A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF RESEARCH IN PRISONS

CONDUCTING NIH-FUNDED RESEARCH IN U.S. STATE PRISONS

By Alyssa Speier, MS, CIP
with the SBER Subcommittee of Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program

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 public health researcher will conduct an NIH-funded study in U.S. state prisons. The study seeks to assess health status and the perceived need for health services among inmates. The principal investigator hypothesizes that a correlation will exist between absence of health issues (including HIV) and perceived access to healthcare services.

All male inmates over 18 years of age within the selected prisons are eligible to participate. Upon permission of the warden, study staff will attend group events in the prisons to deliver a five-minute recruitment script to the prisoners, and provide a flyer for all to take, including the times and dates of the different components of the study. Inmates will inform their guards whether they are interested and, if so, will be escorted to the study location at the appropriate times and dates.

The study involves:

1) A structured, interviewer-administered questionnaire (covering medical history)
2) Focus groups (regarding experiences with, and perceptions of, available health services)
3) A standardized physical examination with rapid HIV testing

Each participant may take part in any one or more of the above procedures. Study staff (not affiliates of the prison) will conduct all study-related procedures (including recruitment, consent, and data collection) in a private space. Consent will be conducted prior to each component, and will occur one-on-one with
each participant. The researchers are requesting a waiver of documentation of consent, as it would be the only record linking the subject and the research.

Focus groups will be audio recorded, but no identifiers will be collected for the other parts of the study. Participants will not receive compensation for participating. Prisoners will receive no direct benefit for participating. Only aggregate results will be communicated to prison and government authorities.
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DISCUSSION

Questions/Comments for the researcher:

• Will it be possible to keep order during the focus group discussions?
• Could the inmates find out sensitive information about each other in focus groups? How might this damage their reputation or place them at harm?
• What are the cultural implications of HIV testing?
• How do the various state laws impact the HIV testing component?
• Why not recruit female participants as well as males?
• Who will comprise the study staff? Are staff members familiar with prison populations/dynamics?
• How many people will take part (i.e., are there enough participants so that individuals will not be singled out?)

REGULATORY, CULTURAL, & ETHICAL ISSUES:

According to the "OHRP Guidance on the Involvement of Prisoners in Research":

"'Prisoner' is defined by HHS regulations at 45 CFR part 46.303(c) as 'any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.'"

"A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB."

"At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement."

"In the absence of choosing someone who is a prisoner or has been a prisoner, the IRB should choose a prisoner representative who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner."

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:

- Who will act as the IRB prisoner representative? A former prisoner, former prison case worker/counselor; nurse practitioner with experience working in a prison, clergy member who visits inmates, etc.?
- Has the IRB met all additional duties related to prisoner involvement (See OHRP Guidance on the Involvement of Prisoners in Research)?
- Should compensation be provided?
- The superiors at the prison will know who is participating, as participants will have to be taken to a private space to do so. Could this make a prisoner feel compelled to participate when he would not otherwise choose to do so (i.e., create undue influence)?
- Do all prisoners have the capacity to give informed consent considering the prevalence of mental illness in prisons? Should there be conditions and provisions in place for a legally authorized representative to be used during the consent process, when necessary?
- Given the prevalence of comorbidity between HIV and HCV, should there be a further plan for referrals and testing?
- Is on-on-one space realistically achievable in the prison setting?

Resolution & Discussions:

Risk/Benefit Analysis:

- Are focus groups the right forum for this population? Could it place them at physical risk (e.g., violence breaking out) or emotional risk (e.g., someone finding out sensitive information about participant(s))?
- Is it ethical not to provide the results of the HIV testing to individual participants? Would the benefits of doing so outweigh the risks of collecting identifiers for this part of the study?

Mitigation/Management of Risks:

- Should the investigator consider ways to avoid including prisoners who are housed closely together (e.g., in the same wing) and/or those who have a lot of interaction in one focus group, in order to try to maintain confidentiality?
- During the consent process, will each participant be clearly informed in advance that participation in the research will have no effect on his parole?
- Should a guard be present outside vs. inside of the focus group room to ensure confidentiality while also assuring that he/she can be easily called upon if needed? How will assurance be made that the guard cannot overhear the discussion but will know whether intervention is necessary?

Alternate Details:

- What would happen if pregnant females were recruited? What kinds of ethical considerations would become relevant if a woman were pregnant and diagnosed as HIV-positive (i.e., resulting in mother-child transmission)?
• How might a funding source (e.g., manufacturers of rapid HIV testing, Institutes of Justice, etc.) affect the appropriateness of the prisoner research as well as the IRB’s determinations and requirements?

• What if there was mandatory reporting to the state of positive HIV results? If there was, would you suggest any changes to the study?

• What would happen if a prisoner reveals potential abuse or negligence within the healthcare environs?

• What implications would it have to the study if participants were given the option of receiving their HIV test results?

Other Events:

• An inmate who has taken part in the focus group component of the study uses information revealed during it to tease a fellow inmate publicly.

• While the approved research protocol does not allow for reporting of HIV results to participants, a research staff member reveals a positive HIV test result to a participant as he feels that it is not ethical to withhold such information.

• An inmate reports physical abuse or violence by the guards.

• During the focus groups participants report that they are denied access to HIV treatment.

• A parolee requests that a researcher write a letter for his parole hearing.

• The PI changes the location of the research to a different prison without prior IRB approval.

• A researcher is physically injured during a fight that breaks out during a focus group session.

• A family member of an inmate contacts the researcher to find out the results of a participant’s HIV test.

REFERENCE(s)

45 CFR 46 subpart C
(additional protections pertaining to biomedical and behavioral research involving prisoners)
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

45 CFR 46.117: Waiver of Documentation of Consent at
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117

OHRP Guidance on the Involvement of Prisoners in Research
http://www.hhs.gov/ohrp/policy/prisoner.html