharing subject data only with other study team members; encrypting and password-protecting data files; maintaining lists of subject names/study identification numbers separately and securely from all other private study data. For assistance with data security, consult the CPHS guidelines available at http://cphs.berkeley.edu/datasecurity.pdf. The protocol and consent documents should include sufficiently-detailed descriptions of the planned procedures for securing subjects' data.

- *Privacy* is defined as control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Examples of protecting subject privacy include conducting interviews in private areas; closing exam room curtains when conducting physical exams; including a reminder at the end of Internet-based surveys that subjects should close their browsers in order to help protect their privacy.

- The protocol and consent documents should cover these topics in sufficient detail.

- For research involving focus groups, the confidentiality limitations associated with group process should be acknowledged in the protocol and consent documents, using language similar to this:

    - "The focus group facilitator(s) and note-take will treat discussions as confidential, although they cannot promise that other members of the focus group will do the same. Members are asked to agree that, once outside of the focus group setting, they will respect each other's privacy by not revealing the names of group members or the consent of the discussions.

Anonymous Data Collection

- Anonymous data collection means that no identifiable information (e.g. name, address, student ID number, email address, phone number) is connected to the data either directly or indirectly through a coding system at any point in the study.

- Audio recordings are not considered to be anonymous (re. potential for voice recognition). Digital recordings should be encrypted. Additionally, consider the use of voice-disguising software when collecting sensitive data.

- Keep in mind 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 not be considered anonymous.

- For information on existing data, consult the CPHS guidelines on Secondary Use of Data available at http://cphs.berkeley.edu/secondarydata.pdf.

- Data collection that occurs over the Internet is not considered to be anonymous. The reason is that interception of data by third parties and/or the limitations of the technology used may lead to unintended breaches of confidentiality see CPHS Internet Research guidelines, section 2g, available at http://cphs.berkeley.edu/internet_research.pdf).

    - Language similar to this should be included in the Confidentiality section of the protocol and in the consent documents: "Confidentiality may only be kept to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet by any third parties."

Risks/discomforts

- All anticipated risks and discomforts (e.g., physical, psychological, economic, social or legal) should be adequately discussed in the protocol and in the consent documents.

- When making a risk assessment, CPHS reviewers take into account both *probability* and *magnitude* of harm. Accordingly, both should be discussed in the protocol.

- Participation in all research involves the risk of an unintended breach of confidentiality. Including this risk factor is mandatory for all CPHS protocols.

Resources

- *Student Guide* (http://cphs.berkeley.edu/student.html) – All student investigators should read this before starting an eProtocol application. The Guide contains an overview of the submittal/review processes 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. Topics include:
    - 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?

- Consult the CPHS Website: http://cphs.berkeley.edu/ (Use the search box to locate desired topics)

- Call our office: 510-642-7461 and speak with the analyst who answers the phone. We answer the phone between 1pm - 4:30 pm, Mon – Fri. If you have already submitted an application, contact your assigned panel manager directly.

- Meet with an OPHS staff analyst—**by advance appointment only**. Send request to ophs@berkeley.edu). Include best day(s)/indicate any preference for morning or afternoon. State topics you wish to discuss.

Commonly Requested Revisions:

- Include maximum total sample size. Over-estimating is always better than under-estimating.
- Include recruitment details specific to the proposed study, and copies of all recruitment scripts (e.g., verbal, phone, email, web site posting, etc).
- Include copies of all data collection materials.
- Include interview questions. At a 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.
- Complete the *human research curriculum* most germane to your project, i.e.,: - Group 1 (bio-medical) or Group 2 (social-behavioral).
- Provide thorough but concise answers. Only include information relevant to the question posed.
- When responding to requests for clarifications, be sure to respond to each comment and make the applicable revisions to the protocol. Do not paste updated sections of the protocol into the response text boxes. Generally, a simple notation such as "updated" will suffice. If the comments included specific questions, provide a brief explanation. At the end of the process, 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.
- In general, the protocol and consent documents should be made consistent (e.g., study procedures, risks/benefits, confidentiality, compensation, etc).
- CPHS adverse event and unanticipated reporting timeframes (i.e., section 13f, biomedical, or 11c, social behavioral). All researchers should familiarize themselves with the CPHS reporting timeframes (see http://cphs.berkeley.edu/reviewtypes.html#adverse). The following language should be inserted into all CPHS protocols: "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, include in the eProtocol Attachments section either copies of the original data collection forms (i.e., blank copies) or a variable names list.