Federal Funding From DHHS or Another Federal Agency Requiring FWAs

Yes: Does the collaborating institution hold an FWA?

No: Is the collaborating institution regularly engaged in human subjects research?**

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

No: Collaborating institution's engaged researcher signs a UM Individual Investigator Agreement. Appropriate authorities at the collaborating institution state in writing that the conduct of the research is permitted at their institution.

Yes: Does the collaborating institution want to defer to a UM IRB?

No: Collaborating Institution may establish its own IRB or defer to another institution's IRB.

UM IRB, OVPR must approve referral to UM** and collaborating institution must amend its FWA and sign a UM IRB Authorization Agreement.

Collaborating Institution must apply for an FWA.

* 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 UM review.
Is an IRB Authorization Agreement or Individual Investigator Agreement Necessary?

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

Yes

Individual or Institution?

Individual

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

Yes

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

No

Individual should sign a standard IIA or similar agreement**

No

Individual must sign a standard IIA or equivalent agreement***

Yes

Go to IRB Authorization Agreement Flowchart

No

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

Is the non-UM institution engaged in research?*

Yes

Yes

Go to IRB Authorization Agreement Flowchart

No

* 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)

** Consult with the IRB. Exceptions may be made based on literacy, nationality, or cultural consideration.

*** The IRB may grant an exception in cases involving literacy or technology constraints.