Human Research Protection Program
Policies & Procedures

Federal-Wide Assurance (FWA)

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Background

A Federal-Wide Assurance (FWA) is an institution's commitment to the federal government that it will comply with the Federal Policy for the Protection of Human Subjects at 45 CFR 46 (known as the "Common Rule") in all federally funded or supported human subjects research activities. Under an assurance, the institution must conduct such research activities in accordance with all human subjects regulations and policies adopted by the federal department or agency that conducts or supports the research, as well as any other applicable federal, state, local, or institutional laws, regulations, and policies.

I. Scope

This policy applies to human subjects research in which OHSU is engaged that have been determined to involve human subjects and are not exempt under HHS regulations at 45 CFR 46.101(b). Determining engagement in research is covered separately in the Engagement in Research policy.

II. Responsible Parties

- **A.** ORIO Staff
- **B.** IRB Chair/Co-Chairs
- **C.** Investigators

III. Policy

- **A.** OHSU maintains an FWA (FWA00000161) and assures that all federally conducted or supported human subjects research activities in which OHSU is engaged comply with the terms of the FWA.
  1. OHSU requires IRB review of all applicable research according to the terms of the FWA.
  2. OHSU assures that approved research is subject to continuing IRB review according to the terms of the FWA.
- **B.** Non-exempt human subjects research activities in which OHSU is involved must comply with the terms of the FWA whenever OHSU becomes engaged in research. See the Engagement in Research policy.
- **C.** When OHSU collaborates with another institution on a research project and OHSU is either the primary recipient of financial support for the research or the coordinating center or lead site for the project:
  1. OHSU will ensure that, when required by federal regulation or OHSU policy, all collaborating institutions are covered by their own FWA, or
  2. OHSU may extend, for one or more research protocols, the applicability of its FWA to cover collaborating individual investigators. See the Collaborations with Non-OHSU Institutions and Investigators policy for further information.

IV. Procedure

- **A. OHSU's FWA and Registered IRBs**

1. Documentation of OHSU's active FWA (FWA00000161) is available through the OHRP's online FWA Database.
2. OHSU designates four internal IRBs on its FWA to provide review as required by federal regulations and the terms of the FWA. The OHSU Research Integrity Office (ORIO) maintains registration of the IRBs in accordance with OHRP requirements and procedures. They are:
   IRB #1 – Registration No. 00000469
   IRB #2 – Registration No. 00000470
   IRB #3 – Registration No. 00000471
   IRB #4 – Registration No. 00003277
3. Further information about OHSU's IRBs, including updated membership rosters, is available on the IRB website under Board Information.

B. Collaboration with other institutions

1. In applying for initial IRB approval, researchers are asked to provide FWA numbers, if available, for collaborating institutions in the eIRB Initial Review Questionnaire (IRQ) when non-OHSU investigators are engaged in research.
2. FWA numbers for assured institutions can be found in the OHRP online FWA Database.
3. The IRB will verify that collaborating institutions have FWAs where required. In certain cases, the OHSU IRB may not approve research until a collaborating institution obtains an FWA.
4. Collaborating investigators that are not covered under an FWA may be covered under OHSU's FWA pursuant to an Individual Investigator Agreement (IIA).
5. More information about research collaborations is available in the Collaborations with Non-OHSU Institutions and Investigators policy.

V. Authority

45 CFR 46.101 (a) applies the federal policy on the protection of human subjects (the Common Rule) to all research involving human subjects that is conducted, supported, or otherwise subject to regulation by any federal department or agency that has adopted the policy.

45 CFR 46.103(a) requires that each institution engaged in research subject to 45 CFR 46 must provide assurance that it will comply with the requirements of that section.

OHRP Terms of the Federal-Wide Assurance for the Protection of Human Subjects (FWA)

Guidance:

OHRP Guidance on Extension of an FWA to Cover Collaborating Individual Investigators and Introduction of the Individual Investigator Agreement (January 31, 2005)

OHRP Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008)

OHRP Correspondence on "Non-engaged" Scenarios (September 22, 2011)

VI. Definitions

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject: 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.

Institution: Any public or private entity or agency (including federal, state, and other agencies) and agents of that entity.

OHSU Employees or Agents: Individuals who (1) act on behalf of OHSU; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. This may include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

Intervention: 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: Communication or interpersonal contact between investigator and subject.

Private information: 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 (bolding added for emphasis). Coded information is considered individually identifiable if a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Obtaining identifiable private information: Receiving or accessing identifiable private information or identifiable specimens for research purposes (OHRP interprets *obtain* to include an investigator's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator).

Federal-Wide Assurance (FWA): An institution's formally documented assurance to the federal government that it will comply with the Federal Policy for the Protection of Human Subjects (known as the "Common Rule") in all federally funded or supported human subjects research activities.

Coordinating Center: A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.

VII. Additional Resources

OHSU HRPP Policies & Procedures:

- Engagement in Research
- Collaborations with Non-OHSU Institutions and Investigators

Documents:

- Individual Investigator Agreement (IIA)
- Memo from IRB Chair verifying compliance with 45 CFR 46, Subpart E (IRB Registration)

Helpful Websites:

- OHSU Board Information (IRB registration information and rosters)
- OHRP FWA Database
- OHRP IRBs and Assurances