Engagement Determination Tool

Find out whether an organization or individual is engaged in non-exempt Ohio State human subjects research
**Background**

When external collaborators are engaged in non-exempt human subjects research conducted by Ohio State researchers, their activities are subject to IRB review and the requirements of human subjects research regulations. Not all collaborative research activities constitute engagement in human subjects research.

This interactive decision tree tool has been adapted from OHRP's guidance document “Engagement of Institutions in Human Subjects Research” (2008) to assist researchers in determining if the involvement of non-Ohio State collaborators engages them in human subjects research activities.

**How to Use This Tool**

Answer the questions that follow to determine if an external collaborator or institution is engaged in human subjects research that has been or will be reviewed by one of Ohio State’s IRBs.

- Proceed through the questions in order.
- If multiple external personnel will be involved with the project, use the decision tree *for each individual or institution separately*, beginning with Question 1.
- This document is not meant to provide guidance on whether Ohio State personnel are engaged in research conducted by other institutions.
- This document covers the most common collaborative research scenarios; however, there are others not included here. Contact ORRP at IRBAgreements@osu.edu for further guidance.
Question 1

Will the study be supported by federal funds awarded to an institution other than Ohio State (i.e., is Ohio State a sub-recipient of a federal grant)?

Yes

No
Q: Is Ohio State a sub-recipient of federal funding?
A: Yes

Additional Info: The prime awardee institution must provide an IRB approval letter for the study, or we must execute an IRB Authorization Agreement (IAA) to manage the collaboration.

Click [here](#) for more info about IRB oversight.
Question 2

Will external personnel OBTAIN CONSENT from human subjects for the study?

Yes

No

Back
Q: Will external personnel obtain consent for this study?
A: Yes

External personnel are ENGAGED in Ohio State research.

Additional Info: The activities performed by external collaborators require IRB oversight.

Click here for more information and next steps.
Will external personnel INTERVENE with research participants by performing invasive or non-invasive procedures, or by manipulating subjects’ environment?

Examples of interventions:
• Administering a study drug
• Drawing blood
• Using a virtual reality device
• Conducting an exercise program
In order to be considered a commercial service, all of the following conditions must be met:

• The services performed will not merit professional recognition or publication privileges
• The services performed are typically performed by those institutions for non-research purposes; and
• The institution’s employees or agents will not administer any study intervention being tested or evaluated under the protocol

**Example:** Study hires a commercial lab service to perform blood draws on subjects who do not reside near Ohio State and send the specimens to the research team.
Q: Will external personnel perform interventions for research?  
A: Yes

Q: Do those interventions meet the definition of a commercial service?  
A: No

Additional Info: The activities performed by external collaborators require IRB oversight.

Click [here](#) for more information and next steps.
Will external personnel interact for research purposes with any human subjects for the research?

Examples of interactions:
• Conducting interviews
• Administering questionnaires
• Engaging in protocol-dictated communication (e.g., follow-up phone calls, recruitment conversations)
If external personnel will INTERACT with participants, are their activities limited to the following?

- Informing prospective subjects about the availability of the research;
- Providing prospective subjects with information about the research (which may include a copy of the relevant consent document or other IRB-approved materials) without acting as a representative of the investigators;
- Providing subjects with information about how to contact investigators for more information or enrollment; OR
- Seeking or obtaining prospective subjects’ permission for investigators to contact them and providing contact information to the study team.
In order to be considered a commercial service, all of the following conditions must be met:

• The services performed will not merit professional recognition or publication privileges
• The services performed are typically performed by those institutions for non-research purposes; and
• The institution’s employees or agents will not administer any study intervention being tested or evaluated under the protocol

Example: Investigators hire a transcription service to transcribe research study interviews.
Q: Will external personnel interact with subjects for research purposes?
A: Yes

Q: Are their interactions limited to providing information about the study without acting as a representative of the investigators?
A: No

Q: Do their interactions meet the definition of a commercial service?
A: No

External personnel are **ENGAGED** in Ohio State research.

Additional Info: The activities performed by external collaborators require IRB oversight.

Click [here](#) for more information and next steps.
Will external personnel RELEASE existing, identifiable materials (private information or biospecimens) to the Ohio State study team for use in the study?

Examples:
- Schools that release identifiable test scores
- Medical centers that release identifiable human biological specimens

Yes
No

Back
Besides releasing materials, will the external personnel be involved in the Ohio State research in any other way, including but not limited to analyzing data or receiving authorship credit/professional recognition?

Yes

No

Back
Q: Will external personnel RELEASE identifiable materials to the Ohio State study team?
A: Yes

Q: Will the personnel be involved in the research in any other way?
A: Yes

External personnel are ENGAGED in Ohio State research.

Additional Info: The activities performed by external collaborators require IRB oversight.

Click here for more information and next steps.
Q: Will external personnel RELEASE identifiable materials to the Ohio State study team?
A: Yes

Q: Will the personnel be involved in the research in any other way?
A: No

External personnel are NOT ENGAGED in Ohio State research.

**ACTION REQUIRED:** The study team must execute a Material Transfer Agreement (MTA) for specimens and/or a Data Use Agreement (DUA) for data through the Corporate Engagement Office (https://ceo.osu.edu/cdas-mtas-and-duas) to manage the transfer of materials between institutions. This document does not need to be submitted for IRB review.
Will external personnel COLLECT or OBTAIN identifiable* materials (private information or biospecimens) from any source—including from the Ohio State study team—for the research?

*In general, OHRP considers private information or specimens to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Examples include:

• Observing or recording private behavior
• Using, studying, or analyzing identifiable private data or biospecimens provided by another institution
• Using, studying, or analyzing identifiable private data or biospecimens already in the possession of the investigators
Q: Will external personnel COLLECT or OBTAIN identifiable materials from any source?
A: No

Additional Info: No additional action is required at this time; however, if the activities performed by external personnel change, engagement in human subjects research should be reassessed.
Will the identifiable materials be CODED?

Yes

No

Coded means:

Direct personal identifiers have been removed from materials and replaced with words, letters, figures, or symbols for purposes of protecting the identity of the source(s), but the original identifiers are retained in such a way that they can be traced back to the source(s) by someone with the code key.
Q: Will external personnel COLLECT or OBTAIN identifiable materials?
A: Yes

Q: Will the identifiable materials be CODED?
A: No

External personnel are ENGAGED in Ohio State research.

Additional Info: The activities performed by external collaborators require IRB oversight.

Click here for more information and next steps.
Question 6

Will the identifiable materials be CODED?

Yes  No

If materials will be coded, will external personnel have access to the CODE KEY?

Yes  No

Back
Q: Will external personnel COLLECT or OBTAIN identifiable materials?
A: Yes

Q: Will the identifiable materials be CODED?
A: Yes

Q: Will external personnel have access to the CODE KEY?
A: Yes

External personnel are ENGAGED in Ohio State research.

Additional Info: The activities performed by external collaborators require IRB oversight.

Click here for more information and next steps.
Q: Will external personnel COLLECT or OBTAIN identifiable materials?
A: Yes

Q: Will the identifiable materials be CODED?
A: Yes

Q: Will external personnel have access to the CODE KEY?
A: No

External personnel are NOT ENGAGED in Ohio State research.

These activities do not constitute engagement provided that an agreement is in place prohibiting the release of the code key.

The study team must execute a Material Transfer Agreement (MTA) for specimens and/or a Data Use Agreement (DUA) for data through the Corporate Engagement Office (https://ceo.osu.edu/cdas-mtas-and-duas) to manage the transfer of materials between institutions.

The MTA/DUA must stipulate the following:

• The code key will not be shared with the external collaborator(s)
• The external collaborator(s) will not attempt to ascertain the identity of the individuals whose materials they receive
ENGAGEMENT DETERMINATION

Based on the responses provided, the external personnel ARE ENGAGED in the Ohio State research.

When external personnel are engaged in Ohio State research, their activities require IRB oversight. This can be achieved in one of three ways:

1. An external institution’s IRB reviews and approves the external collaborator’s involvement in the research project;

2. An external institution cedes review of the external collaborator’s activities to Ohio State’s IRB (i.e., Ohio State serves as the IRB of Record) via an IRB Authorization Agreement; OR

3. The external investigator is “covered” by Ohio State’s Federalwide Assurance via an Individual Investigator Agreement (available only when the collaborator is not an agent of or acting on behalf of an external institution.

Contact ORRP at IRBAgreements@osu.edu for assistance in determining which method of IRB oversight is appropriate for your collaborative research project.
ENGAGEMENT DETERMINATION

Based on the responses provided, the external personnel ARE ENGAGED in the Ohio State research.

When external personnel are engaged in Ohio State research, their activities require IRB oversight. This can be achieved in one of three ways:

1. An **external institution's IRB reviews and approves** the external collaborator’s involvement in the research project;
2. An external institution cedes review of the external collaborator’s activities to Ohio State’s IRB (i.e., Ohio State serves as the IRB of Record) via an **IRB Authorization Agreement**; OR
3. The external investigator is “covered” by Ohio State’s Federalwide Assurance via an **Individual Investigator Agreement** (available only when the collaborator is not an agent of or acting on behalf of an external institution.

Contact ORRP at [IRBAgreements@osu.edu](mailto:IRBAgreements@osu.edu) for assistance in determining which method of IRB oversight is appropriate for your collaborative research project.

ADDITIONAL ACTION NEEDED: Your responses indicated data or biological specimens may be shared between external personnel and Ohio State for this project.

The study team must execute a **Material Transfer Agreement (MTA) for specimens and/or a Data Use Agreement (DUA) for data** through the Corporate Engagement Office ([https://ceo.osu.edu/cdas-mtas-and-duas](https://ceo.osu.edu/cdas-mtas-and-duas)) to manage the transfer of materials between institutions. This document does not need to be submitted for IRB review.