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SBER 301

IRB Assessment of Risks Associated with
Social, Behavioral, and Educational Research

The SBER Subcommittee
of The Regulatory Foundations, Ethics, and Law Program

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Presentation Outline

- IRB Responsibilities
- Risk in Social, Behavioral, and Educational Research
 - Identifying Risk
 - Evaluating Risk
 - Minimizing Risk
- Special Considerations and Challenges
- Case Studies

IRB Responsibilities

- Identify Risks
- Determine that risks are minimized
- Determine that “risks to subjects are reasonable in relation to anticipated benefits”
- Determine that subjects are adequately informed about “any reasonably foreseeable risks or discomforts”

Risks

Social, Behavioral, and Educational Research

Risks are:

- Time- and situation-specific
- Variable
- Very subjective
- Less predictable than many biomedical risks
- Often unknown (there is little or no empirical data on the likelihood of risk in behavioral or social research)

Identifying Risks

Consider all types of risk?

- Physical
- Psychological
- Social
- Legal
- Economic

Identifying Risks

Primary source of risk in social behavioral research results from a breach of confidentiality

- Confidentiality is not the same as anonymity
- Names are not the only identifiers
- Subjects' *participation* in the research may need to be kept confidential as well as their *data*

Possible Risks

- **Breach of confidentiality**
If identities are not properly protected, subjects risk embarrassment or more serious harms
- **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 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

Possible Risks (cont'd)

- **Physical Harm**
Harm from devices (e.g. sensor pads, etc.) or interventions (e.g. exercise) used in the study OR 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 a 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

Evaluation of Risk/Benefit Ratio

- IRB must decide whether the anticipated benefit justifies asking subjects to undertake the risks
- Should take into account different subject populations and individual differences among subjects

Evaluation of Risk/Benefit Ratio

- **Focus on risks directly related to the research**
 - Consider only those risks and benefits that may result from the research
 - Do not include risks and benefits of therapies subjects would receive even if not participating in the research
- **Focus on immediate or reasonably foreseeable risks**
 - Do not consider possible long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of the IRB [45 CFR 46.111(a)(2)]
 - E.g., the possible effects of the research on public policy

Minimizing Risk

Mechanisms to minimize risk:

- Require Certificate of Confidentiality
- Ensure adequate consent processes
- Restrict access to data
- Waive documentation of consent
- Require timely scoring/review of mental health assessments
- Require post-approval monitoring
- Appropriate safeguards to protect data

Certificate of Confidentiality

- Certificates of Confidentiality are issued by the National Institutes of Health (NIH)
- Intended to protect identifiable research information from forced disclosure (e.g., subpoena)
- Allows the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level

NIJ Privacy Certificate

National Institute of Justice (NIJ) policy provides for the protection of the privacy and wellbeing of individuals who are participants in NIJ research studies

www.nij.gov/funding/humansubjects/Pages/confidentiality.aspx

NIJ Privacy Certificate

These regulations:

- **Protect the privacy of individuals** by limiting the use of private, identifiable information for research or statistical purposes
- **Protect private information** provided by individuals from use in any judicial, legal, or administrative process without the individual's prior consent
- **Improve the scientific quality of NIJ research programs** by minimizing the subject's concerns over the use of the data
- **Clarify limitations on the use of privately identifiable information** for only research or statistical purposes
- **Ensure continued advancement of our understanding and knowledge of the broad criminal justice system** by providing individual privacy protections
- **Provide specific requirements on data access and security**, limitations on the transfer of the data, and specifications for final disposition of the information

Special Considerations & Challenges

- **Respect for Privacy**
What is a reasonable expectation of privacy?
- **Informed Consent**
Much 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 in which they have legal obligation to report (e.g., abuse)

Case Study #1

A faculty investigator at University A wants to conduct a research study about alcohol use in college students

- The subjects will be aged 18-21
- University A is located in Massachusetts where the legal age for drinking alcohol is 21
- The study data will be coded

Case Study #1

Identify the risk

- Legal liability
- Violation of university policies

What protections can be built into the research to minimize risk? For example:

- Certificate of Confidentiality (COC)
- Restricting data from access beyond the research group
- Password-protected files
- Code key maintained separately from study data
- Delete code key as soon as possible
- Waive documentation of consent

Case Study #2

An investigator wants to conduct a study on end-of-life issues.

- The investigator will conduct interviews with subjects who have a cancer diagnosis
- The investigator will conduct a one-time interview around end-of-life decision making

Case Study #2

Identify the risk

- Emotional reactions of subjects

What protections can be built into the research to reduce the probability and magnitude of harm? Consider:

- Qualifications of the investigator
- Subjects' stage of illness
- Time of diagnosis
- Mechanisms of recruitment
- Adequacy of consent: subjects should be informed upfront about the nature of study questions

Case Study #3

A researcher is studying depression and anxiety among high school students in order to develop an intervention for youth at risk of stress-related suicide attempts.

- The investigator will administer an online survey at random intervals to gauge subjects' feelings at different times and identify triggers for these feelings
- Subjects will be asked to keep emotional journals
- A mobile device will deliver surveys and store the journal data

Case Study #3

Identify the risk

- Depression or Anxiety – worsened by thinking about/dwelling on negative feelings
- Suicide Ideation – if the topic of the study (suicide aversion) is known by the participant
- Increased Stress – caused by added responsibilities
- Social Unease– if device prompts at inconvenient times or when with peers
- Safety – Device may make the subjects a target of envy, ridicule, or crime
- Privacy concerns – journal will contain sensitive information

What protections can be built into the research to reduce the probability and magnitude of harm? Consider:

- Careful and timely monitoring of journals and survey responses by a qualified person who can detect problems before they get too severe
- Instructing subjects to ignore device prompts as necessary
- Instructing subjects to let device go if “mugged” for it
- Password-protecting the device; allowing it to be remotely wiped to protect privacy

Case Study #4

An investigator wants to conduct a study about attitudes toward European and North American women's rights among a remote religious community in Western Asia.

- The investigator will live in the village and interview members of the community using a standard questionnaire
- The investigator will look for variation according to
 - Gender
 - Occupation
 - Wealth
 - Education, and
 - Access to western media

Case Study #4

Identify the risk

- Stigma or persecution associated with spending time with an outsider
- The researcher may influence and confound the research

What protections can be built into the research to reduce the probability and magnitude of harm? Consider:

- The values and attitudes of the close-knit community
- Social orders (e.g., chief or imam may need to give approval)
- Need for different processes of consent in compliance with local norms (individual women? need consent of spouse? Etc.).
- Learning as much as possible about the community before entering it
- Approaching community leaders to get input on the process of consent and also the content of the research
- Seeking local context review

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>

Harvard Catalyst Website: <http://catalyst.harvard.edu>

Introduction to Behavioral Science: https://www.youtube.com/watch?v=7_4o26enmGs

Behavioral Sciences (HS102): <http://www.slideshare.net/jogiitr/behavioral-science>

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