~~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

UCDAVIS OFFICE OF RESEARCH

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?

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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

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,

Governmental Reaction to Tuskegee

National Research Act of 1974

- ↳ Established **I**nstitutional **R**eview **B**oards (**IRB**s)
- ↳ 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

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Institutional Review Board

- Administration
- Biomedical Committee A
- Biomedical Committee B
- Social and Behavioral Committee C

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The IRB Reviews Human Subjects Research

The IRB Reviews Human Subjects Research

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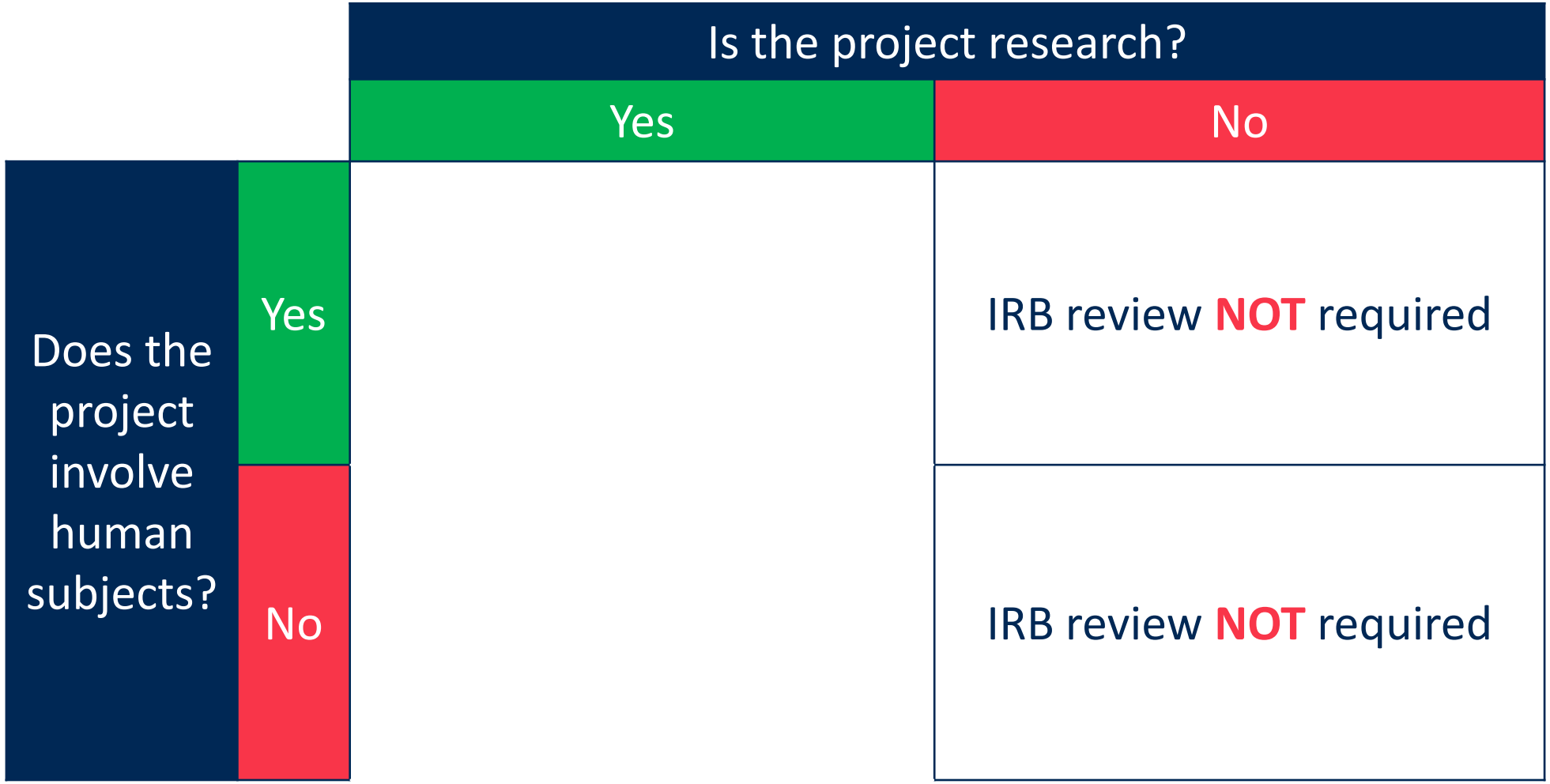
Is the project research?	
Yes	No
	IRB review **NOT** required
	IRB review **NOT** required

The IRB Reviews Human Subjects Research



The IRB Reviews Human Subjects Research

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		Yes	No
Does the project involve human subjects?	Yes		IRB review **NOT** required
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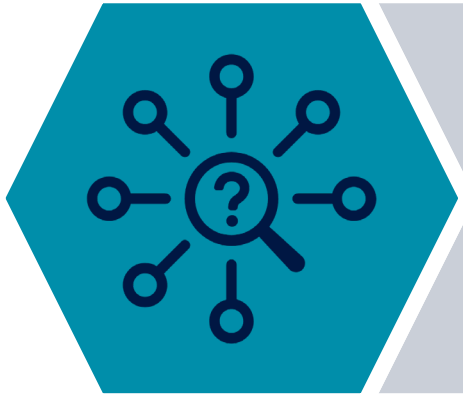
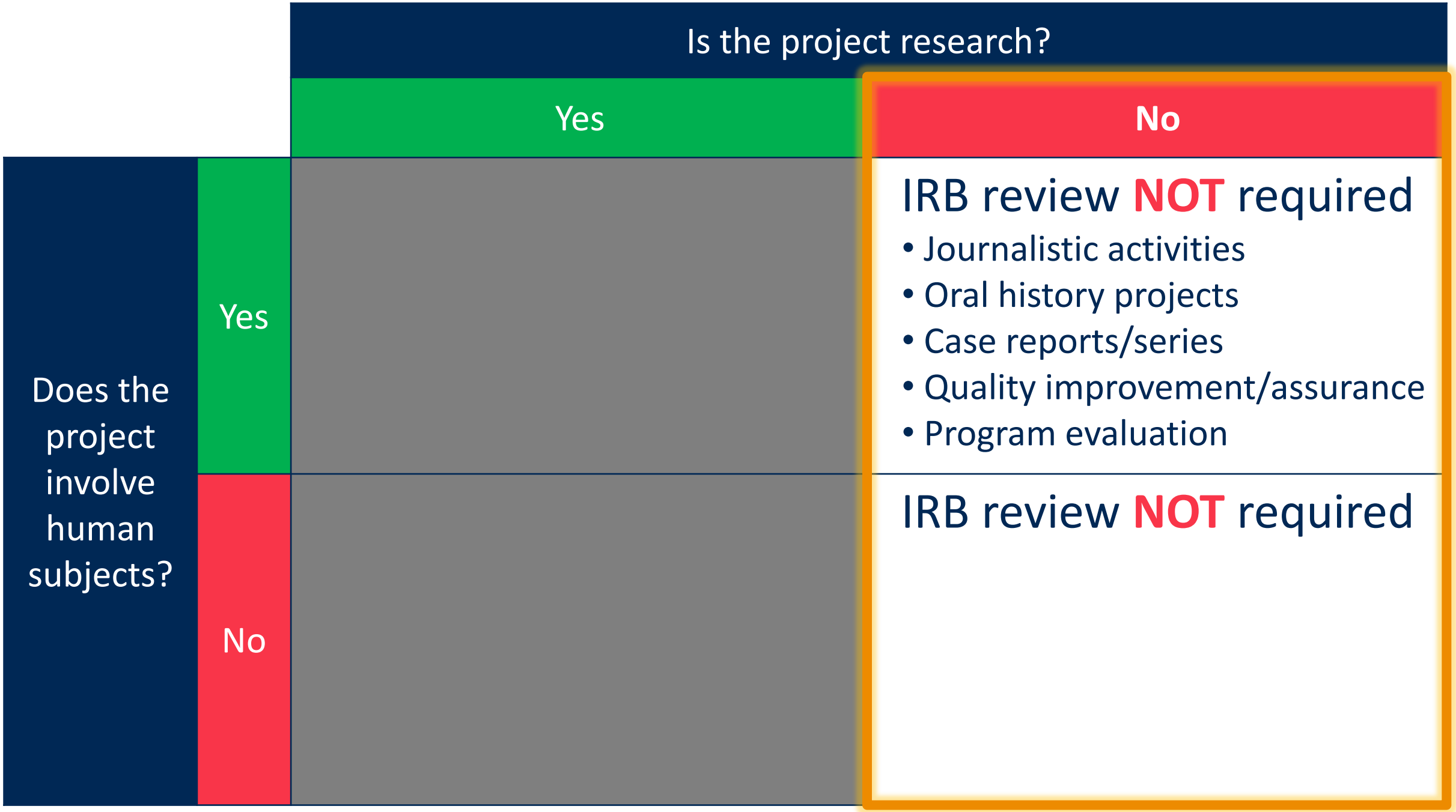
What is Research?



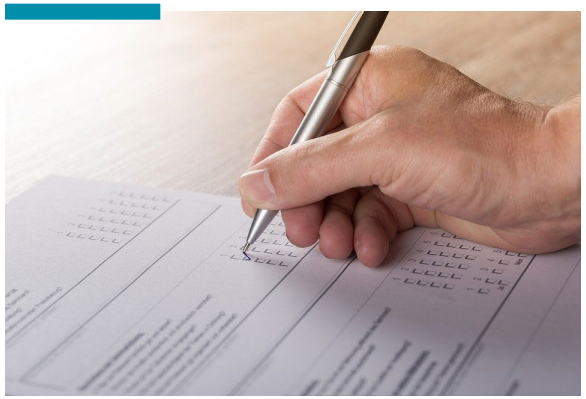
Systematic Investigation

Generalizable Knowledge


Is the project research?
Yes
No
Does the project involve human subjects?
Yes
No
IRB review NOT required
• Journalistic activities
• Oral history projects
• Case reports/series
• Quality improvement/assurance
• Program evaluation
IRB review NOT required

What are human subjects?

Intervention



Interaction

Private Identifiable Information

		Is the project research?	
		Yes	No
Does the project involve human subjects?	**Yes**	**Submit to the IRB** • Clinical Trial • Surveys to develop generalizable knowledge • Retrospective study using data from patient medical records	IRB review **NOT** required • Case reports/series • Quality improvement/assurance • Program evaluation
	No		IRB review **NOT** required

		Is the project research?	
		Yes	No
Does the project involve human subjects?	Yes	**Submit to the IRB** • Clinical Trial • Surveys to develop generalizable knowledge • Retrospective study using data from patient medical records	IRB review **NOT** required • Case reports/series • Quality improvement/assurance • Program evaluation
	No	IRB review **NOT** required • Analysis of publicly available, anonymous, or de-identified data or biospecimens • Non-human animal research	IRB review **NOT** required

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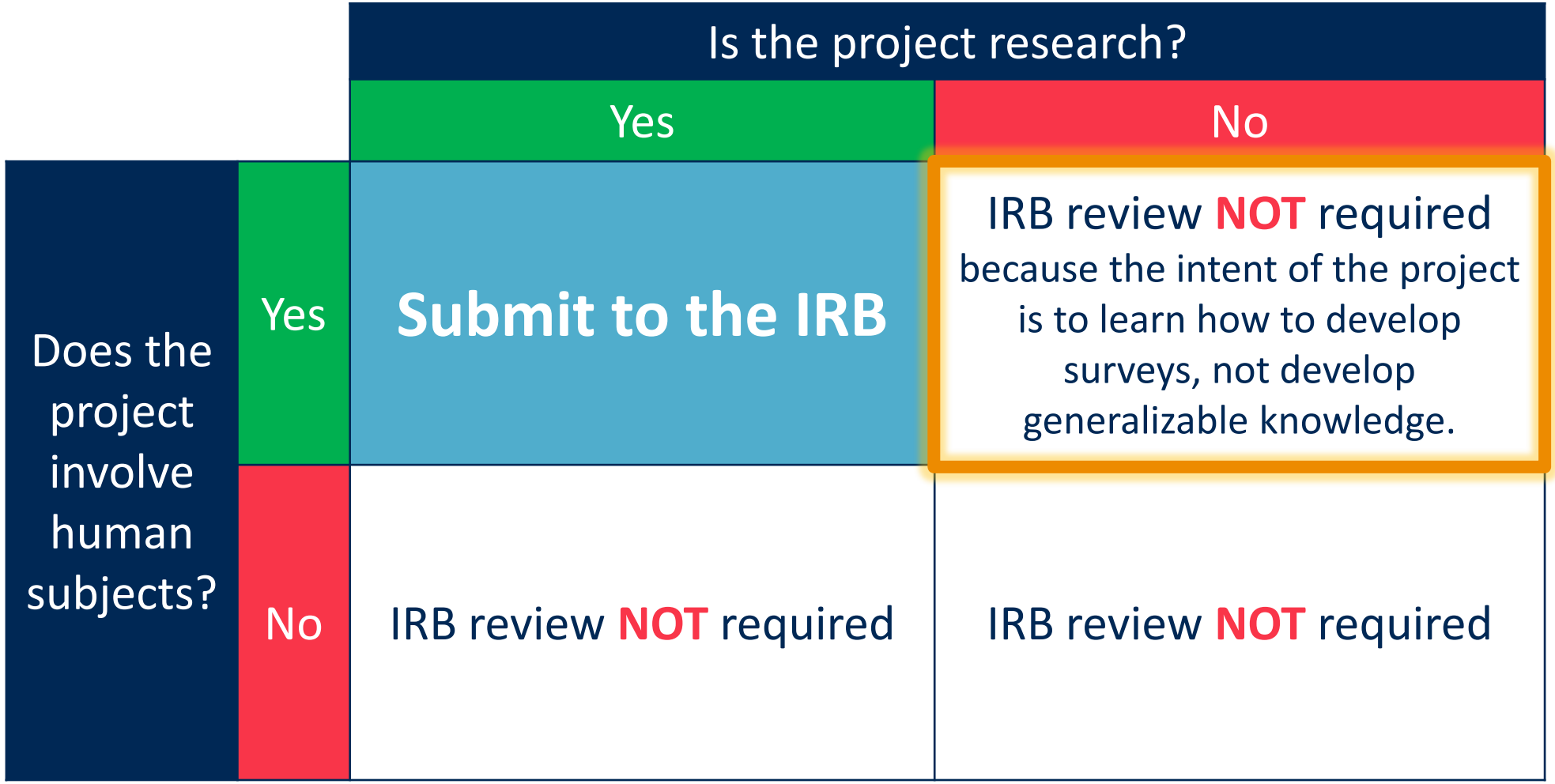
		Is the project research?	
		Yes	No
Does the project involve human subjects?	Yes	**Submit to the IRB**	IRB review **NOT** required
	No	IRB review **NOT** required because no interaction or intervention with humans and no use of private identifiable information	IRB review **NOT** required

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.

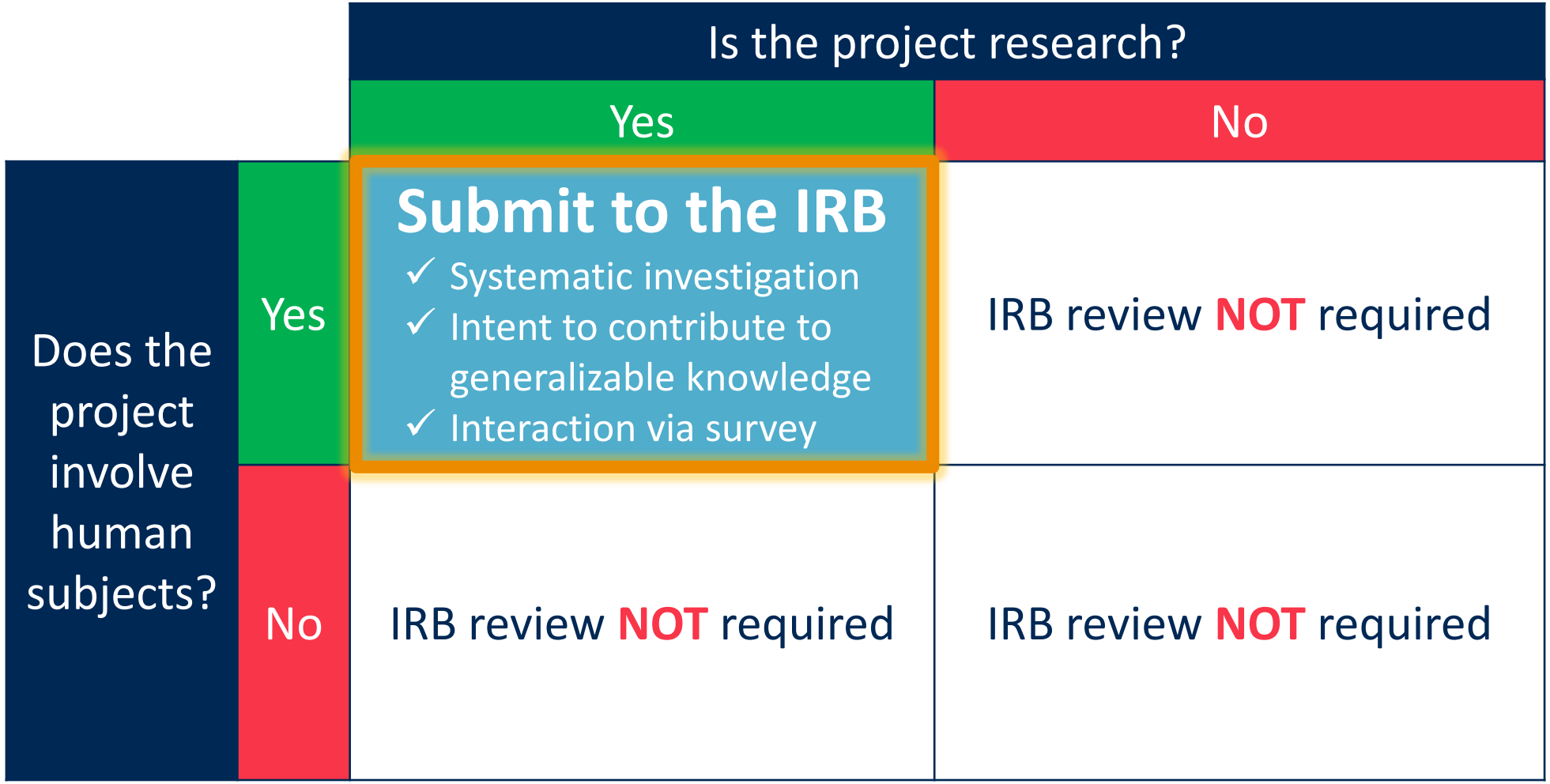
The IRB Reviews Human Subjects Research



Is 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 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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		Is the project research?	
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Does the project involve human subjects?	Yes	**Submit to the IRB**	IRB review **NOT** required
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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

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wcg IRBNet Innovative Solutions for Compliance and Research Management

Login: Username Password Login

New User Registration | Forgot Your Password?

Home | The IRBNet Difference | Demo | Contact Us | FAQ |

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

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What if my project is human subjects research?

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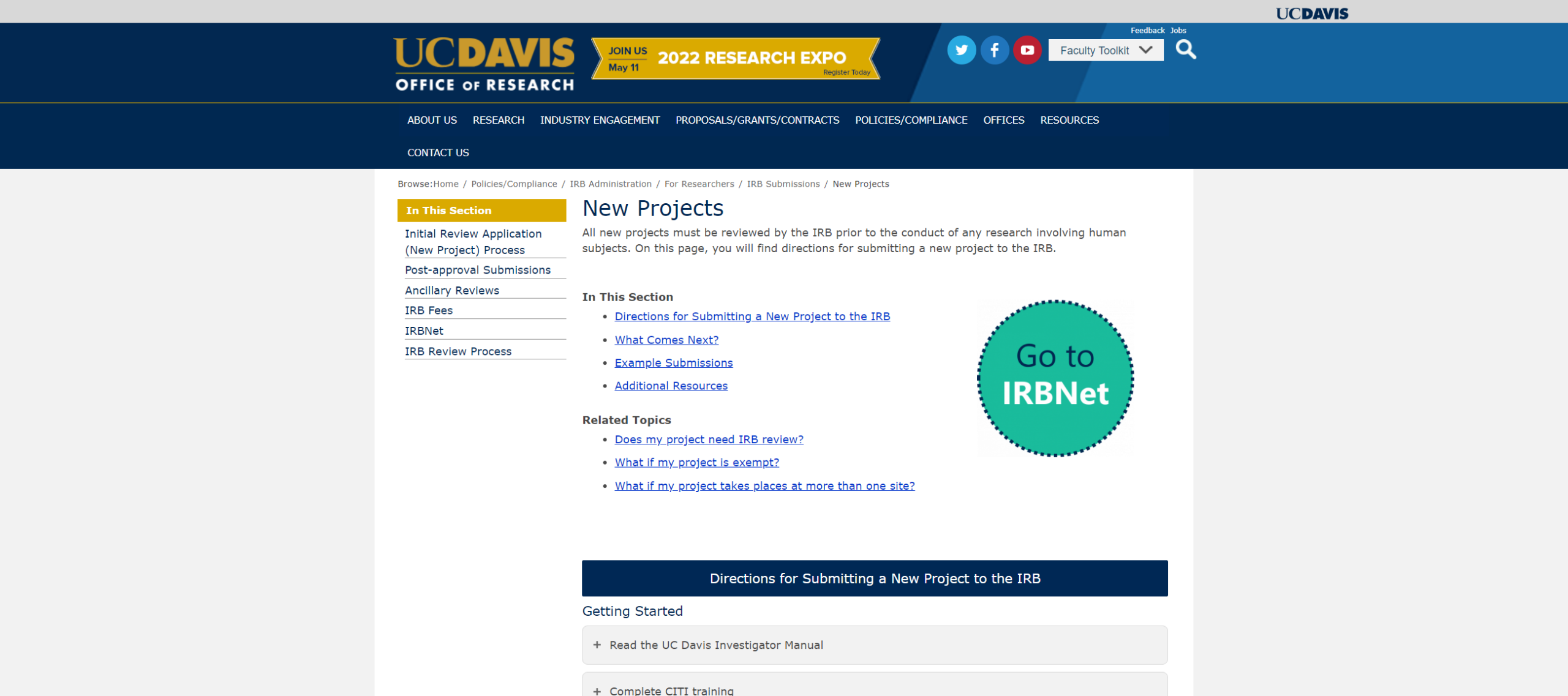
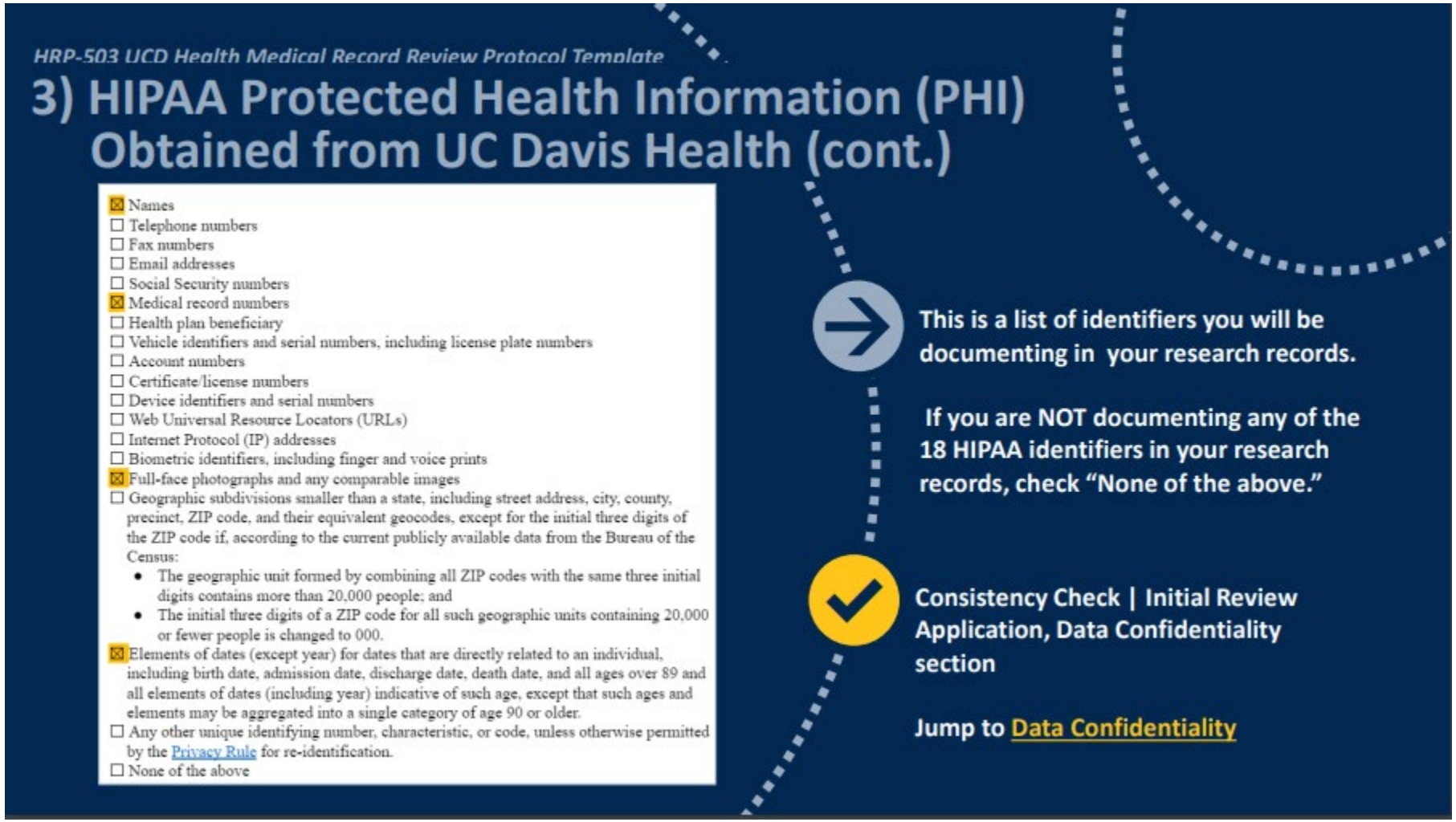
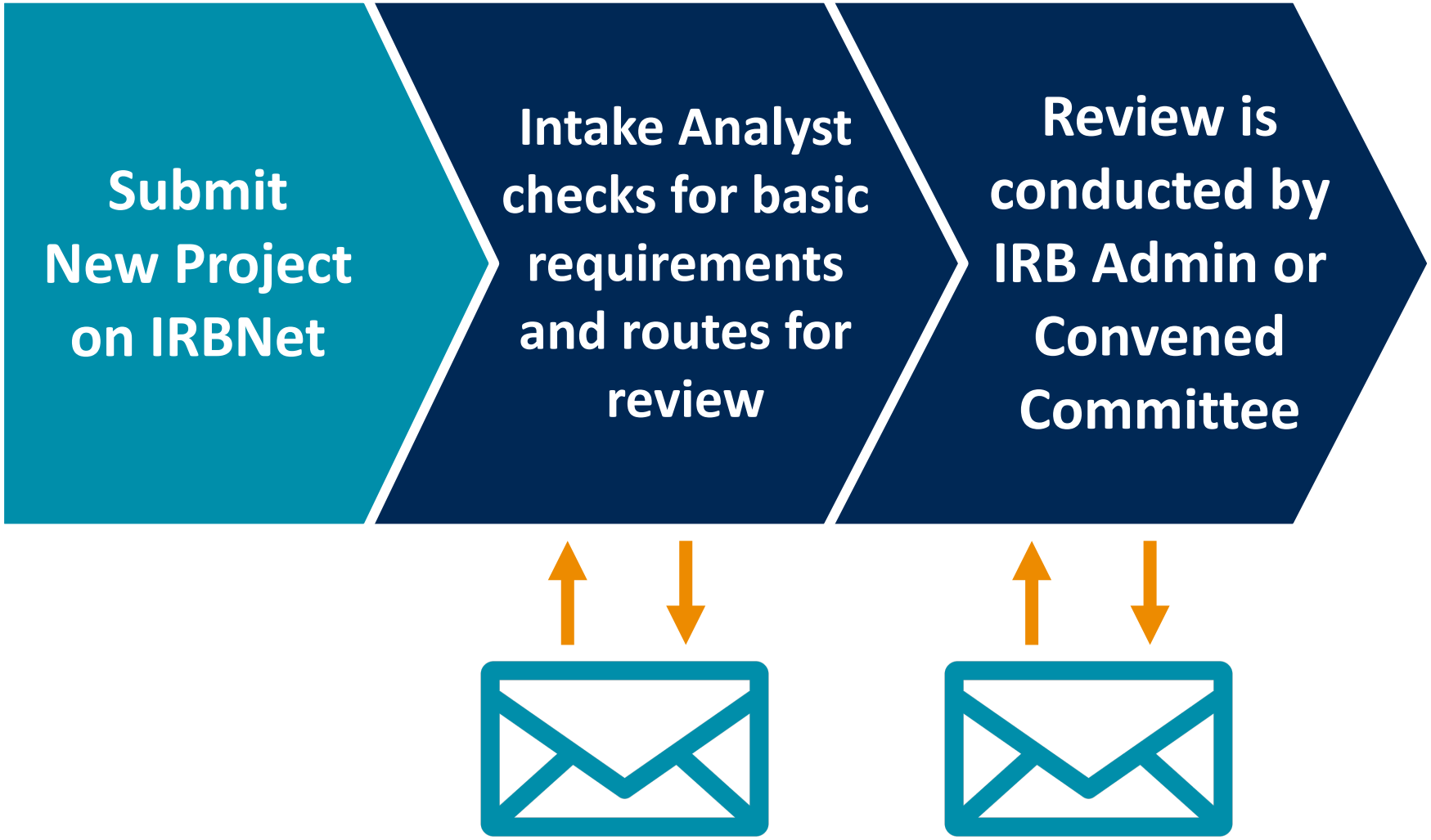


Additional Resources | Example Submissions



IRB Review Process



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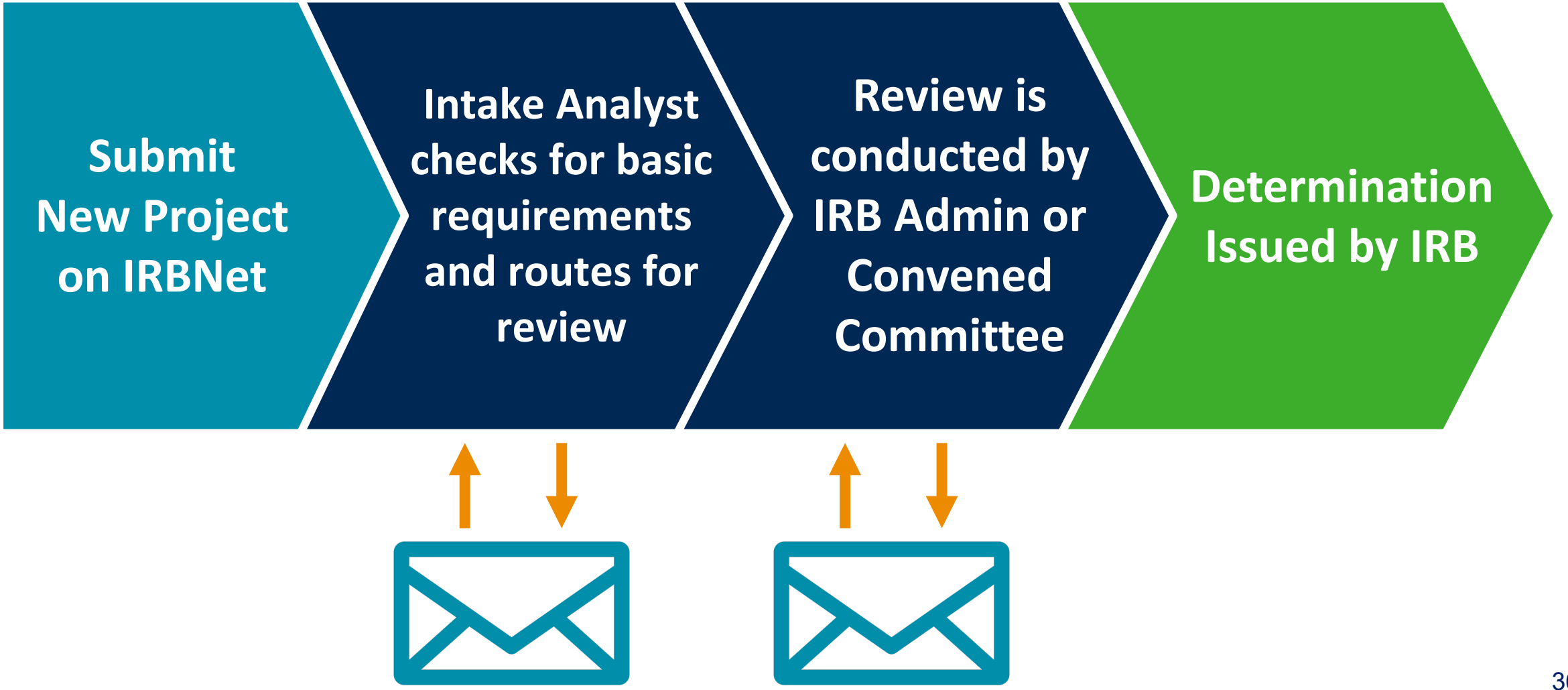

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IRB Determinations for New Projects

- 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?

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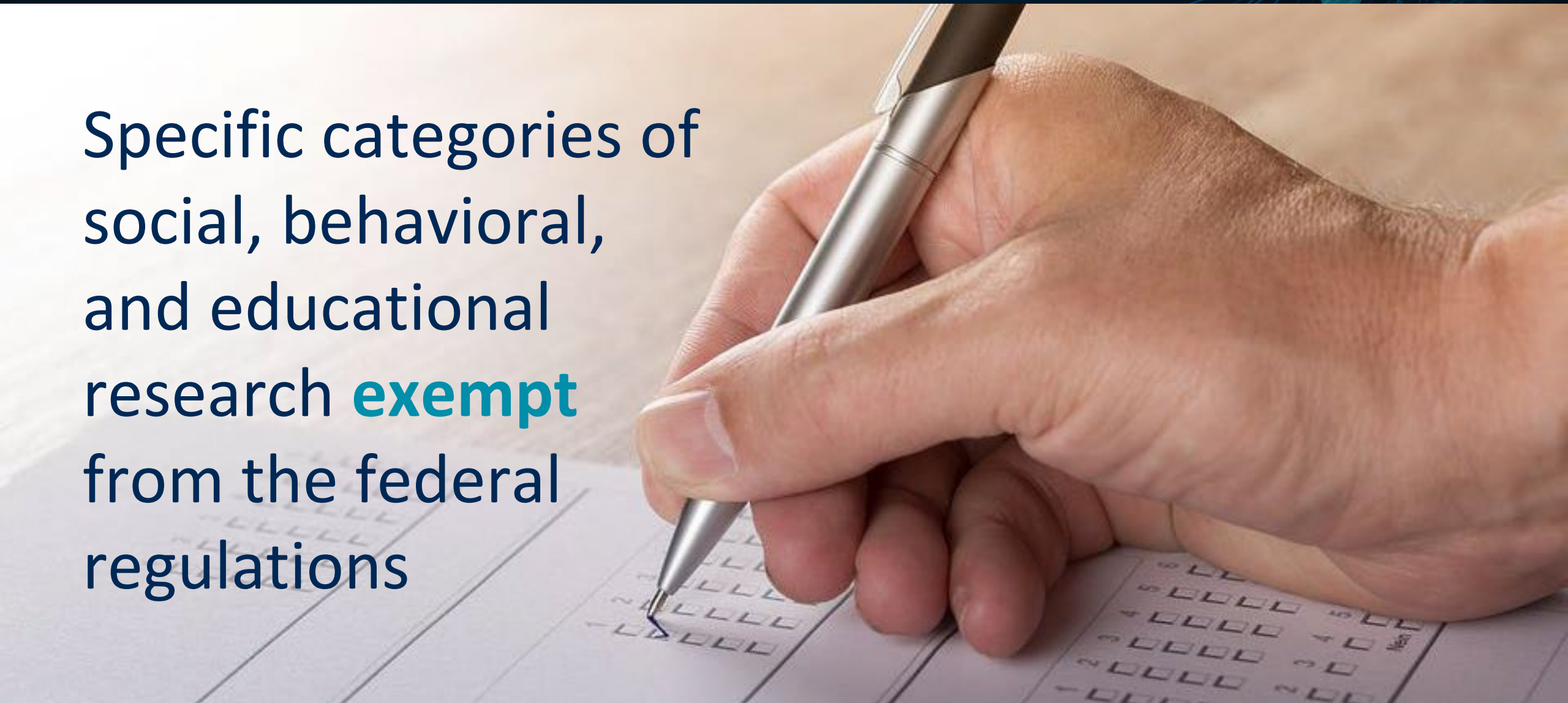
Specific categories of social, behavioral, and educational research **exempt** from the federal regulations



What happens after approval?

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- Modifications
- Reportable New Information
- Continuing Review
- Closure

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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

or

GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)

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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