

# ~~Human Subjects Research for Undergraduates~~

*How to impress your professor by knowing important things about human subjects research*

**UCDAVIS**

**OFFICE OF 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**

**2**

**What is Human Subjects Research?**

**3**

**Submitting a New Project**

**4**

**What can I do to get a leg up now?**

*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





# The New York Times

## *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,

1972



# 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

**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?**

# The IRB Reviews Human Subjects Research

| Is the project research? |    |
|--------------------------|----|
| Yes                      | No |

# The IRB Reviews Human Subjects Research

| Is the project research? |                                |
|--------------------------|--------------------------------|
| Yes                      | No                             |
|                          | IRB review <b>NOT</b> required |
|                          | IRB review <b>NOT</b> required |



# The IRB Reviews Human Subjects Research

|  |     | Is the project research?       |                                |
|--|-----|--------------------------------|--------------------------------|
|  |     | Yes                            | No                             |
| Does the project involve human subjects? | Yes | IRB review <b>NOT</b> required | IRB review <b>NOT</b> required |
|  | No  | IRB review <b>NOT</b> required | IRB review <b>NOT</b> required |

# The IRB Reviews Human Subjects Research

|  |     | Is the project research?       |                                |
|--|-----|--------------------------------|--------------------------------|
|  |     | Yes                            | No                             |
| Does the project involve human subjects? | Yes |                                | IRB review <b>NOT</b> required |
|  | No  | IRB review <b>NOT</b> required | IRB review <b>NOT</b> required |

# The IRB Reviews Human Subjects Research

|  |     | Is the project research?       |                                |
|--|-----|--------------------------------|--------------------------------|
|  |     | Yes                            | No                             |
| Does the project involve human subjects? | Yes | Submit to the IRB              | IRB review <b>NOT</b> required |
|  | No  | IRB review <b>NOT</b> required | IRB review <b>NOT</b> required |

# What is Research?



**Systematic  
Investigation**



**Generalizable  
Knowledge**

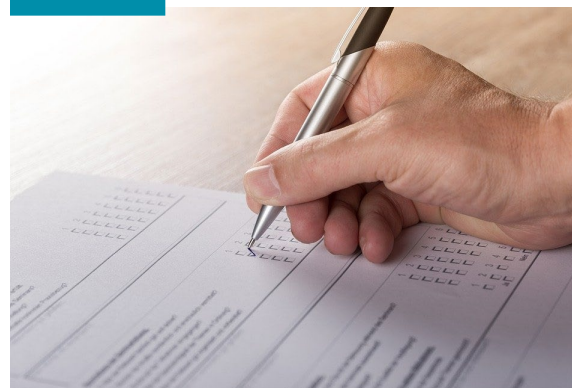


|  |     | Is the project research? |  |
|--|-----|--------------------------|--|
|  |     | Yes                      | No   |
| Does the project involve human subjects? | Yes |                          | <p>IRB review <b>NOT</b> required</p> <ul style="list-style-type: none"> <li>• Journalistic activities</li> <li>• Oral history projects</li> <li>• Case reports/series</li> <li>• Quality improvement/assurance</li> <li>• Program evaluation</li> </ul> |
|  | No  |                          | <p>IRB review <b>NOT</b> required</p>  |

# What are human subjects?



Intervention



Interaction



Private  
Identifiable  
Information

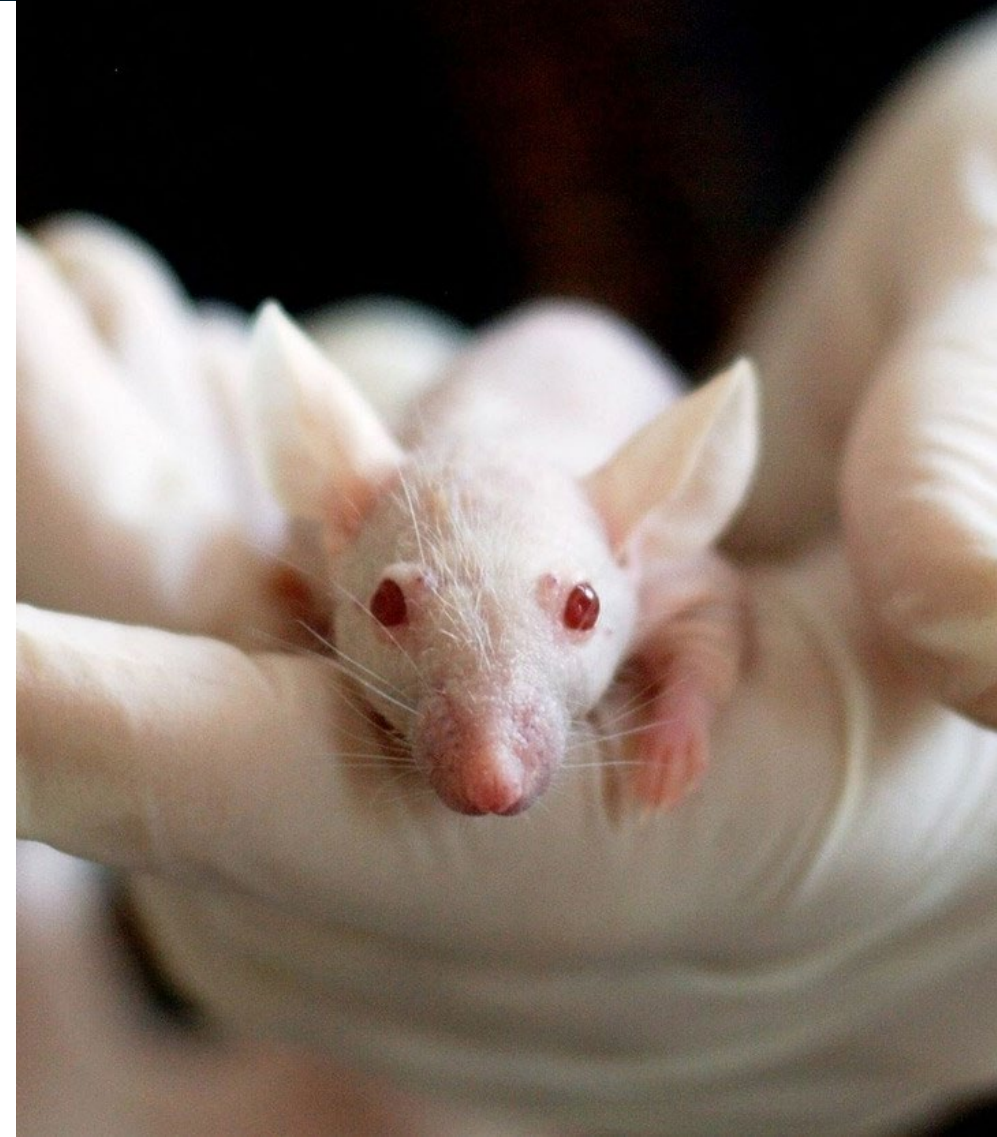
|  |     | Is the project research?  |  |
|--|-----|---|--|
|  |     | Yes   | No   |
| Does the project involve human subjects? | Yes | <p><b>Submit to the IRB</b></p> <ul style="list-style-type: none"> <li>• Clinical Trial</li> <li>• Surveys to develop generalizable knowledge</li> <li>• Retrospective study using data from patient medical records</li> </ul> | <p>IRB review <b>NOT</b> required</p> <ul style="list-style-type: none"> <li>• Case reports/series</li> <li>• Quality improvement/assurance</li> <li>• Program evaluation</li> </ul> |
|  | No  |   | <p>IRB review <b>NOT</b> required</p>  |

|  |     | Is the project research?  |  |
|--|-----|---|--|
|  |     | Yes   | No   |
| Does the project involve human subjects? | Yes | <p><b>Submit to the IRB</b></p> <ul style="list-style-type: none"> <li>• Clinical Trial</li> <li>• Surveys to develop generalizable knowledge</li> <li>• Retrospective study using data from patient medical records</li> </ul> | <p>IRB review <b>NOT</b> required</p> <ul style="list-style-type: none"> <li>• Case reports/series</li> <li>• Quality improvement/assurance</li> <li>• Program evaluation</li> </ul> |
|  | No  | <p>IRB review <b>NOT</b> required</p> <ul style="list-style-type: none"> <li>• Analysis of publicly available, anonymous, or de-identified data or biospecimens</li> <li>• Non-human animal research</li> </ul>                 | <p>IRB review <b>NOT</b> required</p>  |



# 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

|  |     | Is the project research?   |                                |
|--|-----|--|--------------------------------|
|  |     | Yes  | No                             |
| Does the project involve human subjects? | Yes | Submit to the IRB  | IRB review <b>NOT</b> required |
|  | No  | IRB review <b>NOT</b> required because no interaction or intervention with humans and no use of private identifiable information | IRB review <b>NOT</b> required |

# 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

|  |     | Is the project research?       |   |
|--|-----|--------------------------------|---|
|  |     | Yes                            | No  |
| Does the project involve human subjects? | Yes | Submit to the IRB              | IRB review <b>NOT</b> required because the intent of the project is to learn how to develop surveys, not develop generalizable knowledge. |
|  | No  | IRB review <b>NOT</b> required | IRB review <b>NOT</b> 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

|  |     | Is the project research?   |                                |
|--|-----|--|--------------------------------|
|  |     | Yes  | No                             |
| Does the project involve human subjects? | Yes | <b>Submit to the IRB</b> <ul style="list-style-type: none"><li>✓ Systematic investigation</li><li>✓ Intent to contribute to generalizable knowledge</li><li>✓ Interaction via survey</li></ul> | IRB review <b>NOT</b> required |
|  | No  | IRB review <b>NOT</b> required   | IRB review <b>NOT</b> required |



# 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

|  |     | Is the project research?   |                                |
|--|-----|--|--------------------------------|
|  |     | Yes  | No                             |
| Does the project involve human subjects? | Yes | Submit to the IRB  | IRB review <b>NOT</b> required |
|  | No  | IRB review <b>NOT</b> required because no interaction or intervention with humans and no use of private identifiable information | IRB review <b>NOT</b> required |

# 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](mailto: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](http://IRBNet.org)

Login:

 [New User Registration](#) | [? Forgot Your Password?](#)

## 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

## Test Drive IRBNet

See for yourself...

[Demo](#)

## Satisfied Members

"Our first electronic meeting went so smoothly! It was over so fast the members didn't know what to do. They just sat there for a few minutes in disbelief."

- Bruce Day

Director, Office of Research Integrity

# 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?



## In This Section

[Initial Review Application  
\(New Project\) Process](#)

[Post-approval Submissions](#)

[Ancillary Reviews](#)

[IRB Fees](#)

[IRBNet](#)

[IRB Review Process](#)

## 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 places at more than one site?](#)



## Directions for Submitting a New Project to the IRB

### Getting Started

+ Read the UC Davis Investigator Manual

+ Complete CITI training



HRP-503 UCD Health Medical Record Review Protocol Template

## 3) HIPAA Protected Health Information (PHI) Obtained from UC Davis Health (cont.)

- Names
- 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 finger 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."

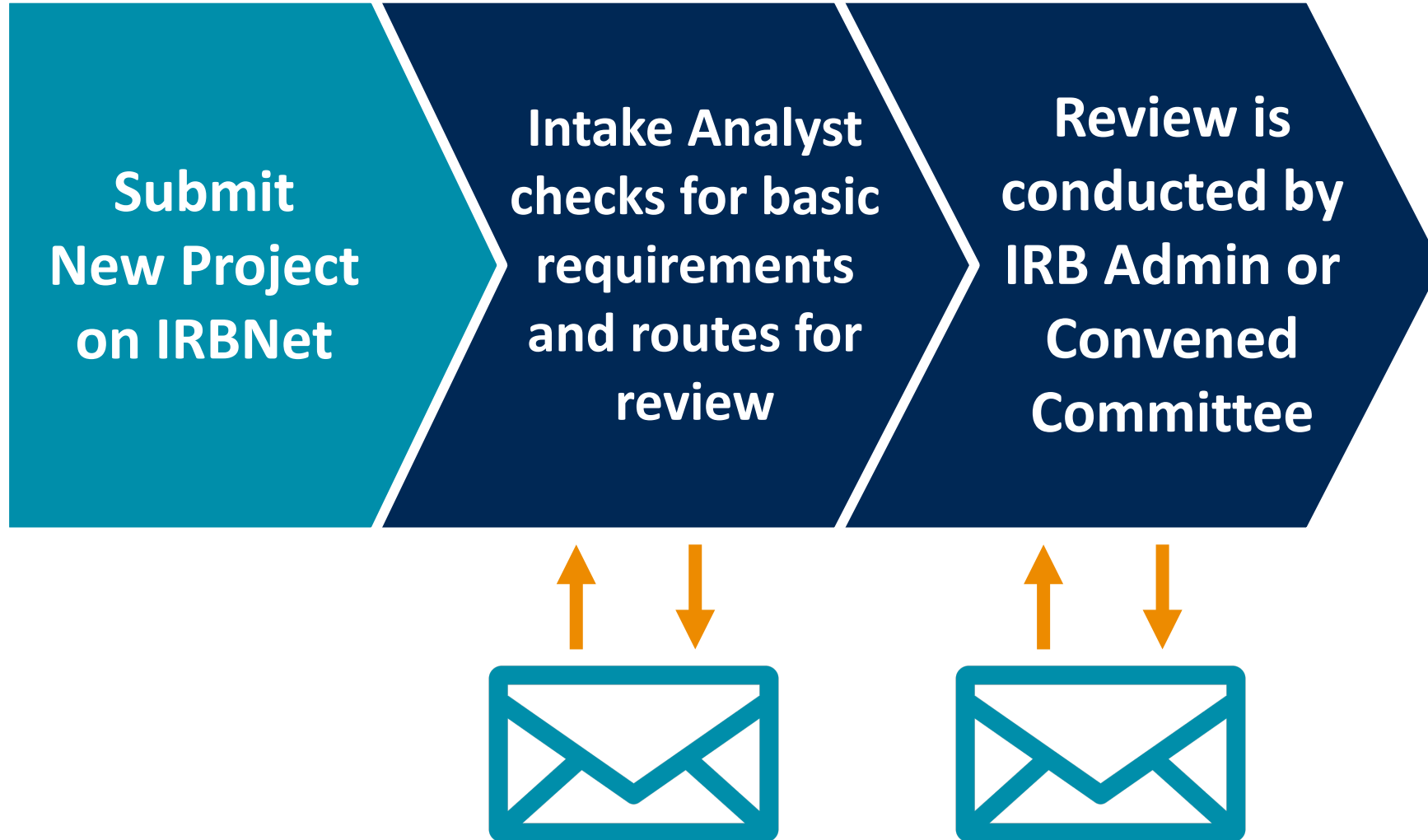


Consistency Check | Initial Review Application, Data Confidentiality section

Jump to [Data Confidentiality](#)



# IRB Review Process



# Structure of the IRB

## Institutional Review Board

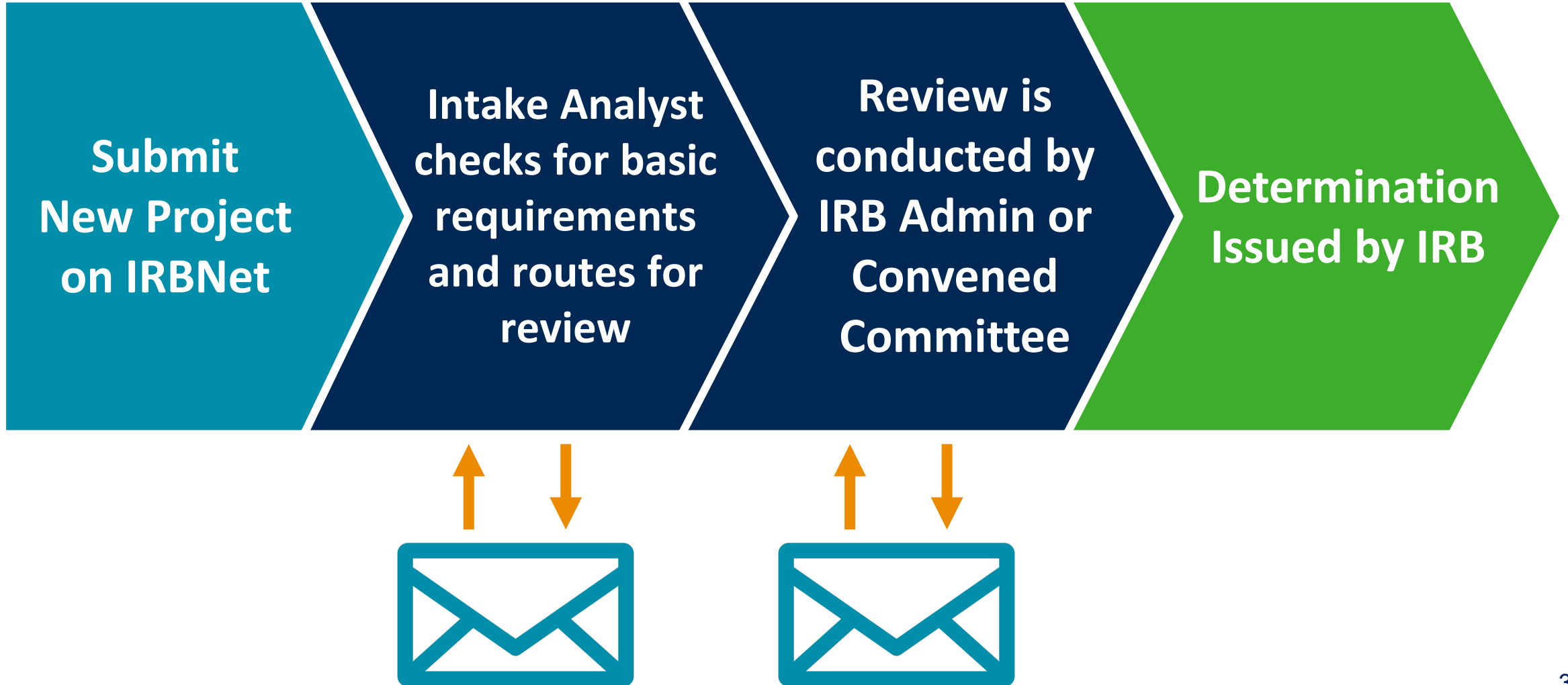
Administration

Biomedical  
Committee  
A

Biomedical  
Committee  
B

Social and  
Behavioral  
Committee  
C

# IRB Review Process



# 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

**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?**

# 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

or

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](http://www.citiprogram.org)
- ✓ [IRBNet](#) webpage
  - ↳ [www.irbnet.org](http://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](mailto:hs-irbeducation@ucdavis.edu)*