

Determining Engagement – Tips and Tricks

Background

[OHRP Engagement of Institutions in Human Subject Research \(2008\)](#)

Although it is not always obvious, as part of every IRB application, the IRB is determining if their institution is engaged in the conduct of human subject research. This determination is not always documented as “engagement” unless the project is a multi-site research study.

The following areas are addressed in the document below:

[Engagement Tool](#)

[Engagement Decision Process](#)

[Community Member Engagement](#)

[Research Activity Examples to determine engagement](#)

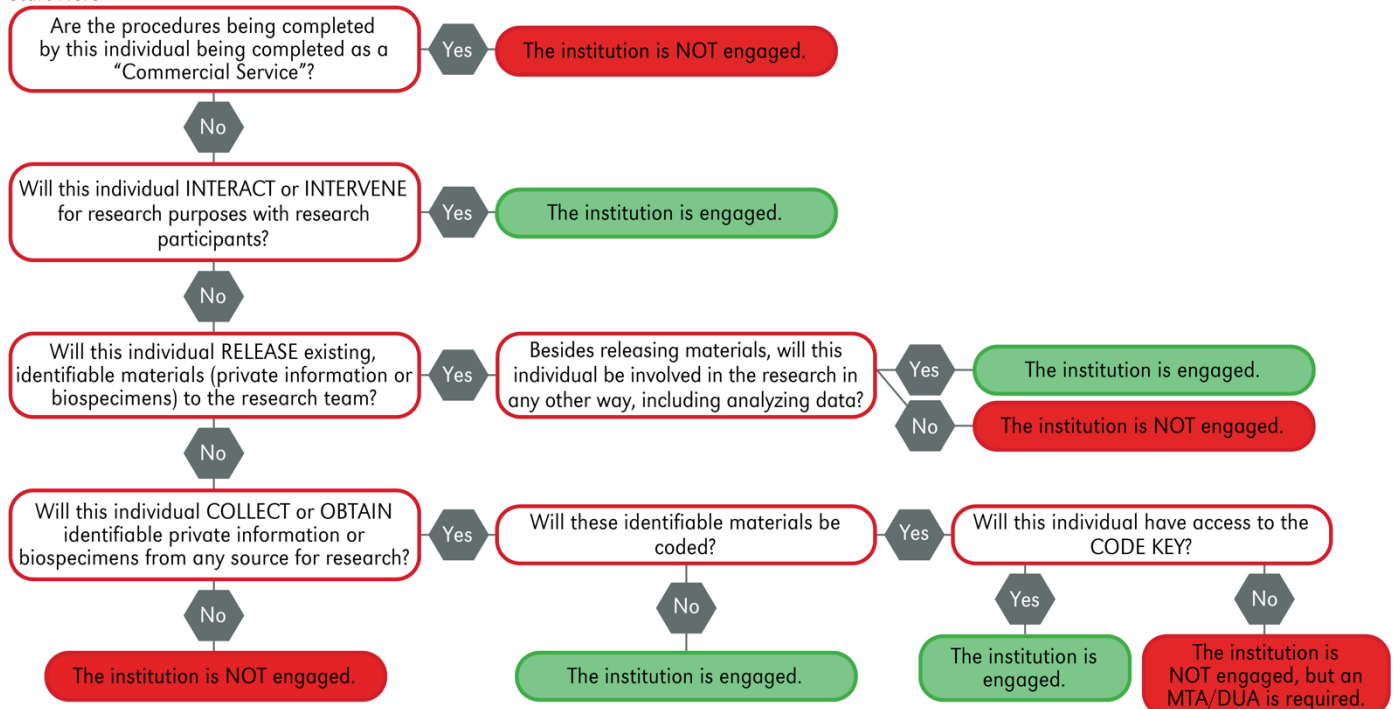
[Exempt Research with engaged community member processes](#)

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Engagement Tool

The OHRP guidance (linked above) provides information for IRBs to make determinations and provides tools for that decision making. The decision tool below is based on that guidance and is adapted from Ohio State University’s Engagement Determination Tool and the University of Nebraska-Lincoln’s guidance. Note that “individual” or “organization” could be substituted for “institution”.

Start Here



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Engagement Decision Process

Single-Center study – Researcher affiliated with institutional IRB

1. IRB determines if the project meets the definition of human subject research
 - a. If yes, the researcher and institution are engaged in the conduct of human subject research
 - b. If not human subject research, the IRB will issue a Non-Human Subject Research determination (NHSR). But, this also means the research and institution are not engaged in the conduct of human subject research (since it's not HSR!).

Multi-Center study – Researcher affiliated with institutional IRB

1. IRB determines if the researcher/institution are engaged in the conduct of human subject research. Factors include:
 - a. What are the local researchers doing?
 - b. Is the overall project human subject research?
 - c. What is the funding mechanism (Federal? Prime awardee?)
 - d. Some institutions have policies whereby a researcher may be engaged but the institution is not engaged, what is institutional policy?
2. If the other center(s) have an institutional IRB, that IRB will make the engagement decision for their own site.
 - a. If yes, site is involved, IRBs will determine if single IRB review process is appropriate or if they will review individually.
 - b. If other center determines their local PIs are not engaged, they will make an NHSR determination for their site.
3. If the other center(s) do not have an institutional IRB (e.g. community groups, businesses, individuals) the researcher's institutional IRB may act as the IRB or provide guidance for engagement determination.
 - a. If IRB acts as the IRB for other center(s) or individuals, the IRB's single IRB review process must be followed.

What does it mean if a community member is “engaged” in the conduct of human subject research?

It depends, of course. The basic answer is the same but depending on whether the research is determined to be Exempt or Non-exempt (minimal risk or greater than minimal risk) additional items are required.

If an individual, regardless of whether or not they are affiliated with an academic institution, is engaged in the conduct of human subject research, they must follow all federal regulations for human subject research.

- Human subject research training
- Conflict of Interest declarations
- Compliance with regulations and other applicable policies, including documentation requirements

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- A. Non-exempt research (minimal risk or greater than minimal risk, reviewed via an expedited review process or convened board review process)
 - a. IRB oversight is required
 - b. If not affiliated with an institutional IRB, an agreement between the individual or organization and an IRB is required before an IRB can provide the needed oversight.
 - c. Follow the IRB's single IRB review process. This may require additional processes or procedures.
- B. Exempt research
 - a. Federal regulations do not require IRB oversight, or an IRB determination, of exempt research; however, most academic institutions and hospitals do not permit researchers to make their own exempt determinations and thus require a submission to the IRB for exempt research.
 - b. Some IRBs will agree to the single IRB review process for exempt research, many will not and will utilize one of the methods described later in this document.

Recommendations – Due to the amount of work for the PI, community members, and IRB in cases of community member engagement, it is recommended that research activities and procedures be designed to avoid the engagement of non-affiliated individuals. This recommendation is not meant to diminish the importance or contribution of community members, it is purely meant to streamline and increase compliance with HSR regulations. “Engagement” according to the IRB does not need to impact the relationship or how the community members are described in non-IRB materials.

Engagement examples

(OHRP Engagement of Institutions in Human Subject Research (2008))

The following are examples provided in the OHRP guidance of situations where a person *is* engaged in the conduct of human subject research:

1. Prime awardee of federal funding if there are some aspects of human subject research even if not conducted by that organization or individual
2. Individuals who intervene for research purposes with human subjects
3. Individuals who interact for research purposes with human subjects
4. Individuals who obtain informed consent for research
5. Individuals who obtain identifiable private information for human subjects including, but not limited to:
 - a. Observing or recording private behavior
 - b. Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution
 - c. Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of investigators.

Not engaged examples (additional descriptions provided in OHRP guidance document)

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The following are examples where a person *is not* engaged in the conduct of human subject research:

1. Individuals who inform prospective subjects about the availability of the research
2. Individuals who provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators
3. Individuals who provide prospective subjects with information about contacting investigators for information or enrollment;
4. Individuals who seek or obtain the prospective subjects' permission for investigators to contact them
5. Institutions (e.g., schools, nursing homes, businesses) that permit use of their facilities for intervention or interaction with subjects by investigators from another institution
6. Institutions whose employees or agents **release** to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research

Exempt Research with Community Members Engaged in the conduct of research

IRBs will need to determine internal policies when requested to act as the IRB for unaffiliated research team members conducting exempt research. IRBs must determine if they will utilize a reliance process for exempt research, or will not act as the IRB for unaffiliated organizations or individuals.

No Reliance for Exempt Research Method

Federal regulations do not require IRB oversight, or determination, of exempt research; however, most academic institutions and hospitals do not permit researchers to make their own exempt determinations and thus require a submission to the IRB for exempt research. In this method, the IRB provides general guidance documentation, but the PI maintains responsibility for all oversight.

- The PI remains responsible for all research team members' conduct of research regardless of whether they are listed on the institutional IRB application.
- Once the IRB makes the exempt determination (per institutional policy), the unaffiliated organization or individual must document their own determination that they are conducting exempt human subject research. The IRB determination letter can be the basis for this documentation. For example, the individual/organization could create a memo describing the project and/or their role and noting their agreement with the exempt determination made by the XXXX IRB. They should document their willingness to abide by all federal regulations related to exempt research.
- The PI must document individuals have completed appropriate human subject research training and any conflicts of interest. The unaffiliated individuals can (and should) be included in all standard research documentation (e.g. delegation logs, staff training logs, etc).

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- Unaffiliated individuals/organizations should be listed in the IRB application as per IRB policy (e.g. not by name but noted as a group and that they are not covered by this IRB application and what their responsibilities are, listed by name and affiliation).

Reliance for Exempt or Non-Exempt Research Method

The IRB and researchers will follow the IRB's standard single IRB review process when the institutional IRB is the reviewing IRB. The IRB should have policies in place for the type of agreement they will use and who will provide the required sign off based on the agreement type. The PI has full responsibility for the conduct of research at the unaffiliated organization or by the unaffiliated individual. This will require more oversight than PIs may be accustomed to when working with other institutions that have an IRB or Human Research Protection Program. While the IRB will be responsible for IRB oversight, the PI maintains responsibility for the conduct of all research activities and should be prepared for the community members to not have the same amount of research experience as the academic research team members.

1. Types of Agreements that may be used by the IRB
 - a. Reliance Agreement
 - b. IAA
 - c. Individual/Collaborating Investigator Agreement
2. Human Subject Research Training
 - a. IRB should have policy on what will be accepted
 - b. CITI may not be appropriate, some institutions have own trainings, others will accept external trainings (e.g. CIRTification)
3. Conflict of Interest documentation
 - a. IRB should have process for confirming
 - b. If organization, as part of reliance agreement may be organization's responsibility
 - c. If individual, as part of agreement may include separate disclosure or just statement in agreement
 - d. IRB may decide unnecessary due to nature of project

FWA Considerations

The majority of community organizations do not have an FWA. IRBs need to consider what their requirements or processes are in those situations. An institution can enter into a reliance agreement with an institution who is not covered by an FWA, but the reliance agreement template that is used should include any necessary language as determined by legal counsel. It may not be appropriate to utilize an IAA in these cases, but that is something that must be reviewed and considered by legal counsel. IRBs should understand that there are methods for reliance with organizations that do not have FWAs and it is not necessary to add an organization to the institution's FWA. However, the individual institutional process for doing so is at the discretion of the regulatory and legal policies of the institution.