Protecting people who participate in research

CITI Training Study Guide
Assessing Risk in Social & Behavioral Sciences

What are the risks in Social & Behavioral Research?

- Invasion of privacy
- Breach of confidentiality
- Study procedures

What are the risks in Social & Behavioral Research?

- Invasion of privacy
  - Personal information collected without subjects’ knowledge or consent
  - Participation in a study revealed to a third party
What are the risks in Social & Behavioral Research?

- Breach of confidentiality - information obtained in research disclosed outside the research setting
- Examples of potential harms from disclosure:
  - Health status information results in loss of health insurance coverage
  - Workers’ attitudes about their managers result in job loss
  - Information about illegal activities or immigrant status result in legal action

Assessing risks in Social & Behavioral Research

- Evaluate both likelihood and magnitude of potential harm
- Consider specifics of situation, time and culture
  - What may be socially sensitive in one time, place or culture may not be in another
- Consider subject population
  - For example, risks of a study may be different for children than for adults

Balancing Risks and Benefits

- Risks must be reasonable in relation to anticipated benefits
- Benefits may be to a population, not to the individual participants
- Risks must be minimized, consistent with sound research design
- Participants must be given sufficient information to decide if they are willing to accept potential risks
- Confidentiality cannot be guaranteed in a focus group, or if child or elder abuse is disclosed
Options when the Primary Risk is Disclosure of Subjects’ Responses

- Collect data anonymously
- Remove direct identifiers as soon as possible
- Substitute codes for identifiers
- Maintain code lists and data files in separate secure locations
- Use and protect computer passwords
- Report only aggregate data (all individual combined)
- Use pseudonyms
- Encrypt transmitted & stored data
- Access and store data on computers that don’t have internet connections

Options when the Primary Risk is the Disclosure of Subjects’ Responses

- Obtain a “Certificate of Confidentiality”
  - Issued by NIH to protect identifiable research information from compelled disclosure in legal proceedings
- Kinds of information that can be protected:
  - Substance abuse or other illegal behaviors
  - Sexual attitudes, preferences, or practices
  - Genetic information
  - Psychological health
- Certificates of Confidentiality do not override requirements to report suspicion of child abuse or neglect or other state mandated reporting

Options when the Primary Risk is the Consent Document

- Risk is from others knowing that subjects are participants in a study being conducted of a stigmatizing or illegal activity
- Apply to IRB for a waiver of the requirement to document consent
  - Does not waive the obligation to obtain informed consent
  - Elements of consent can be provided in other ways, such as cover letter, information sheet, or verbal script delivered to participant