Engagement in Research

Definition of "engaged in research"

Department of Health and Human Services (HHS) regulations at 45CFR46.103(a) require that each institution "engaged" in human subjects research provide the Office of Human Research Protections (OHRP) with a satisfactory Assurance to comply with the regulations, unless the research is exempt under 45 CFR 46.101(b). Woman's Hospital's IRB has filed a Federal Wide Assurance (FWA) with HHS and will renew the FWA in a timely manner.

An institution becomes "engaged" in human subject research [45CFR 46.102(d),(f)] when its employees or agents:

- intervene or interact with living individuals for research purposes; or
- obtain individually identifiable private information for research purposes

An institution is automatically considered to be "engaged" in human subject research whenever it receives a direct HHS award to support such research. In such cases, the awardee institution bears ultimate responsibility for protecting human subjects under the award.

Examples of being "engaged in research" include:

1). Institutions whose employees or agents intervene with living individuals by performing invasive or noninvasive procedures for research purposes (e.g., drawing blood; collecting other biological samples; dispensing drugs; administering other treatments; employing medical technologies; utilizing physical sensors; utilizing other measurement procedures).
This intervention may be a clinical trial. A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

2). Institutions whose employees or agents intervene with living individuals by manipulating the environment for research purposes.

3). Institutions whose employees or agents interact with living individuals for research purposes.

4). Institutions whose employees or agents release individually identifiable private information, or permit investigators to obtain individually identifiable private information, without subjects' explicit written permission.

When an institution is engaged in only part of a cooperative research project, the institution must ensure that the IRB reviews and approves the part(s) of the research in which the institution is engaged.

Examples of *not* being "engaged in research" include:

1). Consultants who do not obtain, receive, or possess identifiable private information and use coded data only.

2). Commercial service providers who adhere to commonly recognized professional standards for maintaining privacy and confidentiality, such as a contracted laboratory, even if they are given private, identifiable information.

Institutions whose employees or agents perform commercial or other services for investigators provided that **all** of the following conditions also are met:

a. the services performed do not merit professional recognition or publication privileges;
b. the services performed are typically performed by those institutions for non-research purposes; and
c. the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

The following are some examples, assuming the services described would not merit professional recognition or publication privileges:

d. an appropriately qualified laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service.
e. a transcription company whose employees transcribes research study interviews as a commercial service.
f. a hospital whose employees obtain blood through a blood draw or collect urine and provide such specimens to investigators as a service.
g. a radiology clinic whose employees perform chest x-rays and send the results to investigators as a service.

3). Sites that provide written information or contact information about a research project, but do not obtain subjects' consent, enroll subjects, or act as representatives of the investigator.

4). Institutions that allow the use of their facilities for intervention or interaction with subjects by research investigators.

5). Institutions that release private, identifiable information to investigators *with the prior written permission of the subject.*

6). Institutions whose employees release identifiable private information or specimens to a state or local health department for legitimate non-research public health purposes.

7). Institutions that release information or specimens to investigators in non-linkable form as long as the information/specimens were obtained for purposes other than the investigator's research.

For more guidance on activities that constitute research, consult the OHRP guidance on Institutions Engaged in Research at:

Engagement of Institutions in Human Subjects Research (2008) | HHS.gov