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

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.

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 agreements required.

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

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.

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

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

Is the study federally funded?

NO

YEs

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

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 is engaged in OHSU 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.