

Back to Basics:

Does My Project Fall Within the Scope of the Regulations?

Misti Ault Anderson, MS, MA
Senior Advisor for Public Health Education

Division of Education and Development (DED)
Office for Human Research Protections (OHRP)
Department of Health and Human Services (HHS)

Learning Objectives

- ❖ Recognize the role of the HHS Office for Human Research Protections (OHRP)
- ❖ Describe the basics of the Common Rule
- ❖ Understand how to apply the regulations

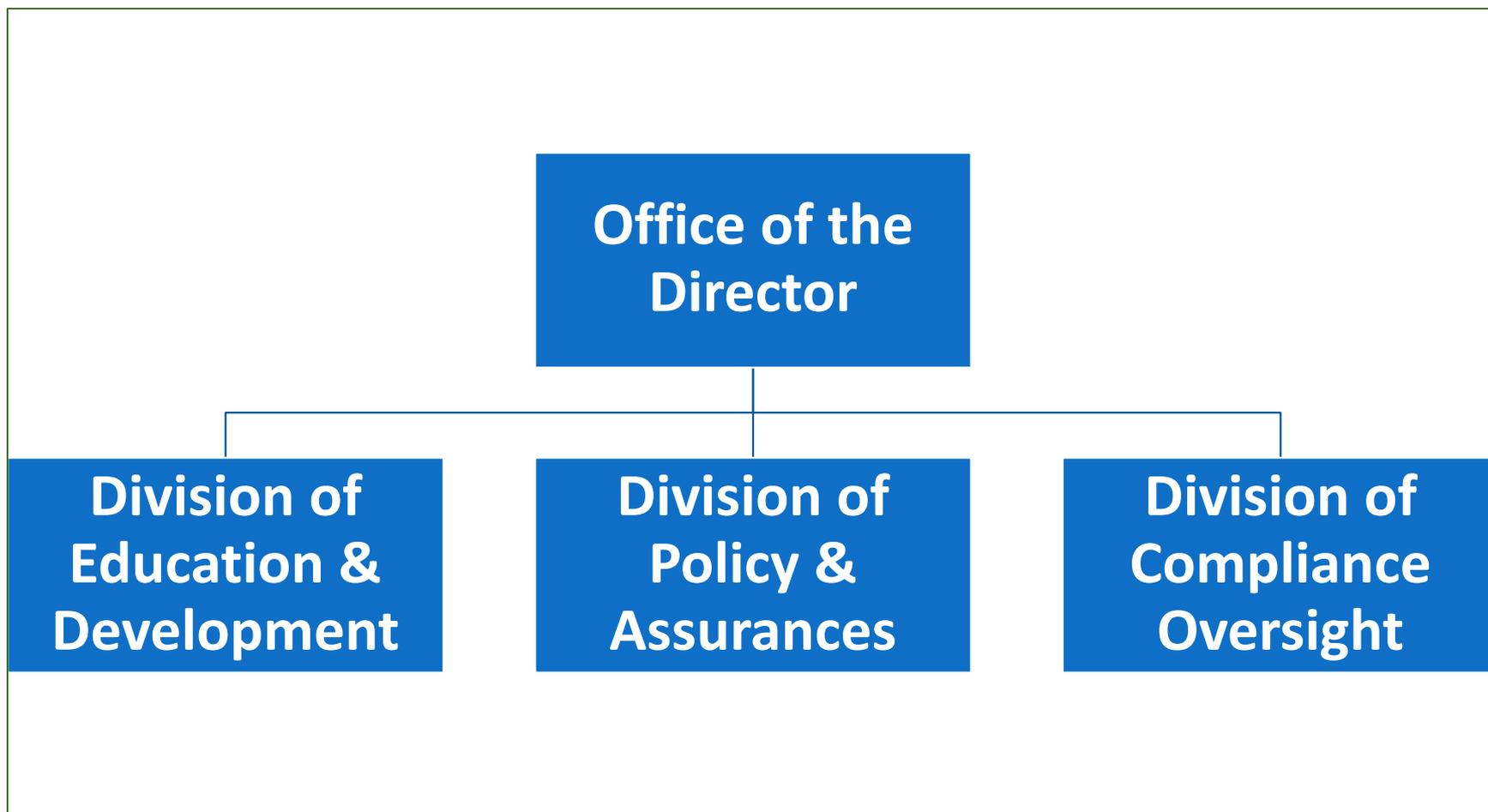
Who is OHRP?

Office for Human Research Protections

Mission

Provide leadership in protecting the rights, welfare, and wellbeing of human subjects in research conducted or supported by HHS

OHRP Structure





HHS REGULATIONS ON HUMAN RESEARCH PROTECTIONS

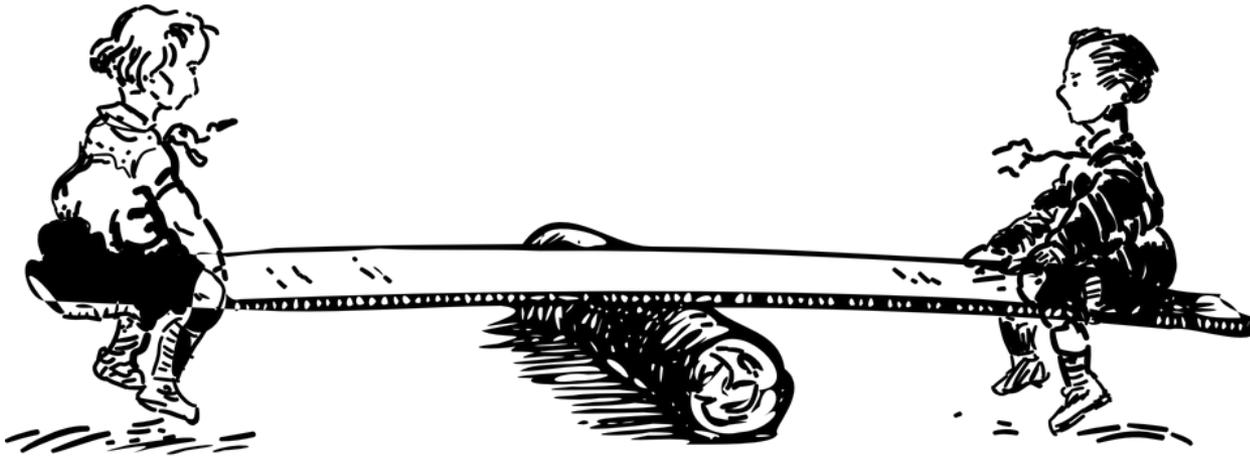
Research

“A systematic investigation ... designed to develop or contribute to generalizable knowledge”

45 CFR 46.102(d)

- Research serves the common good
- Research subjects are the ‘means’ to achieve this goal
- Primary interest of research is to society, not to benefit individual subjects

The Challenge



**Societal benefit of
science through human
subjects research**

**Respecting research
subjects as individuals, not
as a means to an end**

Historical Cases Led to Regulations

For example:

Tuskegee Syphilis Study (1933-72)



Led to:

1974: National Research Act

1979: *Belmont Report*

1981: Protection of Human Subjects laws

The *Belmont Report*

Main Principles

1. **Respect for Persons**

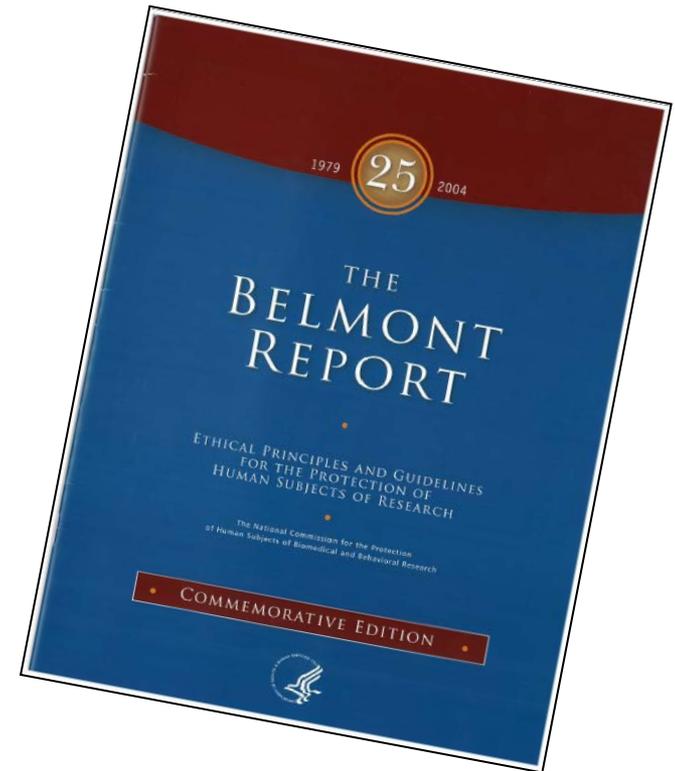
- Promote autonomy

2. **Beneficence**

- Maximize benefits; minimize harms

3. **Justice**

- Ensure equitable distribution of burden & benefits



HHS Regulations on Human Research Protections 45 CFR Part 46

- ❖ **Subpart A –
“The Common Rule”**
- ❖ Subpart B – Pregnant
women, fetuses, neonates
- ❖ Subpart C - Prisoners
- ❖ Subpart D – Children
- ❖ Subpart E – IRB
Registration



The Common Rule 45 CFR Part 46 Subpart A

Adopted by 18 federal departments & agencies

| | | |
|----------------------------------------------------------------------|---------------------------------------------------------------|--------------------------------------------------------------------------|
| Department of Agriculture 7 CFR Part 1c | Department of Energy 10 CFR Part 745 | National Aeronautics and Space Administration 14 CFR Part 1230 |
| Department of Commerce 15 CFR Part 27 | Consumer Product Safety Commission 16 CFR Part 1028 | Agency for International Development 22 CFR Part 225 |
| Department of Housing and Urban Development 24 CFR Part 60 | Department of Justice 28 CFR Part 46 | Department of Defense 32 CFR Part 219 |
| Department of Education 34 CFR Part 97 | Department of Veterans Affairs 38 CFR Part 16 | Environmental Protection Agency 40 CFR Part 26 |
| Department of Health and Human Services 45 CFR Part 46 | National Science Foundation 45 CFR Part 690 | Department of Transportation 49 CFR Part 11 |
| Central Intelligence Agency * | Department of Homeland Security* | Social Security Administration* |

**Denotes compliance with ALL subparts of 45 CFR part 46, but have not issued the Common Rule in regulations*

The Common Rule

Providing the ABCs in Human Protections

- ❖ Institutional Assurance of Compliance (Federalwide Assurance - FWA)
- ❖ Institution Review Boards (IRB)
- ❖ Informed Consent

HHS and FDA Regulations

❖ Differences in Scope

- HHS regulations apply to HHS-funded research (including NIH funding)
- FDA regulations apply to clinical investigations involving FDA regulated products: drugs, devices, and biologics

❖ Consider

- Where does your research \$ come from?
- Does your research involve drugs, devices, or biologics regulated by FDA?
- Will you be considering the U.S. market for the drugs, devices, or biologics that you study?



APPLYING THE HHS REGULATIONS

When Do the Regulations Apply?

- ❖ Non-exempt human subjects research conducted or supported by HHS
- ❖ Non-exempt human subject research covered by the Assurance of Compliance
 - ‘Checking the box’



Do the Regulations Apply?

Ask these questions in THIS ORDER:

1. Does the activity involve Research?
2. Does the research involve Human Subjects?
3. Is the human subjects research Exempt?
4. Is your institution Engaged?

See Human Subject Regulations [Decision Charts](#).

Is it Research?

“Research refers to a **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**”

(emphasis added)

45 CFR 46.102(d)

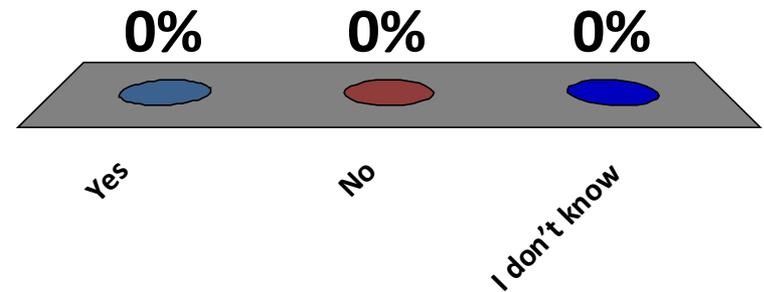
Test Your Knowledge

A team of physicians see a patient with an unusual constellation of symptoms. They run a variety of diagnostic tests and procedures. Results of the test do not yield a known diagnosis.

They write up a case summary of their observations and submit it to a medical journal for publication.

Is this research?

- A. Yes**
- B. No**
- C. I don't know**



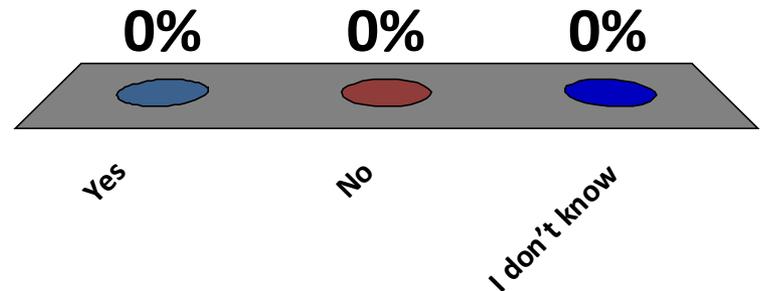
Test Your Knowledge

An investigator hypothesizes that strong study habits are related to on-time graduation. He collects survey data with identifiable information about study habits from students in their first semester of graduate school.

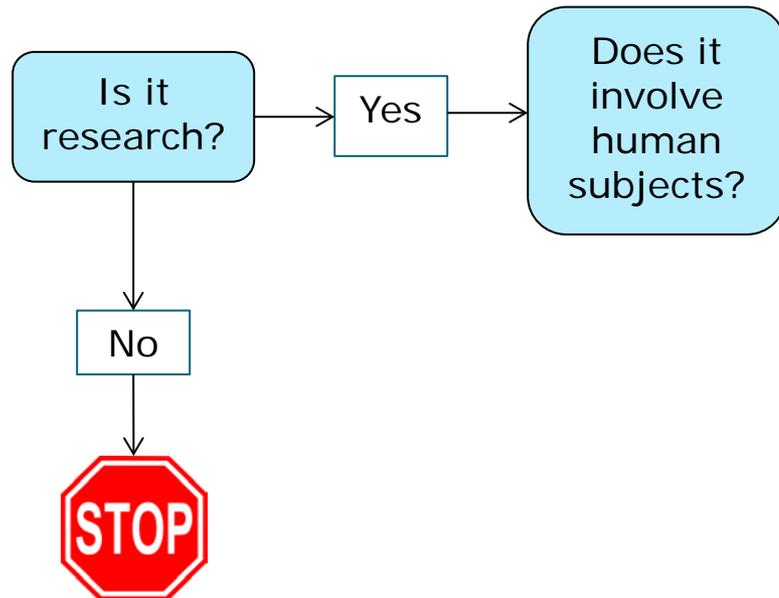
He tracks graduation status to determine whether a correlation exists between study habits and time to graduation, and plans to publish his results.

Is this research?

- A. Yes**
- B. No**
- C. I don't know**



Does the Activity Involve Research?



Does it Involve Human Subjects?

❖ Human subject – a **living** individual **about whom** an investigator obtains:

- data through **intervention** or **interaction** with the individual, or
- **identifiable private information***

** Identity of the subject is or may readily be ascertained by the investigator or associated with the information*

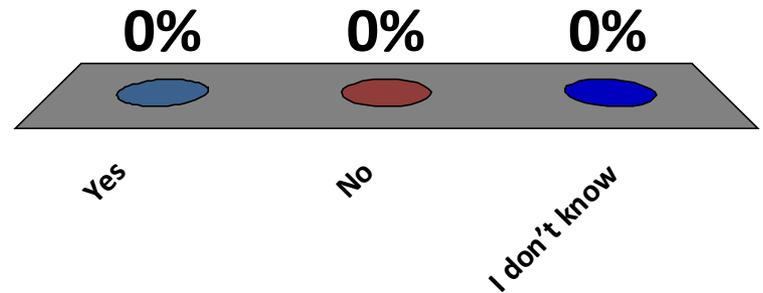
Test Your Knowledge

A researcher forms a hypothesis about certain groups of individuals and their responses to some controversial current events in the news.

She wants to study twitter postings (tweets) related to those current events to establish a correlation and predict behaviors.

Is this human subjects research?

- A. Yes**
- B. No**
- C. I don't know**



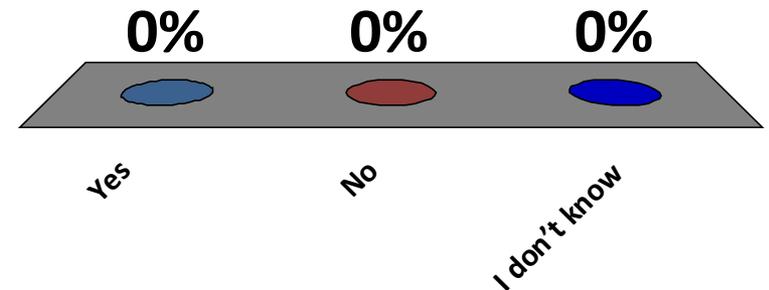
Test Your Knowledge

An investigator receives survey data on the use of opioid pain medications from an outside source to use in a new study. The investigator receives no individually identifiable information with the data.

The data were obtained for a previous and unrelated research study, not the current research.

Is this human subjects research?

- A. Yes**
- B. No**
- C. I don't know**



Test Your Knowledge

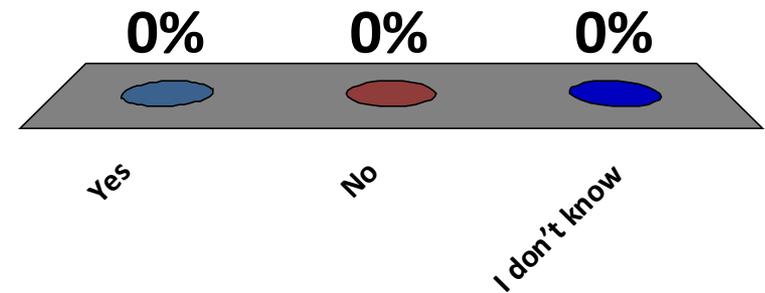
A PI receives de-identified biological specimens from an outside provider. The provider plans to provide intellectual input on the current research.

The specimens were obtained for a previous and unrelated research study, not the current research.

The PI cannot identify the individuals from whom the specimens were obtained.

Is this human subjects research?

- A. Yes**
- B. No**
- C. I don't know**

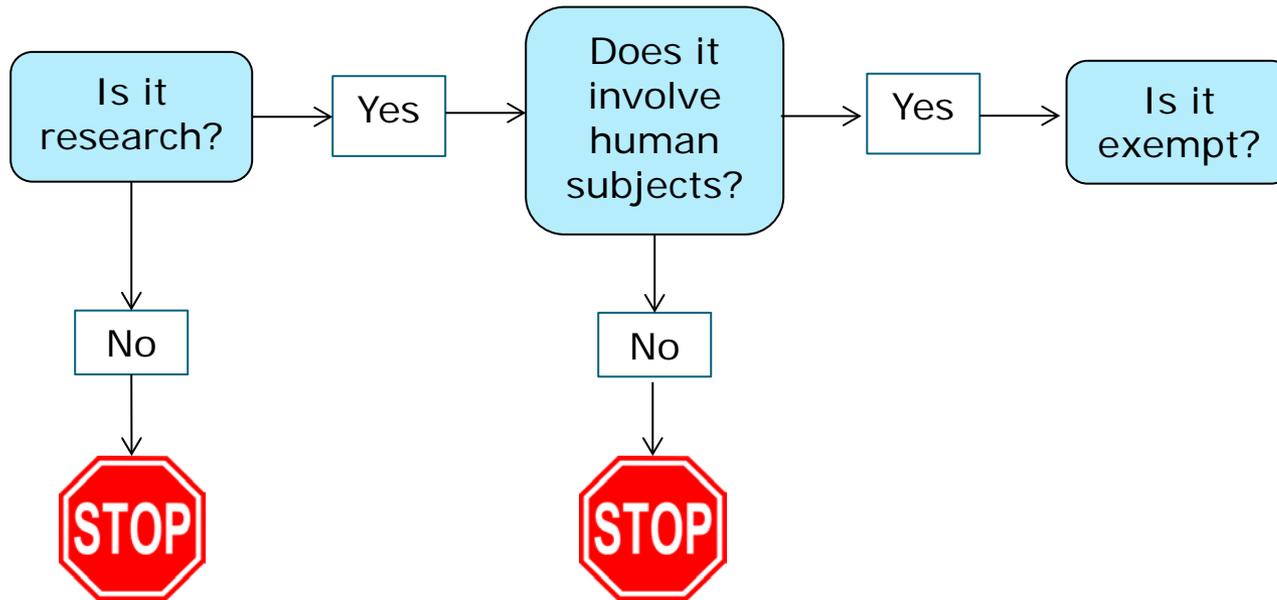


Research With Biospecimens or Coded Private Information

If research involves only coded biospecimens or private information and meets both conditions below:

- ❖ not collected specifically for research in question;
and
 - ❖ investigator(s) cannot readily ascertain identity of the individual(s) to whom data/specimens pertain,
- then it is **not human subjects research**.

Does the Research Involve Human Subjects?



Is the Human Subjects Research Exempt?

(Note: Exemptions do not apply to research with prisoners)

1. Normal educational practices in established educational settings
2. Educational tests, surveys, interviews, or observation of public behavior— unless identified & sensitive*
3. Research on elected or appointed public officials or candidates for public office
4. Research using existing data, if publicly available or recorded without identifiers
5. Evaluation of public benefit service programs
6. Taste and food quality evaluation and consumer acceptance studies

46.101(b)(1-6)

Exemption (b)(1)

Normal educational practices in established educational settings.

Consider:

- ❖ A study comparing two curricula that are currently being implemented in a school. Researchers will observe classrooms as well as interview instructors about their experiences implementing the instructional materials.
- ❖ Students will participate in a pre- and post-test administered by their teachers.

Exemption (b)(2)

Educational tests, surveys*, interviews*, or observation of public behavior

UNLESS

- Identifiable and
- Any disclosure could cause harm

* Does not apply to children

Exemption (b)(4)

Research using **existing** data, if publicly available or recorded without identifiers

Consider:

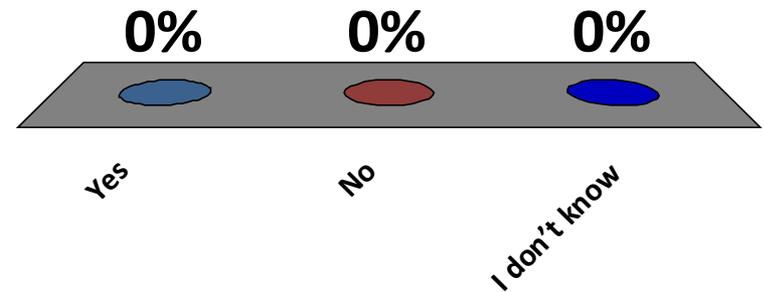
- ❖ A research study of treatment outcomes for a certain drug that involves the review of patient charts at a local medical facility. The research team records patient age, sex, diagnosis, and treatment outcome from existing data sets without other individually identifiable information.

Test Your Knowledge

A researcher plans to interview a group of teenagers with Type 1 diabetes about their exercise habits. The researcher will not collect any identifiable information about the participants.

Is this exempt human subjects research?

- A. Yes
- B. No
- C. I don't know



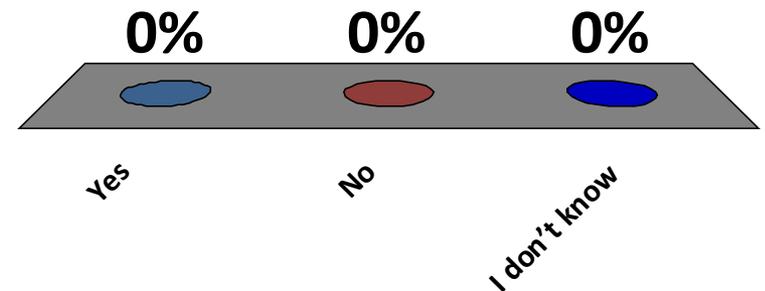
Test Your Knowledge

A researcher asks therapists from several institutions to complete an online survey about their practices involving specified situations. The survey includes the therapists' email addresses.

The researcher will not share the email addresses with anyone outside the study team, and will destroy this information after completing data collection.

Is this exempt human subjects research?

- A. Yes
- B. No
- C. I don't know



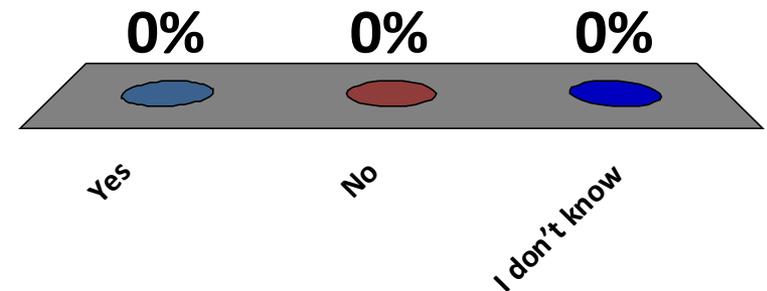
Test Your Knowledge

An investigator at your institution wants to review medical records of patients admitted at another institution for a specified condition between the years 2000-2015. She wants to use this information in a new research study.

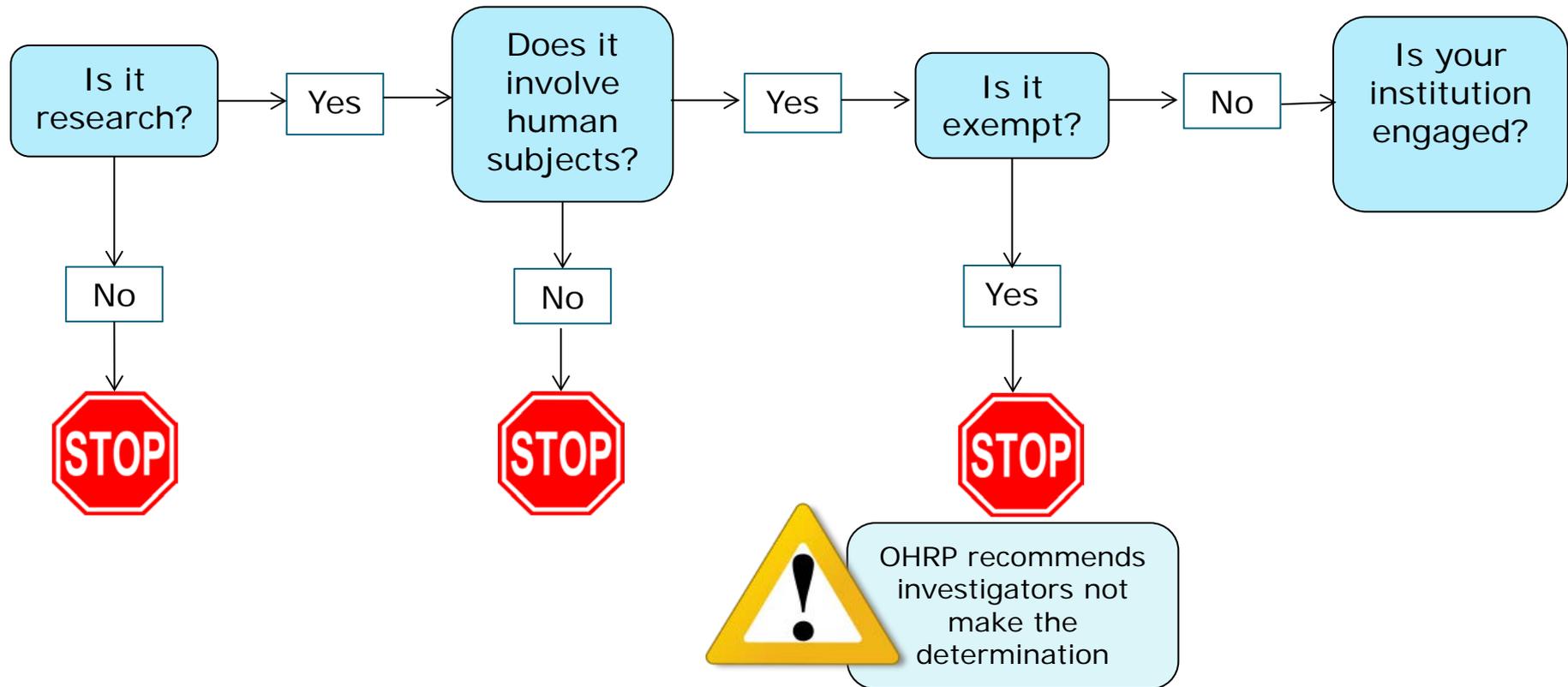
A clinician at the other institution has agreed to extract the relevant medical information and provide it to the investigator with no associated individually identifiable information. Other than extracting the relevant information, the clinician has no role in the new research.

Is this exempt human subjects research?

- A. Yes
- B. No
- C. I don't know



Is the Human Subjects Research Exempt?



Is Your Institution *Engaged* in Non-Exempt Human Subjects Research?

Many gray areas:

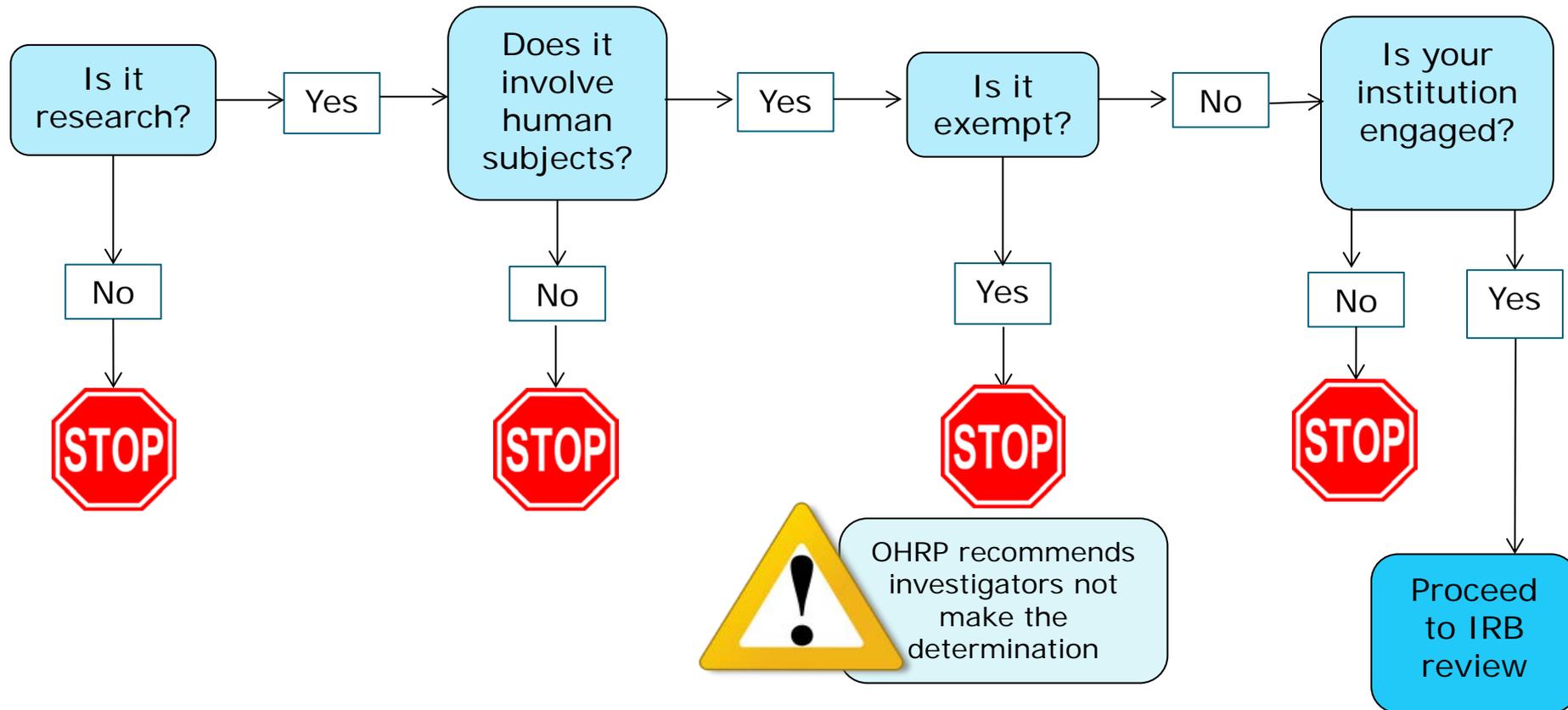
“I am collaborating on this research but will only receive coded data for analysis. I will not have ready means to link the data back to the subjects.”

“Sure, I will help you with patient recruitment by distributing your research flyers in my clinic.”

See the guidance document on engagement, available on OHRP website:

“Engagement of Institutions in Human Subjects Research”

Is the Human Subjects Research Exempt?



Next Steps

- ❑ The activity is research, and
- ❑ The research involves human subjects, and
- ❑ The human subjects research is not exempt, and
- ❑ Your institution is engaged, then ...

IRB review!

THANK YOU!

OHRP WEB PAGE:

[HTTP://WWW.HHS.GOV/ORHP](http://www.hhs.gov/orhp)

CONTACT OHRP:

PHONE: (240)453-6900 (866)447-4777

E-MAIL: OHRP@HHS.GOV

EDUCATION E-MAIL: OHRP-EDU@HHS.GOV