

Obtaining an Assurance

What is a Federalwide Assurance (FWA)?

This is an assurance of compliance. An assurance of compliance is a written document submitted by an institution (not an Institutional Review Board) that is engaged in non-exempt human subjects research conducted or supported by HHS. Through the assurance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46. The Federalwide Assurance is the only type of new assurance accepted and approved by the Office of Human Research Protections (OHRP).

In general, an institution is considered to be engaged in human subjects research when its employees or agents:

1. obtain data about living individuals for research purposes through intervention or interaction with them, or
2. obtain individually identifiable private information for research purposes (45 CFR 46.102(d),(f)). Employees and agents, including students, are individuals performing institutionally designated activities and acting on behalf of the institution or exercising institutional authority or responsibility.

For details, please see [OHRP Guidance on Engagement of Institutions in Human Subjects Research](#).

What is an Individual Investigator Agreement (IIA)?

This is an assurance between an individual collaborator and Washington University (WU) specifying that the terms of the WU FWA will be followed in the conduct of research. The individual investigator agreement only applies in two situations:

1. A collaborating independent investigator is:
 - a. not otherwise an employee or agent of the assured institution;
 - b. conducting collaborative research activities outside the facilities of the assured institution; and

c. not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the assured institution.

2. A collaborating institutional investigator is:

a. not otherwise an employee or agent of the assured institution;

b. conducting collaborative research activities outside the facilities of the assured institution;

c. acting as an employee or agent of a non-assured institution with respect to his or her involvement in the research being conducted by the assured institution; and

d. employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.

The appropriate version of the IIA to be used will be decided dependent on the circumstances of the research. This is a document prepared by Washington University and signed by the individual and a WU institutional official usually the Dean of the WU School of Medicine.

Please note that if HHS-conducted or -supported human subjects research activities routinely occur at a non-assured institution, the institution should obtain an OHRP-approved FWA because the individual investigator agreement does not apply. Also, if the non-assured institution is the primary awardee for an HHS-supported award providing support for non-exempt human subjects research, the institution must obtain its own OHRP-approved FWA.

For details, see [OHRP Guidance on Individual Investigator Agreement \(WU Individual Researcher Agreement\)](#).