Acland CPHS presentation
Econ 219B, Prof. DellaVigna
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Goals

1. ***Overcoming the vagueness barrier***.

   Unproved (but true) theory of how people botch simple but vaguely-understood tasks:

   In the absence of clear information about the dimensions of a new task, we will either

   a. over-estimate the task and thus postpone it because we dread it,

      or,

   b. under-estimate the task and thus postpone it because we assume it is trivial.

   My first goal is to give you a correct assessment of the dimensions of the task so you can avoid either of the above pitfalls.

2. ***Eliminating the "CPHS would never allow that" syndrome***.

   Question:

   How is it possible that CPHS routinely approves medical research in which people die, but won't approve your research in which someone gets tickled under the chin with probability rho?

   Answer:

   It isn't possible. They *will* (eventually) approve your research.

   My second goal is to give you a clear understanding of what CPHS cares about so that you can open your mind to the full range of creative research that they are almost certain to approve.

3. ***Inculcating you with a positive attitude and a proactive strategy***.

   Lemma 1 about bureaucracies:

   The primary purpose of any bureaucracy is to separate people into two groups, those who can be dispatched with a set of daunting forms, and those who realize that there are human beings behind the forms and insist on being treated as an individual by those human beings.

   Lemma 2 about bureaucracies:

   - Low-level bureaucrats typically do not care enough, nor do they have the authority, to give you the attention you deserve.
   - High-level bureaucrats typically are too busy to do so unless your case is very interesting.
   - But mid-level bureaucrats are typically interested in what they are hired to do and have time to answer your questions and help you out. This is especially true when the mid-level bureaucrats have technical expertise.

   My third goal is to provide you with a strategy that will help you to get your protocol approved as quickly as possible and hopefully avoid nasty surprises.

What kind of research requires review? I.O.W. what is "human subjects research"?

Research — means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject — means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- data through intervention or interaction with the individual, *or*
- identifiable private information.

Translation:

- If you are going to be using personally identifiable information *from any source whatsoever*, you need CPHS approval.
- If you are going cause *anything whatsoever* to happen in the lives of your subjects that otherwise would not have happened, you need CPHS approval.

Examples:

- *Any* microdata with personally identifiable information.
- Conducting a survey, online or anywhere else.
- Conducting interviews for case studies.
- Conducting an experiment.
- Being involved in the design of an experiment that someone outside academia is going to conduct and then give you the data.

Exceptions? Very few but worth learning about. See the pdf cited below.

[Policies and Procedures, RR401 1.1 or http://cphs.berkeley.edu/content/CPHSguidelines_activities_that_require_review.pdf]

What does CPHS "protect" against? I.O.W what are the criteria for approval?

[Important note: this is not an exhaustive list of criteria. It is, however, the heart of the matter.]

A. **Confidentiality.**

What to look out for:

In general, private information is considered to be individually identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person could ascertain the identities of individuals.

What to do about it:

Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

B. Risk.

- First, you must be absolutely clear about what risks exist in your research.
- Then you must demonstrate:
  - Risks to subjects are minimized
  - Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.
  - Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by appropriate local, state and federal regulations

C. **Other stuff.**

The truth is that IRB's exist primarily to protect the University from getting sued. You ought to be able to identify the real risks to your subjects. However, the minute legal risks to the University that CPHS is trained to spot in your protocol sometime boggle the mind. There's no way you are going to figure this stuff out on your own. That's why I recommend talking directly to the analyst(s) as much as possible so that they will red-flag these issues before your protocol is reviewed.

Action steps. I.O.W. what do I actually need to do?

1. Take the training: www.citiprogram.org

- This is the online training that you need to complete before you submit a protocol.
- The rational, self-interested way to do the training is this:

  1. Read a module,
  2. Answer the quiz for that module at random (or to the best of your ability without wasting time)
  3. Submit the quiz, get the correct answers, and write them down,
  4. Click the link to go back to the beginning of the module,
  5. Take the quiz again and enter the correct answers this time.

  Note: if you use this method, you do need to actually read the modules because you need the information in order to avoid making time-consuming and potentially dangerous or costly mistakes.

- Print out the certificate of completion and submit it with your first protocol.

2. Fill out two short(ish) forms:

The official list of what you need to submit for various different kinds of applications is here: http://cphs.berkeley.edu/content/INS0-whattosubmit.htm

However, it will be easier if you think of it this way. There are two short and relatively content-free forms that must be submitted with every CPHS application, renewal, ammendment, etc.

a) Application Cover Sheet http://cphs.berkeley.edu/content/FRM2-CoverSheet.doc
b) Conflict of Interest Checklist http://researchcoi.berkeley.edu/cphscoi.doc

Then there is the Protocol Narrative Form. This is a huge form which, when completed, will read almost like a prospectus. Everything else you need to submit can be thought of as an attachment to this form. Hence, I give it its own section, as follows:

3. Write your protocol:

This is the actual work of submitting a protocol. Download the Protocol Narrative Form http://cphs.berkeley.edu/content/FRM4-ProtocolNar.doc and get started as early in the process as you possibly can. **Do Not** wait until you have got every last detail of your design worked out. This is because a) approval will take at least two months, and b) writing the protocol will help you a lot with sorting out your research design.

As you work through the form you will find yourself prompted to include the following attachments:

- Any recruiting and/or screening material that you will use to get/sort your subjects.
- Any data collection "instruments" you will be using, including surveys, experimental tasks, etc.
- Your consent form(s).

In addition you will be required to address things like how you will handle payments, how you will handle confidentiality, how you will handle unforeseen risks or adverse events, how you determined your sample size, and various other issues.

The completed form is typically twelve to fourteen pages without attachments.

My number one recommendation for submitting a CPHS protocol is to view the Protocol Narrative Form as a valuable part of the creative process rather than as a necessary evil.

3a. A note about guidelines

To help you sort out the various intricacies of the process, CPHS has created a suite of "guidelines" documents. Most of them are referenced in the body of the Protocol Narrative Form at exactly the point that you need them. To see them (almost) all in one place, go to:
cphs.berkeley.edu/content/guideline.htm

To find exactly everything you could possibly need to know, all in one place, check out the compendious and extremely clear "Policies and Procedures of the UC Berkeley Human Research Protection Program." This is a gold mine. In particular check out sections 401, 701 and the worksheets at the end.