

Research Integrity Office

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Collaborations with Non-OHSU
Institutions and Investigators

Introduction

When conducting human subjects research among multiple organizations, it is necessary to verify that all who are engaged in the research have the appropriate assurances and IRB review mechanisms in place to meet the applicable regulatory oversight requirements. This is to ensure that investigators who interact with a study subject or the subject's personal information for research purposes are adequately educated about research protections and also that each institution is knowledgeable about their requirements as a responsible party in the conduct of research. As such, research collaborations may necessitate additional administrative requirements.

In determining the applicable regulatory and administrative requirements for a collaborative research project, consider the following (*click the question for more detailed information*):

1. Which institutions are "engaged" in human subjects research per federal definitions, and to what extent?
2. Which institutions must have a Federal-Wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP)?
3. Which institutions must provide IRB review for the project? How will each institution's IRB review requirements be met? Who handles reportable events?
4. What steps must be taken when OHSU provides IRB oversight for non-OHSU investigators regarding Conflict of Interest in Research regulations and training in the responsible conduct of research?
5. What protections must be in place when data and/or specimens are shared across institutions?

Note that International collaborations involve additional considerations. See the International Supplement and "WORKSHEET HRP-410: Additional Criteria International" for more information.

1. Engagement in Research

When OHSU is involved in a research project with a non-OHSU institution or investigator(s), it is necessary to determine if each institution or investigator is engaged in research in order to determine what IRB oversight requirements apply. The IRB uses "WORKSHEET HRP-422: Engagement" to determine whether the institution is engaged in research as defined by federal regulatory authorities.

Generally, an institution/investigator is engaged in research when its employees or agents obtain:

- Data about research subjects through intervention or interaction with them;

- Identifiable private information about research subjects; or
- Informed consent of human subjects for research.

An institution may also be considered engaged in research if it receives financial support for the conduct of the research, even when activities involving human subjects are conducted elsewhere.

Not sure if your project engages OHSU in research? Submit a Request for Determination in the eIRB. For complex collaborative projects, we recommend contacting the IRB early in the development process for guidance.

2. Federal-Wide Assurance (for federally funded projects)

When a collaborating institution/investigator meets the regulatory definition of being engaged in OHSU human subjects research and the project is federally funded, one of the following is required:

- The institution must be covered under its own FWA;
- The individual investigator(s) engaged in the research must sign an Individual Investigator Agreement (IIA) to be covered under OHSU's FWA; or
- The individual investigator(s) must have approval as a Visiting Scientist or another type of affiliation with OHSU that covers his/her work under OHSU's FWA.

The IRQ contains questions and instructions to help determine FWA requirements for other institutions and investigators.

To submit an IIA from an outside investigator, upload the signed agreement to the eIRB submission. The agreement is available on our IRB website. Note that the OHSU PI is responsible for supervising collaborative research activities performed by individual investigators under IIAs.

3. IRB Review Responsibilities

Generally, each institution engaged in a research project must ensure IRB review for at least the portion of the research project in which it is engaged. However, in some cases, institutions may rely on other IRBs to review research on their behalf.

OHSU will consider relying on another IRB or providing oversight on behalf of another institution on a case-by-case basis. Factors we will consider include:

- Risk level. Reliance on an outside IRB is generally permitted for minimal risk research but is not usually allowed if the research is greater than minimal risk.
- Local context. The reviewing IRB must be knowledgeable about local context considerations for the relying institution(s).
- Nature of OHSU involvement. If OHSU is the coordinating center or lead site for a study, OHSU generally will not rely on another IRB.

If a project involves an individual investigator who is not acting on behalf of another institution, the investigator will need to sign an Individual Investigator Agreement (IIA) to be covered by OHSU's IRB review, even if the study is not federally funded.

To request that OHSU rely on the review of another IRB:

- Create a new study submission in the eIRB and select the “Request Waiver of Oversight to Another IRB” option on the first page of the questionnaire.
- Upload the signed PPQ, protocol, Brief Project Description, consent forms (if applicable), IRB approval memo from the reviewing institution (if available), and any other documents that support the reliance request.
- Upload the “IRB Authorization Agreement (IAA) – OHSU Waiving Oversight” for signatures by the OHSU IRB Chair and the relevant official of the other institution. If there is a Memorandum of Understanding (MOU) or similar agreement between the institutions that dictates the terms of reliance, that agreement may take the place of an IAA.
- Ensure compliance with any applicable policies and procedures of the reviewing IRB.
- If approved by the OHSU IRB, the reliance is effective upon approval or upon OHSU’s receipt of the fully executed IAA from the institution providing oversight, whichever is later.
- Researchers will be notified via the eIRB when ORIO staff has uploaded the fully executed IAA to the study documents.
- The approved submission will remain active in the eIRB. The review category will be “waived.”
- No human subjects research may take place at OHSU until the reviewing IRB has approved the study.
- Documentation of IRB approval by the reviewing institution must be provided to the OHSU IRB when available. Submit this as a modification if it was not available at the time of initial approval.
- ***Unless otherwise specified in a reliance agreement, investigators are still required to submit Unanticipated Problems and Protocol Deviations to the OHSU IRB per policy.*** Additionally, investigators should consult the reviewing IRB for its reporting requirements.

To request that OHSU provide IRB oversight for another institution:

- Submit a full new study application in the eIRB and upload all required documents.
- Ensure that the institutions relying on the OHSU IRB are listed on the Non-OHSU Study Activities page of the IRQ.
- Upload an IRB Authorization Agreement (IAA) for the relying institution, signed by the appropriate institutional official. You may use the “IRB Authorization Agreement (IAA) – OHSU Accepting Oversight.” If there is a Memorandum of Understanding (MOU) or similar agreement between the institutions that dictates the terms of reliance, that agreement may take the place of an IAA.
- An institution wishing to rely on the OHSU IRB for review of a federally funded study must be covered under an FWA. An IAA or other IRB reliance agreement does not extend OHSU’s FWA to cover the relying institution.

If each institution is providing its own IRB review, note the following:

- If one institution is the “lead site” or coordinating center, that institution should typically conduct the first IRB review, and proof of that approval should be shared with the collaborators. Once sub-sites have obtained IRB approval, proof of that approval should be submitted to the lead site or coordinating center.
- When two or more IRBs are reviewing a project, the investigators are responsible for relaying communications between the reviewing IRBs, including approvals, required changes to the protocol or study documents, etc.

4. Requirements for Non-OHSU Investigators

Non-OHSU investigators engaged in OHSU research must satisfy all applicable Conflict of Interest in Research disclosure requirements and complete required training in the responsible conduct of research. If the non-OHSU investigator's involvement in the project will be reviewed by another IRB, such as when each institution provides its own IRB review, review by the non-OHSU investigator's IRB is generally sufficient to ensure compliance. For federally funded studies, the investigator must be covered by an FWA.

If the non-OHSU investigator's involvement in the project will be reviewed by the OHSU IRB, such as when an investigator has signed an Individual Investigator Agreement (IIA) or the investigator's institution is relying on the review of the OHSU IRB under an IRB Authorization Agreement (IAA), the investigator must submit additional evidence of compliance with CoIR and training requirements.

The preferred method of ensuring compliance is for each investigator subject to OHSU IRB oversight to register in the eIRB system and be listed as a sub-investigator or research staff on the eIRB submission.

- To register in the eIRB, complete the [Account Registration Form](#). A separate link for non-OHSU employees is located at the top of the form.
- The Personnel Selection form within the IRQ will ask specific questions for non-OHSU Personnel that will guide investigators on how to comply with OHSU requirements for CoIR and RCR.

If registering all non-OHSU investigators and research staff in the eIRB is not feasible, the PI may choose to submit a list of all investigators and staff, along with documentation of compliance with CoIR and RCR requirements for each individual.

- An example tracking sheet is available on the Policies and Forms website.
- Please contact the IRB for questions regarding the acceptability of CoIR disclosures and RCR training programs from other institutions.

5. Sharing of Data and/or Specimens

Transfer of data and/or specimens between institutions must comply with all applicable laws, regulations, and policies, including the use of material transfer agreements and following HIPAA regulations.

Key points to consider:

- When transferring biological specimens from OHSU to another institution, a material transfer agreement (MTA) is required. Contact the Office of [Technology Transfer and Business Development](#) (TTBD) for assistance.
- When sharing Protected Health Information (PHI) with collaborating institutions or investigators, compliance with all applicable HIPAA regulations is required.
- A HIPAA Research Authorization or an approved waiver or alteration of authorization is required if OHSU PHI will be used or disclosed for research purposes.
- If OHSU is relying on the review of another IRB:
 - The reviewing IRB may approve a waiver or alteration of authorization that covers the entire study. In this case, an additional request for a waiver or alteration need not be submitted to the OHSU IRB.

- A HIPAA Research Authorization from the reviewing institution may also be used at OHSU if it is appropriate for the study and it specifically describes the use and disclosure of PHI by OHSU.
- If available, submit HIPAA authorizations or an approved waiver or alteration of authorization from the reviewing institution with your Request for a Waiver of Oversight in the eIRB.
- If the reviewing institution does not ensure compliance with the HIPAA Privacy Rule with regard to the use and/or disclosure of PHI by OHSU, submit the necessary OHSU HIPAA documents (authorization or waiver/alteration form) with your Request for a Waiver of Oversight in the eIRB.
- Regardless of which institution approves a waiver of authorization, OHSU must account for its own disclosures of PHI pursuant to the waiver.
- If the PHI being used or disclosed is a Limited Data Set, a Data Use Agreement (DUA) may be executed between OHSU and the collaborating institution.
- If a collaborating institution is acting as a Business Associate, a Business Associate Agreement (BAA) is required.
- Refer to the [HIPAA and Research](#) website for more information.

Additional Resources

[HIPAA and Research](#)

[Visiting Scientists & Other Affiliates](#)

[Conflict of Interest in Research Committee](#)

[Big Brain](#)

[Technology Transfer and Business Development](#)

[eIRB](#)