PI Eligibility and Research Collaborations

Andrea Johnson, JD, Regulatory Specialist
Kara Drolet, PhD, Associate Director
Agenda

• PI Eligibility

• Collaborations
  – Engagement in Research
  – Federal-Wide Assurance (FWA)
  – IRB Review
    • Reliance
    • Local Context
  – Sharing of Data and Specimens
  – Non-OHSU Researchers – with Kara Drolet
    • Conflict of Interest in Research Requirements
    • Responsible Conduct of Research Training
Who can be a Principal Investigator (PI) on an IRB protocol?

- **Faculty members** of OHSU or PVAMC with a **paid academic appointment** (e.g. clinical professor, assistant professor, associate professor, professor, assistant scientist, associate scientist, senior scientist, or instructor).

- Must be eligible at the time of protocol submission.

- Students and Trainees MAY NOT be PIs.

- Refer to the [IRB/IBC/IACUC PI Eligibility Policy](#) for more information.
Exceptions: PIs with Special Permission

The following individuals may be approved by the IRB as a PI on a case by case basis:

– **Other OHSU employees** (including licensed medical professionals when project activities are within scope of licensure/practice)

– OHSU faculty with **affiliated appointments** (e.g. emeritus faculty, adjunct faculty)
Exceptions: PIs with Special Permission (cont.)

• Chair or institute director must submit a letter of support. What should the letter say?
  – State why the individual is qualified to be a PI.
  – State that the chair or institute director will assume administrative responsibilities, including financial matters.

• The chair or institute director DOES NOT need to be listed as a Co-Investigator on the submission.
What if I’m the PI on my grant?

- May or may not be eligible to be a PI on the IRB submission (e.g. students).
- The PI on the grant and the PI on the eIRB application do not need to be the same person.
- Refer to the RGC PI Eligibility Policy for more information on who may be a PI on a grant.
Agenda

• Collaborations
  – Engagement in Research
  – Federal-Wide Assurance (FWA)
  – IRB Review
    • Reliance
    • Local Context
  – Sharing of Data and Specimens
  – Non-OHSU Researchers – Kara Drolet
    • Conflict of Interest in Research Requirements
    • Responsible Conduct of Research Training
Collaborations: What do you mean?

• Collaborations have little defining criteria and may include:
  – Partnerships with other institutions;
  – Multi-site clinical trials;
  – Cooperative group studies;
  – International studies;
  – Partnerships with community clinics;
  – Sharing data/specimens across institutions; and
  – Many others...

• Requirements depend on the nature of the research and the extent of OHSU’s involvement.

• Multi-site, cooperative group, and similar studies are generally straightforward.
Key Considerations for Collaborative Research

- Who is **engaged** in research?
- Who must have a **Federal-Wide Assurance (FWA)**?
- Who must conduct **IRB review**? Are there opportunities for single IRB review?
- Am I going to **share** identifiable data or specimens with someone at another institution?
- What requirements apply to **non-OHSU investigators**? Who do I need to list on the eIRB submission?
Who is engaged in research?

• “Engaged in Research” generally means obtaining:
  – Data about subjects through *intervention or interaction* with them;
  – **Identifiable private information** about subjects; or
  – **The informed consent** of subjects.

• An institution is engaged in research if its *employees or agents* do any of the above. An employee or agent:
  – Acts on behalf of the institution;
  – Exercises institutional authority or responsibility; or
  – Performs institutionally designated activities.
Examples: Engaged

- **Money**: Institution receives a federal grant.
- **Procedures**: Investigators implant a study device at the institution.
- **Intervention**: Investigators at the institution manipulate subjects’ environment.
- **Interaction**: Investigators ask survey questions.
- **Identifiable Private Information**: Investigators obtain identifiable medical records data for research.
- **Informed Consent**: Investigators conduct the informed consent discussion for a research study.
Examples: NOT Engaged

- **Commercial or Medical Services:** Institution takes an X-ray and provides the results to outside investigators, as long as the X-ray is not being “tested or evaluated” under the protocol.

- **Providing Information:** Doctor informs patient of a study and provides a study brochure and copy of informed consent document.

- **Only Releasing Existing Data/Specimens:** Doctor sends stored blood samples to a colleague at another institution for a research project.

- **De-Identified or Strictly Coded:** Investigator obtains de-identified data from a colleague, or coded data if the colleague agrees in writing not to release the key to the code.
OHSU and Institution X are both engaged in research. Now what?

- Federal-Wide Assurance (FWA): Who has one and who needs one?
- An FWA is an institution’s formally documented assurance to the federal government that it will comply with the Common Rule in all **federally funded** human subjects research activities.
When does an institution need an FWA?

• Generally, when it is engaged in federally funded, non-exempt human subjects research.

• What if Institution X doesn’t have an FWA?
  – Federally funded: Two options.
    • Get an FWA
    • Individual Investigator Agreement (IIA) – covers the investigators under OHSU’s FWA.
  – Non-federally funded: FWA not required.

• Note: International institutions can get an FWA!

• Contact the IRB with questions.
What does an FWA have to do with IRB review?

- **FWA Terms of Assurance** require IRB review.
- “Checking the box” extends an FWA to cover all research, regardless of funding.
- OHSU has done this.
Who must ensure IRB review?

- OHSU (regardless of funding source – we’ve checked the box)
- Institution X if:
  - Federally funded and FWA; or
  - FWA and checked the box; or
  - Policies and procedures otherwise require it

Institution X is **not** responsible IRB review if:
- No FWA (including when investigators have IIAs with OHSU); or
- Not federally funded and unchecked the box

IRB Review Required
(plus other requirements, such as HIPAA and CoIR)

www.ohsu.edu/researchintegrity
Does every institution that is engaged in a research project have to do its own IRB review?

• Not necessarily - RELIANCE
• Decision to rely on another IRB is made on a case by case basis.
• OHSU may consider relying on another IRB if:
  – OHSU is not the coordinating center;
  – The research is minimal risk (some exceptions exist for greater than minimal risk research); and
  – It is appropriate in light of local context considerations.
• Submit a Request for a Waiver of Oversight to Another IRB in the eIRB.
• For complex projects, contact the IRB.
What are “local context considerations?”

• General characteristics of the potential subject population in a particular area:
  – Attitudes toward research
  – Cultural groups
  – Vulnerable populations
  – Social structure
  – Etc.

• Reviewing IRB must have sufficient expertise to evaluate local context.

• Particularly important in international collaborations. See the International Research policy for more details.
What must be in place for one IRB to rely on the review of another?

• Memorandum of Understanding (MOU)
  – Long-term agreement between institutions
  – Addresses terms of IRB reliance across multiple studies
• For complex projects or situations where two institutions are expected to collaborate often, contact the IRB.
## Review IIAs v. IAAs: What’s the difference?

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Covers a single investigator (including an investigator not acting on behalf of any institution)</td>
<td>Covers an entire institution</td>
</tr>
<tr>
<td>Brings an individual non-OHSU investigator under OHSU’s FWA</td>
<td>Does not extend OHSU’s FWA to cover a non-assured institution or investigator</td>
</tr>
<tr>
<td>Collaborating institution does not need to get an FWA</td>
<td>For federally funded research, relying institution must have an FWA</td>
</tr>
<tr>
<td>Non-OHSU investigator is subject to OHSU IRB review</td>
<td>Relying institution is subject to OHSU IRB review</td>
</tr>
</tbody>
</table>
I will be sharing data and specimens with my collaborators at Institution X...

• Transferring specimens requires a material transfer agreement – call Tech Transfer and Business Development (TTBD)!

• HIPAA requirements may apply.
  – Authorization or waiver
  – Data Use Agreement (Limited Data Set)
  – Business Associate Agreement
  – *Prep to Research: remember that PHI cannot leave OHSU – if it does, a Waiver of Authorization is needed.*
We are relying on Institution X’s IRB. Can they approve a waiver of HIPAA authorization that covers us?

- Yes!
- You may, in some cases, even use Institution X’s HIPAA authorization form.
- If the reviewing IRB does not provide a HIPAA authorization or an approved waiver, submit the appropriate OHSU HIPAA documents with your Request for a Waiver of Oversight in the eIRB.
- Waiver - Accounting for disclosures still required.
Determining administrative steps for inclusion of outside researchers in OHSU human subjects research:

FWA = Federal-Wide Assurance**
IIA = Individual Investigator Agreement
MOU = Memorandum of Understanding

START: Outside researcher is engaged in OHSU research.

Is the outside researcher's involvement on behalf of another institution, or is it independent?

INDEPENDENT

Does the outside researcher have an affiliation with OHSU that covers him/her under OHSU's FWA?

Examples: Visiting Scientist status***, contract, joint appointment, etc.

NO

IIA is required to cover the outside researcher under OHSU's FWA.

NO agreements required.
The outside researcher is considered an agent of OHSU and is covered under OHSU's FWA and subject to OHSU IRB review.

Note: The outside researcher should check with his/her IRB for notification or review requirements.

YES

No agreements required. The research project may not be covered by the outside institution's FWA, or the outside institution may not have an FWA or an IRB.

Note: If the institution routinely conducts federally funded human subjects research, OHSU may require the institution to obtain an FWA under certain circumstances.

ON BEHALF OF ANOTHER INSTITUTION

Is the study federally funded?

NO

Does the other institution have an FWA?

NO

If relying on a single IRB review: IAA, MOU, or other appropriate agreement.
If dual IRB review: No agreements required.

Note: If the institution routinely conducts federally funded human subjects research, OHSU may require the institution to obtain an FWA under certain circumstances.

YES

If relying on a single IRB review: IAA, MOU, or other appropriate agreement.
If dual IRB review: No agreements required.

Engaged in research* means obtaining:

1. data about research subjects through intervention or interaction with them;
2. identifiable private information about the research subjects; or
3. the informed consent of human subjects for research.

*For further guidance on when an institution is engaged in research, see http://www.hhs.gov/ohrp/policy/engage08.html.
**For more information on FWAs, see http://www.hhs.gov/ohrp/assurances/.
***See the OHSU Institutional Policy on Visiting Scientists & Other Affiliates.
Non-OHSU Researcher Decision Tree

START: Outside researcher is engaged in OHSU research.

Is the outside researcher's involvement on behalf of another institution, or is it independent?

INDEPENDENT

ON BEHALF OF ANOTHER INSTITUTION
Non-OHSU Researcher Decision Tree

Does the outside researcher have an affiliation with OHSU that covers him/her under OHSU's FWA?

Examples: Visiting Scientist status, contract, joint appointment, etc.

NO

IIA is required to cover the outside researcher under OHSU's FWA.

YES

No agreements required.
The outside researcher is considered an agent of OHSU and is covered under OHSU's FWA and subject to OHSU IRB review.

Note: The outside researcher should check with his/her IRB for notification or review requirements.
Non-OHSU Researcher Decision Tree

1. **ON BEHALF OF ANOTHER INSTITUTION**
   - Is the study federally funded?
     - **NO**
       - If relying on a single IRB review: IAA, MOU, or other appropriate agreement.
         - If dual IRB review: No agreements required.
         - **Note:** The research project may not be covered by the outside institution’s FWA, or the outside institution may not have an FWA or an IRB.
     - **YES**
       - Does the other institution have an FWA?
         - **NO**
           - **IAA is required** to cover the outside researcher under OHSU’s FWA.
             - **Note:** If the institution routinely conducts federally funded human subjects research, OHSU may require the institution to obtain an FWA under certain circumstances.
         - **YES**
           - If relying on a single IRB review: IAA, MOU, or other appropriate agreement.
             - If dual IRB review: No agreements required.
Non-OHSU Investigators- Compliance Requirements

- When the OHSU IRB reviews studies involving non-OHSU investigators, the personnel selection page of the IRQ asks the following questions:

  - Check if this person is not affiliated with OHSU?:  

  - The following questions only pertain to those individuals who are not employees of OHSU.

  - What type of agreement is in place?:

  - 1. Consulting Agreement
  - 2. Subcontract
  - 3. Other

  - Is there a conflict of interest in research policy in compliance with PHS regulations 42 CFR Part 50, Subpart F, and 45 CFR Part 94 in place at the person’s institution?  
    - Yes  
    - No  

    - If No:  
      - A current OHSU Conflict of Interest in Research disclosure for Outside Investigators is required. This disclosure form is completed online at: [http://www.ohsu.edu/coir](http://www.ohsu.edu/coir)

- Any collaborator NOT serving on behalf of another institution should complete the OHSU CoIR disclosure
Non-OHSU Investigators – CoIR requirements

• For Public Health Service funding, the awardee Institution is responsible for ensuring any subrecipient’s compliance with the CoIR regulations.

• Revised CoIR regulations will require that subcontracts specify if the subrecipient will follow OHSU’s policy or that of the subrecipient.
  – This information should be verified upon application to determine whether OHSU CoIR disclosures must be submitted by collaborators on a subcontract.

• More info to come!
Non-OHSU Investigators-Compliance Requirements

• Responsible Conduct of Research training:

  Has this person completed responsible conduct of research (RCR) training at his/her institution or at OHSU?
  ○ Yes  ○ No  Clear

  If Yes, Please upload an electronic copy of the certificate showing RCR completion. If your RCR compliance history can be found via the "Visual CoIR RCR" link you do not need to upload evidence of completion.

  If No, Please complete the OHSU RCR training at https://bigbrain.ohsu.edu/

• Exceptions may be made to registering and listing all non-OHSU investigators and research staff in the eIRB.
  – In this case, a list must be separately submitted that provides documentation of compliance with CoIR and RCR requirements.
Hot off the presses...

• Because of the new eCRIS system, coordinating center and site submissions will be coming together as a single submission in the eIRB.

• Stay tuned for new policies, procedures, and guidance.

• New submissions should follow the combined model. Consult the IRB if you have a new coordinating center/site submission.

• Existing submissions may eventually be combined in the eIRB. Watch for updates.
Contacts and More Information

• **IRB Main:** 503-494-7887, option 1
  - Andrea Johnson: 503-494-8999 or johnandr@ohsu.edu
  - Kara Drolet: 503-494-6727 or manningk@ohsu.edu

• **Policies and Help Sheets:**
  - [PI Eligibility – Human, Animal, and Biosafety](#)
  - [Collaborations with Non-OHSU Institutions and Investigators](#)
  - [Engagement in Research](#)
  - [Federal-Wide Assurance](#)
  - [International Research](#)
  - [Non-OHSU Researcher Decision Tree](#)
Mark your calendars!

Visit our website for more information:
www.ohsu.edu/researchintegrity