Leah's tips for completing your human subjects protocol with a minimum of pain and suffering (last revised 3/7/18)

Note OURS deadlines for 2018 – If you miss these deadlines you will not be able to continue as a SURF fellow/Haas Scholar

Haas Scholars:
-All selected and wait list Haas Scholars must have a complete draft of their protocol ready for inspection on Monday morning, March 19
-All Haas Scholars whose protocols might go to full committee must submit their protocols by March 19
-All others must submit protocols by March 22.

SURF:
-All selected and wait list SURF fellows must have submitted a protocol by March 19.

Before we start: Why do this? Two reasons:
-Because it's required
-Much more importantly: because it is the right thing to do to ensure that you are taking every possible precaution to avoid harming the people you are studying. In the worst case scenario, e.g. your notes, with interviewees' names attached, falling into the hands of their enemies -- your research could do a lot of harm. That would be something you would have to live with forever, and it would also harm UC Berkeley and generations of future researchers. Try to think of this process as a way to improve your research.

I (Leah Carroll) carried out interviews of peasant activists in Colombia war zones. They noticed that I was taking many precautions to keep them safe. I have recently (twenty years later) reconnected with some of them, and they still remember that. I am glad that the human subjects process really helped me think through all the things I could do to avoid putting my interviewees at more risk.

How to proceed (note: this text is illustrated by the graphic that appears on this link: https://cphs.berkeley.edu/DecisionTree.pdf

1. Determine if you need to turn in a protocol at all -- research (not art, journalism, public service)? human subjects (identifiable, living people)? Generalizable (not an oral history of one person, for example)? There are many gray areas: ask OPHS staff to make a determination.

See "What Needs Review": http://cphs.berkeley.edu/review.html . It provides the definition of Human Subjects Research.

2. If so, do the CITI course. It's linked to the "for researchers"-->education/training link on the CPHS web site (cphs.berkeley.edu). Unless you are doing biomedical research, you will be doing "Group 2 Social and Behavioral Research Investigators and Key Personnel, Basic Course ". It will take you anywhere from 2 to 6 hours to complete. You do NOT have to do "Social and Behavioral Responsible Conduct of Research, Basic Course". That's a longer course that's not required or even recommended by the OPHS. Make a pdf of the certificate of completion when you're done. The e-protocol will ask for the date that you completed the course, and the OPHS staff can see if you've done it or not, but you don't need to upload the certificate.

3. Study the "types of review" link to figure out your likely level of review (off the researchers link on the CPHS web site: http://cphs.berkeley.edu/reviewtypes.html). Try to figure out if you should create an exempt protocol, or a non-exempt protocol. There are very specific reasons for exempt, and you must be able to argue that your project is exempt under at least one of those reasons. In essence, though, an exempt protocol is for a lower risk situation (very low risk questions/procedures or subjects who are not very vulnerable, or both), whereas non-exempt is for higher risk questions/procedures and/or more vulnerable subjects. Exempt is also a shorter form, and does not require you to submit an informed consent document with all required elements (but when appropriate, consent should be obtained). In contrast, non-exempt is longer and requires you to submit informed consent document (or request a waiver).

In addition to reviewing Types of Review (http://cphs.berkeley.edu/reviewtypes.html) students should read the Exempt Research Guidelines: https://cphs.berkeley.edu/exempt.pdf to help them determine if their project fits in one or more exempt category, or not.

4. Verify your level of review with your mentor and OPHS staff
Once you've studied the "types of review" page and *you think* you know which kind of protocol you should start, and if applicable which exemption/s apply/applies to your project, run this decision (to create an exempt or a non-exempt protocol) by your faculty advisor, if s/he has experience with human subjects protocols, or by someone at the CPHS office before you actually create a new protocol. I would recommend, a detailed email to ophs@berkeley.edu where you describe

•Who are your subjects? How vulnerable are they? How many of them will there be, maximum? If you have several different types of subjects, describe this.
•procedures (what will you be doing to your subjects)
•questions (what questions will you ask – how risky are they? Ideally attach a draft of your list of questions)

Please cc me (if you are a Haas Scholar/on the waiting list) or the SURF coordinator (if you are a SURF fellow/on waiting list) on this correspondence.

• *Note: if you create the wrong kind, you will have to paste all of your answers into a new form and submit it again, which is a big hassle and will set you back a few weeks at least,* so you must be sure about which kind to create before you start. It's especially problematic to err in the direction of exempt when really you're non-exempt. During this email conversation, they may also be able to brainstorm with you about ways to lower the risk level of your study so it *could* go through on exempt, or if not, at least expedited review. For example, your subjects can be anonymous (you don't ever know their names) instead of just confidential (you know their names but don't reveal them). You can also call the OPHS staff from 1-4:30 on weekdays, at 642-7461, but it will help to have emailed your question first.

Note that you might also ask them whether your faculty mentor (PI) will need to complete the CITI online class as well. Some tenure-track faculty members who have already sponsored protocols may not have to complete CITI, and some non-tenure track faculty members may have already completed it in previous years, but many faculty members will need to complete CITI *before your protocol can be approved.* If so, make sure to relay this info to your faculty mentor.

5. Log in to e-protocol and create and complete either an exempt or a non-exempt protocol. (E-protocol is one of the top links on the cphs web site). Click on the IRB tab (the IACUC is for animal research), and then click on the blue tab that says "create protocol". Make an attempt at all the questions on the e-protocol, as well as the informed consent if it's a non-exempt protocol (see templates on the "for researchers" list), and any "data collection instruments" (what questions you'll ask your subjects), ideally with a sample protocol in hand.

It may be helpful to take a look at the application questions before beginning their eprotocol application. There are blank sample forms of each application type available at the "eprotocol instructions" tab:
http://cphs.berkeley.edu/eprotocol.html

<u>Things to keep in mind</u>:

-e-protocol doesn't like Chrome (which is a drag since bmail likes **only** Chrome, but anyhow...). Use Firefox or Saffari.

-If your mentor does not come up on the list of eligible PIs, here is what to do: (PI = your mentor, by the way. You are the "student researcher", part of the key personnel). Ask OPHS staff if your mentor has been granted Exceptional PI status in the past; your mentor may also know. (When contacting OPHS staff, be sure to include mentor's name and title (adjunct professor, lecturer, etc.) and department. If OPHS staff say your mentor is "not in the system" (so they can't add them quickly--this most often happens with lecturers), ask your advisor if they have "exceptional PI status" -- they will probably know. If they do not, then contact Jeff Martin (for SURF), Leah Carroll (for Haas Scholars), or the McNair staff for McNair Scholars.

These three programs have an arrangement with the Vice Chancellor of Research to add lecturers who are mentoring students for our programs automatically to the "Special exemption" list.

-Remember to add me, Leah Carroll, carroll2@berkeley.edu, as your administrative contact if you're a Haas Scholar, and Jeff Martin, (j.vance.martin@berkeley.edu) if you're a SURF fellow, so we get cc'd when you submit and I can see your protocol as it progresses. This allows me to intervene on your behalf a lot more effectively, even make corrections, and also saves me from asking you over and over what stage you're at.

-Remember to not leave ANY question blank; leaving a question blank prevents submission. If it's not relevant to your project, enter "n/a".

Student should use the "Check for Completeness" option in eprotocol to identify if anything is missing.
http://cphs.berkeley.edu/eprotocolguide/investigator/check.pdf

-On the funding question on eProtocol, unless you are being funded as part of your faculty member's grant (e.g., you are being paid out of your mentor's NSF grant, which would require the Responsible Conduct of Research CITI module in addition), you would enter any funding you've received (McNair, Haas Scholars, SURF, etc.) under OTHER.

-If you get stuck on a certain question and the on-line protocol won't let you go to the next page, use a completed protocol, or the blank sample forms available on the CPHS web site, as a model so you can know what questions come next, and you can continue preparing your protocol while you get unstuck. You can also complete the application in a word document and paste your responses into eprotocol.

6. Once you have a full draft – Haas Scholars must have this by the morning of March 19 -- extract a list of questions/things you're unsure about.

7. Make an appointment first with your faculty advisor to answer your questions, the Leah/Jeff/McNair staff, and then follow up with a human subjects office staff by member by email or phone. Often they can help you brainstorm about ways to reduce the risk level of your study, so it can go through faster. Note that the OPHS staff will not read drafts of your protocol, but will answer just specific questions.

8. Based on their answers to your questions, tweak your draft.

9. Have your faculty mentor log in to e-protocol, "sign" your protocol in two places near the end – conflict of interest and approval -- and submit it. Note: you can not submit your own protocol – only your faculty mentor can do that. Ideally, you would be with your faculty sponsor when s/he does it, to guide him/her through. If you experience problems, look at the tips for submission (e-protocol link, "quick guides" in the pull down menu, then item #7 in the list, “submit a protocol”). Remember to tell your faculty mentor to use Firefox or Saffari. Also remember to turn off the pop-up blocker. If that doesn't work, contact the OPHS staff (ophs@berkeley.edu, 642-7461) for technical assistance.

10. Respond to requests for revisions, quickly but thoroughly, until you are approved. The OPHS will eventually (two months later, roughly) get back to you with revisions. It is imperative that you turn these revisions around as fast as possible, but be sure to accurately and completely address the comments and make applicable revisions to the protocol before submitting their responses to comments. Note that there may be more than one round of comments, but eventually, the OPHS will find your protocol acceptable.

11. Usually, a week or two after you've turned in the final round of revisions, you'll be approved. Woo hoo!!

Please contact me about any ways that occur to you to make this guide more effective.

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