Is an IRB Authorization Agreement or Individual Investigator Agreement Necessary?

Any non-WSU individual or institution involved in the research?

Yes

Individual or Institution?

No

Is the individual acting as an employee or agent of a non-WSU institution?

Yes

Is the non-WSU institution engaged in research?*

No

Is the research supported by any HHS agency or other agency that requires IIA’s?

Yes

Individual should sign a standard IIA or similar agreement

No

Individual must sign a standard IIA or equivalent agreement

Go to IRB Authorization Agreement Flowchart

Obtain written permission from non-WSU institution for research activity.

* An institution becomes “engaged” in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)]. Agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility. (See http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm)
Federal Funding From DHHS or Another Federal Agency Requiring FWAs

Does the collaborating institution hold an FWA?

Yes

Is the collaborating institution regularly engaged in human subjects research?*

Yes

Collaborating institution’s engaged researcher signs a WSU Individual Investigator Agreement. Appropriate authorities at the collaborating institution state in writing that the conduct of the research is permitted at their institution.

No

Collaborating Institution may establish its own IRB or defer to another institution’s IRB.

Yes

WSU IRB must approve deferral to WSU** and sign a WSU IRB Authorization Agreement

No

Collaborator Institution must apply for an FWA.

Yes

Is the collaborating institution a primary awardee for an HHS-supported award for a non-exempt human subjects research project?

Yes

No

* An institution is considered “regularly engaged in research” if HHS-conducted or -supported human subjects research activity routinely occurs at the institution. (See http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm)

** IRB review criteria include:
- The time and resources required to accept the review, given other demands;
- The expertise required for initial and continuing review;
- The ability to comply with requirements for "local" knowledge of the research context at the outside organization and any research sites;
- The resources, ability, willingness of the outside organization, the principal investigator and the research sites to handle complaints, review adverse events, and to monitor compliance with applicable laws and regulations and IRB requirements, and
- The ability and willingness to comply with any additional requirements the outside organization my impose on the WSU review.

Developed by University of Michigan IRB, https://research-compliance.umich.edu/human-subjects