

Human Research Protection Program Policies & Procedures



Collaborations with Non-OHSU Institutions and Investigators

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Research Integrity Office
Mail code L106-RI
Portland, Oregon 97239-3098
Phone: 503-494-7887
Fax: 503-346-6808

Background:

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 necessitate additional administrative requirements.

In determining the applicable regulatory and administrative requirements for a collaborative research project, points to consider include the following:

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 OHRP?
3. Which institutions must provide IRB review for the project? How will each institution's IRB review requirements be met?
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?

Scope:

This policy describes special considerations for certain types of collaborations between OHSU and a non-OHSU institution or investigator(s). This includes international collaborations; however, see the [International Research](#) policy for additional considerations. This collaborations policy does not specifically apply to multi-site studies, cooperative group studies, or the sharing of data and/or specimens stored in a repository.

I. Policy:

- A. **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. OHSU determines engagement in research according to the IRB's Engagement in

Research policy and applicable guidance from the Office of Human Research Protections (OHRP) (see Authority section below).

- B. Federal-Wide Assurance.** When a collaborating institution/investigator meets the regulatory definition of being engaged in OHSU human subjects research and the project is federally funded, OHSU requires one of the following:
 - 1. The institution must be covered under its own Federal-Wide Assurance (FWA); or
 - 2. The individual investigators engaged in the research must have an agreement (Individual Investigator Agreement) to be covered under the FWA of another institution (usually OHSU).
- C. IRB Review.**
 - 1. Each institution engaged in a research project that is covered under the institution's FWA must ensure IRB review for at least the portion of the research project in which it is engaged.
 - 2. OHSU will determine appropriate IRB review arrangements with collaborating institutions on a case by case basis, considering the nature of OHSU's involvement, the possible risks to subjects, how the study is funded, and any other relevant factors. IRB review of collaborative human subjects research may occur in the following ways:
 - a. Each institution conducts its own IRB review;
 - b. OHSU agrees to rely on the review of the IRB of a collaborating institution;
 - c. A collaborating institution agrees to rely on the review of the OHSU IRB; or
 - d. An OHSU-approved third-party IRB provides review.
- D. Oversight 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.
- E. 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.

II. Procedure:

- A. Engagement in Research (see also [Engagement in Research](#) policy)**
 - 1. Generally, an institution/investigator is engaged in research upon obtaining:
 - a. Data about research subjects through intervention or interaction with them;
 - b. Identifiable private information about research subjects; or
 - c. Informed consent of human subjects for research.
 - 2. 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.
 - 3. When there is a question as to whether OHSU is engaged in a collaborative research project, investigators may submit a Request for Determination in the eIRB.
 - 4. For complex collaborative projects, it is recommended that investigators contact the IRB early in the development process for guidance.
- B. Federal-Wide Assurance (FWA) Requirements (see also [FWA](#) policy)**
 - 1. Institutions engaged in federally funded human subjects research generally must have an FWA on file with the Office for Human Research Protections (OHRP). OHSU

- will verify that other institutions engaged in federally funded OHSU research projects have an FWA.
2. If a collaborating institution on a federally funded project does not have an FWA, the individual non-OHSU investigators engaged in the research may be covered under OHSU's FWA by submitting an [Individual Investigator Agreement \(IIA\)](#).
 - a. Signed IIAs must be submitted to the OHSU IRB with the eIRB application.
 - b. The OHSU PI is responsible for supervising the collaborative research activities performed by individual investigators under IIAs.
 - c. If the institution frequently conducts federally funded human subjects research, the OHSU IRB may require that it obtain an FWA before the OHSU IRB will approve the research.
 3. If a collaborating investigator is involved in an OHSU research project independently, and is not acting on behalf of another institution, that investigator may be covered under OHSU's FWA in one of the following ways:
 - a. By submitting an [Individual Investigator Agreement \(IIA\)](#) as above; or
 - b. The non-OHSU investigator may receive approval as a Visiting Scientist or have another type of affiliation with OHSU that covers his/her work under OHSU's FWA.

C. IRB Review

1. **Determine requirements for IRB review.**
 - a. Each institution engaged in a human subjects research project that is covered by an FWA must ensure IRB review of at least the portion of the project in which the institution is engaged.
 - b. Research projects not covered under an FWA may still require IRB review under the collaborating institution's policies.
 - c. OHSU policy requires IRB review of all research activities in which OHSU is engaged, regardless of funding source.
 - d. An institution may satisfy its IRB review requirements by:
 - i. Conducting its own IRB review; or
 - ii. Entering into an IRB Authorization Agreement (IAA) or other agreement to rely on the review of another IRB.
2. **Determine whether reliance on a single IRB is appropriate.**
 - a. The OHSU IRB will consider relying on another IRB or accepting oversight on behalf of another IRB on a case-by-case basis.
 - b. Reliance is generally permitted for minimal risk research but is not usually allowed if the research is greater than minimal risk.
 - c. The reviewing IRB must be knowledgeable about local context considerations for the relying institution(s). See [Knowledge of Local Context](#) policy for details.
 - d. When OHSU is the coordinating center for a study, OHSU generally will not rely on another IRB.
3. **Requesting that OHSU rely on the review of another IRB:**
 - a. Create a new study submission in the eIRB. On the first page of the Initial Review Questionnaire (IRQ), select the option entitled, "Request Waiver of Oversight to Another IRB."

- b. Upload the signed PPQ, protocol, lay language summary, consent forms (if applicable), IRB approval memo from the reviewing institution (if available), and any other documents that support the reliance request.
 - c. 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.
 - d. Ensure compliance with any applicable policies and procedures of the reviewing IRB.
 - e. 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.
 - i. Researchers will be notified via the eIRB when ORIO staff has uploaded the fully executed IAA to the study documents.
 - ii. The approved submission will remain active in the eIRB. The review category will be "waived."
 - f. No human subjects research may take place at OHSU until the reviewing IRB has approved the study.
 - g. 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.
- 4. Requesting that OHSU provide IRB oversight for another institution:**
- a. Submit a full new study application in the eIRB and upload all required documents.
 - b. Ensure that the institutions relying on the OHSU IRB are listed on the Non-OHSU Study Activities page of the IRQ.
 - c. Upload an IRB Authorization Agreement (IAA) for the relying institution, signed by the appropriate institutional official. You may use the [IRB Authorization Agreement – 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.
 - d. 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.
- 5. When each institution provides its own IRB review:**
- a. 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.
 - b. 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.

D. Requirements for Non-OHSU Investigators

1. OHSU requires evidence of compliance with federal Conflict of Interest in Research (CoIR) disclosure requirements and appropriate training in the Responsible Conduct of Research (RCR) for each investigator who is engaged in OHSU research.
2. **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, proof of review from the non-OHSU investigator's IRB is generally sufficient evidence of compliance. For federally funded studies, the investigator must be covered by an FWA.
3. **If the non-OHSU investigator's involvement in the project will be reviewed by the OHSU IRB**, such as when an investigator is covered by OHSU's FWA through 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.
 - a. The **preferred method** of ensuring compliance is for each investigator to register in the eIRB system and be listed as a sub-investigator or research staff on the eIRB submission.
 - i. 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.
 - ii. 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.
 - b. 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.
 - i. [Click here for an example tracking sheet for non-OHSU investigators](#).
 - ii. Please contact the IRB for questions regarding the acceptability of CoIR disclosures and RCR training programs from other institutions.

E. Sharing Data and/or Specimens

1. 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.
2. When sharing Protected Health Information (PHI) with collaborating institutions or investigators, compliance with all applicable HIPAA regulations is required.
 - a. 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.
 - b. If OHSU is relying on the review of another IRB:
 - i. 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.
 - ii. 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.

- iii. 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.
- iv. 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.
- v. Regardless of which institution approves a waiver of authorization, OHSU must account for its own disclosures of PHI pursuant to the waiver.
- c. 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.
- d. If a collaborating institution is acting as a Business Associate, a Business Associate Agreement (BAA) is required.
- e. Refer to the [HIPAA and Research](#) website for more information.

III. Authority

45 CFR 46.103(a) requires that each institution engaged in research subject to 45 CFR 46 must provide assurance that it will comply with the requirements of that section.

[OHRP Terms of the Federal-Wide Assurance for the Protection of Human Subjects \(FWA\)](#)

Guidance:

OHRP Guidance on [Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement](#) (January 31, 2005)

OHRP Guidance on [Engagement of Institutions in Human Subjects Research](#) (October 16, 2008)

OHRP Correspondence on ["Non-engaged" Scenarios](#) (September 22, 2011)

IV. Definitions

Institution: Any public or private entity or agency (including federal, state, and other agencies, as well as community organizations) and agents of that entity.

Engaged in Research: Obtaining: (1) data through intervention or interaction with human subjects for research purposes; (2) identifiable private information about a human subject; or (3) informed consent of human subjects for participation in research. An institution may also be considered "engaged" if it receives financial support for the research.

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. Coded information is considered individually identifiable if a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Federal-Wide Assurance (FWA): An institution's formally documented assurance to the federal government that it will comply with the Federal Policy for the Protection of Human Subjects (known as the "Common Rule") in all federally funded or supported human subjects research activities.

Individual Investigator Agreement (IIA): An agreement that may be used by an institution engaged in research to extend its FWA to a collaborating investigator not covered by another institution's FWA.

IRB Authorization Agreement (IAA): An agreement between two institutions to rely on one of their IRBs for oversight of a collaborative research project in which both are engaged.

Memorandum of Understanding (MOU): An agreement that governs the conduct of collaborative research between two or more institutions. May address provisions for relying on each other for IRB review.

Material Transfer Agreement (MTA): A contract that addresses the physical transfer and ownership of specimens from one entity to another.

Protected Health Information (PHI): Health information that is individually identifiable. HIPAA delineates [18 identifiers](#). Examples include names, addresses, dates of service, and medical record numbers.

Coordinating Center: A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.

V. Additional Resources

OHSU HRPP Policies & Procedures:

- [Engagement in Research](#)
- [Federal-Wide Assurance](#)
- [HIPAA and Research](#)
- [Coordinating Centers](#)
- [International Research](#)
- [Knowledge of Local Context](#)

OHSU Institutional Policy: [Visiting Scientists & Other Affiliates](#)

IRB Forms:

- [Individual Investigator Agreement \(IIA\)](#)
- [IRB Authorization Agreement \(IAA\) – OHSU Waiving Oversight](#)
- [IRB Authorization Agreement \(IAA\) – OHSU Accepting Oversight](#)
- [Collaborations - Example Tracking Sheet for Non-OHSU Investigators](#)
- [Non-OHSU Researcher Decision Tree](#)

Helpful Websites:

- [Conflict of Interest in Research Committee](#)
- [Big Brain](#)
- [Technology Transfer and Business Development](#)
- [eIRB](#)