

## Section 2: Definitions

### 2.1. Definition of Human Subject Research

#### Policy

UIR policy defines human subject research as any activity that either represents *research* that involves *human subjects* as those terms are defined by the Department of Health and Human Services (DHHS) regulations or any activity that represents *research/clinical investigation* that involves *human subjects* as those terms are defined by Food and Drug Administration (FDA) regulations.

For drugs, the FDA regulations also apply when there is any use of a drug in research except the use of a marketed drug in the course of medical practice.

For devices, FDA regulations apply to studies where the purpose is to determine the safety or effectiveness of a device or data will be submitted to or held for inspection by the FDA as a part of a marketing permit. The FDA definition of a human subject includes an individual on whose specimen a medical device will be used if the previously mentioned criteria were met.

Human subject research that is conducted by employees or agents of UIR on its premises, associated clinics, or under its sponsorship, whether or not supported by outside funds, is to be reviewed and approved by the UIR IRB. Activities that meet the definitions of research, below, are subject to review by the UIR IRB.

#### Procedures

UIR uses the following definitions to determine what constitutes human subject research:

#### Health and Human Services Common Rule Definitions:

##### *Research*

45 CFR 46.102(d) defines research as a systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge.

##### *Human Subject*

45 CFR 46.102(f) defines a human subject as an individual about whom an investigator conducting research obtains data through intervention or interaction with individual or identifiable private information.

**Intervention or Interaction** includes physical procedures performed on an individual,

manipulation, communication, or interpersonal contact with an individual or manipulation of an individual's environment.

**Private information** includes information that an individual can reasonably expect will not be made public, and information about the behavior that an individual can reasonably expect will not be observed or recorded.

**Identifiable** means that the identity of the individual is or may be readily ascertained by the investigator or associated with the information.

*Systematic Investigation*

A study following a methodical plan to establish factual information concerning the truth of a specific hypothesis or theory.

*Generalizable*

Knowledge that may be justifiably transferred or extrapolated to a broader population or situation than that in which it has been derived.

## **Food and Drug Administration (FDA) Definitions:**

*Research*

21 CFR 50.3(c) defines research as an experiment that involves a test article and one or more human subjects.

*Human Subject*

21 CFR 50.3(e) defines a human subject as:

1. An individual who is or becomes a participant in research, either as a recipient of a test article or as a control.

OR

2. An individual on whose specimen a device was used.

*Test Article*

21 CFR 50.3(j) defines test article as any drug including a biological product for human use, medical device for human use, human food additive, color, adaptive, electronic product, or any other article subject to regulation under the jurisdiction of the FDA.

## **Process for Determining Whether an Activity Constitutes Human Subject Research**

Using the above definitions, institutional policies, and guidance documents investigators are responsible for filling out a *Determination of Whether an Activity Represents Human Research* application form. This form is submitted using IRBNet and then will be reviewed by the IRB chair or the designee who is authorized to provide a determination. The determination is based upon whether an activity either represents *research* that involves *human subjects* as those terms are defined by DHHS regulations (please see [decision chart](#) for guidance) or represents *research* that involves *human subjects* as those terms are defined by the FDA regulations. Determinations will be communicated through IRBNet with a determination letter being posted in the submission package.

## **2.2. Definition of Engagement of Institutions in Human Subjects Research**

### **Policy**

UIR IRB is responsible for the oversight of all *research* that involves *human subjects* (as defined by DHHS and FDA regulations) that is conducted by members of UIR. See section 1.3.1 UIR HSPJ Jurisdiction.

### **Procedures**

UIR uses the following definitions to determine what constitutes engagement of institutions in human subject research:

#### *Institution*

45 CFR 46.102(b) defines institution as any public or private entity or agency (including federal, state, and other agencies).

#### *Employee or agent*

An individual who acts on behalf of the institution; exercises institutional authority or responsibility; or performs institutionally designated activities. *Employees and agents* can include staff, faculty, students, contractors, and volunteers, among others, regardless of whether an individual is receiving compensation.

## **Process for Determining Whether an Institution is Engaged in Human Subject Research**

An institution is considered *engaged* in human subject research when its employees or agents for the purposes of research obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; (3) the informed consent of human subjects for the research; (4) and the research has not been deemed exempt from 45 CFR 56. The following should serve as examples of employees or agents engaged in research:

- Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e. awardees institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.
- Institutions whose employees or agents intervene for research purposes with any human subjects of the research performing invasive or non-invasive procedures.
- Institutions whose employees or agents intervene for research purposes with any human subject of the research by manipulating the environment.
- Institutions whose employees or agents interact for research purposes with any human subject of the research.
- Institutions whose employees or agents *obtain* for research purposes identifiable private information or identifiable biological specimens *from any source* for the research. (Note: in general, institutions whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt human subject's research are considered engaged in research, even if the institution's employees or agents do not directly interact or intervene with human subjects. In most cases, obtaining identifiable private information or identifiable specimens includes, but is not limited to: (1) observing or recording private behavior; (2) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and (3) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigator).

OHRP considers private information or specimens to be individually identifiable as defined in 45 CFR 46.102(f) when they can be linked to specific individuals by an investigator(s) either directly or indirectly through coding systems.

For examples of institutions NOT engaged in human subject's research, please refer to [Guidance on Engagement of Institutions in Human Subjects Research](#).

## Source

1. U.S. Department of Health & Human Services. Guidance on Engagement of Institutions in Human Subjects Research, Policy & Guidance Oct. 16, 2008. <http://www.hhs.gov/ohrp/policy/engage08.html>