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.

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.

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?

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

NO

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

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.

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

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.**

YES

Does the other institution have an FWA?

NO

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.

YES

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

*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.

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