

A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY ON RESEARCH WITH HIV-INFECTED INDIVIDUALS

CONDUCTING A HIV HEALTH INITIATIVE NEEDS ASSESSMENT IN BOSTON AND SURROUNDING COMMUNITIES

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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:

In an effort to identify the most prominent unmet medical needs affecting HIV-infected people living in and around Boston, the Massachusetts Department of Public Health has funded an investigator at a mid-size academic medical center to conduct a citywide wellness needs assessment that will be used to plan the future of HIV services. To recruit participants, the principal investigator (PI) and two research assistants will inform HIV treatment providers throughout the city of the needs assessment, and will give providers IRB-approved recruitment materials that can be given to patients who would like to learn more about participating in the assessment. Participants will also be recruited using advertisements (health clinic fliers, print, and electronic media) and through face-to-face outreach at community events.

Individuals who are at least 18 years old, report as HIV-positive, and live within a 100-mile radius of Boston will be eligible to participate. Before taking a screening questionnaire, potential participants will be informed that all other participants in the group will also be HIV-positive, and that by attending, everyone else in the focus group session will be made aware of their serostatus. Individuals who verbally acknowledge that others may learn their HIV status as part of participation in the study will then be asked to complete the screening questionnaire to assess eligibility. If deemed eligible, volunteers who are interested in joining the study will then be asked to provide identifying/contact information. To confirm

eligibility, participants will be instructed to bring evidence of their age, home address, and HIV serostatus (e.g., HIV test results, lab results with HIV viral load values, medication bottles) to a focus group session.

Focus groups will be conducted in a private conference room at the hospital with up to fifteen participants. At the beginning of the session, a research team member will provide an overview of the nature of involvement in the study (i.e., informed consent, a survey to quantitatively assess health needs, and a focus group to qualitatively assess health needs). The team member will also discuss the importance of keeping information shared by other participants during the focus group session confidential, and inform participants that study staff cannot promise that other participants will keep everything confidential. Participants will be reminded that they are free to refuse to share personal information about themselves or their healthcare experience during the session, and that they can end their participation at any time. Participants will undergo the informed consent process as a group, and be asked to provide verbal informed consent (i.e., waiver of the signature on a consent form). After verbal consent is obtained, an information sheet will be given to each participant.

Participants will then be asked to complete a survey that includes 50 questions about demographics, general health awareness, healthcare utilization and access, sexual behaviors, social support, substance use patterns, and discrimination related to HIV status. The survey will be administered on paper and will take approximately 30 minutes to complete. Survey answers will be kept confidential and stored in a locked file separate from any study documents that include participant names. If information from paper surveys is transcribed into an electronic database, these data will be password-protected and only accessible to the PI and two research assistants working on the study.

After all participants have finished the questionnaire, study staff will conduct an hour-long focus group intended to solicit participant insight on the availability and utility of HIV-related community programming in Boston. The focus group will be audio recorded and transcribed verbatim. To protect confidentiality, participants will each be given an identification number, and transcripts from audio recordings will only contain participant identification numbers. Participant names and ID numbers will not be linked in any way, and after audio recordings are transcribed, one of the research assistants will review to ensure that there are no identifying data in the transcripts. Transcripts and audio files will be kept confidential, stored in a secured electronic folder on a secure hospital server, and will only be accessible to the three study staff members.

Participants will be compensated \$50 for completing the survey and engaging in the focus group discussion. This money is intended to reimburse participants for their time and effort, and to assist in paying any travel expenses, lost wages from work, child care, etc.

Data collected on the survey will be used to examine which socio-demographic variables are most closely associated with unmet health needs amongst HIV-infected individuals in Boston. Focus group discussions will be used to identify health needs of the HIV+ community. The investigator intends to use the data collected to provide recommendations to the Massachusetts Department of Health to design new services and modify existing programs to reach the community.

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DISCUSSION

Questions/Comments for the researcher:

- Are there exclusion criteria beyond simple failure to meet all of the inclusion criteria? (e.g., an active psychiatric condition that may interfere with the ability to provide informed consent and/or adhere to study protocol; visibly distraught or visibly emotionally unstable; intoxicated or under the influence of alcohol or other substances at the time of consent)
- Who will screen participants into the study? Should providers be able to screen their patients directly? Could screening conversations occur during in-person recruitment?
- What is the rationale for waiving documentation of written consent?
- Is it ethical to exclude from participation homeless individuals who are unable to provide verification of a home address?
- What training will be required for the study staff responsible for facilitating the focus groups?
- Will an interview guide be used to direct the focus group conversation?
- Can you ensure individuals completing the needs assessment reflect the demographic of HIV-positive individuals in the Boston area? Is it possible to adapt recruitment strategies throughout the course of the study to focus outreach in appropriate ethnic and sexual minority communities?
- What if a study volunteer wishes to participate only in the survey OR the focus group?
- Will the survey and focus group be conducted in languages other than English?
- Is it possible that responses to the 50 survey questions could make a participant identifiable?
- What procedures are in place to minimize the potential of indirect disclosure that a participant is engaged in an HIV-related research study?
- Will audio recordings from focus groups be retained after the data are transcribed?
- How many participants are needed for scientific validity?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

45 CFR 46.117 (c) states that an IRB may waive the requirement for the investigator to obtain a signed consent form 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the identity of research participants from forced disclosure. They allow (but do not require) the investigator to refuse to disclose identifying information about research participants in any civil,

criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers 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. They are available even for research that is not funded by NIH.

Questions for the IRB:

- Is the risk of harm due to breach in confidentiality as related to the disclosure of participants' HIV serostatus great enough to request that the investigator perform individual rather than group interviews with participants?
- Should the study seek a Certificate of Confidentiality from the NIH?
- The investigator is requesting approval to obtain verbal consent (e.g. waiver of a signature) from each participant. Is this type of consent appropriate given that the one-time study visit will take place in a group setting? How will the Investigator ensure that each individual feels comfortable saying "yes" or "no" to participation in the study?
- Does the investigator have an obligation to disseminate research findings to participants?
- Do researchers have an ethical responsibility to provide referrals for clinical and behavioral services to focus group participants at the completion of the trial?
- What if a participant identifies a critical unmet health need? Does the researcher have appropriate plans in place to refer for ancillary care or direct participants to resources that they may otherwise be unaware of?

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

Study volunteers may receive some indirect benefit from the opportunity to share their experiences and guide the development of future programs for HIV-infected people living in the Boston area. Participants may feel good about themselves as a result of helping researchers to address issues related to health disparities in HIV-infected people living in Boston.

Participants may become uncomfortable, embarrassed, or emotionally upset by questions (and ensuing discussions) about healthcare access, sexual behavior, substance use, and mental health that will be asked during the survey and focus group procedures. However, this risk to participants is no greater than that encountered in standard group counseling relationships.

There is a potential risk of breach of confidentiality if other individuals in the focus group see the responses that a participant is providing on the survey. In addition, there is a risk that participants will break confidentiality by sharing information from the focus group with individuals who are not part of the study.

Mitigation/Management of Risks:

- To minimize the risk of HIV status disclosure, researchers should confirm with participants at their enrollment visit whether anyone else potentially has access to each mode of communication that will be used to inform participants of the study visit. No study-related communication should mention HIV, the nature of the research study, the name of the PI or medical providers, or the name of the institution (if it is obviously connected to HIV).
- Information provided to volunteers during recruitment, pre-screening, and enrollment should describe the nature of the questions that will be included in the survey and asked in the focus group. Given the sensitivity of questions, participants must be free to skip questions on the survey, refuse to answer questions during the focus group, and may terminate participation at any time.

- To reduce the risk of revealing private information, the importance of confidentiality will be discussed at the beginning of the group. Investigators should ensure that only first names or pseudonyms are used in the group session. To protect participant confidentiality, participant names should not be transcribed.
- Study staff should enforce personal space for participants completing the survey, and discourage others from reviewing their answers. To reduce the risk of revealing private information, surveys should be identified by a participant ID number, not participant name.
- Because the study will not directly address mental health problems, substance use issues, high-risk sexual behavior, or access to HIV treatment, facilitators should be expected to provide participants with a list of HIV-related and auxiliary services available nearby. In addition, investigators should be equipped to provide referrals to counselors or other means of support if participants become emotionally upset during the study.

Alternate Details:

CONSIDER IF...

- The principal investigator on the study proposes an amendment, which the Department of Public Health supports. As part of the amendment, focus groups will take place not only in Boston, but in Worcester (less than 100 miles from Boston) and Springfield (less than 100 miles from Worcester). How might this influence the study, including recruitment tactics?
- The study is expanded to collect data about children and child care, partner support, and antiviral drug use. This may result in the introduction of secondary subjects. How might the principal investigator justify inclusion of these data when the stated purpose of the study is about unmet medical needs?
- Would the inclusion of minors impact the study? If yes, how?

Other Events:

- An individual arrives to the focus group session and immediately recognizes someone they know. Even though they immediately decide to leave the room and do not participate in the study, their serostatus has now been disclosed. How would study staff appropriately handle the incident? Would the incident merit reporting to the IRB?
- A participant brought a medication bottle to the focus group session to demonstrate eligibility for the study. After the focus group is over, the principal investigator learns that this participant was prescribed the anti-retroviral medication for pre-exposure prophylaxis rather than for HIV treatment. Should the principal investigator make other participants from the focus group aware that this occurred?

REFERENCE(S)

45 CFR 46.117(c).

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117>

NIH Certificates of Confidentiality Kiosk.

<http://grants.nih.gov/grants/policy/coc/index.htm>

Muthuswamy V. Ethical issues in HIV/AIDS research. *Indian Journal of Medical Research*. 2005 Apr; 121: 601-610. <http://icmr.nic.in/ijmr/2005/april/0429.pdf>

The Massachusetts HIV Care Continuum. Released December 1, 2014 by the Massachusetts Department of Public Health HIV/AIDS Surveillance Program

<http://www.mass.gov/eohhs/docs/dph/aids/hiv-care-continuum-factsheet.pdf>

ADDITIONAL RESOURCES:

The World Health Organization (WHO) Guidance on Ethics and Equitable Access to HIV Treatment and Care. http://www.who.int/ethics/en/ethics_equity_HIV_e.pdf

UNAIDS / WHO Guiding principles on Ethical issues in HIV surveillance
http://apps.who.int/iris/bitstream/10665/90448/1/9789241505598_eng.pdf