

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
