

Protecting people who participate in research

*CITI Training Study Guide
Defining Research with Human Subjects*

**Federal Regulations
Definition of Research**

- Researcher intends to contribute to generalizable knowledge
 - Will derive general conclusions from specific cases
 - Research may include surveys, interviews, oral history, focus groups

**Federal Regulations
Definition of Research**

- Researcher intends to contribute to generalizable knowledge, NOT:
 - an internal report
 - a class exercise
 - a feasibility study
 - a needs assessment

**Federal Regulations
Definition of Human Subject**

- The research is ABOUT living human being(s)
- IRB review does not include:
 - historical studies
 - investigative journalism (e.g. questions that are about what is happening or what happened)

**Federal Regulations
Definition of Human Subject**

- Research seeks to obtain:
 - data through intervention or interaction with the individual (can be virtual); and/or
 - identifiable private information, for example:
 - ✦ Context where the subject could reasonably expect no observation/recording
 - ✦ Information provided for a specific purpose, expecting not to be made public (e.g. school)

**Federal Regulations
Definition of Human Subject**

- IRB review for research on human subjects would NOT include:
 - study or analysis of public information, or individuals' public behavior or communication
 - analysis of aggregated, anonymous data (nothing private, and investigation is not about the individuals)
