A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF EDGES OF RESEARCH/IRB PURVIEW

ORAL HISTORY, JOURNALISM, OR RESEARCH?

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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 PhD candidate in sociology at the local university has teamed up with a journalism student for an ambitious project that will inform their dissertation and thesis projects, which are requirements for graduation. They plan to work with a group that provides counseling to victims of the Boston Marathon bombings to collect an oral history of the event—and to learn about how different groups react to and remember traumatic events in terms of resilience, group affinities, and allegiances. This information will be used as part of a video documentary.

Participants will be interviewed on camera; they will be asked open-ended questions about how that day started for them, how the blasts impacted their lives, how the following weeks affected their emotional and social lives, how they feel they have been changed by the events, and how they see their city impacted by the events.

As a secondary aim, a subset of participants will be asked to take a series of tests designed to gauge how connected they now feel to their city or in unity with their town, as compared to how they felt before the event. The assumption is that victims who were spectators may have a different response from those
who were runners. Among this subset, focus groups will also be utilized to identify themes for secondary analyses and follow-up research.

The students plan to post flyers about the project at the counseling center and have received approval from the center to speak briefly about the project at the beginning of upcoming group therapy meetings. The researchers will review the details of the project with each participant in advance of each portion of the project (interview, test, focus group).

There is no funding for this project and participants will not be compensated.

Questions/Comments for the researcher:

• What are the risks to participants in asking them to re-live traumatic events?
• What measures are in place to detect and address the need for appropriate intervention or referrals?
• What are the risks to subjects from sharing personal stories in the very public medium of a documentary?
• Where will the interviews occur and who will conduct them?
• What questions will be asked?
• What is the defined scope for the interviews? What if participants raise topics beyond the scope?
• Will there be interviews with children?
• Will a trained counselor be on hand during interviews and/or focus groups?
• What information about participants will be revealed in the documentary?
• Are participants allowed to edit or redact portions of their story before the documentary is finalized?
• How will the data from the secondary portion of the research be used? Will test results be identifiable?

REGULATORY, ETHICAL, & CULTURAL ISSUES:

46.102 Definitions.

(d) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).
(f) **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

### 46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1. **Risks to subjects are minimized:** (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. **Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.** 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). 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.

3. **Selection of subjects is equitable.** In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. **Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.**

5. **Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.**

6. **When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.**

7. **When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

(b) **When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.**

### 46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

**Questions for the IRB:**

Visit: [http://catalyst.harvard.edu/programs/regulatory/sber.html](http://catalyst.harvard.edu/programs/regulatory/sber.html)
Email: regulatory@catalyst.harvard.edu
• What components of this project qualify as human subjects research?
  o Is this research, oral history, or journalism?
  o Does the IRB need to regard the discipline from which the investigators come, the methodologies to be employed, or the aims of the project?
  o If a part of the project is not human subjects research does the IRB apply the approval standards for that part? Or ask the students to remove non-research components from the protocol before reviewing?
• Even if this could be designated beyond IRB purview, might the institution require some protections put in place for the participants?
• Do IRBs still have a responsibility to determine policies for projects that are not subject to the Common Rule?
• Having sought counseling following a traumatic event, should this be considered a vulnerable population?
• Are there exclusion criteria for the research? Are there individuals who may be too vulnerable, or experiencing too much distress, to participate?
• Are there other institutional policies to consider? (e.g., communications policies)

RESOLUTION & DISCUSSIONS:
Risk/Benefit Analysis:
• Is there a psychological benefit to these subjects? Could one be built in?
• What are the risks and benefits of each separate component of the research? Do all need to be considered by the IRB?
• Are special protections required/appropriate before asking participants to commit such personal statements to a permanent public record?
• Does participation in the research project put subjects at increased risk?
• How prepared are the researchers to handle risky situations that may arise during the course of the study?
• What is the IRB’s responsibility if non-human subjects research components are the more risky parts of the project?

Mitigation/Management of Risks:
• Utilize a robust, bi-directional consent process to make sure participants understand how public their story will become (and other risks).
• Pre-screen to gauge a potential participant’s emotional fitness to participate.
• Include at least one of the counselors in the research planning and as part of the research team.
• Ask researchers to submit a plan for monitoring participant progress/status during the research (e.g., communication w/counselor) and include plan for addressing possible adverse events.
• Limit participants/interviewees to an adult population.
• Ensure test data is de-identified.
REFERENCE(S):
45CFR46.111-112:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111

45CFR46.102:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102

http://www.oralhistory.org/about/do-oral-history/oral-history-and-irb-review/

Oral History Association: Principles and Best Practices
http://www.oralhistory.org/about/principles-and-practices/

NIH Office of Behavioral and Social Sciences Research (OBSSR): Qualitative Methods
http://www.esourceresearch.org/eSourceBook/QualitativeMethods/1LearningObjectives/tabid/258/Default.aspx