Before Saying “I Do” to the Common Rule: Figuring Out “Engagement”

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

OASH | Office for Human Research Protections

Disclaimer

The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services.

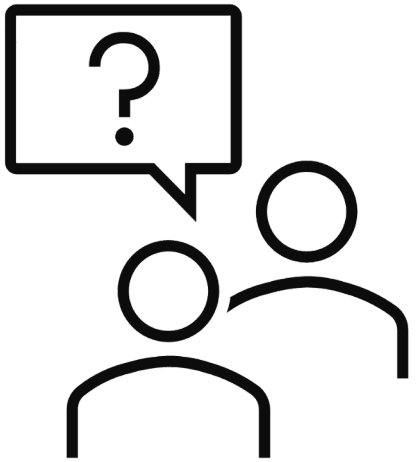
For a complete and accurate description of the regulatory requirements, please refer to the text of the revised Common Rule available on OHRP's website.

Learning Objectives

- Explain when you need to think about “institutional engagement”
- Examine what activities “engage” an institution
- Describe the requirements of an ”engaged” institution

Quick Overview

- In general, an institution is “engaged” when:
  - Its employees or agents perform non-exempt human subjects research supported or conducted by HHS, or
  - It is the primary awardee of HHS funding for nonexempt human subjects research.
- When multiple institutions are collaborating in cooperative research – consider the actual activities conducted by each institution to determine if it is engaged.
- All institutions engaged in the research must be covered by a FWA, and, with few exceptions, follow the single IRB review requirement at §46.114.



When Do We Need to Think About Engagement?

- The regulatory concept of institutional engagement **ONLY** applies to non-exempt human subjects research conducted or supported by HHS.
- When there is cooperative research among multiple institutions on one nonexempt research project, the activities of each institution should be examined.
- The cooperating institutions *need not* be performing the **same** activities:
  - Institutions that conduct human subjects activities and are engaged must have their activities reviewed by the single IRB (sIRB).
  - Institutions **CANNOT** individually apply exemption categories to human subjects research and avoid review by the sIRB.
  - Non-engaged institutions do not need to have their activities reviewed by the sIRB.

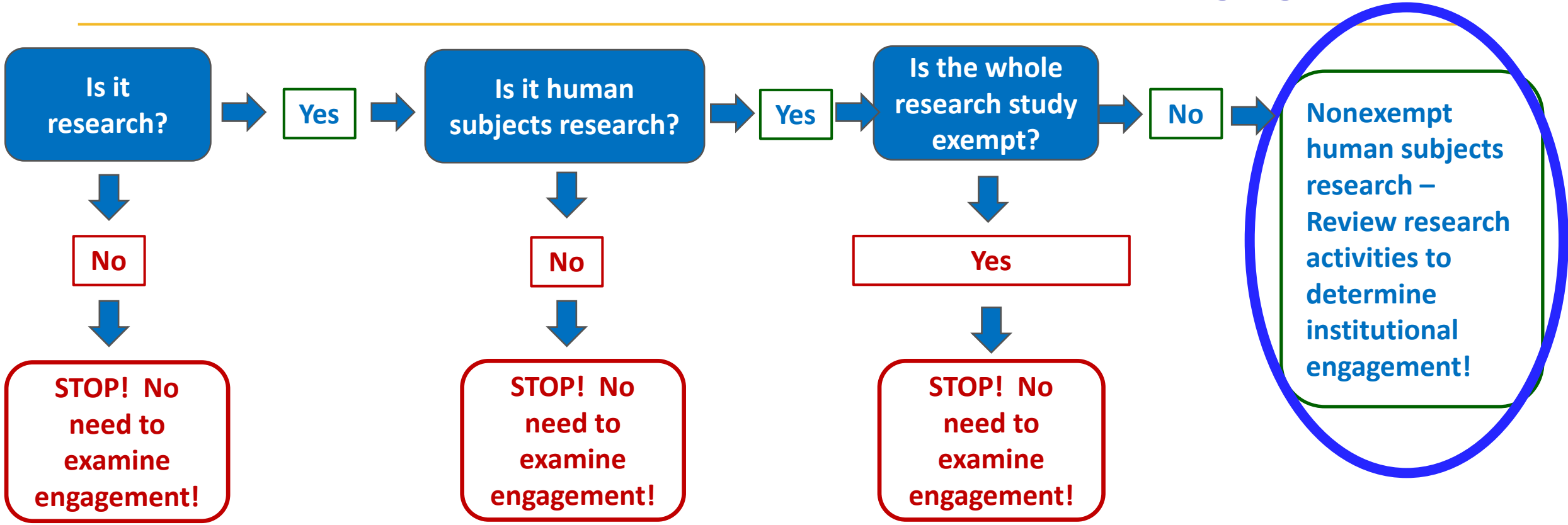
How to Determine if the Research is Non-exempt

- Is it *Research*?
  - **Research** means a systematic investigation… designed to develop or contribute to generalizable knowledge (45 CFR 46.102(l)).
- Is it *Human Subjects Research*?
  - A **human subject** is a **living** individual **about whom** an investigator conducting research:
    - ✓ Obtains information or biospecimens through an **intervention** or **interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; **OR**
    - ✓ Obtains, uses, studies, analyzes, or generates **identifiable** private information or identifiable biospecimens. (45 CFR 46.102(e)).
- Is it *Exempt Human Subjects Research?*
  - Does all of the study meet the criteria for one or more of the eight exemption categories?

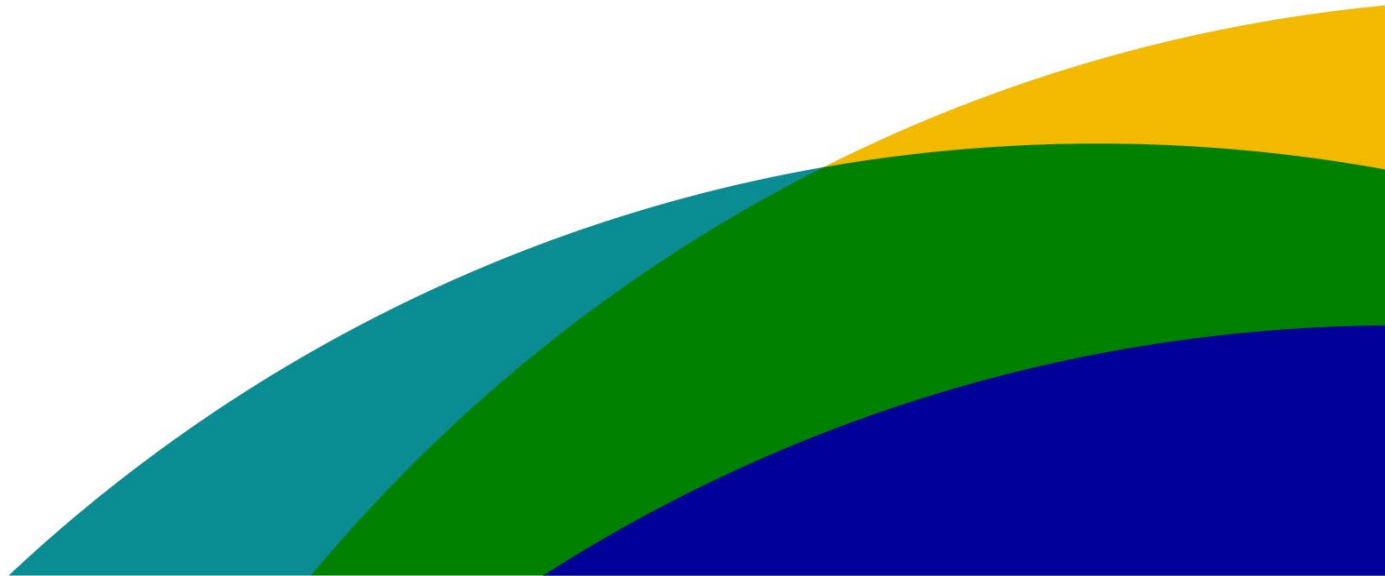
What About Exempt Research?

- If the entire project is exempt research, there is no need to worry about engagement.
- The Common Rule at 45 CFR 46.104(a) states, "…research activities in which the **only involvement of human subjects** will be in one or more of the categories…" (emphasis added)
  - This means there is no compartmentalization of one research study into nonexempt and exempt parts – even if different parts are performed at different institutions.
  - Institutions cannot issue exempt determinations for their research activities if they are part of a bigger nonexempt study!

Flowchart: When to Consider Institutional Engagement



Examining Institutional Engagement



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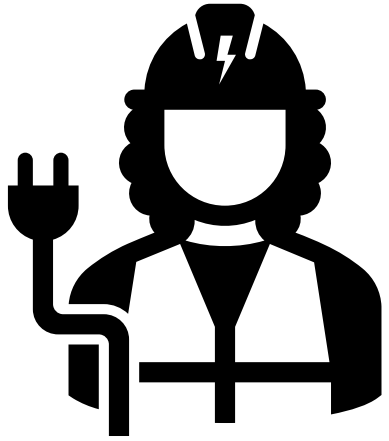
What Activities Engage an Institution?

- Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (even if not doing any activities), or
- Generally, engagement occurs when an employee or agent, for the purposes of a research project performs these human subjects research activities:
  - Obtain data about the subjects of the research through **intervention** or **interaction** with them;
  - Have access to **identifiable private information** about the subjects of the research or **identifiable biological specimens**; or
  - Obtain the **informed consent** of human subjects for the research.

Who Qualifies As an Employee or Agent of an Institution?

- Institutions are considered “engaged”, not individuals. But, institutions become engaged through the activities their employees or agents undertake for the research.
- Employees or agents are those who:
  - Act on behalf of the institution;
  - Exercise institutional authority or responsibility; or
  - Perform institutionally designated activities.
- Employees and agents can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.



Scenario 1

Alpha University receives a grant from the NIH to conduct a clinical trial to test the effectiveness of a heart disease drug. Dr. Smith of Local Hospital, will obtain consent and perform EKGs on participants for the study.

Is Alpha engaged?

First, do we have non-exempt human subjects research supported by HHS? Yes.

Yes, Alpha is engaged as the primary awardee.

Is Local engaged?

Yes, its employee, Dr. Smith, is obtaining consent.

We will use this non-exempt human subjects research study funded by HHS throughout the webinar

The Details of the Activities Matter

- The default is for institutions is to be engaged when its employees or agents have interactions or interventions for research purposes, but, there are instances when such activities do not rise to the level of engagement.
- Contrast obtaining informed consent with only supplying study information. Institutions are **NOT ENGAGED** if their employees or agents only:
  - Inform prospective subjects about research;
  - Provide prospective subjects with information about the research (including an informed consent document and other IRB approved documents) and about contacting investigators for information or enrollment; and/or
  - Ask if investigators can contact them about research.

(Refer to section B.4 of the 2008 Engagement Guidance)

Scenario 2

Alpha reaches out to a local retirement facility to help with recruitment and provides fliers, posters, and consent forms to be distributed to the residents. Is the retirement facility engaged in the research if:

Nurses at the retirement facility distribute fliers?

No, even though it is an interaction for research purposes, they are only providing information.

Nurses distribute consent forms?

No, as above, they are only distributing information.

Nurses obtain consent from the residents?

Yes, conducting informed consent is a human subjects activity that would engage the retirement facility.

What About a Partner Who Performs Some Research Activities as a Service?

Institutions whose employees or agents only perform commercial or other services are **NOT engaged** provided that **all** of the below conditions are met:

a. the services performed do not merit professional recognition or publication privileges;

b. the services performed are *typically* performed by that institution for *non-research* purposes; AND

c. the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

(Refer to section B.1 of the 2008 Engagement Guidance)

Scenario 3

Alpha contacts Blood Diagnostics to take conduct blood chemistry tests. Diagnostics routinely provides this service for hospitals as part of clinical care. Participants will visit Diagnostics and have their blood drawn and analyzed. Is Diagnostics engaged?

Default is they would *probably be engaged* because of interaction and intervention for research purposes.

BUT, what about the services carve out?

- Professional recognition or publication credit? No.
- Typically performed for non-research purposes? Yes.
- Administering the study intervention? No.

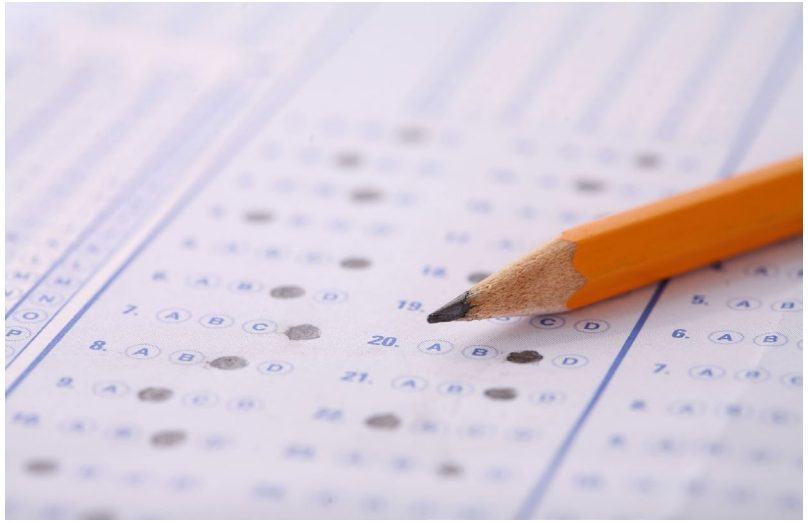
No, Diagnostics is probably not engaged based on the services provision.

What if a Survey Firm is Used, Is it Engaged?

- Conducting surveys is usually viewed as a human subjects activity because it involves interacting with research participants.
- Using a commercial survey firm to conduct surveys might fall within the commercial services exception.
- The firm is not engaged with a "**no**" answer to all of the following questions:
  - Does the firm obtain consent?
  - Does the service warrant recognition/ credit?
  - Does the survey firm typically perform surveys for research purposes?
  - Is the firm administering any study intervention being tested or evaluated under the protocol?

Scenario 4

Alpha contracts with a local College to administer surveys with participants about their lifestyles as part of the ongoing clinical trial. The College's fees are high but they specialize in research and, despite the quality of work, they never seek publication credits.



Is the College engaged in the research?

Let's examine the survey firm exception:

- Is the College obtaining consent? No.
- Does the service warrant recognition/ credit? No.
- Does the survey firm typically perform surveys for research purposes? Yes.

Yes, the College is likely to be considered engaged. The survey firm exception does not apply because the College normally conducts surveys for research.

Providing Medical Services

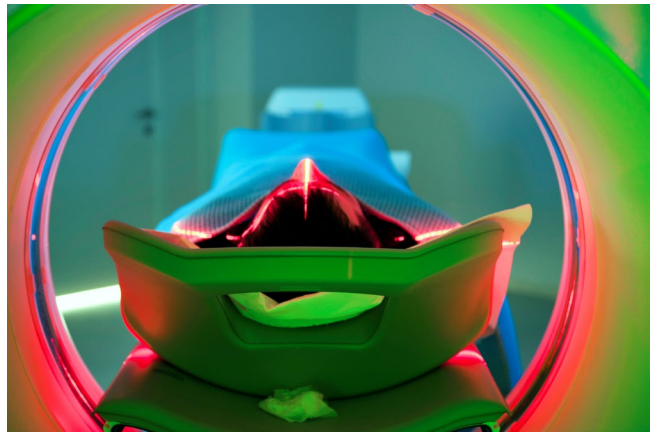
Institutions that only provide medical services required by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators are **NOT ENGAGED** provided that **ALL** of the following conditions also are met:

a. the institution's employees or agents **do not** administer the study **interventions** being tested or evaluated under the protocol;
b. the medical services are *typically* provided by the institution for **clinical purposes**;
c. the employees or agents **do not enroll** subjects or **obtain** informed consent; and
d. An institution engaged in the research oversees the study-related procedures and make arrangements for reporting data.

(Refer to section B.2 of the 2008 Engagement Guidance)

Scenario 5

A participant lives far from Alpha's campus and the window to complete a follow-up MRI is closing. Alpha arranges with a radiology practice, associated with area hospitals, to conduct the research MRI. The radiology practice will send the MRI to Alpha for evaluation. Is the radiology practice engaged?



Is the radiology practice administering the intervention the research is studying? No.

Does the radiology practice typically perform the MRIs for clinical purposes? Yes.

Is the radiology practice enrolling or consenting the participant? No.

Does Alpha oversee the MRI and make arrangements for reporting the data? Yes.

No, the local radiology practice is likely not engaged in the research.

Obtaining Identifiable Information or Specimens

Institutions whose employees or agents obtain **identifiable** private information or **identifiable** biological specimens from *any* source for *research* - even if the institution's employees or agents **do not** directly interact or intervene with human subjects are typically considered ***ENGAGED***. This includes through means such as:

- observing or recording private behavior; or
- using, studying, or analyzing for research purposes **identifiable** private information or **identifiable** specimens *provided* by another institution or already in the *possession* of the investigators

(Refer to section A.6 of the 2008 Engagement Guidance)

Obtaining *Coded* Information or Specimens Without the Key

Institutions are **not engaged** when their employees or agents only:

a. obtain **coded** private information or human biological specimens from *another institution* involved in the *research* that retains a link to individually identifying information; and

b. are ***unable*** to readily ascertain the identity of the subjects to whom the coded information or specimens pertain because, for example:

- ✓ the institution's employees or agents and the holder of the key enter into an agreement **prohibiting** the **release** of the key to those employees or agents under any circumstances;
- ✓ the releasing institution has IRB-approved written policies and operating procedures applicable to the research project that **prohibit** the **release** of the key to the institution's employees or agents under any circumstances; or
- ✓ there are other legal requirements **prohibiting** the **release** of the key to the institution's employees or agents.

(Refer to section B.7 of the 2008 Engagement Guidance)

Scenario 6

Alpha University collects identifiable participant information through interviews along with corresponding blood samples. Both information and samples are sent to a collaborator at a nearby college to look for patterns between self-reported behavior and elevated cholesterol.

Is the college engaged?

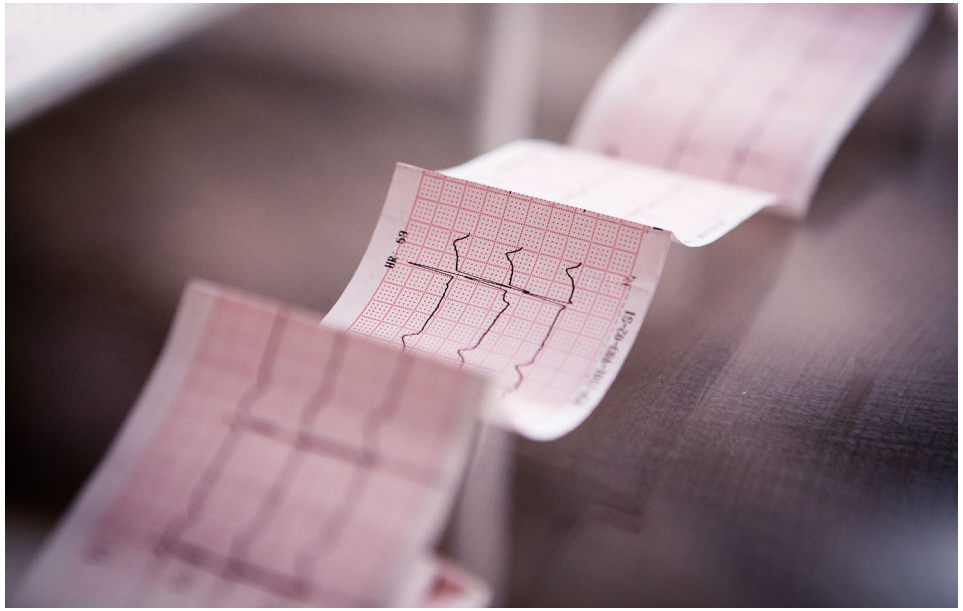
Yes, the college is obtaining identifiable information and specimens and analyzing them for research purposes. It does not matter that the college has no interaction with the participants or that the samples are provided by another institution.

What if the same information and samples are first coded by Alpha with a key and the institutions sign an agreement never to share the key with the college?

No, the college would not be engaged because the samples are coded and there is no access to the key; the identities of the participants cannot be determined.

Releasing Identifiable Information or Specimens

Institutions whose employees or agents are releasing to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research and have no other role in the research are **not engaged**.



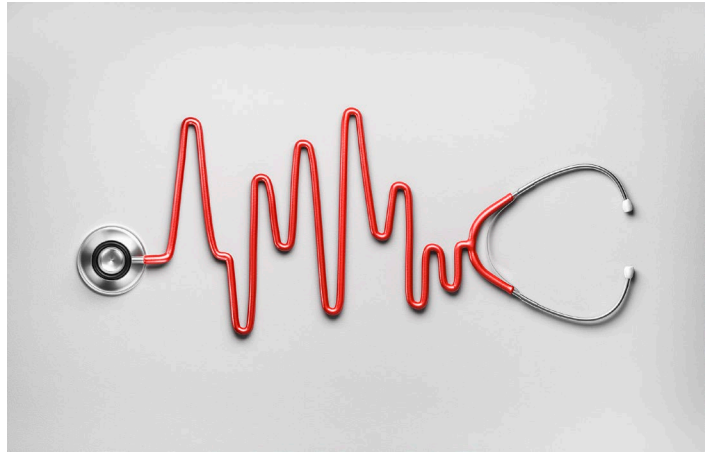
(Refer to section B.6 of the 2008 Engagement Guidance)

Scenario 7

Alpha obtains permission from study participants to contact their primary care physicians to obtain past medical histories to use in the clinical trial.

Are the employers (hospitals and clinics) where these physicians work engaged in the research?

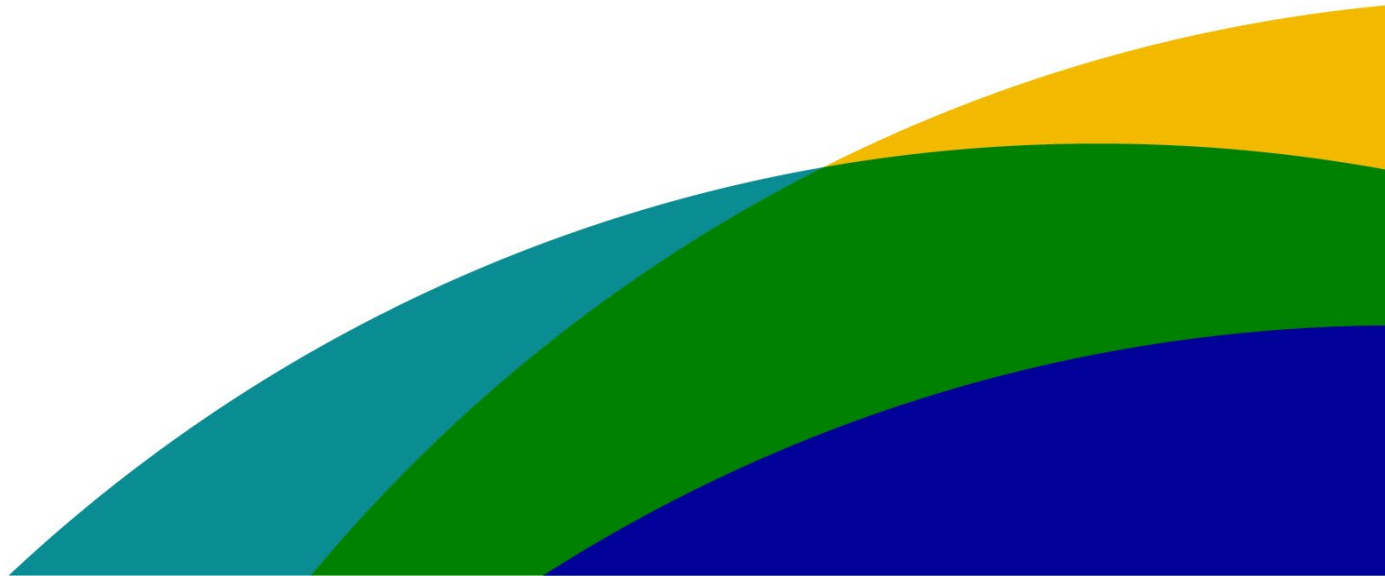
No, only providing identifiable data does not engage an institution.



What if Alpha shares identifiable participant information with these same physicians to add to their patients' medical records? Does this engage the employers of the physicians in the research?

No, the physicians would be using the information for clinical purposes.

Congrats, You’re Engaged! Now What?



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Engaged Institutions Need an FWA

- Institutions engaged in HHS-funded nonexempt human subjects research need to be “covered” by a Federalwide Assurance (FWA).
- Through a FWA, an institution commits to HHS that it will comply with the requirements for the protection of human subjects found at 45 CFR 46.
  - This means that in order to receive HHS money, you comply with the Common Rule and its subparts!

What May "Being Covered by an FWA" Look Like?

- An institution can file its own FWA with OHRP, e.g., the primary awardee of the human subjects research.
- An institution may extend its FWA to cover a collaborating investigator who does not belong to an institution or belongs to an institution without a FWA.
- An institution with a FWA can recognize investigators from another institution as its own agents or employees for the research.
- See Extending an FWA to Cover Collaborating Investigators (2005)

The Single IRB Provision Applies

- Cooperative research requires single IRB review when:
  - There is HHS-supported or conducted nonexempt human subjects research involving more than one institution located in the US.
    - ✓ sIRB approval is required for the portion of the study taking place in the US.
    - ✓ Unless an exception under 45 CFR 46.114(b)(2) applies.
- Again, when there is a non-exempt human subjects research project, the activities of each cooperating institution need to be individually examined to determine if they are engaged.
  - To determine if the research project as a whole is non-exempt human subjects research, use our decision charts found at: Regulations and Policy Decision Charts

Additional Resources

- Engagement of Institutions in Human Subjects Research
- OHRP Guidance on when survey firms are engaged
- Information on FWAs
- Correspondence on Non-engaged Scenarios
- Watch the mini-tutorial on Institutional Engagement in Human Subjects Research.

Questions? Email:

ohrp@hhs.gov

Thank you!