Conducting Human Subjects Research at UCB

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February 28, 2018
Agenda

- Am I doing human subjects research?
- Risk determinations and levels of review
- Informed consent
- Data security
- Amendments
- eProtocol
- Resources
- Knowledge quiz
True or False?

• If my research is exempt, I don’t need to submit an application to OPHS
• If I am conducting secondary data analysis with existing data, I don’t need approval from UCB
• Written (signed) consent is required for all studies involving humans
Research Ethics Highlights

Nuremberg Code (1948) “The voluntary informed consent of the human subject is absolutely essential.”

Tuskegee Syphilis Study (1932-72)

Declaration of Helsinki (1964) “This protocol should be submitted...to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence.”

National Research Act (1974)
Ethical Principles of Belmont Report

- Respect for persons
- Beneficence
- Justice

The Belmont report is the foundation for the federal regulations (45 CFR 46, AKA the “Common Rule”) that govern human subjects research in all institutions that receive federal funding.
IRB Review Is Required

When:

• You are “engaged” in “research,” AND

• The activity involves “human subjects.”

• See [CPHS Guidelines on Activities that Require CPHS/OPHS Review](http://cphs.berkeley.edu/review.html)
Research

- a **systematic investigation** designed to contribute to **generalizable knowledge**

- **Systematic investigation**: a study or examination involving a methodical procedure or plan.

- **Generalizable knowledge**: conclusions, facts, or principles derived from particulars (individual subjects, medical records, etc.) that are applicable to or affect a whole category (members of a class, kind, or group, a field of knowledge, etc.) and enhance scientific or academic understanding.
Human Subject

A *living* individual about whom an Investigator obtains:
- data through *intervention* or *interaction* with the individual, or
- identifiable *private information*
Projects That May Not Involve Research with Human Subjects

• Class projects
• Case reports
• Quality assurance/quality improvement activities
• Oral histories
• Use of coded private information or biological specimens

*If not sure, contact OPHS.*
Risk in Research

Risk = probability x magnitude of harm

- Physical
- Psychological: Emotional distress, psychological trauma
- Social: Invasion of privacy, economic, employability, insurability, stigmatization, embarrassment

Ask yourself: What are the worst harms that can result from the study AND what is the likelihood of those harms occurring?
Minimal Risk

*Minimal risk* means:

“the probability and magnitude of harm or discomfort anticipated in the research are not greater...than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

Three Levels of IRB Review

1. Exempt Review
2. Expedited Review
3. Full Committee Review

- Greater than Minimal Risk
- Minimal Risk
Exempt Research

- Risk is negligible/benign
- Fits within one or more exempt categories (anonymous survey/interviews, observation of public behavior)
- Research involving interactions with children does not qualify

**Reviewed by staff on a rolling basis without an expiration date

See [http://cphs.berkeley.edu/exempt.pdf](http://cphs.berkeley.edu/exempt.pdf) for additional guidance

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Exempt categories

- Category 1: Normal educational practices
- Category 2: Surveys, public observation, interviews, focus groups
- Category 3: Similar to category #2 but with elected officials
- Category 4: Use of existing data/materials
- Category 5: Federal Agency initiated programs
- Category 6: Food quality and taste
- Category 7: UCB specific
Exemption Categories

– Most common at UCB:

(2) Surveys, interviews, focus groups, and observation of public behavior (if anonymous or present negligible risk).

➤ Surveys & interviews with children are **NOT** exempt.

(4) Existing data (if recorded anonymously)
Category 7 Exemption

• Unique to UCB
• Non-physically invasive interventions or performance of tasks
• Only of minimal-risk activities that will not induce distress beyond that of daily life and that could not reasonably place the subject at risk of criminal or civil liability, be damaging to the subject’s financial standing, employability, insurability, or reputation, or be stigmatizing in any other way
Category 7 Exclusions*

- Children/minors as subjects.
- Prisoners as subjects.
- Federal funding.
- Federal personnel or the Department of Veterans Affairs.
- Procedures, devices, or drugs subject to FDA oversight.
- Biomedical procedures.
- Clinical interventions.
- An NIH-issued Certificate of Confidentiality is being obtained to protect identifiable research data.
- Deception or incomplete disclosure to subjects.
- Identifiable, private existing data.
- *In addition to minimal risk statement on previous slide
Activities under Category 7

- Reading/writing/drawing tasks.
- Physical activities such as walking, sitting, or manipulating an object.
- Computer tasks and/or Internet searches.
- Talking and/or listening to words, then making selections, or “think-aloud” exercises.
- Viewing media.
- Role-playing.
- Completing a specific physical or mental action (“imagining”).
- Passive monitoring of space (environment) with sensors.
- Playing a game.
- Height/weight measurements.
Exempt Examples

- A study involving interviews with college seniors (age 18 and older) about their plans after graduation. The answers to questions asked would present minimal risk to subjects if divulged outside the research.

- An observational study of pedestrians crossing a street; the researcher takes notes of what occurs, recording sex, race, and type of clothing of pedestrians, but does not interact with subjects.
Expedited Review

No greater than minimal risk

Fits within one or more expedited categories

Includes non-exempt survey/interviews, collection of biological specimens (blood, saliva), and other non-invasive data collection (standard eye exams, EEG, MRI, etc.).

**Reviewed by a subcommittee or IRB Chair/designee, for one or ten year approval periods**
Expedited Review

The most common expedited categories (of 9 total) used here at UC Berkeley:

• # 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
• # 5: Research on materials that were collected or will be collected, for non-research purposes (such as academic records or medical records)
• # 6: Collection of data from voice, video, digital, or image recordings made for research purposes.
• # 7: Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
Expedited Example

- Secondary data analysis of private, personally-identifiable data.

Why is this expedited?

- Does not fit into one or more exempt categories.
- Does not present greater than minimal risk to subjects.
Full Committee Review

- Risk is greater than minimal or research does not fit within exempt or expedited categories
- Sensitive data (e.g., genetic analysis, illegal activities)
- Some research involving protected populations (prisoners, cognitively impaired)
- **Reviewed by a quorum of IRB members at a convened meeting (w/deadlines), for one or 10 year approval periods**
Full Review Examples

- A study involving interviewing undocumented immigrants about their experience immigrating to the US.

  Why is this Full Review?
  - Participation and breach of confidentiality could present greater than minimal risk to subjects.
  - Target population has diminished rights.

- A study involving the collection of identifiable data about illicit drug use and other illegal behavior or criminal activity.

  Why is this Full Review?
  - Participation and breach of confidentiality could present greater than minimal risk to subjects.
  - Target population has diminished rights.
• Undergraduate researchers are strongly discouraged per CPHS guidelines from collecting sensitive information, using deception, asking questions on topics that may cause emotional/psychological trauma (e.g., victims of abuse), or research with pregnant women or prisoners.

• If submitted with the above, these must have full board review.
See CPHS Guidance for Undergraduate Research

Undergraduate Research, Part 1: Ethical Issues in Undergraduate Research Activities with Human Participants

Undergraduate Research, Part 2: Guidance on Designing Undergraduate–Initiated Research Activities

http://www.cphs.berkeley.edu/guideline.html
Protected Populations

- Pregnant women, fetuses and neonates (Subpart B)
- Prisoners (Subpart C)
- Children (Subpart D)
Protected Populations cont.

- **CPHS strongly recommends** that an undergraduate student who wishes to study a vulnerable population turn to group spokespeople, group representatives, expert informants, and professionals working with the population if they wish to learn sensitive information about the population.

- **Special attention should be paid** to the potential for risks in research involving certain activities, e.g., disclosure of identifiable sensitive information, interviewing on topics of emotional or psychological trauma, and deception.
Consent for Exempt Research

• Consent forms not reviewed, **BUT**:  
• Expected that subjects will be informed of:  
  – Identity/affiliation of the researcher  
  – Study procedures  
  – Research is voluntary  
  – Contact information for questions
Consent for Non-Exempt Research

• Signed consent generally required
• Must include required elements
• Unsigned Consent can be used if:
  – only record linking the subject and the research and the principal risk is a breach of confidentiality
  – research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context
Consent Form Resources

• Consent Guidelines:
  – https://cphs.berkeley.edu/consent.pdf

• Child Assent/Parent Permission Guidelines:
  – https://cphs.berkeley.edu/assent_permission.pdf

• Consent/Parent Permission/Child Assent Templates and Samples:
  – http://cphs.berkeley.edu/informedconsent.html
Data Security: Key Concepts

• The level of data security necessary is relative to the risk posed to the subject should personally identifiable information be inadvertently disclosed or released.

• For data that retains identifiers, investigators must consider adequate administrative, physical, and technical safeguards.

• Use secure data encryption if identifiable information is: (1) stored on a networked computer or device, (2) stored on or transmitted via the web, (3) stored on a device which is not permanently located in a secure location.

• Limit access to personally identifiable information.

See data security guidelines: https://cphs.berkeley.edu/datasecurity.pdf
Modifications/Amendments

• Submit an amendment for any changes to study (other than correcting grammatical errors), such as:
  – Changes that could alter the risk or burden to study participants
  – Changes in key personnel
  – Changes to recruitment or adding procedures
  – New funding source

Any modifications MUST be reviewed and approved by the IRB before implementation, unless life threatening.
International Research

• Same standards apply, but special attention should be given to local law and customs.
• Researcher should demonstrate knowledge of the local context and provide additional information in the protocol.
• Local approvals might be required.
• Consent forms should be translated into local language and submitted to IRB for approval.
CITI Training

All UCB personnel* must complete Human Subjects Research Protections training (online CITI course; register as UCB).

– Complete Group 1 Biomedical Research or
– Group 2 Social/Behavioral Investigators and Key Personnel

*unless grandfathered—see policy

(The Responsible Conduct of Research Module is only required for NSF funded research, you do not submit with your eProtocol)
All protocols must be submitted online via eProtocol:  [http://cphs.berkeley.edu/eprotocol.html](http://cphs.berkeley.edu/eprotocol.html)

Student Investigator Guide:  [http://cphs.berkeley.edu/student.html](http://cphs.berkeley.edu/student.html)

Read eProtocol FAQs before starting your application:  [http://cphs.berkeley.edu/eprotocol_faqs.html](http://cphs.berkeley.edu/eprotocol_faqs.html)

Use Quick Guides for detailed instructions:  [http://cphs.berkeley.edu/eprotocol_guides.html](http://cphs.berkeley.edu/eprotocol_guides.html)
Researcher’s Responsibility

• Design ethical research
• Obtain IRB approval and conduct study as approved
• Ensure participation is voluntary and informed
• Maintain privacy of participants and confidentiality of data
• Promptly report:
  – Unanticipated problems involving risks to subjects or others
  – Noncompliance or protocol deviations
For More Information and Assistance

| Call  | • 510–642–7461  
|       | • Monday to Friday, 1pm–4:30pm  
|       | *Speak with the analyst who answers the phone*  |
| In–person Meeting | • 1608 Fourth Street, Suite 220  
|      | • Monday to Friday, 8:30am–12pm, 1pm–4:30pm *In–person assistance must be scheduled in advance*  |
| Website | • [http://cphs.berkeley.edu/](http://cphs.berkeley.edu/)  |
| Email  | • ophs@berkeley.edu  |
Knowledge Quiz

1. What is the definition of “human subjects research”?
2. What are the 3 levels of IRB review?
3. If I’m conducting secondary data analysis, when do I need to obtain IRB review?
4. If I need to obtain IRB review for secondary data analysis, what level of review do I need?
5. How do I submit an application for IRB review?
6. What training do I need in order to apply for IRB review?
7. What do I do if I’m not sure that I need IRB review and/or don’t know what level of review I need?
8. Where do I go for guidance on creating an informed consent document?