

# IDENTIFYING, ASSESSING, AND RESOLVING ISSUES IN SOCIAL, BEHAVIORAL, AND EDUCATIONAL RESEARCH (SBER)

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# Objectives

- Overview of SBER
- Risks of SBER
- Assessing SBER risks
- Minimal risk vs. greater than minimal risk
- Mechanisms to reduce risk

# Social, Behavioral, and Educational Research (SBER)

- Themes of SBER:
  - Focus on human behaviors, attitudes, and beliefs
  - Designed to further our understanding of fundamental mechanisms and patterns of behavioral and social functioning
  - Designed to predict or influence health outcomes, risks, or protective factors
  - Concerned with the impact of illness or risk for illness on behavioral or social functioning

# SBER Methodologies

- Surveys and questionnaires
- Interviews
- Focus groups
- Direct observation
- Physiological or behavioral manipulations
- Standardized tests
- Economic analyses
- Ethnography
- Evaluation

# Identifying Risk

- May be difficult to identify risks in SBER
  - Less predicabile
  - Subjective
  - Variable
  - Unknown

# Risks of SBER

- Breach of confidentiality
  - If identities are not protected properly, subjects risk embarrassment or more serious harm
- Violation of privacy
  - Individuals have a right to privacy (control over the extent, timing, and circumstances of sharing information about themselves).
- Validation of bad behavior
  - Subjects may feel that their bad behaviors (drug use, violence, etc.) are acceptable due to the non-judgmental relationship with the investigator
- Risks of Harm to Others
  - Consideration of secondary subjects in studies where primary subjects provide information about others

# Risks of SBER (cont'd)

- Physical Harm
  - Harm from devices (e.g. sensor pads, etc.) or interventions (e.g. exercise) used in the study
  - Harm if revelations get back to others (e.g. in studies of gang violence, domestic violence, etc.)
- Emotional or psychological Distress
  - Subjects may become upset or emotional due to discussion/interview on sensitive or traumatic topics
- Legal Harm
  - Disclosure of illegal activities
- Financial Harm
  - Loss of employment
- Social Harm
  - Stigma associated with study participation

# Special Considerations

- **Respect for Privacy**
  - What is a reasonable expectation of privacy?
- **Informed Consent**
  - Many social and behavioral research is exploratory. There may be no prior or accurate information about risks.
- **Distortion of subject's behavior**
  - Observation or interviews may cause subjects to change their behavior to meet the perceived expectations of the investigator
- **Reportable Situations**
  - Social and behavioral research may involve sensitive topics. Investigators may encounter situations that require reporting such as abuse. Investigators may have legal obligation to report



# Definition of Minimal Risk

- **Minimal risk:** The **probability** and **magnitude** of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons
- Healthy Person Standard

# Minimal Risk SBER--Examples

- Survey/interview research where disclosure of the information would not place the subjects at risk or be damaging to them or their reputation in any way
- Study involving MRI and EEG to study brain function
- Collecting tissue samples via cheek swabbing to analyze stress hormones

# Greater than Minimal Risk SBER-- Examples

- Studies involving identification of the subjects and/or their responses which would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk
- Studies involving deception
- Manipulation of subjects' emotions

# Criteria for Approval

- Sections 111 of both DHHS and FDA regulations outline the criteria for approval:
  - Risks are minimized through a sound research design
  - Risks are reasonable relative to the anticipated benefits
  - Selection of subjects is equitable
  - Informed consent will be obtained and documented
  - Data safety monitoring is adequate
  - Privacy and confidentiality provisions are adequate
  - Appropriate safeguards are included for vulnerable subjects

# Assessing Risk

Focus on risks **directly related** to the research

- In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research)

Focus on **immediate or reasonably foreseeable** risks:

- The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility **[45 CFR 46.111(a)(2)]**

# Assessing Risk

- Consider all types of risk: physical, psychological, social, legal, economic, legal
- Consider subject population
  - Experience of subjects
  - Health status of subjects (exercise study)
  - Age of subjects
  - Local context
- Timing of research intervention
  - Newly diagnosed
- Qualifications of investigator

# Assessing Risk

- Probability and Magnitude of Harm:
  - **Probability:** What is the likelihood that a specific harm might occur?
  - **Magnitude:** What is the severity, duration and reversibility of a potential harm?
- Is the probability and magnitude of harm greater than the ordinary daily life of a healthy person?
- Probability of harm may be low but magnitude of harm may be high

# IRB Mechanisms to Reduce Risk

- Require more frequent continuing review
- Certificate of Confidentiality
- Restrict access to data
- Adequate consent
- Appropriate safeguards to protect data
- Waive documentation of consent
- Plan for support/resources
- Post-approval monitoring



# Resources

- National Science Foundation: <http://www.nsf.gov/bfa/dias/policy/human.jsp>
- American Anthropological Association: <http://aaanet.org/cmtes/ethics/IRB.cfm>
- Certificates of Confidentiality Kiosk: <http://grants1.nih.gov/grants/policy/coc/index.htm>
- NIH Office of Behavioral and Social Sciences Research: <http://obssr.od.nih.gov/index.aspx>