Summary of Human Subjects Requirements

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This document summarizes the process at Cal for handling human subjects issues. OPHS has analysts on call each day for questions, and they encourage researchers to contact them. While there is no substitute for becoming familiar with the details by browsing the documents on their website (http://cphs.berkeley.edu), here are the core elements of the process:

1. Training: All PIs and key personnel who will be funded through NIH must undergo human subjects training for NIH grants. Just recently the powers-that-be decided that all investigators (people with design, analysis or data handling roles) must have CITI training in addition to NIH online certification. The NIH training is at: http://phrp.nihtraining.com/users/login.php. I completed it in one sitting, of about 2.5 hours. This gets you a certificate, which I recommend saving to a file as a .pdf. (see the end of this document for a picture of the certificate.)
You only have to do this training once. All students – undergraduate and graduate students - including GSR's on BPC pilot grants - take a different training called CITI, https://www.citiprogram.org/default.asp. Students must complete this training before commencing work, regardless of funding source.

2. What needs review: Most research conducted by faculty and grad students who conduct behavioral research is likely to need review. Some of the exceptions are class projects, single-organization projects for internal use, single case reports, and established third-party data sets. Researchers may not decide for themselves that their research is exempt, but if, after reading their definitions of exempt research (http://cphs.berkeley.edu/review.html) you think your work is exempt, then a quick phone call or email may be all you need.

3. There are three kinds of review: Exemption, Expedited, and Full. 'Expedited' does not mean faster, it means that the demands on the subjects are simpler and so that just the analyst and one committee member, usually the chair or co-chair of the committee, reviews it then signs it off. 'Full' means that the whole committee examines the design.

a. In order to get any kind of funding including our Pilot Grants, one must request either an exemption or approval.
b. For expedited review also include consent form, emails, flyers, etc., about the study, survey document or interview guide, etc.
c. All applications will be submitted online at eprotocol.
d. Theoretically Campus Shared Services provides assistance with all of these documents, including drafting human subjects protocols. However, I have not found this to be the case. The OPHS analysts are good starting places and will upload text and documents for you, but this Summary will help you through with some specific policies.
e. Exempt research means that the research requires a review by CPHS, but not a full review or expedited review. Researchers do not have the authority to decide on their own whether their research is exempt. This document explains exempt research: http://cphs.berkeley.edu/exempt.pdf

4. When to Submit: It takes up to 8 weeks for a CPHS review, so they encourage you to plan accordingly.

a. For BPC Pilot Grants, you can submit after you get approved, and any work not involving human subjects (e.g., a grad student doing a lit review) can be done prior to approval. Any data collection involving human subjects would have to wait until formal approval.

b. For NIH grants, one can submit materials to CPHS after submitting the grant proposal to NIH but you want to be ready for approval, so at the very least, have the first draft ready by the time you get the score.
c. For research projects of any level (exempt, expedited and full board) that have funding should be specified in the packet submitted to OPHS. For projects that receive, or want to receive funding at a later date need to submit an amendment to OPHS to add the new funding at the appropriate time.

5. How and What to Submit: Submitting the application for human subjects research decisions and review is now done online using eProtocol, http://cphs.berkeley.edu/eprotocol.html. It's worthwhile to do this during business hours so that you can easily pick up the phone and call OPHS 642-7461 and ask a question, which you will likely do. For example, e-protocol asks you to select either 'exempt' or 'non-exempt' which you can't decide for yourself. So call and ask and they will tell you. The online procedure involves logging in, and then going through many web pages and entering information. eProtocol will time you out, so do click on the SAVE button periodically.
Advice:

1. Start with filling out a Word document with the text required for each section. CPHS provides a pdf version (http://cphs.berkeley.edu/sample_forms/soc_behav_ed_nonexempt.pdf) but you can use the word version posted on the Popcenter website, http://popcenter.berkeley.edu/soc_behav_ed_nonexempt.doc. I will be happy to read over this and let you know if I see anything obvious.
2. Campus Shared Services has former OPHS staff and they will assist in entering in the information and uploading it to the e-protocol system (https://eprotocol.berkeley.edu/). Sending them the completed document in #1 will greatly assist them, too.
3. Familiarize yourself with the guidelines on this page: http://cphs.berkeley.edu/guideline.html. When you write your protocol regarding any of these issues (e.g., data security) you want to use as much of the exact same phrasing as possible as this is what they are looking for.
4. Get a successful protocol from someone with a relatively similar project and use it as a guide.
5. There are three problems that are most likely to cause revisions. (1) Not being specific about data security steps ('steps will be made to ensure the security of the data' versus "personal identifiers will be given a unique code, and then separated from the main data, and held in a locked filing cabinet that only the PI has the key, and encrypted.). (2) Making a statement that is not backed up with defined procedure (e.g., "the data collection vendor will conduct their own IRB approval." (At what stage? With what company?). (3) Informed Consent: again, find out what is required (in the Guidelines) and do it and keep in mind there are waivers but follow the rules for those, too. For the informed consent, download the template (I found the Builder to be laborious) and use the elements related to your research.
6. One resource are the 'check lists' that the analysts use to check for compliance: http://cphs.berkeley.edu/checklists_worksheets.html. These are particularly useful for some of the specialized populations (e.g., prisoners, neonates).

For these documents and more, visit http://cphs.berkeley.edu.

Certificate of Completion

The National Institutes of Health (NIH) Office of Extramural Research certifies that **Leora Lawton** successfully completed the NIH Web-based training course "Protecting Human Research Participants".

Date of completion: 07/30/2009

Certification Number: 262063