Defining Research with Human Subjects

An IRB Determination Worksheet is available to help you determine if your project constitutes human subject's research per the definitions provided by the federal regulations for the protection of human subjects.

The information provided below highlights the type of activities that meet the definition of human subject's research. When considering whether an activity meets the definition of human subject's research per DHHS regulations one must consider two federal definitions: **research** and **human subject**.

RESEARCH is as a *systematic investigation*, including research development, testing and evaluation, designed to *develop or contribute to generalizable knowledge*.

A "systematic investigation" is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

Examples of systematic investigations include:

- surveys and questionnaires
- interviews and focus groups
- analyses of existing data or biological specimens
- epidemiological studies
- evaluations of social or educational programs
- cognitive and perceptual experiments
- medical chart review studies

Investigations designed to ***develop or contribute to generalizable knowledge*** are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication. Research that never is published is still research.

Examples of activities that typically are not generalizable include:

- oral histories that are designed solely to create a record of specific historical events
- biographies
- classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- service or course evaluations, unless they can be generalized to other individuals
- services, courses, or concepts where it is not the intention to share the results beyond the USA community
- quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the USA community.

A **HUMAN SUBJECT** is as a living individual about whom an investigator conducting research obtains (1) information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens or (2) uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

- **Intervention** includes both physical procedures by which data are gathered (e.g., 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.
- **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **Identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Note: Thesis or dissertation projects involving human subjects conducted to meet the requirement of a graduate degree are usually considered generalizable, and require IRB review and approval.

FDA regulations define **human subject** as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. Examples of clinical investigations include:

- Investigational drug clinical trials
- Research testing the safety and effectiveness of an investigational device
- Medical outcomes study comparing approved drugs/devices
- Research testing the safety and effectiveness of an In Vitro Diagnostic (IVD) device using human tissue specimens (identifiable or unidentifiable) requires IRB review per FDA 21 CFR Parts 50 and 56, even though under DHHS regulations research involving unidentified tissue specimens would not be considered human subjects research.

Examples of Studies That May Not Meet the Definition of Human Subjects Research

- Analysis of de-identified data
- Key words in the definition of a human subject are "a living individual about whom" a researcher obtains information. Some interactions with people for the purpose of collecting information do not any collect information about that person. For example, a researcher may contact a non-governmental organization to ask about its sources of funding.

- Program evaluations and quality improvement studies
  Not every study is designed to contribute to a field of knowledge. For example, if data are

being collected to improve a program within an institution and will be used only for that purpose, the collection of that information would not constitute research with human subjects.

- Classroom research
  In classes teaching research methods such as fieldwork, statistical analysis, or interview techniques, students may be assigned to conduct interviews, distribute questionnaires, or engage in participant observation. If the purpose of these activities is solely pedagogical and they are not designed to contribute to a body of knowledge, the activities do not meet the definition of research with human subjects.