

All institutions engaged in human subjects research that is not exempt from the regulations, and that is conducted or supported by any Department of Health and Human Services agency, must be covered by an Office for Human Research Protections (OHRP) approved assurance of compliance called a federalwide assurance or FWA. An institution may extend its FWA to cover a collaborating individual investigator or other institution. This may minimize regulatory burden and reduce duplicate review.

The procedures and requirements outlined in this presentation apply only

- to regulated, non-exempt human subjects research
- and to engaged collaborators, meaning those collaborators who
  - receive a direct HHS award
  - obtain subjects' consent
  - collect data through interaction/intervention
  - or obtain subjects' individually identifiable private information

There are two types of agreements between collaborating institutions:

- IRB Authorization Agreements (IAA)
- and Individual Investigator Agreements (IIA)

## IAAs

An IAA involves two or more institutions that hold FWAs with HHS. UM may use an IAA

- to accept oversight, becoming the IRB-of-Record for another institution
- or to cede IRB oversight to another institution

## IIAs

An IIA is used to provide IRB oversight for external collaborators who are not affiliated with an assured institution. These may be faculty or students at a non-research institution such as a hospital or college.

UMOR must determine whether UM is willing to oversee the work of an individual collaborator. A separate IIA must be prepared for each collaborator.

## CIAs

Collaborating Institution Agreements (CIA) are used exclusively at the University of Michigan, in cases where the research is not federally sponsored and there are multiple collaborators at a non-FWA site

# **U-MIC TRANSCRIPT Collaborator Agreements: IAAs, IIAs, and CIAs**

who would otherwise require numerous Individual Investigator Agreements.

The CIA designates a single qualified individual at the non-assured institution to hold responsibility for oversight of individuals at the institution engaged in the research.

Contact the IRB for more information about IAAs, IIAs, and CIAs.

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