Determining administrative steps for inclusion of outside researchers in OHSU human subjects research:

**FWA = Federal-Wide Assurance**
**HRPP = Human Research Protection Program**
**IIA = Individual Investigator Agreement**
**IAA = IRB Authorization 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 HRPP?

- **NO**
  - IIA is required to cover the outside researcher under OHSU’s HRPP.
  - **Note:** The outside researcher should check with his/her IRB for notification or review requirements.

- **YES**
  - No agreements required.
  - The outside researcher is considered an agent of OHSU and is covered under OHSU’s HRPP and subject to OHSU IRB review.

**ON BEHALF OF ANOTHER INSTITUTION**

Is the study federally funded?

- **NO**
  - IIA is required to cover the outside researcher under OHSU’s HRPP.

- **YES**
  - No agreements required.

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.

- **YES**
  - IIA is required to cover the outside researcher under OHSU’s HRPP.
  - **Note:** If the institution routinely conducts federally funded human subjects research, OHSU may require the institution to obtain an FWA under certain circumstances.

Engaged in research* generally 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.

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