Human Subjects Research for Undergraduates

How to impress your professor by knowing important things about human subjects research
Agenda for the Day

1. Introduction to the IRB
2. What is Human Subjects Research?
3. Submitting a New Project
4. What can I do to get a leg up now?
Agenda for the Day

1. Introduction to the IRB
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1932-1972
Tuskegee Syphilis Study

- Conducted by US Public Health Service in Macon County, AL
- Designed to study progression of untreated syphilis
- All research participants were Black men
  → Told they were being treated for “bad blood”
  → Prevented from getting treatment

1932-1972
Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,....
Governmental Reaction to Tuskegee

National Research Act of 1974

- Established Institutional Review Boards (IRBs)
- Mandated that IRB approval is required for human subjects research studies
What is the purpose of IRB review?

- Protect rights and welfare of research participants
- Compliance with applicable regulations, laws, and policies
Structure of the IRB

Institutional Review Board

Administration

Biomedical Committee A

Biomedical Committee B

Social and Behavioral Committee C
Agenda for the Day

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The IRB Reviews Human Subjects Research

Is the project research?

<table>
<thead>
<tr>
<th>Yes</th>
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Does the project involve human subjects?

Yes  No
The IRB Reviews Human Subjects Research

<table>
<thead>
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**Table:**

- **Yes**: If the project is research and involves human subjects, submit to the IRB. IRB review **NOT** required.
- **No**: If the project is not research or does not involve human subjects, IRB review **NOT** required.
What is Research?

Systematic Investigation

Generalizable Knowledge
<table>
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<td>- Journalistic activities</td>
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<td>- Oral history projects</td>
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<td>- Case reports/series</td>
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<td>- Quality improvement/assurance</td>
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<td>- Program evaluation</td>
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What are human subjects?

- Intervention
- Interaction
- Private Identifiable Information
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<td>• Surveys to develop generalizable knowledge</td>
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<td>• Retrospective study using data from patient medical records</td>
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<tr>
<td></td>
<td></td>
<td>• Analysis of publicly available, anonymous, or de-identified data or biospecimens</td>
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<td></td>
<td></td>
<td>• Non-human animal research</td>
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Is it human subjects research?

A researcher is using a rat model to test if a potential drug for the treatment of epilepsy can bind to its therapeutic target.
## The IRB Reviews Human Subjects Research

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Is it human subjects research?

• In your political science class, you are learning about how surveys of potential voters are conducted.
• One of the assignments includes developing a survey in a group ahead of this year’s election.
• This survey will be distributed online.
• Results will be presented in class.
The IRB Reviews Human Subjects Research

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<td>Submit to the IRB</td>
</tr>
<tr>
<td></td>
<td>IRB review NOT required because the intent of the project is to learn how to develop surveys, not develop generalizable knowledge.</td>
</tr>
<tr>
<td>No</td>
<td>IRB review NOT required</td>
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No IRB review NOT required
Is it human subjects research?

• You are working with your political science professor to develop a survey ahead of this year’s election.
• This survey will be distributed online.
• Intent to contribute to the field of research around using social media for political surveys.
The IRB Reviews Human Subjects Research

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<td></td>
<td>✓ Systematic investigation</td>
</tr>
<tr>
<td></td>
<td>✓ Intent to contribute to generalizable knowledge</td>
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<td></td>
<td>✓ Interaction via survey</td>
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Is it human subjects research?

Your principal investigator (PI) has purchased anonymous blood samples from a biobank to determine the effect long-term storage has on the integrity of a specific protein.
The IRB Reviews Human Subjects Research

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<tr>
<td>Yes</td>
<td>IRB review NOT required because no interaction or intervention with humans and no use of private identifiable information</td>
</tr>
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Yes

No
What if I’m not sure if I need to submit to the IRB?

You have the following options:

Check out the IRB website
- Does My Project Need Review by the IRB page
- Interactive Determination Questionnaire

Contact the IRB
- hs-irbeducation@ucdavis.edu

Submit the HRP-210 Request for Determination on IRBNet
- No other documents need to be submitted
Where do I submit to the IRB? IRBNet.org

Comprehensive Solutions

The Industry's Most Complete Solution
IRBNet's unmatched suite of electronic solutions drives compliance and productivity for your Administrators, Committee Members, Researchers and Sponsors. These powerful research design, management and oversight tools support your IRB, IACUC, IBC, COI and other Boards with a unified solution.

Flexible, Intuitive and Easy to Use
Your own forms. Your own processes. Your own standards. Powerful reporting and performance metrics. The data you need. From electronic submissions to form wizards, to agendas, minutes, and more. Our flexible solutions are designed to meet your needs.
Agenda for the Day

1. Introduction to the IRB
2. What is Human Subjects Research?
3. Submitting a New Project
4. What can I do to get a leg up now?
What if my project is human subjects research?

New Projects
All new projects must be reviewed by the IRB prior to the conduct of any research involving human subjects. On this page, you will find directions for submitting a new project to the IRB.

In This Section
- Directions for Submitting a New Project to the IRB
- What Comes Next?
- Example Submissions
- Additional Resources

Related Topics
- Does my project need IRB review?
- What if my project is exempt?
- What if my project takes place at more than one site?

Getting Started
- Read the UC Davis Investigator Manual
- Complete CITI training

Go to IRBNet
3) HIPAA Protected Health Information (PHI) Obtained from UC Davis Health (cont.)

- Name
- Telephone numbers
- Fax numbers
- Email addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary
- Vehicle identifiers and serial numbers, including license plate numbers
- Account numbers
- Certificate/license numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) addresses
- Biometric identifiers, including fingerprint and voice prints
- Full-face photographs and any comparable images

Geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
- The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
- The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000.

Elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

- Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.
- None of the above.

This is a list of identifiers you will be documenting in your research records.

If you are NOT documenting any of the 18 HIPAA identifiers in your research records, check “None of the above.”

Consistency Check | Initial Review Application, Data Confidentiality section

Jump to Data Confidentiality
IRB Review Process

Submit New Project on IRBNet

Intake Analyst checks for basic requirements and routes for review

Review is conducted by IRB Admin or Convened Committee
Structure of the IRB

Institutional Review Board

- Administration
- Biomedical Committee A
- Biomedical Committee B
- Social and Behavioral Committee C
IRB Review Process

Submit New Project on IRBNet

Intake Analyst checks for basic requirements and routes for review

Review is conducted by IRB Admin or Convened Committee

Determination Issued by IRB
IRB Determinations for New Projects

- Not Research
- Not Human Subjects Research
- Not Engaged
- Modifications Required
- Deferred
- Not Approved
- Exempt
- Approved
IRB Determinations for New Projects

- Not Research
- Not Human Subjects Research
- Not Engaged

IRB review **NOT** required

- Exempt

→ IRB review required
Then what is Exempt research?

Specific categories of social, behavioral, and educational research **exempt** from the federal regulations
What happens after approval?

- Modifications
- Reportable New Information
- Continuing Review
- Closure
Agenda for the Day

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Complete CITI Training

✔ Required for anyone engaged in human subjects research at UCD

If you are engaged in biomedical research...
CITI Basic Course for Biomedical Researchers and Staff

If you are engaged in social or behavioral research...
CITI Basic Course for Social and Behavioral Researchers and Staff

Do not take the RCR versions of these courses!
Complete CITI Training

☑ Required for anyone engaged in human subjects research at UCD

If you are engaged in an FDA-regulated clinical investigation or an NIH clinical trial...

CITI Basic Course for Biomedical Researchers and Staff and either

- GCP for Clinical Trials with Investigational Medical Devices
- GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)
Helpful Resources for New Submitters

✔ Join our listserv
✔ Required Education webpage
  ⟷ www.citiprogram.org
✔ IRBNet webpage
  ⟷ www.irbnet.org
✔ IRB Forms webpage
✔ New Projects webpage
✔ UC Davis Investigator Manual
Come to Office Hours!

Friday, October 14 | 12:00 PM–2:00 PM  
Combined CTO + IRB office hours!

Friday, October 21  | 12:00 PM–1:00 PM  
Friday, October 28  | 12:00 PM–1:00 PM  
Friday, November 4 | 12:00 PM–1:00 PM
Questions?

hs-irbeducation@ucdavis.edu