Introduction to the IRB

Stephen Falwell
IRB Education, Training, and Outreach

UC DAVIS
OFFICE OF RESEARCH

How Familiar Are You With the IRB?

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. Required Training

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. Required Training


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,

Reaction to Tuskegee

1972 Office for Protection from Research Risks (OPRR) established

1973 Sen. Edward Kennedy convenes hearings on "human experimentation"

1974 National Research Act of 1974
Dept. of Health, Education, and Welfare publishes 45 CFR 46 subpart A *Basic Policy for Protection of Human Research Subjects*

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

IRB Membership Requirements

Scientific

Non-Scientific

Non-Affiliated

Structure of the IRB

UCDAVIS OFFICE OF RESEARCH

Institutional Review Board

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

Reaction to Tuskegee

1972 Office for Protection from Research Risks (OPRR) established

1973 Sen. Edward Kennedy convenes hearings on "human experimentation"

1974 National Research Act of 1974
Dept. of Health, Education, and Welfare publishes 45 CFR 46 subpart A *Basic Policy for Protection of Human Research Subjects*

1978 *Belmont Report* released

Basic Ethical Principles in Human Research

UCDAVIS OFFICE OF RESEARCH

- Respect for Persons
- Beneficence
- Justice

Basic Ethical Principles in Human Research

UCDAVIS OFFICE OF RESEARCH

Respect for Persons

↳ Treating persons as **autonomous agents**

Beneficence

Justice

MOTHERBOARD
TECH BY VICE

'Horribly Unethical': Startup Experimented on Suicidal Teens on Social Media With Chatbot

Koko, a mental health nonprofit, found at-risk teens on platforms like Facebook and Tumblr, then tested an unproven intervention on them without obtaining informed consent. “It’s nuanced,” said the founder.

Basic Ethical Principles in Human Research

UCDAVIS OFFICE OF RESEARCH

- Respect for Persons
- Beneficence
- Justice

Basic Ethical Principles in Human Research

UCDAVIS OFFICE OF RESEARCH

Respect for Persons

Beneficence

↳ Maximize the potential benefit while minimizing harm

Justice

UCLA Pauses 'Unethical' Study Designed to Mentally Distress Trans People

Advocacy groups warned people to avoid participating in the study due to "grave concerns about the unethical research design."

EC By Eleanor Cummins

February 8, 2021, 12:17pm

Basic Ethical Principles in Human Research

UCDAVIS OFFICE OF RESEARCH

- Respect for Persons
- Beneficence
- Justice

Basic Ethical Principles in Human Research

UCDAVIS OFFICE OF RESEARCH

Respect for Persons

Beneficence

Justice

↳ Equal distribution of benefits and burdens of research

GOATS AND SODA

Remembering Zika: Parents offered their kids for studies, then say they were forgotten

October 21, 2021 · 3:04 PM ET

MARIANA LENHARO

FROM UNDARK

Rochelle dos Santos embraces her daughter, who was born with microcephaly in 2016 after dos Santos contracted Zika during her pregnancy in midwest Brazil.

Agenda for the Day

UCDAVIS OFFICE OF RESEARCH

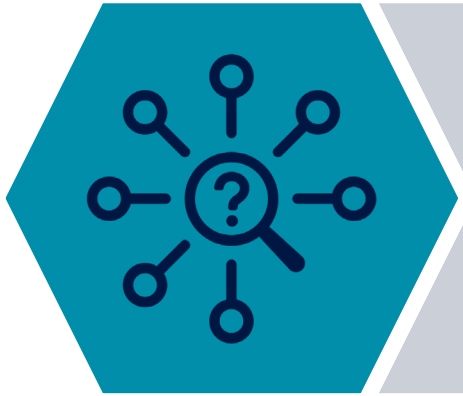
1. Introduction to the IRB
2. What is Human Subjects Research?
3. Submitting a New Project
4. Required Training

The IRB Reviews Human Subjects Research

UCDAVIS OFFICE OF RESEARCH

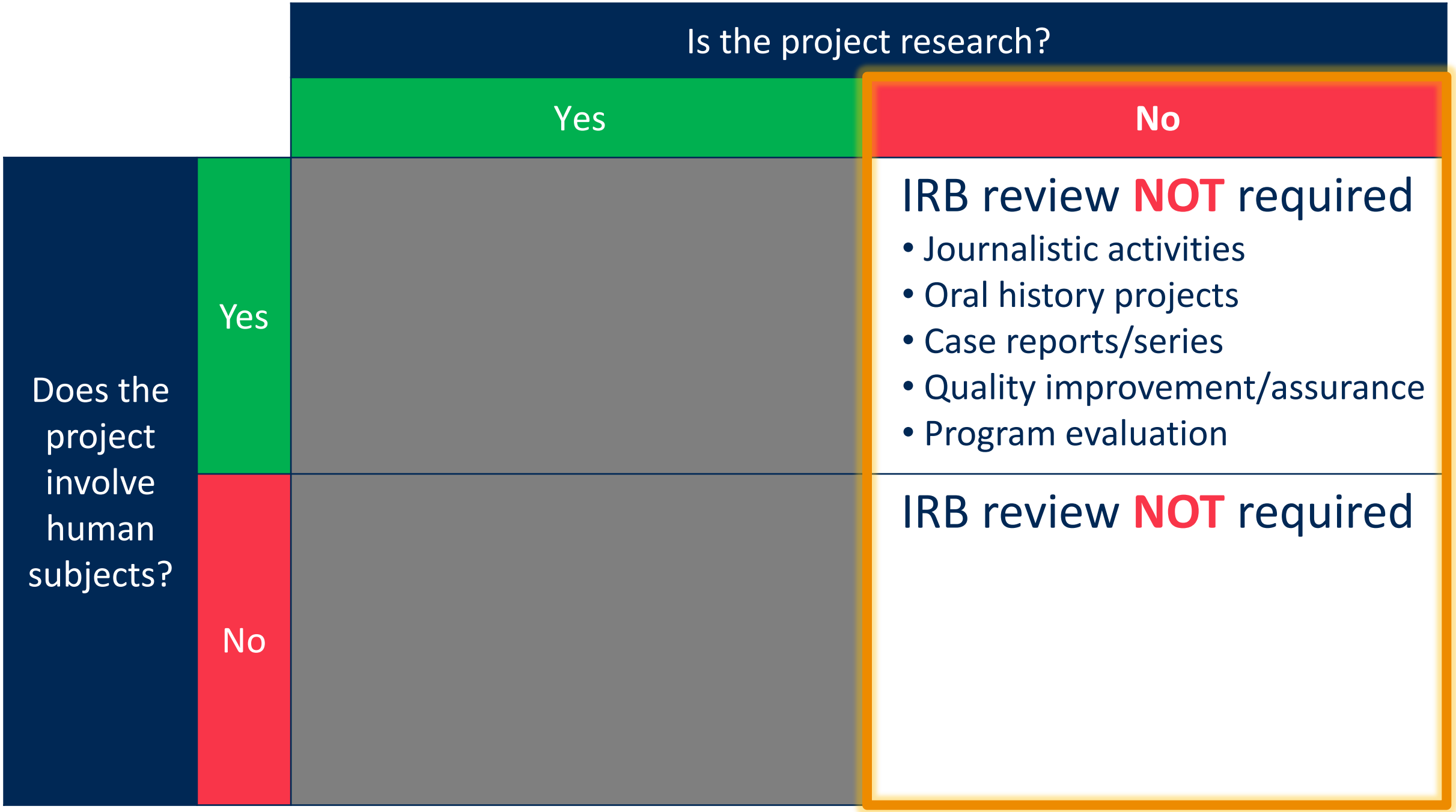
		Is the project research?	
		Yes	No
Does the project involve human subjects?	Yes	**Submit to the IRB**	IRB review **NOT** required
	No	IRB review **NOT** required	IRB review **NOT** required

What is Research?



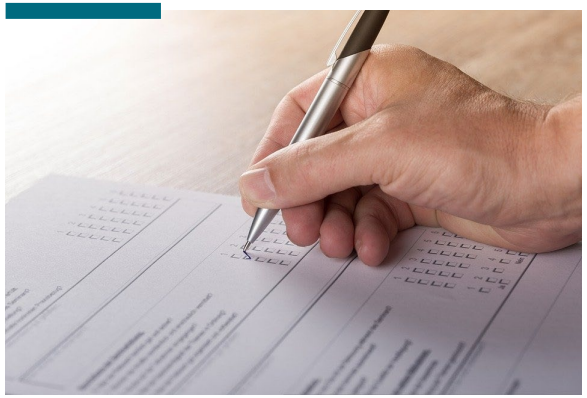
Systematic Investigation

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?

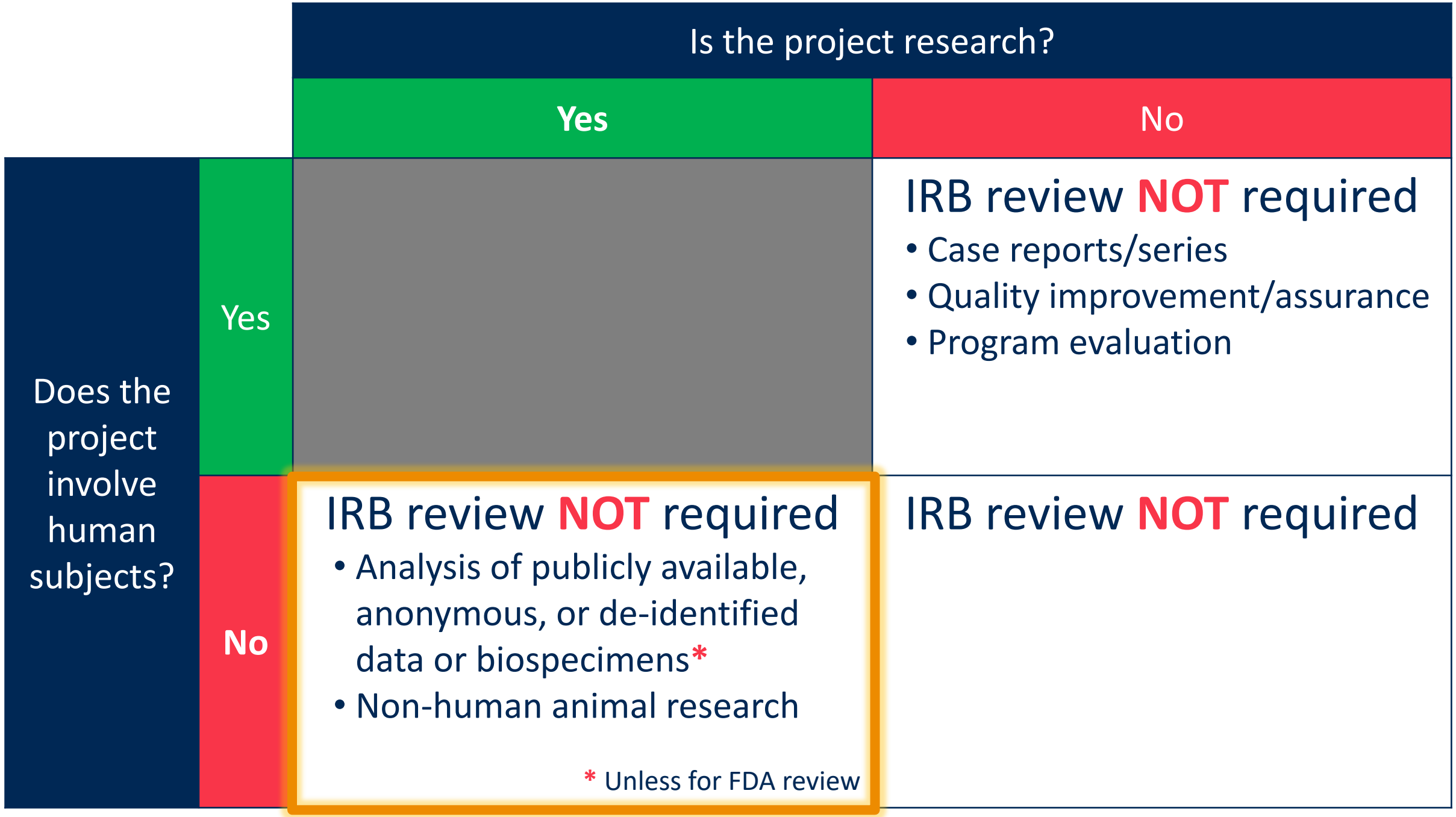
Intervention



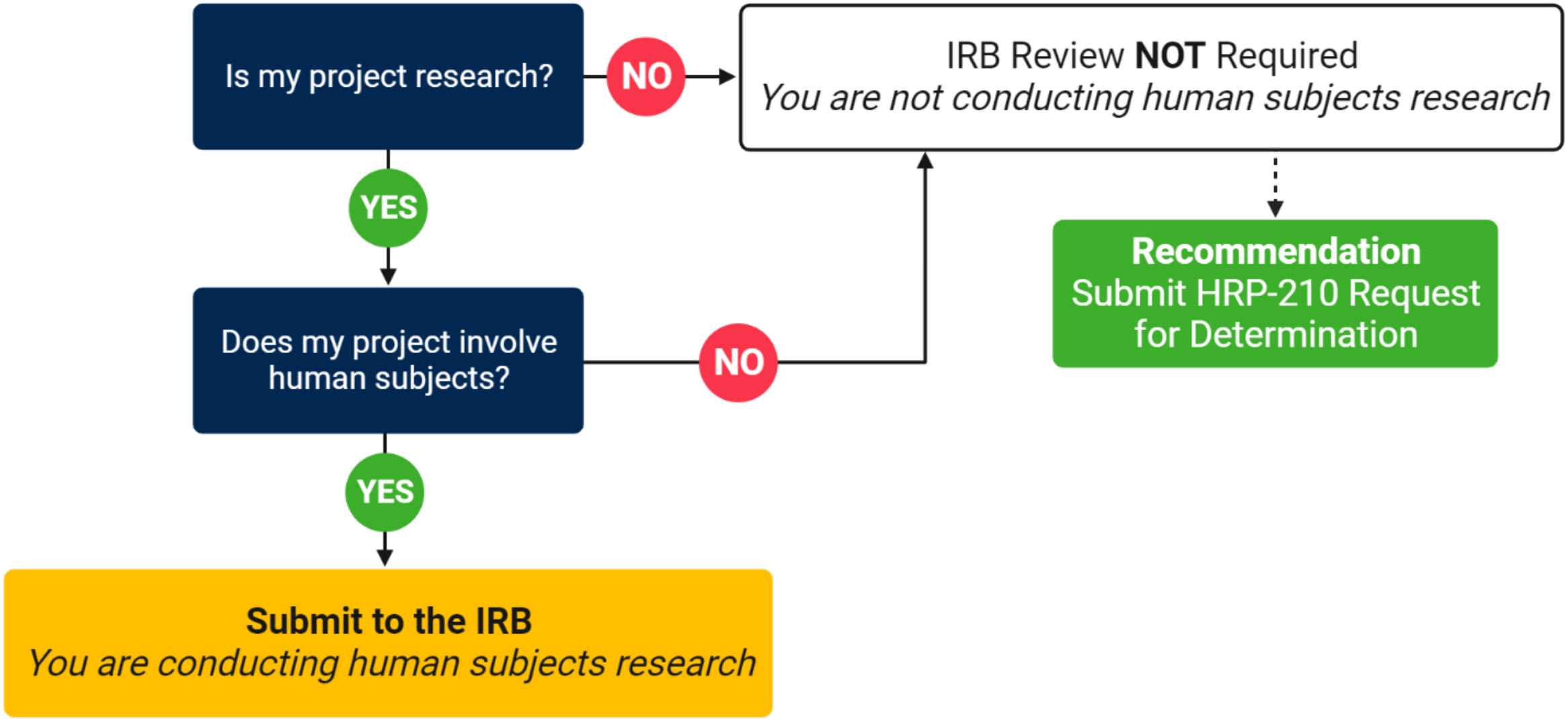
Interaction

Private Identifiable Information

Private Identifiable Biospecimens


Is the project research?
Yes
No
Does the project involve human subjects?
Yes
No
IRB review NOT required
• Case reports/series
• Quality improvement/assurance
• Program evaluation
IRB review NOT required
• Analysis of publicly available, anonymous, or de-identified data or biospecimens*
• Non-human animal research
* Unless for FDA review
IRB review NOT required

Does the project involve human subjects?	Is the project research?	
	Yes	No
Yes	**Submit to the IRB** • Clinical Trial • Chart Review • Analysis of identifiable biospecimens for research • Survey for research	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 * Unless for FDA review	IRB review **NOT** required


Is my project research?
NO
IRB Review **NOT** Required
You are not conducting human subjects research
YES
Does my project involve human subjects?
NO
Recommendation
Submit HRP-210 Request for Determination
YES
Submit to the IRB
You are conducting human subjects research

Human Subjects Research

NOT Human Subjects Research

Is it human subjects research?

A physician is conducting a clinical trial with an investigational drug to prevent stroke.

Human Subjects Research

NOT Human Subjects Research

Is it human subjects research?

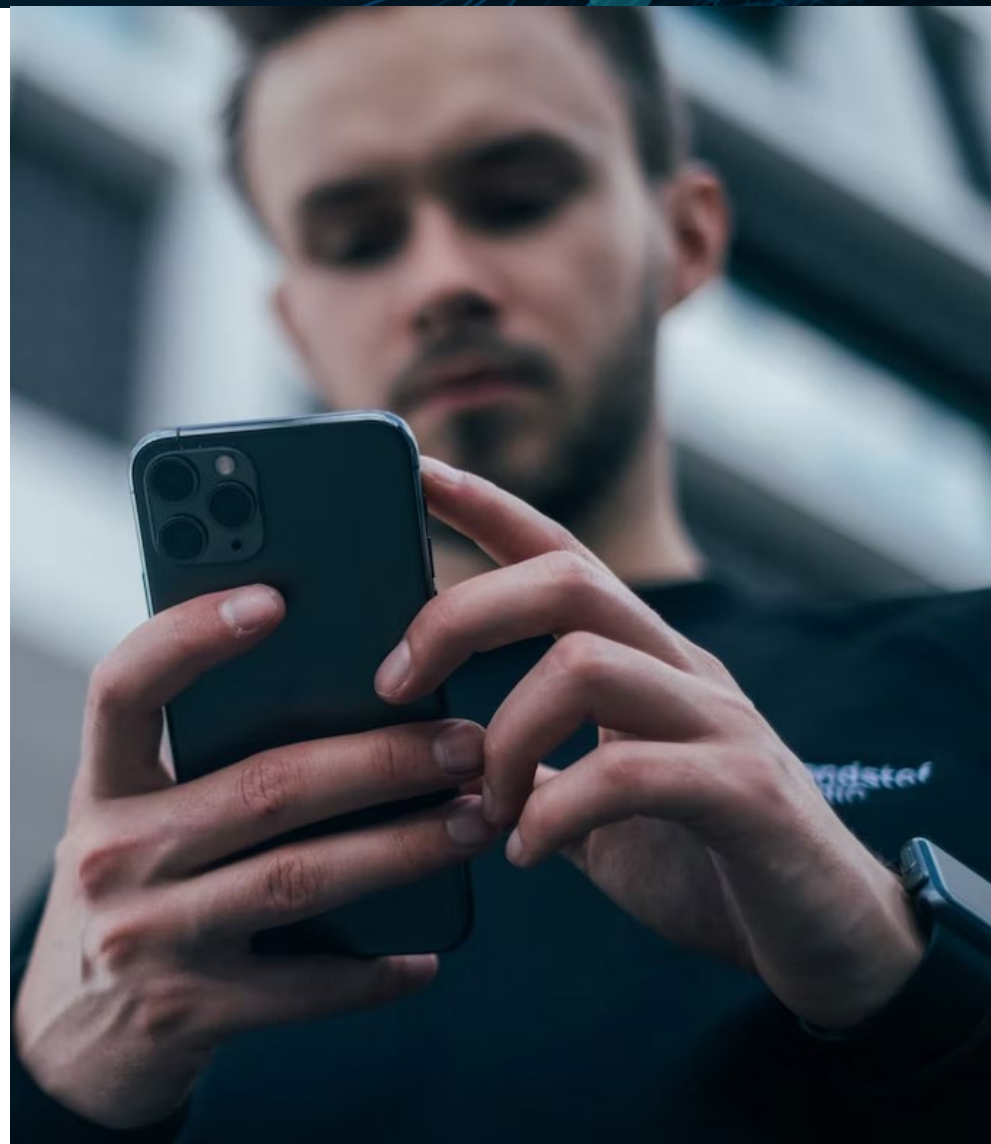
A researcher is using a rat model to test if a potential drug for the treatment of epilepsy can bind to its therapeutic target.

Human Subjects Research

NOT Human Subjects Research

Is it human subjects research?

A physician is conducting a quality improvement project to see if automated text reminders help her patients increase the number of steps walked in a day.

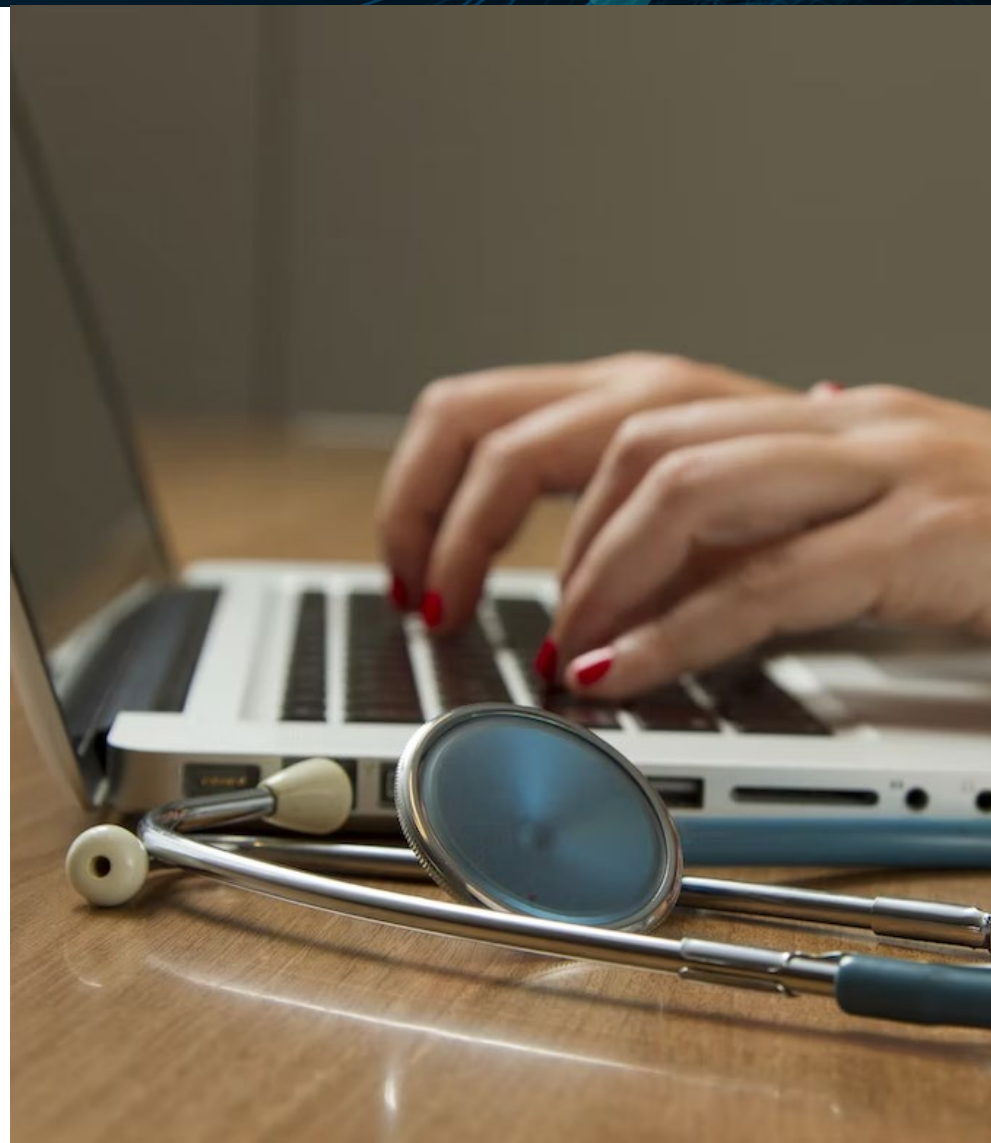


Human Subjects Research

NOT Human Subjects Research

Is it human subjects research?

A medical student is conducting a chart review to determine there is a correlation between age and severity of long COVID symptoms.



Human Subjects Research

NOT Human Subjects Research

Is it human subjects research?

UCDAVIS OFFICE OF RESEARCH

A physician is asking his patients with a rare cardiac condition for permission to use leftover blood collected per standard of care to study if there is a genetic component to the disease.

Human Subjects Research

NOT Human Subjects Research

Is it human subjects research?

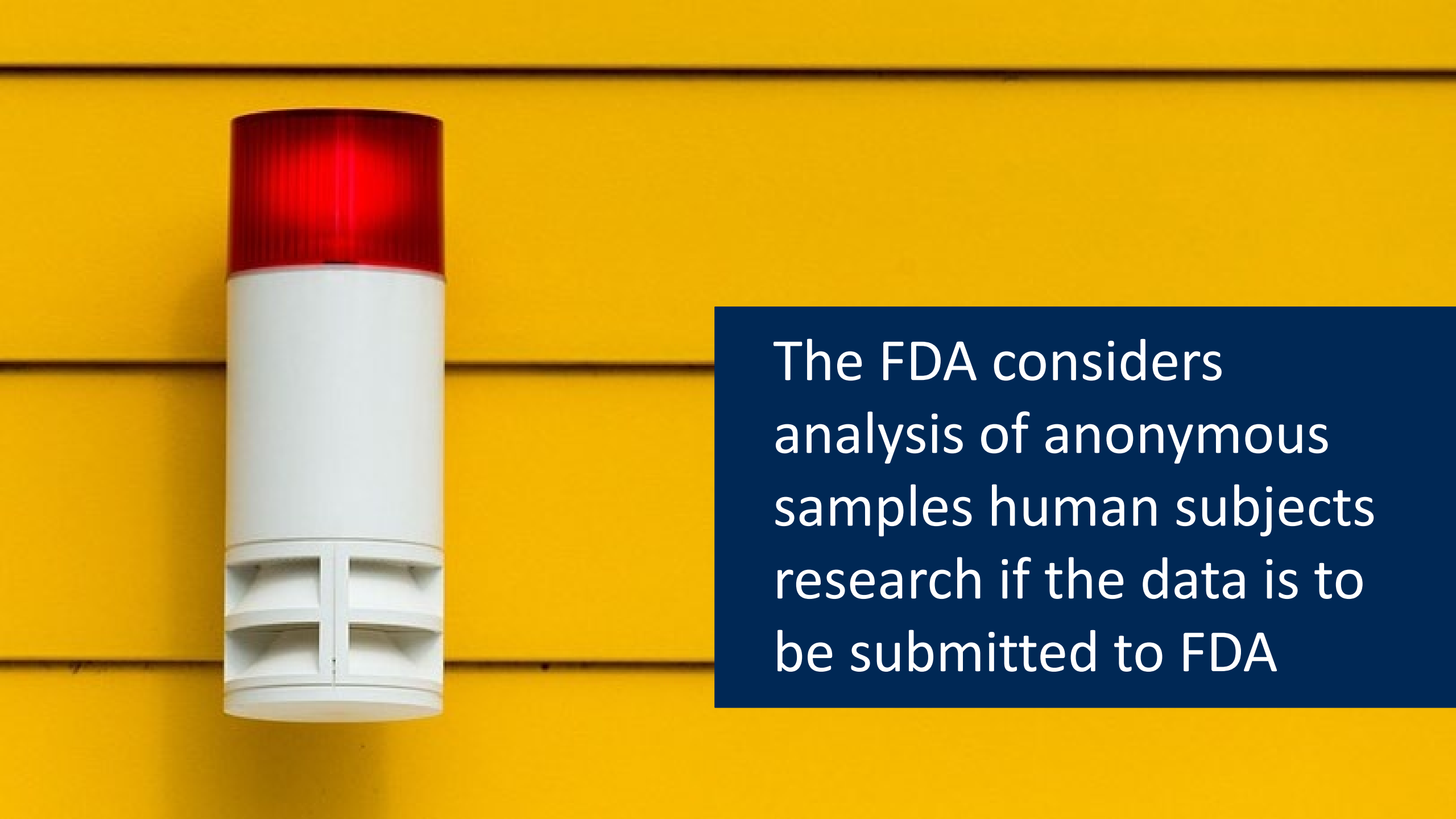
A physician has obtained de-identified blood samples to determine if there is a genetic component to a particular disease. There is no way for the physician to identify the people from whom the samples were obtained.

Human Subjects Research

NOT Human Subjects Research

Is it human subjects research?

A molecular biology professor has purchased anonymous blood samples from a biobank to test an assay he intends to get approved by the FDA for the diagnosis of Alzheimer's disease.



The FDA considers analysis of anonymous samples human subjects research if the data is to be submitted to FDA

What if I'm Not Sure if I Need to Submit to the IRB?

UCDAVIS OFFICE OF RESEARCH

You have the following options:

Check out the IRB website

- Does My Project Need Review by the IRB webpage
- 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

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. Required Training

Where do I submit to the IRB? IRBNet.org

UCDAVIS OFFICE OF RESEARCH

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

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

Registration Instructions

UCDAVIS OFFICE OF RESEARCH

1. Go to **www.irbnet.org**
2. Select **New User Registration**
3. Provide the information requested
4. On the **Add Affiliation** page, select “University of California Davis, Davis, CA”
5. Continue until you have completed registration
6. When you receive an email from activation@irbnet.org, follow the link contained in the email to complete the account activation process

IRBNet.org Terminology

UCDAVIS OFFICE OF RESEARCH

Project

Package

Package

Package

Package

IRBNet.org Terminology

IRBNet ID or IRB Number (one per Project)

Project Overview

[590207-17] Use of Autologous Platelet Rich Plasma (PRP) Gel As An Adjunct To The Treatment of Deep 2nd and 3rd Degre...

You have Full access to this project. (Edit)	
Research Institution	University of California Davis, Davis, CA
Title	Use of Autologous Platelet Rich Plasma (PRP) Gel As An Adjunct To The Treatment of Deep 2nd and 3rd Degree Burns
Principal Investigator	
Sponsor	Arteriocyte, Inc./DOD

IRBNet.org Terminology

Package Number

Project Overview

[590207-17] Use of Autologous Platelet Rich Plasma (PRP) Gel As An Adjunct To The Treatment of Deep 2nd and 3rd Degre...

You have Full access to this project. (Edit)	
Research Institution	University of California Davis, Davis, CA
Title	Use of Autologous Platelet Rich Plasma (PRP) Gel As An Adjunct To The Treatment of Deep 2nd and 3rd Degree Burns
Principal Investigator	
Sponsor	Arteriocyte, Inc./DOD

Anatomy of a New Project Submission

UCDAVIS OFFICE OF RESEARCH

- ✓ Initial Review Application
  - ↳ Electronic form in IRBNet
- ✓ Protocol
- ✓ Informed Consent Form (if required)
- ✓ Participant-Facing Materials
- ✓ Ancillary Reviews (if required)
- ✓ Principal Investigator Signature
- ✓ Faculty Advisor Signature (if student/resident is PI)
- ✓ Department Chair Signature

New Projects Webpage

UCDAVIS OFFICE OF RESEARCH

UCDAVIS INSTITUTIONAL REVIEW BOARD ADMINISTRATION

Researchers | IRB Submissions | Project Guidance | Office of Research

Home / For Researchers / IRB Submissions / New Projects

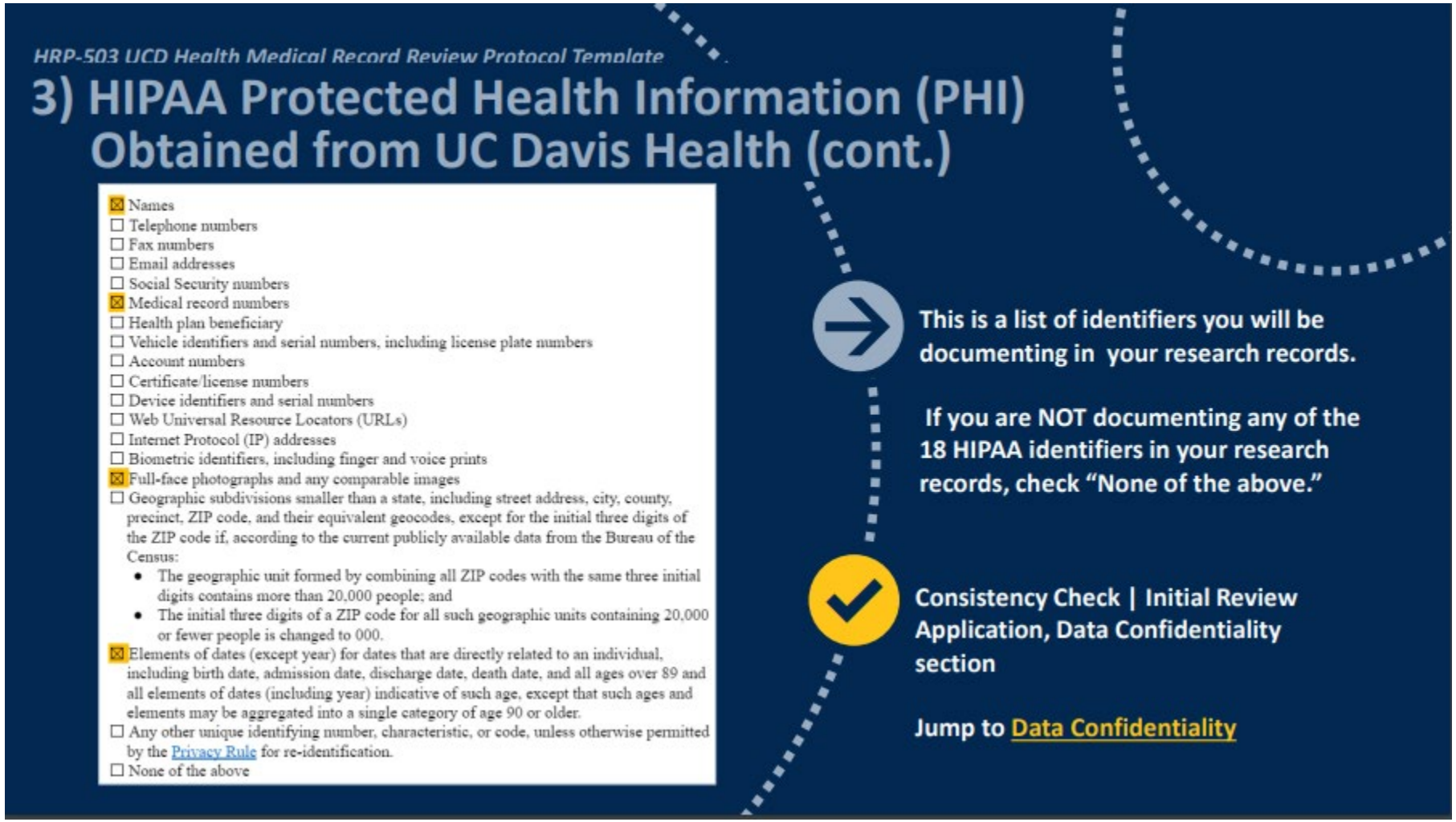
New Projects

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.

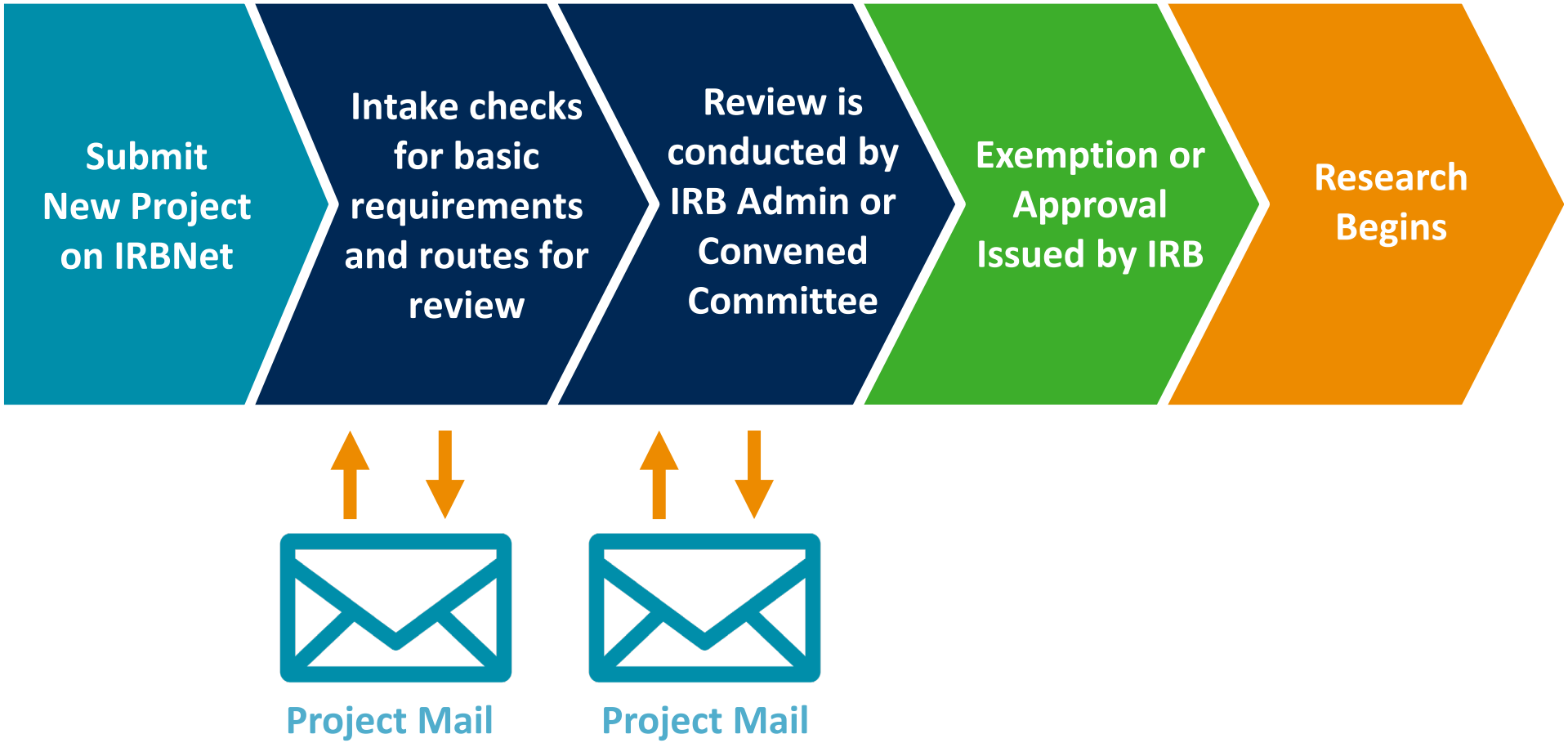
IN THIS SECTION

- Directions for Submitting a New Project to the IRB
- What Comes Next?
- Example Submissions
- Additional Resources
- Related Topics

New Projects Webpage| Example Submissions



IRB Review Process



UCDAVIS
OFFICE OF RESEARCH

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

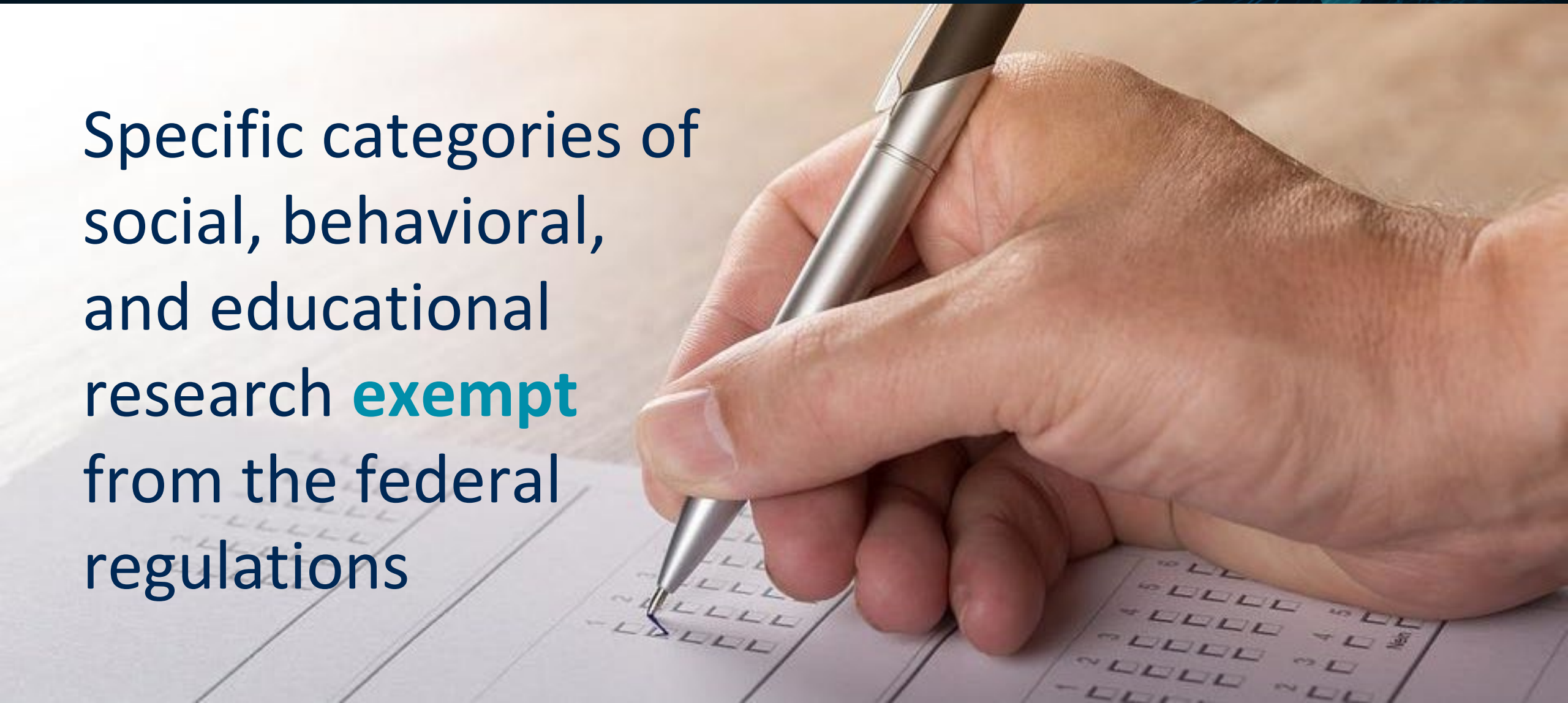
Not Engaged

IRB review **NOT** required

Exempt ← IRB review required

Then What is Exempt Research?

UCDAVIS OFFICE OF RESEARCH



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

What happens after approval?

UCDAVIS OFFICE OF RESEARCH

- Modifications
- Reportable New Information
- Continuing Review
- Closure

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. Required Training

CITI Training

Required for anyone engaged in human subjects research at UC Davis

↳ Basic Course for Biomedical Researchers and Staff

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

↳ Basic Course for Biomedical Researchers and Staff +

↳ Good Clinical Practice (GCP)

UCDAVIS
OFFICE OF RESEARCH

Helpful Resources for New Submitters

- ✓ Join our listserv
- ✓ Required Education webpage
  - ↳ www.citiprogram.org
- ✓ IRBNet webpage
- ✓ IRB Forms webpage
- ✓ New Projects webpage
- ✓ UC Davis Investigator Manual

We're Here to Help!

UCDAVIS OFFICE OF RESEARCH

Email

hs-irbeducation@ucdavis.edu

Virtual Drop-In Office Hours

Fridays (except UC holidays) 12:00-1:00 pm

Zoom **LINK**

Questions?