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)