A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF RESEARCH ON GANG VIOLENCE

LOOKING AT GANG PARTICIPATION AND PERCEPTIONS OF NEIGHBORHOOD SAFETY

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OVERVIEW

The social, behavioral, and educational research (SBER) case studies provide education and guidance on how to identify and mitigate risks associated with SBER. These studies may be used by both IRB administrators and investigators when reviewing and designing research studies that involved SBER components.

Case studies follow a standard format that includes: 1) a fact pattern, 2) regulatory, cultural, and ethical issues, and 3) a risk/benefit analysis and risk management options. This format was created to allow for flexibility in applying the case studies.

By identifying common themes, linking them directly to federal regulations and guidance, and outlining risk mitigation options, the case studies can be used in a variety of ways, which include: 1) as an education tool for training individuals in human subjects research, 2) as a basis for developing reviewer checklists/worksheets, and 3) as a tool in designing research projects.

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CASE STUDY

SCENARIO/FACT PATTERN:
A veteran public health investigator is conducting an unfunded study involving interviews (audio recorded) on gang participation and perceptions of neighborhood safety.

The participants will include 25 gang members (ages 15-40 years) and 25 non-gang members (ages 15-40 years). Police officers, advocacy groups, public health agency staff, and others with knowledge of the neighborhoods will help identify gang members and give investigators information on where to find them. Study staff will approach known gang members at public venues and give them a recruitment flyer with a phone number to call if interested in learning more about the study. Non-gang members will be recruited in the same fashion. The flyer will not mention gang involvement, but when a prospective participant calls he/she will be informed of the details of the study.

Consent (with a waiver of documentation of consent) will be conducted in a private room at a local community center; interviews will immediately follow the consent process. The interview (lasting...
approximately 20 minutes) will contain information regarding perceptions of neighborhood safety, gang involvement, ownership of weapons, and involvement in violence.

The PI hypothesizes that there will be a reverse correlation between perception of neighborhood safety and ownership of weapons, as well as perception of neighborhood safety and gang involvement. He proposes that there will be a direct correlation between violence involvement and gang involvement.

Participants will be provided with a $10 gift certificate to a local pizza shop for their time. There will be no direct benefit to the participants for taking part in this research project.

Questions/Comments for the researcher:
- How will the investigator gain the trust of the gang members so that they agree to participate and are honest in their responses?
- When will audio recordings be transcribed? And then destroyed?
- Will any other personal identifiers, other than the audio recordings, be recorded?
- Will participants be encouraged not to state any identifiable information during the interviews?
- How will researchers deal with their reporting obligations if participants reveal potential harm to self or others? What is the likelihood of this occurring?

REGULATORY, ETHICAL, & CULTURAL ISSUES:
Certificates of Confidentiality,
“Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow 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. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.”

Also consider the following regulations regarding:
Waiver of Parental Permission (45 CFR 46.408):
“(c) … if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements […] of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.”

And Waiver of Documentation of Consent (45 CFR 46.117):
“An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context."

Questions for the IRB:
- What is the IRB’s jurisdiction/role in protecting the researchers?
- Is it appropriate to waive documentation of consent and/or the requirement to obtain parental permission?
- What are the appropriate privacy measures to keep enrollment confidential?

RESOLUTION & DISCUSSIONS:
Risk/Benefit Analysis:
- How would a parent react if he/she knew that their child was in a study on gang violence? Could harm to the participant result from such disclosure (e.g., incarceration, bodily harm, etc.)?
- If fellow gang members find out that a member is participating in this study, could this result in bodily harm/death?

Mitigation/Management of Risks:
- Consider waiving the requirement for parental permission to avoid placing youths at increased risk.
- Consider waiving the requirement to provide participants with a signed consent form.
- Establish privacy measures in order to keep enrollment in this study as confidential as possible (e.g., consider mode of recruitment, i.e., no letters to home or flyers, interview location, etc.)

Questions for Further Discussion
- If someone is paroled/previously incarcerated, how does this change the IRB’s review? (see Research in Prisons/Prisoner Research case)
- If the investigator has collected a participant’s data (participation is complete) and the participant is later incarcerated, can the investigator use his data?
- Could this data be obtained in another way, e.g., recruiting previous gang members rather than current gang members?
- If the investigator were a student, would that change the IRB’s responsibility in protecting him?

REFERENCE(S):
45 CFR 46.408 (c): Waiver of Parental Permission
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.408