

# Conducting Human Subjects Research at UCB

**Emily Harden-Antonio**

**Jason Silva**

Office for Protection of Human Subjects (OPHS)

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# Agenda

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

# Research Ethics Highlights

**Nuremberg Code  
(1947)** “The  
voluntary informed  
consent of the  
human subject is  
absolutely  
essential.”

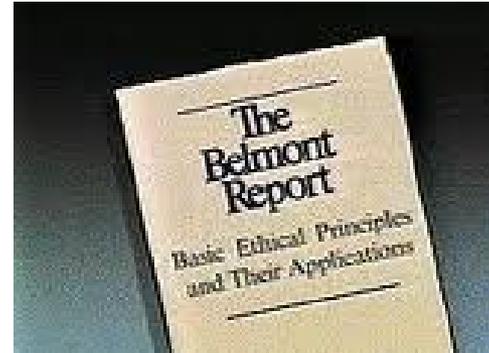
**Declaration of Helsinki  
(1964)** “This protocol  
should be submitted...to  
a specially appointed  
ethical review  
committee, which must  
be independent of the  
investigator, the sponsor  
or any other kind of  
undue influence.”

**Tuskegee Syphilis  
Study (1932-72)**

**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.

# 45 CFR 46

- The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule), 45 CFR 46.
- The revised Common Rule (AKA the 2018 Requirements) went into effect on January 21, 2019.

<https://cphs.berkeley.edu/guide/commonrule.html>

# 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  
(<https://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.

# Research continued...

“Research” has been expanded to list activities that are specifically deemed **not** to be research, because they do not typically contribute to generalizable knowledge. For example:

- journalism;
- certain scholarly activities such as oral history;
- public health surveillance;
- criminal justice or criminal investigative activities; and
- activities in support of intelligence, homeland security, defense, or other national security missions.

# Human Subject:

A **living** individual about whom an investigator conducting *research*:

- (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

# Projects That *May* Not Involve Research with Human Subjects

- Class projects
- Case reports
- Research on institutions or social processes
- Use of coded private information or biological specimens
- ***If not sure, take our self-certification survey:***  
**<https://cphs.berkeley.edu/>**

# 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?**

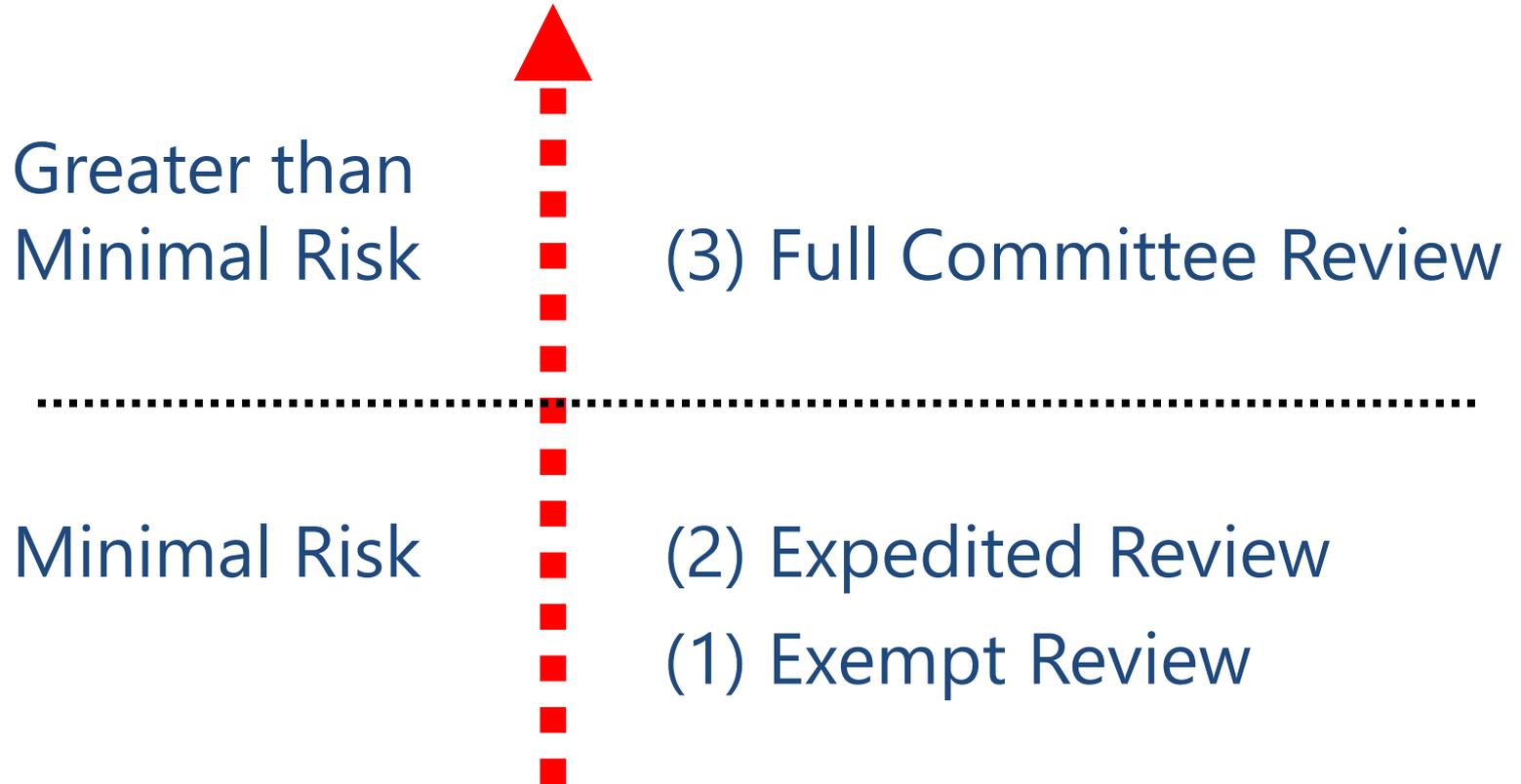
# Minimal Risk

*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.”

(as defined in [45 CFR 46.102](#))

# Three Levels of IRB Review



# 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 and approved for 10 years**

See <https://cphs.berkeley.edu/exempt.pdf> for additional guidance

# Exempt categories

- Category 1: Normal educational practices
- Category 2: Surveys, public observation, interviews, focus groups w/ the possibility of limited IRB review
- Category 3: Benign, behavioral interventions
- Category 4: Use of existing data/materials
- Category 5: Public benefit or service program
- Category 6: Food quality and taste
- Category 70: UCB specific for minimal risk projects that don't fit one or more of the above categories

# Category #70 Exemption

- Institutionally defined category.
- Non-physically invasive interventions or performance of tasks.
- *Only* 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.

# Category #70 Examples

- Physical activities (walking, sitting, or manipulating an object)
- Computer tasks and/or Internet searches
- “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

*NOTE: These activities might also fit under exempt category #3.*

# Category #70 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.
- Identifiable, private existing data if risk of harm.

\*In addition to minimal risk statement on previous slide

# 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.
- A study involving adults (age 18 and older) asking subject to play an online game that takes 30 minutes to complete.

# 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 after staff pre-review, generally approved for 10 years**

# 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 Examples

- A study involving interviews with high school seniors about their plans after graduation. The answers to questions asked would present minimal risk to subjects if divulged outside the research..

## **Why is this expedited?**

- Some subjects may still be minors under the age of 18.
- Does not present greater than minimal risk to subjects.

- A federally funded study involving 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

- Interviews with refugees from conflict zones about their experiences

## **Why is this Full Review?**

- Risk of emotional distress greater than minimal
  - Target population has diminished rights
  - If identifiers are collected, risk of breach of confidentiality greater than minimal
- Obtaining identifiable information about illicit drug use / illegal behavior / criminal activity

## **Why is this Full Review?**

- Risk of breach of confidentiality greater than minimal
- Potential for diminished capacity to consent



# Full Board Review cont.

- CPHS guidelines strongly discourage undergraduate researchers from
  - Collecting sensitive, identifiable information
  - Using deception
  - Asking questions on topics that may cause emotional/psychological trauma (e.g., victims of abuse)
  - Conducting research with pregnant women or prisoners
- If submitted, likely to require full board review

# Protected Populations

Pregnant women, fetuses and neonates (Subpart B)

Prisoners (Subpart C)

Children (Subpart D)

# Protected Populations cont.

- As an alternative to conducting research involving protected populations, e.g., prisoners, student researchers are encouraged to turn to group spokespeople, group representatives, expert informants, or professionals working with the target population
- Special focus on risk of disclosure of identifiable sensitive information and potential for emotional or psychological harm

# 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>

# 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.

<https://cphs.berkeley.edu/international.html>

# Informed Consent 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
  - The CPHS protocol ID number

# Informed Consent

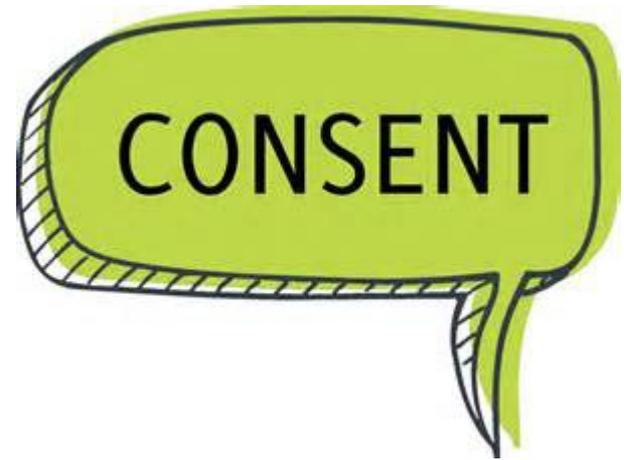
## Non-Exempt Research

- Consent must be obtained by researchers prior to the research.
- Provide sufficient opportunity to consider whether or not to participate (minimize possibility of undue influence).
- Consent form content:
  - Language should be understandable to the subject.
  - Must not include any exculpatory language.
  - Must include all required elements of consent, unless waived.
- Signature generally required, unless waived by the IRB.

# Informed Consent

## Basic Elements

- Study is research
- Purpose
- Duration
- Study procedures
- Identify experimental procedures
- Risks/discomforts
- Benefits
- Alternatives
- Confidentiality
- If greater than minimal risk: compensation/medical treatments



## CONSENT TO PARTICIPATE IN RESEARCH

*Title of Study (Designate any subject sub-group here, e.g., "Controls")*

### Key Information

- You are being invited to participate in a research study. Participation in research is completely voluntary.
- The purpose of the study is to [*one sentence explanation of why*].
- The study will take a total of [*total time commitment*] and you will be asked to [*one sentence explanation of study procedures*].
- Risks and/or discomforts may include [*list possible risks and/or discomforts*].
- There is no direct benefit to you [*or list possible direct benefits*]. The results from the study may [*one sentence explanation of societal benefits of study*].
- [*If applicable, list appropriate alternative procedures or courses of treatment*].

### Key Information - EXAMPLE

- You are being invited to participate in a research study. Participation in research is completely voluntary.
- The purpose of the study is to examine the effect of providing key information to subjects in a consent form on their comprehension of the study.
- The study will take a total of one hour and you will be asked to read the consent form and answer questions about it.
- Risks and/or discomforts may include the risk of breach of confidentiality.
- There is no direct benefit to you. The results from the study may show whether this additional consent element is helpful to subjects.

# Consent Form Resources

- Consent Guidelines: <https://cphs.berkeley.edu/consent.pdf>
- Child Assent/Parent Permission Guidelines: [https://cphs.berkeley.edu/assent\\_permission.pdf](https://cphs.berkeley.edu/assent_permission.pdf)
- Consent/Parent Permission/Child Assent Templates and Samples: <https://cphs.berkeley.edu/informedconsent.html>

# Data Security: Key Concepts

- UC Berkeley Data Security guidelines:  
<https://cphs.berkeley.edu/datasecurity.pdf>
- Data security measures should be commensurate with the risk posed to subjects should personally identifiable information be inadvertently disclosed.
- Investigators must demonstrate adequate administrative, physical, and technical safeguards to protect identifiable data.
- Use secure data encryption when 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 identifiable information.
- “Coding” is recommended.



# eProtocol

All protocols must be submitted online via eProtocol:  
<https://cphs.berkeley.edu/eprotocol.html>

Guide to the IRB Review Process:  
<https://cphs.berkeley.edu/reviewguide.html>

Read eProtocol FAQs before starting your application:  
[https://cphs.berkeley.edu/eprotocol\\_faqs.html](https://cphs.berkeley.edu/eprotocol_faqs.html)

Use Quick Guides for detailed instructions:  
[https://cphs.berkeley.edu/eprotocol\\_guides.html](https://cphs.berkeley.edu/eprotocol_guides.html)

# Getting started with eProtocol

- An eligible Principal Investigator/Faculty Advisor must be identified before you begin (Students cannot serve as PI)
- Web browser tips:
  - On a PC? Use Firefox
  - On a Mac? Use Firefox or Safari
  - Do not use Chrome
  - Turn off Pop-up Blocker

# How to create a protocol

Quick Guide:

<https://cphs.berkeley.edu/eprotocolguide/investigator/create.pdf>

Choose the appropriate application form:

- Soc-Behav-Ed Exempt
- Soc-Behav-Ed Non-Exempt
- Biomedical Exempt
- Biomedical Non-Exempt

For offline prep, use PDF versions:

<https://cphs.berkeley.edu/eprotocol.html>

# Tips for writing your protocol

- Answer each question completely, but avoid including extraneous information.
- Focus on the interactions between researchers and human subjects.
- Describe specific procedures to be used.
  - What exactly is expected from the research participant?
- Write in a style appropriate for an educated audience but one that is not an expert in your field.
- Be consistent (e.g. between the protocol and attachments).
- Refer to Tips for Efficient Approval handout

# CITI Training

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

- Group 1 Biomedical Research Investigators, OR
- Group 2 Social and Behavioral Research Investigators
- \*Legacy PIs exempt from training requirement (See Training Policy at [https://cphs.berkeley.edu/policies\\_procedures/ga102b.pdf](https://cphs.berkeley.edu/policies_procedures/ga102b.pdf))
- NOTE: The Responsible Conduct of Research module is only required for NSF funded research and not submitted with your protocol.

# 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

# Researcher's Responsibility

- Design ethical research
- Obtain IRB approval and conduct study as approved; submit amendments for changes and wait for approval before implementing the changes
- 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  
*Leave a message and an analyst will call you back*

Email

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

Zoom meeting

- Email to schedule a Zoom meeting
- Monday to Friday, 8:30am-12pm, 1pm-4:30pm  
*Zoom assistance must be scheduled in advance*

Website

- <http://cphs.berkeley.edu/>

Questions?