

# Human Subjects Research: Overview



**Colleen Kohashi and Tani Prestage**

Office for the Protection of Human Subjects (OPHS)

February 26, 2016

# Topics to be Covered

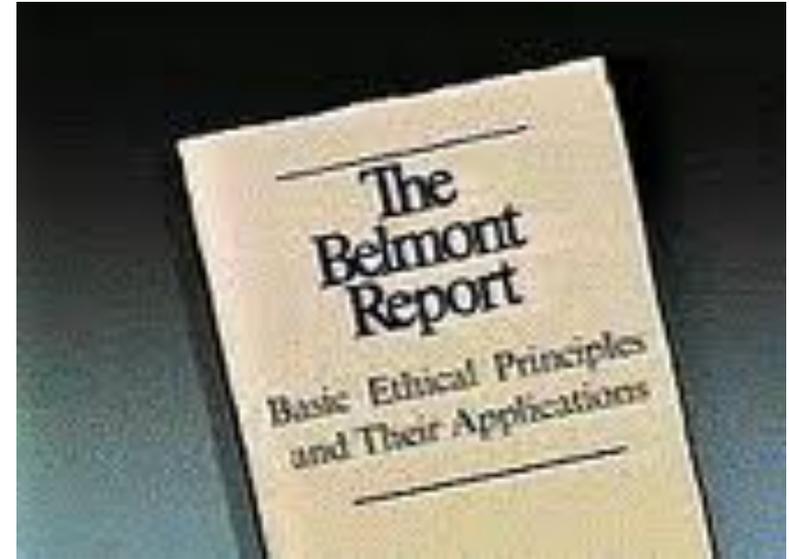
- Am I doing human subjects research?;
- Risk determinations and levels of review;
- eProtocol;
- Informed consent;
- Amendments and continuing review;
- Data security and internet-based research;
- Tips for approval;
- Relying on another IRB; and
- Q&A followed by 1:1 advisement sessions.

# True or False?

- If my research is exempt, I don't need to submit an application to OPHS
- Written (signed) consent is required for all studies involving humans

# 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)  
<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
- Research on institutions or social processes
- 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 ourselves to state the worst harm(s) that can result in a study AND if we are reasonably estimating the probability of (all) various harms.**

# Minimal Risk

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

# Three Levels of CPHS Review

- **Exempt**  
*staff review on a rolling basis - allow 2-4 weeks for approval*
- **Expedited**  
*staff pre-review/approved by committee reviewer on a rolling basis - allow 8-10 weeks for approval*
- **Full Committee**  
*staff pre-review + convened committee review with strict deadlines - allow 2-3 months for*

# 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> for additional guidance

# Exempt categories

- Category 1: Normal education practices
- Category 2: Surveys, Observational studies, interviews, focus groups
- Category 3: #2 with elected officials
- Category 4: Existing data/materials
- Category 5: Federal Agency initiated programs
- Category 6: Food quality and taste
- Category 7: UCB specific

# Exemption Categories

(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 Example

- A researchers conducting an anonymous survey with adults regarding satisfaction of a new bicycle sharing program in Shanghai, China.

Why is this exempt?

- ✓ Fits into exempt category #2

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

# Expedited Review

- No greater than minimal risk
- Fits within one or more expedited categories
- Approved for one or three years by a member of the Committee

# Common Expedited Categories

- # 4: Collection of data through noninvasive procedures routinely employed in clinical practice (excluding x-rays or microwaves).
- # 5: Research on materials that were collected or will be collected, for non-research purposes (such as academic records)
- # 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

- Providing new indoor cook stoves to households in underdeveloped areas. Then interviewing household members about air quality, satisfaction, and safety.

Why is this expedited?

- ✓ Involves an intervention
- ✓ Does not present greater than minimal risk to subject who participate
- ✓ Data collected is not considered risky

# Please 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](#)

# Full Board Review--

- *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.*

# Full Board Review cont.

- 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.

# Full Committee Review

- There is greater than minimal risk present *or* the procedures do not fit within any of the expedited categories
- Sensitive data (e.g., genetic analysis, illegal activities)
- Some research involving protect populations (e.g. prisoners, neonates)
- Approved for one or three years

# Full Review Examples

- A multi-year study on the impacts of pesticides on health outcomes of migratory farm workers.

Why is this Full Review?

- ✓ Participation and breach of confidentiality could present greater than minimal risk to subjects
- ✓ Target population (mostly undocumented workers) has diminished rights

# eProtocol

- All protocols must be submitted online via eProtocol:
  - <http://cphs.berkeley.edu/eprotocol.html>
- Student Investigator Guide:
  - <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:

# Informed Consent



# Elements of Consent

- Title of study
- Researcher introduction
- Purpose
- Procedures
- Voluntariness
- Risks and benefits
- Confidentiality
- Contacts for questions and research rights

# 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 Builder: A web-based tool to create Consent Forms:  
<http://cphs.berkeley.edu/consentbuilder.html>
- Online Consent, Consent with Audio Recording, Parent Permission/Child Assent Templates:  
<http://cphs.berkeley.edu/informedconsent.html>

# Modifications/Amendments

When is an amendment required?

- Changes that could alter the risk or burden to study participants
- Changes in key personnel
- Changes to recruitment or adding procedures
- Changes in study population
- New funding source

*Modifications **MUST** be reviewed and approved by the IRB before implementation*

# Continuing Review

- Non-exempt protocols can be approved for up to 3 years if:
  - involve no more than minimal risk to participants;
  - not supported by federal funds; *and*
  - not subject to federal oversight

*All other protocols are approved for one year; Exempt determinations do not expire.*
- Submit continuing review application two months prior to expiration

# Online Surveys

- IST has advised OPHS/CPHS that investigators should use UCB Qualtrics when administering online surveys.
- The confidentiality of data can never be guaranteed when it is transmitted over the web–this needs to be stated in consent documents.

# 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.
- 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.

# 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
  - Save a copy of Completion Report to submit with eProtocol application

***\*unless grandfathered–see policy***

(The Responsible Conduct of Research Module is only required for NSF funded research, you do not submit with your eProtocol)

# Tips for Efficient Approval

- ❑ Refer to the OPHS Tips for Efficient Approval.
- ✓ Be sure to read through the Commonly Requested Revisions for mistakes to avoid.
- ❑ When responding to comments:
  - ✓ Provide thorough but concise answers. Only include information relevant to the question posed.
  - ✓ Be sure to make the applicable revisions directly into the protocol as well. Be sure to click on the “submit to IRB” button to submit your responses and revisions.

# Relying on another IRB

- Memorandum of Understanding  
(agreements between UC campuses)
- Inter-Institutional Agreement  
(agreement with a non-UC IRB)
- Individual Investigator Agreement  
(agreement with a non-affiliated researcher)

*\*All agreements must be approved by the OPHS  
Director in advance. Inquiries:*

[ophs@berkeley.edu](mailto:ophs@berkeley.edu)

# For Information & Assistance

- |                   |   |
|-------------------|---|
| Call              | <ul style="list-style-type: none"><li>• 510-642-7461</li><li>• Monday to Friday, 8:30am-12pm, 1pm-4:30pm</li><li>• Speak with the analyst who answers the phone</li></ul>                       |
| In-person Meeting | <ul style="list-style-type: none"><li>• 2150 Shattuck Ave., Suite 300</li><li>• Monday to Friday, 8:30am-12pm, 1pm-4:30pm</li><li>• In-person assistance must be scheduled in advance</li></ul> |
| Website           | <ul style="list-style-type: none"><li>• <a href="http://cphs.berkeley.edu/">http://cphs.berkeley.edu/</a></li></ul>   |
| Email             | <ul style="list-style-type: none"><li>• ophs@berkeley.edu</li></ul>   |