

When is a Federal Wide Assurance (FWA) Needed?

Overview:

When Pitt faculty, students and staff collaborate with individuals conducting human subjects research at off-campus sites, it is important – from a regulatory perspective – to determine whether those sites are actually ‘engaged in research’. If the study is federally funded, and the other site (or institution) is ‘engaged’, a Federal Wide Assurance (FWA) is required for that site [45 CFR 46.103(a)], and the site must certify to the HHS agency conducting or supporting the research that the research has been reviewed and approved by an IRB designated in the FWA, and will be subject to continuing review by an IRB [45 CFR 46.103(b)]. For example, if a Pitt researcher with federal funding conducts a study at a local clinic not affiliated with UPMC or Pitt, that clinic will have to obtain an FWA if its employees are ‘engaged’ in research activities.

Determining whether or not an institution is ‘engaged’ can be challenging, and it is critically important to consult with the IRB early on when developing research projects that use facilities that may not be covered by existing Pitt/UPMC FWAs.

Description:

The Office for Human Research Protections (OHRP) provides a [Guidance on Engagement of Institutions in Human Subjects Research](#). This guidance document applies to research involving human subjects that is conducted or supported by the Department of Health and Human Services (HHS). When an institution is engaged in non-exempt human subjects research that is conducted or supported by HHS, it must satisfy HHS regulatory requirements related to holding an assurance of compliance and certifying institutional review board (IRB) review and approval. This guidance document describes:

1. scenarios that, in general, would result in an institution being considered engaged in a human subjects research project
2. scenarios that would result in an institution being considered not engaged in a human subjects research project, and
3. IRB review considerations for cooperative research in which multiple institutions are engaged in the same non-exempt human subjects research project.

Definitions:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. [45 CFR 46.102(d)]

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual, or
2. identifiable private information. [45 CFR 46.102(f)]

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

- Interaction includes communication or interpersonal contact between investigator and subject.
- Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Institution is defined in 45 CFR 46.102(b) as any public or private entity or agency (including federal, state, and other agencies).

For purposes of this document, an institution's employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

Considerations:

You cannot make this determination alone. It is important that you consult with the IRB to assist in making the final determination as to whether the collaborating individual (institution) is engaged in research involving human subjects.

NOTE: It is inappropriate for a collaborating institution to list the University of Pittsburgh as their IRB of record on the FWA without first discussing this with the Assistant Director of the University of Pittsburgh IRB.

Additional Information:

U.S. Department of Health & Human Services

[Guidance on Engagement of Institutions in Human Subjects Research](#)