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

USE OF TEXT MESSAGES IN HUMAN RESEARCH

By: Jennifer A. Graf

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 physician in the Department of Infectious Diseases (ID) at the local community hospital and other members of the clinical practice have observed that patients infected with hepatitis C virus (HCV) and who have low English literacy have a higher rate of non-adherence with scheduled clinical appointments compared to other patients seen in the clinic. As a result, this population tends to, among other things, have worse clinical outcomes. These points are consistent with published literature. The clinical staff has discussed various methods to improve adherence to clinical appointment scheduling and have decided to conduct a research study to test one of the ideas.

A protocol has been submitted for IRB review that proposes to enroll adults aged 18-60 years with HCV who are fluent in English and another cohort of adults aged 18-60 years with HCV who require a bilingual physician or medical translator. Up to 50 patients (25 from each population) who own a smart-phone or other device capable of receiving text messages will be invited by their treating ID specialist to participate in the study. Participants in each group will be randomized to either standard communication procedure or enhanced communication. Standard communication entails following current clinic practice, which
Involves scheduling the patient’s next visit at the conclusion of the present visit, issuing to the patient an appointment reminder card with the date and time of the next scheduled appointment, and no subsequent reminder. The enhanced communication arm will consist of standard procedures plus sending 3 text message reminders to participants. Texts will be sent 2 days prior to an upcoming ID clinic visit, the day before the scheduled visit, and by 8am on the morning of the day of the scheduled appointment. Texts will be translated into the appropriate language for those who are not fluent in English. Participants will be in the study for 6 months and will provide signed consent. In addition, each study participant will be asked to complete a brief study questionnaire at clinic visits related to clinic appointment schedule adherence. Those who do not keep an appointment will be contacted by the study team to have the questionnaire administered.

Participants in the text message arm will be asked if the text reminders were helpful; those in the standard communication arm will be asked if text reminders might be helpful, other possible interventions that might improve appointment non-adherence, etc. At the conclusion of the study the number of appointments kept will be compared and the survey data analyzed. The PI has commented in the protocol that this project constitutes human research as it involves an intervention, is a systemic investigation, and the study team believes that the results are generalizable.

**Discussion**

**Questions/Comments for the researcher:**

- Will all non-English speaking persons be eligible? Clarification is also required regarding study team member fluency in foreign languages.
- If a prospective participant does not speak/read English, will the consent form be translated into the participant’s native language or will a short form consent form be used?
- What smart phone/device will be used by the study team to send text messages? Will a smart phone or other device be purchased/designated for members of the study team to use for this study only?
- What are the physical security details associated with the study smart phone/device (e.g., storage of the device, access to it)?
- What is the content of the text messages?
- Who will send the text messages and are text messages printed or otherwise recorded for the study file? How will data be stored and protected on this device?
- Will the person who sends texts to a non-English speaker be fluent in that language?
- Will participants in the study be asked to confirm receipt of texts?
- What are the procedures if a study participant responds to a text message with a request for medical information or other communication not related to the study?
- Will participants be paid for participation or receive payment to help defray any potential costs associated with text messaging? How will potential costs associated with text messaging be addressed?
- Provide a method by which a participant may withdraw from the study and discontinue receiving text messages (e.g., texting “STOP” to the study team).
REGULATORY, ETHICAL, & CULTURAL ISSUES:

46.102 Definitions (in relevant part)

(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.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

List of categories (in relevant part):

6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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.

46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent.
of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

c An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

d An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

e The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative.
When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) 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.

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.

Massachusetts Mandated Reporter Laws

Child Abuse

M.G.L. c. 119 § 51A requires that nurses who have reasonable cause to believe that a child is suffering physical or emotional injury resulting from: (i) abuse inflicted which causes harm or substantial risk of harm to the child’s health or welfare, including sexual abuse; (ii) neglect, including malnutrition; (iii) physical dependence upon an addictive drug at birth; or (iv) being a sexually exploited child; or (v) being a human trafficking victim must immediately communicate with the Department of Children & Families (DCF) orally and, within 48 hours, submit a written report to DCF detailing the suspected abuse or neglect.

Any mandated reporter who fails to make required oral and written reports of witnessed or suspected child abuse and/or neglect shall be punished by a fine of up to $1,000. Any mandated reporter who willfully fails to report child abuse and/or neglect that resulted in serious bodily injury or death shall be punished by a fine of up to $5,000 and up to 2½ years in jail, and be reported to the person's professional licensing authority. Whoever knowingly and willfully files a frivolous report shall be punished by: (i) a fine of not more than $2,000 for the first offense; (ii) imprisonment in a house of correction for not more than 6 months and a fine of not more than $2,000 for the second offense; and (iii) imprisonment in a house of correction for not more than 21/2 years and a fine of not more than $2,000 for the third and subsequent offenses.

Elder Abuse

M.G.L. c. 19A §15 requires that nurses who have reasonable cause to believe that an elderly person is suffering from or has died as a result of abuse to immediately make an oral report and submit a written report within forty-eight hours. Elder abuse is defined as an act or omission which results in serious physical or emotional injury to an elderly person or financial exploitation of an elderly person; or the failure, inability or resistance of an elderly person to provide for himself or herself one or more of the necessities essential for physical and emotional well-being without which the elderly person would be unable to safely remain in the community. Forms of abuse include physical, sexual, emotional, neglect, financial exploitation, and self-neglect. However, no person is considered to be abused or neglected for the sole reason that such person is being furnished or relies upon treatment in accordance with the tenets and teachings of a church or religious denomination by a duly accredited practitioner thereof.
Mandated reporters who fail to make elder abuse reports when appropriate are subject to a fine up to $1,000. In addition, the law provides mandated reporters with immunity from any civil or criminal liability that otherwise could result from making a report, provided the reporter did not commit the abuse.

Abuse of a Disabled Person

M.G.L. c. 19C, § 10 requires that nurses who have reasonable cause to believe that a disabled person is abused must report the situation to the Disabled Persons Protection Commission (DPPC). Abuse of a disabled person includes acts of physical, sexual, emotional, verbal abuse and omission by a caregiver of a person with a physical disability between the ages of 18 and 59. Abuse of a disabled person under age 18 must be reported as child abuse and if older than 59 as elder abuse (see above). In addition to reporting suspected abuse and neglect, mandated reporters are also required to report to the DPPC all cases in which an individual with a disability has died, regardless of whether or not abuse or neglect is suspected.

Questions for the IRB:

- Would it be acceptable for a medical translator to send foreign language texts or should it be required that a member of the study team be fluent in each language of enrolled participants?
- As it pertains to foreign language communication, should the IRB require that the protocol specify that persons be proficient in writing the foreign language, not just “fluent” (i.e., a person may speak the language fluently, but may not be fluent in written communication)?
- Does the study qualify for a waiver of documentation of consent and a Health Insurance Portability and Accountability (HIPAA) waiver?
- Should participants in the enhanced communication arm be advised about the MA Mandated Reporter laws/requirements?
- Are there other institutional policies to consider (e.g., electronic communication policies, other Information Technology policies)?
- Should the IRB require that only persons with a data plan or access to secure Wi-Fi be enrolled? Should participants in the enhanced communication arm be instructed to text only while using their data plan or secure Wi-Fi?

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

- How could the messages be worded to be sufficiently vague as to the medical nature of the appointment, but still detailed enough to be a useful reminder?
- Is there a need for the Information Technology department to review this study or is IRB review sufficient?
- Are there ways to help reduce inadvertent texts being sent to the study team?
- Does participation in the study potentially put subjects at increased risk for self-disclosure of sensitive information or illegal behavior?

Mitigation/Management of Risks:

- To eliminate the possibility of sending an inadvertent text message, instruct study participants to delete study texts once they are received and read. The consent form is to state whether the data
will still be retained somewhere once the texts are deleted (e.g., cloud). The consent should explain not only how texts might be stored, but also how long data are stored and whether identifiers will be associated with it.

- While the telephone number text messages are sent to is an identifier, by not including information about the nature of the upcoming appointment protected health information, as defined by HIPAA, is not involved.

- To the extent possible, design the study to limit the use of identifiers.

- Make clear at the time of enrollment and periodically remind participants in the enhanced communication arm that other than verifying that a text message has been received, text communications will not be responded to by the study team. Participants need to be reminded that the text system should not be used to obtain medical or other emergency help.

- Inform each participant that if his/her smart-phone or other device is lost or stolen the participant should immediately inform the study team to ensure that study texts are discontinued. It should also be addressed whether a methods exists for the study team to render all data on the smart phone or other device unreadable (i.e., “wipe it”).

**ALTERNATE DETAILS:**

- What if the study population involved minors; what issues might this impact and how?

- What if videoconferencing was used instead of text messaging; would this simplify or complicate matters?

- The researcher is contemplating an amendment, with consent from each participant, to request to activate the GPS function on each participant’s smart phone/device to track location to see if location plays a role in appointment adherence. How might this impact the study?

**Other Events:**

- A participant randomized to the enhanced communication arm accidentally sends a text message of a sensitive nature to the study team. The content would not otherwise have been shared with the study team. How should this be handled by the study team and should the incident be reported to the IRB? Is this an unanticipated problem?

- What if the event described above included information about illegal conduct; how should that be handled by the study team and should the incident be reported to the IRB? Is this an unanticipated problem?

- The partner of one of the study participants saw a study text message and calls the researcher demanding to know what the message and the study are about.

- The research team member who is responsible for sending study texts loses the study smart phone, which includes participants’ contact information, text messages, etc. Should this be reported to the IRB? Is this an unanticipated problem? Should all participants be informed or only those currently enrolled in the study?
Reference(s):

45 CFR 46.111-112:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111

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

45 CFR 46.110:

45 CFR 46.116:

45 CFR 46.117:

Massachusetts Mandated Reporter Laws:
A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF BEHAVIORAL ECONOMICS RESEARCH

A MICROFINANCE STUDY

By Ken Carson, JD
with the SBER Subcommittee of Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program

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CASE STUDY

SCENARIO/FACT PATTERN:

Microfinance includes the provision of credit to those who do not have access to traditional banking services (i.e., residents of rural villages or, more recently, urban residents living in poverty). Microfinance provides economic researchers the opportunity to design “real life” randomized interventions to test economic behavior hypotheses with large numbers of participants. In this case, a team of economics researchers seeks to test the tenet that the framing of default choices affects decision-making.

The researchers plan to structure microfinance lending operations with different default repayment schemes. A microfinance lender, working with the researchers, will move into a previously underserved area in India. The lender will offer one plan in 200 villages, an alternative plan in 200 other villages, and no plan at all in a control group of an additional 200 villages. The first plan will have an automatic savings deposit feature as a default, the other will not; this other plan will only include regular communications encouraging saving. The lending program will exclusively recruit women.
The researchers will evaluate:
- Loan uptake
- Delinquency rates
- Saving behavior

The researchers will also look at more indirect measures of the impact of microfinance, such as assessments of changes in family assets and school enrollment of children. Since the lending program recruits women exclusively, impacts on intra-family relations will also be studied.

Researchers will obtain loan data directly from the microfinance lender, and additional information from borrowers and their families through detailed, in-person surveys (lasting over one hour). When conducting the surveys, the researchers do not plan to disclose their connection to the microfinance lender or the new loan offerings. The microfinance lender's agreements with borrowers will disclose that account information “may be provided to third parties who are evaluating lending programs.”

No compensation will be offered for participation in the research.

The experiment is carried out against a background of reports that microfinance borrowers’ repayment rates are in the high 90 percent range. However, there have been disturbing news reports of some microfinance lenders engaging in what appear to be predatory lending, taking harsh measures to collect from borrowers who are in arrears.
A MICROFINANCE STUDY

DISCUSSION

Questions/Comments for the researcher:

• What role have the researchers played in developing the two plans the lender will offer?
• Do the researchers have any consulting arrangements with the lender?
• Does the lender expect to have access to the survey responses of individual borrowers? If so, could loan officers use the information in a way that could prejudice the respondents?
• Will survey participants ever be told that the research was conducted with the cooperation of the microfinance lender, and that their survey responses were combined with account information provided by the lender?
• Would the microfinance lender have the capacity to roll out the program in all 600 villages at once? If so, what is the justification for withholding credit access in the control group of 200 villages? If not, was the selection of villages that would get the service equitable?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

• Understanding the local conditions is a major challenge for a US-based IRB.
• There may be a question as to whether the local research partner knows the ethnic and cultural make-up of target village groupings.
• A common consent issue in this type of research involves ensuring that borrowers understand participation in the research is not a predicate of their receiving a loan.
• What are the repercussions of conducting household surveys that are quite long, and ask highly sensitive questions ("Do you keep cash at home? Gold? How much? Where is it kept?)?
• Microfinance loans such as these are typically made to women in households, and a common line of research is to vary the way husbands are informed about a program. Such research questions highlight an underlying dynamic of microfinance, namely, the effect of economic empowerment of women on relationships between wife and husband. Is there a heightened risk of domestic abuse as a result of participation in this study?
• Suppose the loans are not repaid: is bad credit, post-intervention worse than no credit in the control arm, in a village setting where there are no formal credit tracking systems?

Questions for the IRB:

• Does the withholding of the information about the relationship between the researchers and the lender qualify as deception? If so, can it be justified?
• What part of this activity is research, and what would take place even if the researchers were not involved?
• How is the risk arising from the research properly characterized? If the risk of defaulting on a loan exists independent of the research, since the lender is going ahead regardless of the research project, is there a heightened risk of default in one treatment arm or the other?

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

Researchers will frequently argue that the risk of their research is minimal because the lenders are moving into this area regardless, and all the research is doing is evaluating which approach helps
borrowers make the best decisions. Even so, steps should be taken to address and mitigate risks associated with participation in this type of research.

**Mitigation/Management of Risks:**

- The data collection and storage challenges can be met by hiring reputable surveyors from outside the area.
- Research institutions associated with universities may be good resources; groups who do this type of research on a regular basis have established meticulous protocol procedures for coding paper surveys, and securing them on a daily basis.
- The IRB should press the researchers to demonstrate that all survey sections are intended to support the research questions (surveys may get adopted from earlier studies, and superfluous sections retained).
- Agencies and NGOs that provide support for victims of domestic abuse must be located, in appropriate cases, and information about them provided. Interim monitoring may also be required.
- In order to carry out their study programs, lenders may agree that they will not take measures to obtain repayment of delinquent loans from participants (though participants can't be told that).
- Pilot trials may be feasible, depending on the timetable of the lender and the researchers.
- An anthropologist, who has a deep, qualitative understanding of the culture and community structure, should review the proposal to provide an opinion on, and suggest changes to, the project.
- Researchers should engage somebody from the area who is knowledgeable about the population and familiar with what is acceptable, to assist the researchers with recruitment (and increase likelihood of participation) and consent processes.

**Alternate Details:**

- Identity of the microfinance lender and relationship to the research
  - Lender: a division of a for profit, publicly traded major in-country bank, or
  - Lender: a non-profit that received initial seed funding from a foundation known for international development work in lesser developed countries
  - Lender: either of the above, but the research is being sponsored by:
    - World Bank
    - USAID
- In addition to the two interventions mentioned above (alternative repayment programs), the researcher wants to know whether access to financing increases corruption: are borrowers who use the loan proceeds to produce goods in their home more likely to be met with payoff demands by local officials, in order to be able to market their goods? Some concerns, not all by any means:
  - If this issue is probed in interviews, will it heighten risk for borrower subjects?
  - What consent disclosure would be required; if word about studying bribery traveled at the outset, the results of the study, or even the ability to carry out the study, might be compromised.
Other Events:

- On continuing review, the researcher reports that, surprisingly, some borrowers are using the loans for unanticipated purposes (possibly any of the following)
  - Financing the sending of household members from village to a distant large city, to work in factories with dangerous working conditions
  - Spending on local communal social activities, e.g. purchasing fireworks or supporting religious holiday ceremonies, that promote status but don’t directly generate income
  - While the microfinance loan program has incentives and rules to bolster school enrollment and attendance of borrowers’ children, borrowers are turning to their extended families and neighbors to recruit very young children to do piece work for extremely low wages, while their own children attend school
  - Loan proceeds are used to finance smuggling and sales of contraband goods

REFERENCE(S)

Researchers affiliated with the Jameel Poverty Action Lab at MIT have carried out important studies using large scale randomized studies to answer economics-based questions in developing countries. [http://www.povertyactionlab.org/methodology/what-randomization](http://www.povertyactionlab.org/methodology/what-randomization).
A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF BUSINESS RESEARCH

“Mystery Shopper” Dealing with Companies and Government Offices

By Ken Carson, JD

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.

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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: 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 team of researchers led by a business school professor is studying the implementation of loan modification programs following the financial crisis of 2007, with the goal of evaluating government interventions in markets during times of stress. Using publicly available records from registers of deeds, the researchers intend to collect information on mortgages from a variety of communities known to be severely impacted by the crisis (inner city neighborhoods in Rust Belt cities, newly developed communities in the suburbs of Las Vegas, and inland California). Information will also be collected from communities thought to have weathered the crisis without high foreclosure rates.

The researchers plan to call the servicers of several thousand mortgages under the ruse of “calling to find out about the availability of a loan modification” for the property in question. They will not explicitly represent themselves to be the homeowner, or say they are working for the homeowner, only that they want to know if loan modifications are available, and what the requirements are to obtain one. If pressed, they plan to say they are calling “on behalf” of the homeowners, on the grounds that the published research will benefit homeowners by providing important information about loan modification programs.

The responses will be scored based on accuracy, and the extent to which they offer help; names of the service representatives of the mortgage companies will be collected. The plan is to publish results comparing companies, as well as comparing overall responses by community, i.e., are similar mortgages treated differently depending on where the property is located?
The researchers also plan to call a variety of non-profit organizations and government offices, and for these calls, they will pose as distressed homeowners from these communities, asking for information and guidance about loan modification programs. The purpose of these calls is to evaluate the accuracy of the information they receive, and determine whether callers from some communities get more encouragement than others.

Studies like this come with many variations, but the standard approach is to have the researchers interact with company or government representatives in the guise of a job applicant, prospective customer, consumer with a complaint, or any call with another routine transaction. The researcher also presents his/her identity characteristic diversely: age, gender, race, or, in a recent prominent published study, length of time out of work. In the case of the last example, when otherwise identical resumes were submitted, with variation for time out of work, “ask backs” for interviews occurred significantly more frequently for those with a shorter out of work time.
“Mystery Shopper” Dealing with Companies and Government Offices

Discussion
Questions/Comments for the researcher:

- Will the mortgage servicers log the call in the file of the property owner, and if so will it be considered evidence of financial distress?
- If it appears from the way they are answering that the service representatives are mistaking callers for the property owners, will you explain that you are researchers, and not the property owner, or a representative or agent of the property owner?
- What is the reason for taking the name of the representatives you speak to?
- How long will each call to the non-profit or government office take? How many of these calls will be made to each entity?

Regulatory, Cultural, & Ethical Issues:
- There is deception in this case, but is it human subject research: Is there anything that the researcher is learning “about” the subject?
- If it is determined that this is not considered human subject research because information “about” an individual is not being collected, but that researchers are interacting with individuals and deceiving them in order to obtain information that could harm the interests of their employers, are there policies of the university, apart from the Common Rule, that permit the IRB or another office to oversee the research?
- Are the subjects identifiable, and could their employers take action against them?
- Costs are being imposed on the targets: these ‘false’ interactions take time and resources to handle.

Resolution & Discussions:
Risk/Benefit Analysis:
This analysis depends on the particular question being asked. In this case, the prevalence of discrimination, dishonesty, or systematic failure to make known the availability of benefits to which a citizen may be entitled seem like reasonablejustifications for interacting under false circumstances.

Mitigation/Management of Risks:
- Examine the number of interactions planned, and possibly require a pilot, to determine the number that’s needed and to “fine tune” the intervention to minimize burden and degree of deception.
- While debriefing is preferred in deception studies, it is rarely if ever practicable (and maybe not desirable) in these cases.
- Careful stipulations about disguising names of companies or offices can protect individual employees.
- In research like this, much depends on the particulars: Are the interactions in person, over the phone, or paper or online? Sometimes the goal is to discern company policy, other times, bias on the part of the individual subject (or dishonesty, if studying differential solicitation of bribes!)
• Even if this is not human subject research, university policy may require IRB review. E.g., Harvard University’s policy requires IRB review of “explicit or implicit deception of the subjects in any aspect likely to be significant to them.” See: http://provost.harvard.edu/policies_guidelines/human_subjects.php

Alternate Details:

• In communicating with financial institutions researchers want “mystery shoppers”, to ask questions that could elicit encouragement to commit fraud, instead of asking very neutral questions, for example “Do I have to put down my real earnings, or can I round up or use the earnings I had in my last job?”

• Along the same lines, researchers want to study clinical trial recruitment integrity by having “mystery shoppers” respond to advertisements, listen to selection criteria, and admit that they did have one of the exclusion criteria, but downplaying it by saying it’s not a problem anymore, to see if they will still be invited to enroll.

• The researcher proposes an amendment to record telephone “mystery shopper” conversations with the company representatives. When the IRB points out the legal prohibition against secret recording, the researcher replies that there is no secret – before every call goes through there is an announcement that the call may be recorded for quality assurance purposes. The PI contends that the research can be considered a form of quality assurance.

Other Events:

• Investigative reporters learn of the study and submit a Freedom of Information Act request to the federal sponsor of the study seeking identities of financial institutions and the results broken down by financial institution.

• A young research assistant, incensed at what appears to be corporate wrongdoing uncovered by the study, posts extremely critical remarks, naming a company, on Facebook.

• A company learns that its call center has been the target of the researcher’s “mystery shoppers” and the CEO, who happens to be an alumna with a history of making major donations, complains to the University President. While this is not a human subjects concern, one consideration is whether an IRB has a procedure for alerting the institution about research that may generate headlines; the IRB is not charged with protecting the institution, but it may wish to inform the institution regarding potentially controversial studies.

REFERENCE(S)


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

CRITICAL INCIDENT STRESS DEBRIEFING (CISD) AND INCIDENCE OF PTSD IN FIREFIGHTERS

By Christina Booth

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.

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CASE STUDY

SCENARIO/FACT PATTERN:

A researcher is given a grant by the Department of Defense (DoD) to identify risk factors related to developing and coping with post-traumatic stress disorder (PTSD) in firefighters following critical incidents (CI). The research will also assess the relationship between PTSD and a widely used, group-based management approach to CI stress debriefing (CISD). CISD allows a group that is having difficulty coping or functioning after a CI to share their experiences, learn coping strategies, and identify those who may benefit from further assistance.

The researcher proposes a controlled study to (1) assess whether or not CISD is helpful or harmful in CI-related stress management among firefighters, (2) assess the effects of CISD on short and long-term psychological well-being, and (3) identify who may benefit from more intensive support and intervention.

The research will consist of phone and internet-based screenings and data gathered from firefighters before and after a CI. The researchers have defined characteristics of a qualifying CI, and selected Chicago, San Francisco, Denver, Dallas, and Boston as research sites. Six fire departments will be followed in each city (three with CISD programs, and three without). To identify when a qualifying CI has occurred, researchers will monitor the FEMA website and subscribe to text warning system for the selected cities.
The PI will contact fire department chiefs as well as each city’s fire superintendent for permission to recruit. Flyers posted in fire departments, bulk email, and a letter sent by US mail will be used to aid recruitment.

The informed consent process will be conducted by phone prior to asking any research questions. Consent forms will be mailed or emailed in advance. Specially trained research assistants or behavioral health clinicians will summarize the consent form section by section and ask for verbal consent. The process will include a clear disclosure of the type of questions that will be asked.

The research will exclude people who have a high risk for serious and persistent mental illness such as those with diagnosed psychosis, bipolar disorder, major depressive disorder, etc., or those who indicate intent to harm themselves or others.

Participants will be screened by phone. The phone screening will use standard psychological scales to screen for depression, psychosis, mental capacity, acute stress disorder, and PTSD. The screening will also capture subjects’ gender and age, and will include questions about prior experiences with CIs, their estimation of how well they coped with prior CIs, and whether or not they received additional assistance (medication, cognitive behavioral therapy, or group support). A follow-up Internet-based questionnaire will be used as well as an online system that repeats some of the psychological scales used at enrollment, and provides a venue for journaling. Following a qualifying CI (a large-scale incident), the researchers will repeat the scales at 90 days, 120 days, and one year.

The PI will also receive anonymous health insurance claim data on medications and behavioral health interventions such as cognitive behavioral therapy or counseling. These data will be grouped by fire department, age, and gender.

There may be no direct benefits to participants. This study will collect data that may be beneficial in determining the effect of CISD on the incidence of PTSD in firefighters following a CI, and may aid in the development of new programs to assist firefighters and other emergency responders.
CRITICAL INCIDENT STRESS DEBRIEFING (CISD) AND INCIDENCE OF PTSD IN FIREFIGHTERS - DISCUSSION

DISCUSSION

Questions/Comments for the researcher:

- Does the capacity for consent change over time? Following a CI? How will you assess this?
- Can the study design, or other procedures, help assure that mental status does not affect a subject’s cognitive capacity to consent?
- Is there a risk that participation could affect the participant’s quality of life, employability, or standing in the community?
- How can study design lower risk to subjects?
- Will a participant’s lack of response to follow-up constitute full withdrawal from the study?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

- **Timeliness**: The specifics of the crisis are unknown. Once an event has met the CI criteria, the PI will need to submit a protocol amendment and the IRB(s) must be able to make a timely review.
- **IRB Review**: It is impossible to foresee a CI and therefore to know which institutions might have researchers involved in the research; there may be multiple institutions (multiple IRBs) on short timetables for review and/or multiple jurisdictions involved in CIs. How will IRB reviews be determined and made prospectively?
- **Meaningful Consent/Capacity for Consent**: Participant consent must be considered throughout the research as capacity to consent may change over time. Is informed consent possible in a disaster zone or following a critical incident? Could changing mental status affect legally authorized consent in such a way that a surrogate legally authorized representation might need to consent?
- **Safety and Monitoring**: Additional protections may be required for this type of behavioral research in a community setting.
- **Level of Risk**: Multiple IRBs must identify benchmarks and use appropriate and equivalent standards for risk assessment and mitigation.
- **Cultural Context, Feasibility, and Ethics**: Stigma may be associated with study participation. Could stigma affect a firefighter's future performance in the team?
- **Applicable Regulations**: This is a complex study occurring in different states; thus, applicable regulations must be determined.

Questions for the IRB:

- Are disaster-affected populations necessarily "vulnerable populations?"
- How do you assess the level of risk in this type of mental health research?
- What standards or benchmarks are there for making risk assessments?
- What are the procedural risks of this study?
- Are there specific study design components that can harm participants?
- If findings indicate large-scale mental illness in first responders how might this affect departments and public confidence in first responders?
RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

- The questions regarding activities of daily life, feelings, and emotions pose minimal risk. While the psychological scale includes sensitive questions, the privacy protections are adequate to reduce the risks to minimal. All screening tools are validated psychological scales used in routine psychological exams.
- Since the CISD would be performed as usual and as per normal procedures, the CISD risks will not be factored into the risk assessment.
- Since the population of interest is actively working first responders, this suggests a level of cognitive capacity and functionality; the risk of including persons with a diminished capacity is low.

Note: DoD regulations stipulate active service persons cannot be involved in research that is greater than minimal risk without a prospect of direct benefit.

Mitigation/Management of Risks:

- IRBs and PI should consult local fire department chiefs and a local FEMA representative when developing the project and/or reviewing/assessing risk.
- Consider working with known and respected associations (unions, professional organizations, etc.) to support outreach and recruitment; this may minimize stigma or perceived stigma associated with participation.
- Train community consultants (firefighters and FEMA administrators) using community-engaged research training materials (such as those designed by Harvard Catalyst (see website)).
- Work with academic centers with public health or behavioral health research programs in the selected cities.
- Choose sites with existing IRB review agreements (i.e., a central IRB, reliance agreement, etc.).
- An action plan and follow-up plan should be in place if a participant (or prospective participant) indicates intent to harm self or others during initial or ongoing screening(s). I.e., the site PI will be paged, will call the (prospective) participant to triage the situation, and then refer or call 911. The screener should disclose this action plan prior to screening.
- A study monitor may be initially assigned to perform spot observation of the enrollment process.
- De-identified data collected from health and behavioral health claims should be scrubbed of identifiers and reported only at the fire department level.
- The online component must use a secure site, where data is encrypted and coded (at a level equal to that required by HIPAA) to prevent electronic privacy breaches.
- Consider using existing data; leaders in the area may already be collecting the same data you are interested in collecting.
- Make plans to attend to the psychological needs of research staff. Choosing staff with experience in first response will help, but do not assume they are immune to experiencing psychological issues related to this work. The PI, or other psychiatrist on staff, should debrief research staff and have an ongoing plan for attending to their occupational health needs.
- Institutions might consider implementing an IRB application process for crisis/disaster research, i.e., allow for a general standing application and fast track review of specific amendments.
Alternate Details:

- The investigators receive additional funding from the National Institute of Mental Health (NIMH) to recruit a portion of their subjects into a substudy to explore correlations between PTSD and healthy relationships. Subjects are asked to recruit their significant others into the substudy which will involve couples interviews and one-on-one sessions with a counselor/interviewer.

- The DoD asks the researchers to include in their sample a specific elite military unit, which was involved in a gruesome attack overseas in which several colleagues were lost as well as civilian life.

Other Events:

- Research staff member who has experience investigating "hero syndrome," in which persons seeking recognition create a situation which they can resolve, approaches the PI when they think that they have identified such an individual after analyzing statements made while completing the journaling activities.

- Researcher staff detects what looks to be prescription medication abuse when reviewing the records of a firefighter who has concurrent and redundant prescriptions to painkillers from three different prescribers. What about the risk of the researcher identifying the firefighter with the prescription medication abuse problem?

REFERENCE(S)


**ADDITIONAL RESOURCES**

Resources for Cognitive Capacity Assessment:


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

ASSESSING ADHERENCE TO A HYBRID TAI-CHI/YOGA REGIMEN IN ANXIETY DISORDER RESEARCH

By Matt Stafford
with the SBER Subcommittee of Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program

OVERVIEW

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CASE STUDY

SCENARIO/FACT PATTERN:

An area fitness club has developed a new tai-chi/yoga hybrid in partnership with a local psychiatry practice with the aim of treating a specific kind of anxiety disorder that can result in hospitalizations of acute patients. A research team led by a senior psychiatrist and comprised of an additional two psychiatrists and two certified instructors from the fitness club will collaborate to evaluate the effectiveness of the regimen.

A trial of the program requires subjects attend a daylong introductory workshop to learn the basic steps. Subjects will then participate in two one-hour sessions per week (for 16 weeks) during which they will learn new moves, discuss their progress with a support group (composed of other subjects), and undergo psychiatric and biofeedback evaluations to measure their progress. These sessions will be co-led by a fitness instructor and psychiatrist. Subjects are also instructed to complete two 30-minute workouts per day, one in the morning and one just before bed.

The researchers worry that some subjects will not truthfully comply with the prescribed regimen of self-directed workouts. Because of this, they also want to measure compliance. They will give each subject a special yoga mat fitted with a hidden chip that can detect temperature changes as well as motion and sunlight. The chip will record when the mat is unrolled, moved, opened in a lit space, or stood upon. The entrance to the room where the biweekly sessions are held is equipped with Wi-Fi receivers that will download the data from each mat’s chip as the mat enters the room. In this way the researchers can know who is compliant with the regimen and account for lapses when they analyze their data. Patients
will not be told about the chip or tracking of usage because the researchers don’t want to influence their behavior or cause them to try and “trick” the device into recording a fake workout.

Subjects must be age 19 or older and physically able to perform the necessary regimen. Participants will be recruited from the psychiatry practice; clinicians will identify patients who qualify for participation and will provide these patients with information about the study and procedures.

Hoping to curb medical expenses, the patients’ health insurance company has agreed to subsidize each subject’s membership in the fitness club as a way to help sponsor the research. Fitness club membership (valid for six months) will not be cancelled should a subject withdraw from the study.
ASSESSING ADHERENCE TO A HYBRID TAI-CHI/YOGA REGIMEN IN ANXIETY DISORDER RESEARCH

DISCUSSION

Questions/Comments for the researcher:

- Who will approach potential subjects to provide information about the study? Their treating clinician? The PI?
- Will subjects undergo a fitness evaluation prior to the first session?
- What instruction will be provided to participants regarding confidentiality among the support group members?
- Would one 30-minute session per day be sufficient, or is the full regimen required?
- Will participants be debriefed at the end of the study? Provided with results?
- What markers would trigger subject removal from research? Hospitalization?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

45 CFR 46.116

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

American Psychological Association's (APA) Ethical Principles of Psychologists and Code of Conduct

8.07 Deception in Research

(a) Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational or applied value and that effective non-deceptive alternative procedures are not feasible.
(b) Psychologists do not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress.
(c) Psychologists explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data.

8.08 Debriefing

(a) Psychologists provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the psychologists are aware.
(b) If scientific or humane values justify delaying or withholding this information, psychologists take reasonable measures to reduce the risk of harm.

Visit: http://catalyst.harvard.edu/programs/regulatory/sber.html
Email: regulatory@catalyst.harvard.edu
(c) When psychologists become aware that research procedures have harmed a participant, they take reasonable steps to minimize the harm.

Questions for the IRB:

• Does use of the chip constitute use of an investigative device; is an IDE required? Consult with an IND/IDE expert.
• Does participation in the research (two sessions per week, plus 30-minute sessions twice per day) place too much burden on research subjects? Increase risk of non-compliance?
• Are sufficient plans in place should a subject experience severe anxiety and/or require hospitalization?
• Is the coverage of the club membership by the health insurance company too coercive?
• Will results of the study be shared with the health insurance company? Aggregate results? Individual results? Compliance (chip) data?

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

• What special challenges does this research pose for this population?
• What information will each research site/group (the psychiatry group and the fitness center) receive? Does this pose additional risks? What about sharing data with the health insurance company?
• Does the recruitment process pose unnecessary risks?
• Consider the following risks: loss of confidentiality, disclosure of mental illness/seeking treatment, risk to insurability.
• Debriefing:
  o If participants will be debriefed, might a participant feel he/she has been coerced and might not have chosen to participate if fully informed?
  o Might a subject feel his/her privacy has been invaded? Could this cause increased anxiety in the population?
  o Could debriefing result in damage to a subject’s self-esteem; could it result in a subject feeling ashamed, guilty, stressed, embarrassed, distrustful or suspicious, or a loss of control/autonomy?
  o Does the cohort suffer from paranoia? If so, might debriefing cause subjects to be more paranoid and experience increase anxiety?

Mitigation/Management of Risks:

• The study should be designed so that participants’ compliance data is protected from disclosure where they could be harmed by others knowing that they were less than truthful (to avoid embarrassment, lowered esteem of family/colleagues, or loss of insurance coverage).
• The insurance company should only receive aggregate, de-identified research data.
• Each session should begin with a confidentiality reminder to all participants (in a similar manner to focus groups).
• All research team members should have an understanding of procedures should a subject experience an anxiety attack during a session.

• A plan should be in place, and instructions communicated to subjects and research team members, should a subject experience severe anxiety at any time during the research.

Alternate Details:

• What if instead of a heat sensor, the mats were fitted with an ambient sound recorder that randomly sends snippets of sound input to a server in the PI’s cloud? Would this study meet the criteria for a waiver of consent? What protections would need to be added?

• What if this study were done in a population of minors? Would parental permission also have to be waived? If not, would parents be entitled to compliance data from their children?

Other Events:

• A participant is detained at an airport security checkpoint while trying to board flight with her yoga mat as a carry-on item. TSA locates the device by x-ray and finds it suspicious. She is held for questioning and ultimately misses her flight.

• A referring psychiatrist contacts the PI to inform them that a patient they referred, which then enrolled into the study, has been admitted to a facility for treatment of an eating disorder.

REFERENCE(S)

American Psychological Association’s (APA) Ethical Principles of Psychologists and Code of Conduct

45 CFR 46.116

Partners IRB Deception and Incomplete Disclosure in Research Guidance for Investigators
A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF EDGES OF RESEARCH/IRB PURVIEW

ORAL HISTORY, JOURNALISM, OR RESEARCH?

By Matt Stafford  
with the SBER Subcommittee of Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program

OVERVIEW

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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 and no compensation for this project.
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, CULTURAL, & ETHICAL 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:

• 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.

Alternate Details:

• What if the researchers had been hired by the City of Boston so that the city could assess emergency response and update its response procedures accordingly?

• What if participants were not specifically recruited from counseling centers, but rather those who answer a more general advertisement?

• What if the tests were anonymous surveys mailed to the participants and sent back?

• What if the interviews were not videotaped and were for an article rather than a documentary? What if they were only audiotaped? What if they were neither video nor audiotaped?

• What if participants were bystanders of the bombings rather than victims (i.e., those at the marathon watching or running, but not hurt or involved in the blasts)?
Other Events:

- After data collection has ended, the investigator learns that one of the focus group participants, a woman whose comments often caused very emotional responses form others, was not actually anywhere near the marathon course when the bombs went off, and is being prosecuted for fraud after having applied for and received assistance from a charity set up to support survivors.

- The investigator receives a request from a spouse or a participant who wants to receive copies of focus group and interview transcripts of her husband. She wants to see if there is any information in them that will help her understand what was going through the mind of her husband, a study participant, who recently took his own life.

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


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

THE EFFECTIVENESS OF MIDDLE SCHOOL “GRIT” TRAINING AS MEDIATED BY TRAUMATIC LIFE EXPERIENCES

By Fanny K. Ennever

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 team led by an experienced researcher from the School of Education wants to study a six-week program initiated by the Heroes Charter School to train middle school students to exhibit "grit" (perseverance and passion for long-term goals). The researchers want to investigate how the students' backgrounds, specifically previous traumatic life experiences, modulate their response to the grit curriculum.

The Principal Investigator (PI) met with the Heroes Charter School leadership to discuss the study. The school Principal is enthusiastic and the PI has obtained a letter of support signed by the Superintendent.

The charter school will stagger the implementation of the grit training due to resource constraints. The researchers plan to study the students in two different classes, comparing educational and behavioral school records at four time points: (1) prior to any training, (2) after the training has occurred in the first class but not in the second, (3) just after the training has occurred in the second class, and (4) at the end of the semester. The research team and school leadership discussed the class selection process and determined that the teacher of each class will be asked to consent to the study being performed in their class.

To determine the students’ history of traumatic life experiences and their psychological profile, the research team proposes to interview students, in the presence of a school staff member. The school is planning to implement the training within the next month, and because of this time constraint, the...
interviews will take place before, during, and after the grit training. Each student will be given a $15 gift card for participating in the interview.

The researchers propose to address a Parent Teacher Association (PTA) meeting to introduce the study and answer questions, making it clear that:

- The school will implement the grit curriculum regardless of the researchers’ involvement;
- A school staff member will be present during the interviews, and thus, because school staff are mandated reporters, any information obtained during the interviews that indicates possible child abuse or neglect will be reported to the appropriate authorities; and
- Any findings of concern from the psychological tests will be reported to the parent/guardian.

For the interviews, the researchers propose to obtain permission from one parent or legal guardian. The school would send home two copies of the permission/assent form with the student. One copy would be signed by the parent/guardian and the student and returned to the school; the other copy would be retained by the parent/guardian. Translated documents will be made available, as needed.

Before scheduling any interviews, the researchers plan to speak to the parent/guardian by telephone to go over the permission form and ensure comprehension. Assent would be obtained again from the students at the start of the interview. If a student seems distressed during the interview, the school staff member will be responsible for following up.

For analysis of school records to evaluate the response to the grit training, the researchers propose waiving parent/guardian permission because they would be analyzing the records as an agent of the school to evaluate the effectiveness of the program, and the analysis would be invalid unless all students were included.

Given the fact that the school would be involved in the permission/assent process and a school staff member would be present during the interviews, during the discussions with school leadership, it was agreed that the school is engaged in research. The letter of support from the superintendent makes clear that the school will pursue its own IRB review and approval.

The researchers argue that the study has the potential to provide direct benefits to the children who are interviewed, because the children will receive a psychological screening during the interview, and that the study has the potential to yield generalizable knowledge about the benefit of a grit training curriculum for students with previous traumatic life experiences.
THE EFFECTIVENESS OF MIDDLE SCHOOL “GRIT” TRAINING AS MEDIATED BY TRAUMATIC LIFE EXPERIENCES

DISCUSSION

Questions/Comments for the researcher:

• What are the training and experience of the researchers who will be interviewing the students about sensitive topics, including trauma, sexuality, and depression?

• Should the parent/guardian permission process require permission from both parents/guardians, because the interview may obtain information about illegal behavior, abuse, and psychological problems of both the child and his/her family and household members?

• How will the researchers verify that the person giving permission is the parent or legal guardian?

• Since a school staff member is present during the interviews, what are the qualifications of these individuals in dealing with sensitive topics, including trauma, sexuality, and depression? What provisions has the school made for following up on concerning information and with whom and in what time frame will the school staff member follow up?

• Could the risks associated with the interview be further minimized by removing sensitive questions less likely to affect the student’s response to grit training?

• What protections are in place to ensure the security of the research data in electronic and paper versions?

• Because communication about the research will come from the school, parents/guardians and students may believe that they will be penalized for not agreeing to participate, particularly since teachers and other school staff will know who is taken out of class to be interviewed. How can the perception of coercion be reduced?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

• School Records: FERPA, the Family Educational Rights and Privacy Act (34 CFR Part 99), specifies the circumstances under which a school can share educational records. These researchers would be able to obtain identifiable records without written parent/guardian permission because they are conducting research on behalf of the school. The researchers must obtain a Memorandum of Understanding (also called a Data Use Agreement), signed by the school and by the researchers’ institution, specifying that the data will be handled in accord with FERPA requirements.

• Waiver of parent/guardian permission for analyzing school records: As described above, FERPA does allow schools to share educational records without written parent/guardian permission in some circumstances. However, obtaining this private identifiable information constitutes human subjects research, so the IRB must also determine that the study meets the criteria for a waiver under 46.116(d) as follows: (1) The research involves no more than minimal risk to the subjects; (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) The research could not practicably be carried out without the waiver or alteration; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

• Obtaining information from students about sensitive topics: Protection of Pupil Rights Amendment (PPRA) (34 CFR Part 98) requires written parent/guardian permission prior to obtain information from students about certain specified topics: (1) Political affiliations; (2) Mental and psychological problems potentially embarrassing to the student and his/her family; (3) Sex behavior, and attitudes; (4) Illegal, anti-social, self-incriminating, and demeaning behavior; (5) Critical appraisals of other individuals with whom respondents have close family relationships; (6) Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and
ministers; or (7) Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program). Although the PPRA applies only to research funded by the Department of Education, many IRBs and school systems apply these standards to all research. Since the researchers plan to obtain written parent/guardian permission for the interviews, the standards of PPRA would be satisfied.

• Mandated reporting: State law governs who is obligated to report suspected child abuse or neglect. In Massachusetts, most school staffs are mandated reporters, as are healthcare (including mental health) professionals, firefighters, police, clergy members, foster parents, parole officers, and social workers. Since the researchers plan to have a school staff member present during the interviews, there will be an obligation to report suspected child abuse or neglect; however, if instead only researchers were present in the interviews, the IRB would have to consider the legal and ethical obligations for reporting.

• Exempt Educational Research: Some educational research is exempt under §46.101(b)(1): Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The inclusion of questions about past trauma in the interviews makes this study ineligible for this exemption determination; however, it could qualify if the interview were limited to questions about the grit training (“What did you like/dislike about the training?” “How did it help/hurt you in school?” etc.)

• Child Research Categories: 45 CFR 46, Subpart D specifies additional protections for minors involved as research participants. Whether or not the research is greater than minimal risk and whether it presents the prospect of direct benefit or not determines which of the child research regulations apply to the study (45 CFR 46.404-406). Minimal risk (45 CFR 46.102(i)) means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered by a healthy child in daily life or during the performance of routine physical or psychological examinations or tests.

• If the research is not greater than minimal risk to children, 45 CFR 46.404 is met; the study can be approved regardless of whether there is benefit to the child. The minor’s assent and one parent’s/guardian’s permission would be required (45 CFR 46.408). The questions about past traumatic events may be determined not to be “routine psychological examinations,” and therefore this study may be determined to present more than minimal risk to children.

• If the research involves greater than minimal risk, but presents the prospect of direct benefit to the individual participants, the research could still be approved (45 CFR 46.405) with the permission of one parent/guardian (45 CFR 46.408). Research that involves greater than minimal risk and no prospect of direct benefit to individual participants, but it is likely to yield generalizable knowledge about the participant’s disorder or condition, is still approvable (45 CFR 46.406). However, if there is no prospect of direct benefit, permission of both parents/guardians is required, unless one parent/guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child (45 CFR 46.408).

Questions for the IRB:

• Is this study greater than minimal risk because of the potential to spark investigations into potential child abuse and/or to cause distress in children asked to recall traumatic events in a non-therapeutic (i.e., school) setting?

• Are the researchers correct in characterizing the benefits of study participation? Is the psychological screening really a direct benefit?

• Are there adequate measures to prevent parents/guardians or students from feeling pressure from the school to agree to participate?
• Is the $15 gift certificate for the interviews appropriate compensation?
• Are the researchers’ measures for documenting guardianship sufficient?
• Does the process for obtaining parent/guardian permission sufficiently protect students and parents/guardians?
• Are the provisions (using school resources) for support of students experiencing distress adequate? How will parents/guardians be notified if a student is determined to have psychological problems requiring further care? For how long after the interview will support services be offered?
• As parents/guardians may refuse permission for the interview because they do not want school officials to know about a past traumatic event, which may have an impact on study enrollment, should school personnel be involved in the interviews? Should only members of the study team be present during the interviews? Should interviews be performed after school to help conceal who participates?
• Is it appropriate to grant the request to waive parental permission for obtaining school records? Should the IRB instead require an information sheet (with appropriate translated versions) be sent home to all parents/guardians, with an option for them to refuse to allow their child’s record to be used for research by contacting the school or the researchers? Some IRBs would consider this a waiver of documentation of consent under 45 CFR 46.117(c) and others a waiver of consent under 45 CFR 116(d), depending on whether it is assumed that all parents/guardians would get the information. The communication would have to be done carefully to avoid confusion with the permission/assent process for the interview.

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

The three main sources of risk in this study are:

• The disruption, potential stigmatization, and potential legal implications to families if an investigation is started into potential child abuse based on statements by the child in the interview since a member of the school staff will be present, as mandated reporters, any suspicions must be reported and investigated
• The psychological distress caused by asking children to talk about past traumatic events
• The possible breach of confidentiality and stigmatization because the research is conducted in a school setting and a school staff member is present during the interviews.

Additional risks include the accidental release of private information because of “hackers” and parental/guardian distrust of the school allowing their children to be used as research subjects, particularly considering the request to waive permission for analysis of school records.

If the background information provided by the researchers indicates the strong likelihood of a connection between past trauma and responsiveness to grit training, then the study may provide generalizable knowledge that could benefit schools implementing grit training, assuming the sample size is adequate. In addition, if the psychological screening and follow-up were handled well, this may provide a direct benefit to the students who were interviewed.

Mitigation/Management of Risks:

The three main risks can be minimized, but not eliminated, by:

• Fully disclosing them to the parents/guardians and children,
• Ensuring that the interviewers have appropriate training and experience in interviewing traumatized children, and
• Following up on concerning findings (the IRB may consider requiring more than just using school resources for immediate distress and notifying the parents/guardians of problems revealed in screening).

The proposal to conduct the research in a school rather than in a therapeutic setting introduces additional questions about whether parents/guardians and students would provide fully informed consent (permission from the parents/guardians and assent from the students) without coercion, and about whether students may be reluctant to pursue support services through a particular school staff member because of personality difference/negative prior interaction, lack of prior relationship, etc. The consent process must find a balance between allowing parents/guardians and children who prefer not to accept the risks of the interviews and recruiting sufficient numbers of children for the interviews to provide meaningful results.

If the IRB finds that the risks are not sufficiently minimized, or are not reasonable in relation to the anticipated benefits, then it could be suggested to the researchers that they change the interviews to administering routine psychological tests, which would be less likely to reveal abuse or cause distress.

Standard measures such as encryption should be used to protect the confidentiality of electronic copies of interview answers and school records. Having a member of the school staff present during the interviews may be required by the research team’s institutional policy requiring that a researcher not be alone with a student; this also means that the staff member must be sensitive to keeping the information from the interview private.

Alternate Details:

• Some of the students to be potentially enrolled are wards of the state.
• The school specializes in special needs students.
• The ages of the students change (older or younger).
• The school was originally planning to implement the grit training in both classes simultaneously, but changed to the staggered schedule at the request of the researchers, thereby delaying this beneficial training for some students.
• The researchers want to observe and videotape the classrooms during the grit training in order to correlate the participation of individual students with their interview results.
• To eliminate the variability between different teachers in how the grit training is delivered, the researchers will be the ones teaching the grit curriculum.
• Two researchers rather than a school staff member will be present at the interview, and none of the researchers are mandated reporters under applicable state law.
• The researchers ask to waive all permission to better protect confidentiality.

Other Events:

• A parent contacts the IRB to complain that her child’s teacher is repeatedly calling out the names of students who have not returned the parent permission form.
• The researchers report that one of the teachers has not been allowing students to miss class for the interviews and requests that they are allowed to interview the children after school instead without re-obtaining parental permission.
**REFERENCE(s)**


PPRA: The Protection of Pupil Rights Amendment ([34 CFR Part 98](http://www2.ed.gov/policy/pc/wb/child的权利/privacy/PPRA.html))

Waiver of consent: 45 CFR [46.116(c) and (d)](https://www.hhs.gov/ohrp/policies/46116.html)

Waiver of documentation of consent: [45 CFR 46.117(c)](https://www.hhs.gov/ohrp/policies/46117.html)

DHHS regulations pertaining to the enrollment of minors ([Subpart D](https://www.hhs.gov/ohrp/policies/subpartD.html))

OHRP Research with Children [FAQs](http://catalyst.harvard.edu/programs/regulatory/sber.html)
A Social, Behavioral, & Educational Research (SBER) Case Study of Education Research

The Effect of Shared Experiences on Mood

By: Fanny K. Ennever

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.

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Case Study

Scenario/Fact Pattern:

Experienced clinical psychologists at two different universities hypothesize that they can detect changes in the overall mood of college students based on whether the college football team wins or loses games. They propose to measure mood by analyzing changes in the proportion of positive vs. negative words in emails sent by students through their university email accounts. They have obtained the agreement of each university’s IT departments to provide emails with the sending and receiving addresses “hashed,” meaning that the actual email addresses are altered by an algorithm to create a code that is consistent for each email address but cannot be converted back to the original address. An automated algorithm would be used to analyze the words in the emails, meaning that no one on the research team would actually be reading the email, and therefore would not see any identifiable information contained in the body of the email.

The researchers recognize that student use of emails through their university account is only a small fraction of their electronic communications, but argue that the convenience of being able to obtain this anonymized data set makes it possible to test the hypothesis that attending a university with a successful football team boosts student moods, and that doing the analysis at two different universities will enhance the generalizability of the results.

In both universities, the athletic department sends out a text message with game results to all students with registered phone numbers, except for those who have opted out of receiving such text messages. To reduce variability in these messages, the researchers have obtained the agreement from each university’s athletic departments to include certain consistent wording in these texts describing the wins
and losses: “Everyone at the university should be proud of the way the team played” for losses and “Everyone at the university should be proud of the way the team won” for wins.

The researchers originally proposed that the students did not need to be notified about this study because no identifiable email addresses would be obtained. However, one of the universities notified the investigator that she would be required to send an email to all student users of the email system describing the study and providing a way for them to opt out from having their emails analyzed. For consistency, the investigators now propose to use this process at both universities. However, the email will only say the purpose is to “analyze patterns in anonymized student emails” without specifically saying that positive and negative words will be counted or that the hypothesis is that the football team’s winning and losing will affect mood.
THE EFFECT OF SHARED EXPERIENCES ON MOOD

DISCUSSION

Questions/Comments for the researcher:

• Is there sufficient justification for using “opt-out” consent, recognizing that some students will not read or fully understand the notification email? Does this plan adequately protect the rights and welfare of the students? Could the study practically be carried out if student emails were only analyzed for students who affirmatively agreed to participate? What provisions are made for telling the students after the study is completed about their participation?

• Is there sufficient justification for not revealing the hypothesis that mood is linked to the football team’s performance and the standardization of the text messaging about wins and losses? Are the rights and welfare of the students adequately protected? Could the study practically be carried out if the notification included information about the standardized text messages? Will students be informed about the incomplete disclosure, and if so, how and when?

• Will undergraduates who are minors (younger than 18 in many, but not all, states) be included? If not, how will they be screened out? If so, will parental permission be obtained or is a waiver requested?

• What are the protections for the electronic information as it is stored and analyzed on the researcher’s computers?

• Should the people to whom a student’s emails are sent be notified about the study and allowed to opt out, possibly by including a standard message accompanying every email from the student’s address?

• Will the researchers obtain any additional “hashed” information about the students, such as gender, class status, or whether they opted out of receiving text messages from the athletics department?

• Are any provisions needed for follow up of students whose emails reveal a plan to harm themselves or others? How would students be notified about these provisions?

• Is the algorithm for analyzing positive and negative words a reliable enough indicator of mood for the study to yield meaningful results?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

• Alteration of consent: There are two proposed alterations in consent, first, that the purpose of the study will not be completely described, and second, that data will be analyzed from all students unless they actively request not to be included; that is, a lack of response is considered consent. In order to approve both proposals, the IRB must determine that the procedures in each case meet the criteria for an alteration of consent under 46.116(d) as follows: (1) The research involves no more than minimal risk to the subjects; (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) The research could not practicably be carried out without the waiver or alteration; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

• Waiver of parental permission: If the researchers plan to include students who are minors, the IRB must make the same findings as above to approve either “opt-out” or no permission from parents or guardians. One common argument for waiver of parental permission for college students is that although they are technically minors, their parents have relinquished oversight of their daily lives and the students are expected to take on many adult responsibilities.

• Privacy protection: Does analysis of emails constitute an unacceptable invasion of privacy, even if the sender and receiver are anonymized and no human reads the emails?

Visit: http://catalyst.harvard.edu/programs/regulatory/sber.html
Email: regulatory@catalyst.harvard.edu
Research in Schools
V2 April 2016
Questions for the IRB:

- What additional institutional review and permissions are required?
- Should the IRB seek the opinion of students as part of the review of this study?
- Do the students need to be informed of the name of the other university where the study is being carried out?
- Are there adequate measures to prevent students from feeling pressure from the school to agree to participate?
- Are the researchers’ measures for safeguarding the data sufficient?

Resolution & Discussions:

Risk/Benefit Analysis:

The main source of risk in this study is the invasion of privacy in analyzing emails and the potential breach of confidentiality if anyone other than the researchers gain access to the email data (for example, through loss of a laptop or hacking).

The research offers no direct benefit to the participants. Knowledge gained from the research may influence debates about the appropriate investment of university resources in athletic departments and possibly provisions for supporting the mood of the student body after athletic team losses.

Mitigation/Management of Risks:

This risk can be minimized by adequate provisions to obtain consent from the students and protect the data from inadvertent disclosure. The key decision, both for the IRB and for other university reviewers, is whether the altered (opt-out) consent process with incomplete disclosure of the hypothesis is in fact adequate.

Alternate Details:

- The researchers decide not to standardize the text messages from the athletic departments and then argue that this is not human subjects research because no interactions or interventions occur and no identifiable information is being obtained.
- An undergraduate doing thesis research under one of the investigators proposes to use his access to undergraduate directories to recruit students to “friend” him on Facebook and give permission for the research team to download and analyze their Facebook posts for positive and negative words during the course of the study.

Other Events:

- A student contacts the university president to object to the study, saying that she didn’t read the email allowing her to opt out but that the university honor code should have required that only those giving active consent should have their emails analyzed.
- The algorithm used for “hashing” the email addresses is revealed to have a flaw that would allow someone with access to substantial computing power to back out the original email addresses.
- The football coach (who does know the purpose of the study) publicly reveals it and calls for all students to opt out of allowing their emails to be analyzed because he does not want the results of the study to put additional pressure to win on the members of the football team.
• When the students are debriefed about the hypothesis, the members of the basketball team object to basketball games being left out of the study.

**REFERENCE(S)**

Waiver of consent: 45 CFR 46.116(c) and (d)

Waiver of documentation of consent: 45 CFR 46.117(c)

DHHS regulations pertaining to the enrollment of minors (Subpart D)

OHRP Research with Children FAQs
A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF RESEARCH ON END OF LIFE ISSUES

ADOLESCENT AND YOUNG ADULTS COPING WITH CANCER

By Sara Harnish, JD
with the SBER Subcommittee of Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program

OVERVIEW

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CASE STUDY

SCENARIO/FACT PATTERN:

A study team wants to compare psychological distress within the adolescent and young adult (AYA) population (defined as ages 29 to 40) with psychological distress described in an older cohort. The study seeks to identify risk and protective factors affecting the likelihood of psychosocial distress as well as to explore how medical-pharmacological factors and psychosocial factors influence the health and broader social and familial functioning of AYAs with cancer.

Potential participants would be cancer patients with advanced and incurable or metastatic cancer with a prognosis of less than 12 months to live. The institution’s recruitment policy requires approval and joint approach by the treating physician. The study team plans to identify potentially eligible participants by reviewing clinic lists from different disease groups as well as a vetting with oncologists and nurses at weekly care team meetings. If the oncology provider approves a request to approach his/her patient, the patient will be sent an introductory letter and the informed consent document. The consent form describes the research as follows:

This research study is evaluating Adolescents’ and Young Adults’ (AYAs) experience with cancer. The research study aims to look at the psychological, physical, social, and emotional aspects of a cancer diagnosis and treatment.

An opt-out card and phone number will be provided. Interested patients will be met in the clinic to discuss the study and to obtain their consent to participate. In an effort to enhance recruitment, several adult oncologists from various disease programs will participate as co-investigators.
Subjects will participate in a baseline interview and will then be asked to complete several instruments pertaining to:

- Socioeconomic and demographic factors
- Mental status
- Quality of life
- Prolonged grief
- Evaluation of suicidality
- Spirituality/religiousness
- Generalized self-efficacy
- Disability
- Human connection
- Emotional acceptance of terminal illness
- Preference for prognostic information
- End of life discussion
- Information-seeking experience
- Cognitive acceptance of terminal illness and patient’s evaluation of health
- Advance care planning
- Treatment preferences
- Social support
- Alcohol dependence
- Mental health service use
- Health status and medical factors
- Lifetime and current mood and anxiety disorders

Participants may choose to be interviewed in the clinic or at home. It is estimated that the interview will last 60 to 90 minutes. Subjects will be compensated for participating in the study. A psychiatrist whose expertise is psychosocial oncology and palliative care will be available in cases of participant distress. Participants who indicate a desire to speak with a mental health professional after the interview will be provided with a referral. In addition, participants whose responses indicate a risk for suicidality or are found to meet the DSM-IV criteria for major depressive disorder or an anxiety disorder will also be offered a referral to a mental health clinician.
ADOLESCENT AND YOUNG ADULTS COPING WITH CANCER

DISCUSSION

Questions/Comments for the researcher:

- What is the typical coping care provided to this population?
- Why is the age range so broad—29 to 40 encompass many stages of life?
- Are participants all from within the same institution, where all receive the same standard of care/support?
- What are the oncologists considering when they review their list of patients? Are they introducing any bias into the investigation by screening in—or out—certain types of patients?
- Consider adding exclusionary criteria such as someone with known suicide attempts, or other similar criteria/questions that will protect subjects, while maintaining scientific integrity.
- Is a letter the right way to make first contact?
- Discuss the question of researcher qualifications to carry out this kind of research.
- Address issues of coercion and willingness to participate (related to institutional policy of joint approach by treating physician)
- When are the responses on the instruments evaluated or reviewed?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

The IRB’s major concerns are:

- The addition of oncologists to the study team
- Participant burden
- How the study team will handle emotional and mental distress issues that may arise

Of additional concern is the language in the consent form describing why these patients are being asked to participate in the study. The issue is two-pronged: how much do the participants need to know about the study’s objectives and how much do they need to understand about the reasons why they are being selected to participate in the study? The study team’s concern is that they should not disclose information about a participant’s prognosis to him/her if the participant’s oncologist has not yet done so.

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

Of primary concern to the IRB is the ability of the study team to identify distress that must be addressed by a mental health professional outside of the study team. The sensitivity of a population with a difficult prognostic situation is of paramount importance in considering such risk.

Mitigation/Management of Risks:

In order to make inclusion criteria and characteristics of the target study population more clear, the IRB might suggest use of the term “advanced cancer” as opposed to just cancer, or adding “difficult to treat” or “has required multiple therapies.”

The study team should have procedures in place to identify situations of distress and to provide assistance and referrals. The study team must be prepared to discuss the meaning of a participant’s advanced cancer during the consenting and interview processes.
Alternate Details:

The study population was all adult participants. If pediatric participants were to be included, the additional risk considerations found under 45 CFR 46.401 et seq. (Subpart D) would apply as well as issues involving assent and the appropriate age group.

Other Events:

1. A surviving spouse requested the investigator to provide the decedent’s questionnaire answers in order to understand what the decedent was feeling at the end of life. The IRB was advised by the General Counsel’s office that as the executor of the estate, the surviving spouse had the legal authority to obtain certain records pertaining to the spouse. However, under HIPAA, the research records fall outside the definition of a Designated Record Set and therefore, the executor is not entitled to obtain the records under HIPAA.

   The IRB reviewed the consent form, which like most research informed consent documents, stated clearly that the data generated by the research would be seen only by the research staff. The IRB was sympathetic to the spouse but felt that the promise to the participant to keep responses confidential was of the highest importance and the request was denied.

2. Participant commits suicide.

REFERENCE(S)

45 CFR 46 (namely: 45 CFR 46.109(b) and 45 CFR 46.111).

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF FOCUS GROUPS

USING FOCUS GROUPS TO PERFORM A NEEDS ASSESSMENT WITH CAREGIVERS OF PERSONS WITH PSYCHOTIC DISORDERS

By Christina Booth, Hila Bernstein, and Jesse Ripton

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 researcher at a community hospital with a psychiatric emergency department would like to perform a needs assessment with caregivers and first-degree relatives of people with psychotic disorders. Specifically, the researcher is interested in learning about the needs of the families who provide support to patients with mental illness (e.g., those with psychosis, schizophrenia, bipolar, etc.). The researcher is especially interested in learning about how family members provide support during exacerbated psychiatric symptoms that can lead to hospitalization, and how they learned to do so. The researcher is also interested in learning how the family member identifies the warning signs, and how they discuss this topic as a group. The researcher proposes convening several small groups of four or five people from different families to discuss:

1) What types of vigilance (in terms of day-to-day activities, caregiver watchfulness, etc.) is needed
2) How to detect worsening symptoms before they become too severe, and
3) What information or education is needed to assist in early symptom management?

A clinician with experience counseling caregivers and families of psychiatric patients will facilitate the focus groups with the aid of a junior researcher and medical student. Groups will meet for 1½ - 2 hours, during which the facilitator will use several open-ended questions to guide the flow of the conversation.
During the consent process, and prior to the beginning of the discussion, participants will be instructed on using the appropriate etiquette of focus group participation and informed that while the group will together acknowledge and affirm the privacy of group discussions, no guarantee of privacy can be made.

There is no funding for this research and the participants will not be compensated for their time. The researcher intends to publish the study in a peer-reviewed journal.
USING FOCUS GROUPS TO PERFORM A NEEDS ASSESSMENT WITH CAREGIVERS OF PERSONS WITH PSYCHOTIC DISORDERS-DISCUSSION

DISCUSSION

Questions/Comments for the researcher:

• How do you plan to screen and recruit study participants?
• What are the qualifications/training of the facilitators?
• What questions will be asked?
• How will the group conversation be managed?
• What steps will be taken if a member becomes agitated or upset?
• What if participants report elder abuse, assault, child abuse, or imminent harm to self or others? How are mandatory reporting requirements disclosed to study participants?
• Will there be any de-briefing or post-discussion survey (e.g. time to allow respondents to indicate if they felt they were able to openly discuss their opinions)?
• Will information be given to the participants about available resources/assistance?
• Is this the right method for getting this information? How will you assure confidentiality in a group setting? Can this be obtained via interview without as many risks (while still obtaining research data useful to the researcher)?
• What is the sample size? Is it sufficient to reach saturation?
• Will the focus groups be audiotaped or videotaped?
• What will happen if participants share information about a family member who has not consented to this research study?
• Should the family member be told about the subject’s participation in the research?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

• Secondary participants: Participants in this focus group may be asked to provide potentially sensitive information about a family member with a psychotic disorder. If the information provided about the family member is private, individually identifiable information, that person becomes a secondary participant.

• Recruiting participants into this study must be done carefully. The study seeks participants who have a family member receiving treatment at a particular hospital, but researchers must be careful to appropriately approach potential participants. Recruitment materials that allow interested participants to contact the research group (but are not targeted based on medical record information) may be useful to consider in this study. Recruitment that utilizes targeted outreach based on medical record information poses additional challenges and will require careful consideration.

• Confidentiality: The nature of a focus group is such that confidentiality cannot be guaranteed. For studies, which involve sensitive information, researchers must consider which types of procedures (i.e. use of pseudonyms, data security plan) are required to minimize breach of confidentiality or violation of privacy.

• HIPAA: The researcher conducting this study is an employee of a covered entity (the hospital) under the HIPAA Privacy Rule. If the focus group elicits individually identifiable health information
(protected health information) the researcher must seek written authorization from the individual or a waiver of authorization; however, if no individually identifiable health information is elicited the requirements of HIPAA do not apply.

- **Existing Stress/Distress:** Family members of people with severe and persistent mental illness experience significant life stress that is associated with caring for a family member with mental illness. They may suffer from conditions of their own that may be difficult to manage in a group setting.

- **Access to care and discussion of mental illness:** The researchers must take into consideration the culture of the participants and placement of the mental health clinic, as well as the fact that participants may have limited access to care, and/or be less comfortable sharing information about mental illness and treatment options.

**Questions/comments for the IRB:**

- How best can the researchers pre-screen participants?
- What procedures are in place to protect the privacy of participants and confidentiality of data collected? Do these procedures protect both the participant and the family member with the psychotic disorder?
- Are the family members with a psychotic disorder considered secondary participants? Consider regulations and guidance regarding subjects who are decisionally impaired or incompetent adults.
- If they are considered secondary participants, can the IRB waive the requirement to obtain informed consent (45 CFR 46.116(d)) from them by documenting:
  - The research involves no greater than minimal risk to the secondary participants
  - The waiver will not adversely affect the rights and welfare of the secondary participants
  - The research would be impracticable without the waiver
  - If possible and appropriate, the secondary participants will be informed of the study when it is over.
- Does the researcher address how the study will respond to social and psychological harms related to participation in the focus group?

**RESOLUTION & DISCUSSIONS:**

*Risk/Benefit Analysis:*

Can this study be considered “minimal risk”? This study may qualify for expedited review under Category 7 if sufficient steps are taken to avoid breach of confidentiality through the disclosure of sensitive information and the facilitator’s questions are determined to have minimal risk. The study might qualify for expedited review if the research team carefully designs a plan of action for if participant becomes distressed or discloses reportable information, (e.g., child abuse, elder abuse, neglect, harm to self or others, etc.) and provides resources and follow-up (if necessary/applicable).

Given that this group maybe a fragile population, steps should be taken to ensure that participants are screened and determined to be capable of engaging in focus group discussions without experiencing distress.

*Mitigation/Management of Risks:*

**Privacy/Confidentiality:**

- Within the focus group, use first names only and consider using pseudonyms for family members, ask participants not to talk specifically about what others say, and emphasize that the PI cannot guarantee that the group discussion will be kept private.
• Protect against inadvertent disclosure of recorded information to the media or the public. If use of this information is intended, it must be viewed and authorized by the participant and institutional communications.

• Explicitly state in the consent form that certain information (e.g. statements regarding assault/abuse/neglect) will be reported to authorities, as required by law.

Consent:
• Make clear to participants that they may excuse themselves from the focus group (and participation in the study) at any time, and that by doing so, this decision will not affect their relationship with the investigators, the institution, or any services that the institution provides.

• Clearly state in the consent form when and why the participants may be asked to leave, and have a method of seeking assistance if necessary.

Study Design:
• Be careful to present questions to the group in a respectful way, and vet the study design with a patient advocate or family specialist who can suggest topics and/or language to avoid.

• Limit the sensitive information elicited about family members with a psychotic disorder. Avoid questions which ask participants to provide information about the family member’s health or history with mental illness.

• Screen participants carefully, and provide information in the consent process to ensure that participants understand the study procedures, how their data will be used, and that they may withdraw from the study at any time for any reason.

• Be sure that participation does not put subjects at risk for harm from family members or others.

Alternate Details:
• The focus group starts with each participant writing for ten minutes in response to a prompt “what is the hardest part about knowing when a family member should be hospitalized?” Participants write their names on the paper but the moderator reads answers to the group without identifying who wrote them.

• The investigators intend to recruit children under 18, who will attend focus groups with adults because of the logistical difficulty of conducting an under-18-only focus group.

Other Events:
• The family member of a subject calls the PI to complain that she is upset that her family member is participating in this study and feels that her own privacy is being invaded by her family member participating. She demands to know what her family member is saying about her in the focus group sessions.

• A subject in the focus group discovers that another subject has been secretly taping the focus group sessions on his phone. The subject reports this to the PI. When the PI confronts the other subject, that subject denies that he has been taping the sessions.
REFERENCE(s)


HHS & OHRP – Categories of research that may be reviewed by the Institutional Review Board (IRB) through an expedited review procedure http://www.hhs.gov/ohrp/policy/expedited98.html and http://www.hhs.gov/ohrp/policy/63fr60364.html.


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

LOOKING AT GANG PARTICIPATION AND PERCEPTIONS OF NEIGHBORHOOD SAFETY

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.

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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.
LOOKING AT GANG PARTICIPATION AND PERCEPTIONS OF NEIGHBORHOOD SAFETY

DISCUSSION

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, CULTURAL, & ETHICAL 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.”

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?
- Are the risks minimized in relation to the benefits?

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.)

Alternate Details:

- 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?
- If only one gang was targeted as participants, would there be additional risks posed by the research? If so, how could these be minimized?

Other Events:

- One of the gang members scheduled for an interview is hospitalized after being shot by a rival gang.
- Word gets out amongst the research population regarding the kinds of questions being asked during these interviews. No one is willing to participate any longer and the study has not reached its enrollment minimum. The research team receives calls from previous participants asking that their data be removed from the study.
- Gang members are hesitant to provide responses to certain of the interview questions and consistently chose to skip handfuls that are most relevant to the research aims.

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Email: regulatory@catalyst.harvard.edu

Research on Gang Violence

V2 April 2016
• One of the full time research coordinators on the project moves away and the study staff is shorthanded; therefore, the audio recordings are not being transcribed as quickly as stated in the research protocol.
• A study staff member is threatened by a gang member.
• A participant is beaten because he/she spoke to the researchers.
• A recording device with the audio interviews is stolen.
• An advocacy group member complains to the research institution that he was approached to identify gang members.

REFERENCE(S)

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

By Jennifer Campbell PhD, Jennifer Graf, and Sabune Winkler JD
with the SBER Subcommittee of Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program

OVERVIEW

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

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.


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

UNAIDS / WHO Guiding principles on Ethical issues in HIV surveillance [http://apps.who.int/iris/bitstream/10665/90448/1/9789241505598_eng.pdf](http://apps.who.int/iris/bitstream/10665/90448/1/9789241505598_eng.pdf)
A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF RESEARCH ON ILLEGAL BEHAVIORS

THE EFFECT OF PEER PRESSURE ON RISK-TAKING BEHAVIORS AMONG YOUTH

By Matt Stafford
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:

An experienced sociologist at a university plans to look at peer pressure’s effect on risk-taking behaviors such as shoplifting for fun and recreational drug use among youth. The research team will conduct focus groups or group therapy sessions in which subjects will be asked to describe their experiences with risk-taking behaviors and the influence of their peer groups upon such behavior. The research team will also ask participants to keep a diary of risk-taking activities that they engage in during the study. Subjects will be provided with a limited-function smartphone for use during the study; subjects will log their risk-taking activities via an app on the device. For each entry they will be prompted to answer questions about the nature of the activity, their decision-making process (if any), and feelings, as well as any factors (social or others) influenced the event.

Subjects will be recruited from behavioral therapy groups at substance abuse clinics; in order to participate in the research a subject must have, or believe he/she has, a substance-abuse problem. The research team will post flyers in clinics and ask clinical physicians to present the research opportunity during group therapy. Subjects must be between the ages of 13 and 18, and age confirmation will be available through the clinic, though participant responses will not become a part of patient records.

The PI will explain the research process and requirements and obtain verbal consent from participants in advance of the focus groups or group therapy sessions and distribution of smartphone. In order to ensure that participants are willing to take part in the study and be honest, the researcher proposes to not obtain parental permission. The research team will clearly explain that the research is being conducted in a
manner that will protect participant privacy but the team will also outline circumstances under which the research team would be compelled to notify participants' parents.

This research is being conducted with departmental funding. The PI plans to examine similarities and differences between focus group discussions and the smartphone entry logs.

The research will last three months during which time subjects will each participate in two focus groups or group therapy sessions and log activities. Subjects will be provided with a $15 Amazon gift card at the end of the study as a token of appreciation for their participation. There will be no direct benefit to the participants for taking part in the research.
THE EFFECT OF PEER PRESSURE ON RISK-TAKING BEHAVIORS AMONG YOUTH - DISCUSSION

DISCUSSION

Questions/Comments for the researcher:

• Are focus groups or group therapy sessions necessary for the conduct of the research? Or could a more private method of discussion (one-on-one interview) achieve the same/similar aims?

• How large will the focus groups or group therapy sessions be? Who will lead/moderate the group discussion?

• How will you ensure confidentiality among focus group participants? What instruction will you provide?

• Will participation in the focus groups or group therapy sessions (and/or the study as a whole) encourage risky behaviors?

• How will you ensure security of data capture/transmission when using the smartphone app?

• How will you ensure that subjects are not at increased risk of assault due to possession/use of the smartphone?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

45 CFR 46.408

(c) In addition to the provisions for waiver contained in §46.116 of subpart A, 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 in Subpart of this part and paragraph (b) 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.

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.

The COPPA Rule, 16 CFR part 312 imposes certain requirements on operators of websites or online services directed to children under 13 years of age, and on operators of other websites or online services that have actual knowledge that they are collecting personal information online from a child under 13 years of age (collectively, "operators"). Among other things, the Rule requires that operators provide notice to parents and obtain verifiable parental consent prior to collecting, using, or disclosing personal information from children under 13 years of age.
Questions for the IRB:

- Is it appropriate to waive the requirement to obtain parental consent?
- How secure is the smartphone app?
- Is sufficient expertise available among the research team and the IRB to address and review data security and privacy concerns?
- What if participants reveal actual/potential harm to others?
- At what point would the PI be compelled to inform parents of subject participation and behavior?

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

- What special challenges does this research pose for this population?
- What will parents think when their child suddenly has a new smartphone?
- Will a subject be thought a snitch if peers find out he/she is participating in the research?
- Are subjects at increased risk of being mugged because of the smartphone component?

Mitigation/Management of Risks:

- The consent form should clearly state that information about illegal behaviors will be collected during the study.
- The study should be designed so that participant data is protected from disclosure by a certificate of confidentiality.
- The consent form should inform subjects of when, and to whom (e.g. parents, doctors, etc.), research data will be disclosed.
- Focus groups or group therapy sessions should be of a manageable size and led by a clinician investigator; if possible, consider utilizing an existing group in which trust and familiarity have been established.
- The researcher should clearly explain the structure of the focus groups or group therapy sessions and instruct participants to keep confidentiality of other participants.
- At the time of consent participants should be provided instruction on how/when to utilize the smartphone and app. In other words, instruct them not to use the smartphone on public transportation, explain data wiping and security features, instruct participants to give up the device freely if held up or otherwise assaulted.
- The research team should establish clear rules for reporting self-harm, harm to others, etc.
- Ensure both the research team and participants are fully aware of reporting rules.
- Ensure the research team has a plan on how to handle a scenario in which they must inform parents of a subject’s behavior and participation.

Alternate Details:

- What if the focus groups or group therapy sessions were being audio recorded? Video recorded?
- What if participants used a hard copy notebook to record their activity rather than a cell phone app?
• What if participants were not recruited form a behavioral therapy group, but rather answer a general advertisement for those with substance abuse problems?
• What if the study was focused on adults/enrolled only those over 18 years of age?
• What if the study was government funded rather than department funded?
• The investigators conclude that the use of the smartphone and app is too risky, and instead propose to call the participant once a day to ask about their behavior in the past 24 hours – the study staff will write down the answers on paper.
• The investigators propose that two different versions of consenting material be used, one with minimal discussion of illegal behavior and the other with extensive warnings, to see whether the consenting process itself alters the results of the study.
• What if the minor reports or records abuse in the app.?

Other Events:
• A parent contacts the study team to say that their child will not be able to continue in the study or return the smartphone since it was confiscated by school authorities during an investigation into an allegation of inappropriate images being shared between classmates.
• The investigator learns that two study participants who did not previously know each other but met at a focus groups or group therapy sessions are now members of the same gang. One of the participants recruited the other into the gang.

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

NIH Certificates of Confidentiality Kiosk
http://grants.nih.gov/grants/policy/coc/

Children’s Online Privacy Protection Rule 16 CFR Part 312

The National Advisory Council on Drug Abuse (NACDA) Guidelines for Substance Abuse Research Involving Children and Adolescents
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.
CONDUCTING NIH-FUNDED RESEARCH IN U.S. STATE PRISONS

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
A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF RECRUITMENT OF EMPLOYEES

RECRUITING EMPLOYEES FOR AN fMRI STUDY ASSESSING THE EFFECTS OF ALCOHOL AND DRUG USE

By Christina Booth and Elizabeth Witte
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.

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CASE STUDY

SCENARIO/FACT PATTERN:

A senior researcher and department head at a mid-size academic healthcare center is the Principal Investigator (PI) of a study to test a new, FDA-approved fMRI imaging method she hopes will provide an easy way to assess the neurobiological effects of alcohol and drug use. The researcher, a neurologist, is working with a small research team in her department and partnering with a faculty member in the department of psychology at a nearby university to review and analyze the data.

The study includes participants who regularly smoke tobacco and drink alcohol. This group will be compared to a control group who neither smoke tobacco nor drink alcohol. Participants will be assigned to the appropriate group during the screening process.

Individuals, who have a drug abuse/dependence diagnosis or currently are prescribed antipsychotic, antidepressant, or other psychoactive prescription drugs, are not eligible to participate. To screen for this, the PI performs an extensive pre-screening for these criteria, as well as for daily use of non-prescription drugs. A clinician then screens prospective subjects via a formal mental health examination that includes structured clinical inventory by DSM-IV criteria (SCID). This interview asks many personal questions about emotions and behaviors; it is used as a screening tool only. The consent process occurs in advance of the screening and, for those who are eligible to participate in the study, a second, shorter consent process occurs after screening.

Participants undergo the fMRI procedure during which they are asked to perform a series of simple tasks. The session will take about two hours. All participants will be paid $35 for completing the screening and
$50 for completing the fMRI session. Payment is prorated. Participants will be paid via a check from the company that manufactures the fMRI machines. There is no direct benefit to participants.

The study received IRB approval and has been in the recruitment phase for quite some time, with low accrual. Because of the difficulty recruiting participants, the PI has submitted a modification at the time of continuing review to include employees of the healthcare center as research participants.
RECRUITING EMPLOYEES FOR AN fMRI STUDY ASSESSING THE EFFECTS OF ALCOHOL AND DRUG USE

DISCUSSION

Questions/Comments for the researcher:

- How do you plan to recruit employees (e.g., flyers, email)?
- Will any employees be ineligible (e.g., direct reports, colleagues)?
- How will you protect employee participant privacy and confidentiality?
- Who will perform the screenings?
- Who will have access to the data?
- What will you do if you suspect dishonest responses during screening (regarding alcohol/drug/smoking use)?
- How will you handle incidental/ancillary findings?
- Will the data be identifiable?
- How will the compensation be processed?
- Will pregnant women be excluded? Limited to pregnant women in the 2nd or 3rd trimester?
- Will the screening include questions about current illegal activity (e.g., illegal drug use)? If yes, what impact will this have on the study?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

Vulnerable Subjects (45 CFR 46.111(b)): The IRB is required by regulation to ensure that “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.” In this study, participants who are employees would be considered a vulnerable population or a potentially vulnerable population, and added protections for privacy will be required.

Undue Influence: Will research assistants, postdoctoral trainees, or subordinates (all formally employed by the institution) feel influenced to participate in order to seek approval of their supervisor, the PI? Since the research group often works on projects with other research groups in the building and department, investigators and staff from other groups may also feel pressure to take part, as the identities of the individuals who participated will become common knowledge throughout the department.

Incidental Findings: The study team will be collecting intimate and personal information as well as health information about employees. In addition, the research may uncover incidental findings such as psychological or structural abnormalities in the course of research.

Payment: For employees who are hourly workers or non-exempt professionals, issues such as overtime might arise as an issue if the employee is not given release time from his/her supervisor. The institution employing the researchers may have policies established regarding remuneration.

Questions for the IRB:

- Has the PI sufficiently pursued other avenues for recruitment?
- Are employees being sought as a population of convenience?
• Does institutional policy allow and/or restrict the recruitment/participation of employees in research conducted at the institution?
• How does the sample size being sought compare to overall employee population? What are the implications of this ratio for the overall culture of the institution?
• What are the relationships of the researchers to the prospective (employee) subjects?

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

The assessments, tests, tasks, and scans are considered minimal risk. The MRI settings are within the required non-significant risk settings and all questions being asked are normal questions in a psychological exam, thus all study procedures are allowable under expedited review categories (Categories 3, 4, & 7). The participants will not benefit directly from the study, but there is a future potential social and scientific benefit for understanding the psychological and biomedical aspects of drug and alcohol use and abuse. The risks are reasonable in relation to the benefits.

Mitigation/Management of Risks:

Employee Recruitment & Participation:

• Employee participation requires additional privacy protections as part of the protections for a “vulnerable population.” The investigators should ensure strong privacy protections, code all the data, implement security measures to limit access to identifiable data, and store the data in password-protected files where only the PI is allowed access to the code.
• The consent process must include explicit statement that:
  o The decision to participate (or not) will have no bearing on employment status or performance reviews, or result in preferential treatment,
  o The information collected will not affect current or future employment,
  o No materials or information collected as part of the research study will migrate to the employee's employment or medical records without express authorization from the participant.
• The IRB may require an individual who is not in a supervisory position (i.e., a study coordinator or other researcher, not the PI) to conduct the consent process.
• The researchers should avoid any recruitment/consent activities being done with a supervisor present and limit the number of other employees involved in the recruitment/consent/research procedures to a bare minimum so as to protect participant privacy.
• Because the possibility of undue influence exists in the recruitment of any subordinates, the IRB may choose not to allow any employees who report directly to the PI to participate, nor allow any other employees in the department to participate.
• The research should take place in a private setting with as few employees present as possible.
• Policy Solutions:
  1. Discuss with institutional officials the possibility of implementing an institutional policy that clarifies the requirements for including employees in research, and in which cases they would not be allowed to participate (i.e., avoid allowing employee participation in research that collects sensitive information).
  2. Institutional policy for non-employees (volunteers and students) should be extended to these populations because the same or similar undue influence issues could arise.
Ancillary Findings:

- While the purpose of the fMRI is not intended to be diagnostic, the licensed clinicians who perform the screening procedures have the ethical responsibility to inform a person about a potential abnormal finding.
- If abnormal ancillary findings are seen in the data, the participant should be informed of the abnormalities and told to follow up with his/her primary care doctor or another appropriate practitioner or program (i.e., a substance abuse counselor or a crisis intervention program for thoughts of suicide or self-harm behaviors).
- The clinician does not have to provide the follow-up or any counseling, but participants must be informed that something suspec was found.
- The IRB may require that the participant be provided with referrals to specialists/counselors for any abnormal/concerning findings.
- Information regarding how the research team will handle incidental/ancillary findings should be provided in the consent form, explained during the consent process, and addressed explicitly in the protocol.
- Note: If a cognitive or structural anomaly is found during screening or data collection procedures, this may question the legality of informed consent. (American with Disabilities Act and the Health Insurance Portability and Accountability Act (HIPAA)).

Payment of Employees:

- The investigator should verify with her institution to see if policy exists regarding research payment to employees of the institution.
- Policy Solution: Have a clear institutional policy on research payment to employees; consider alternative compensation such as gift cards.

Alternate Details:

Several people who successfully screened for the study have expressed that they are nervous about the fMRI due to claustrophobia. The PI is considering amending the study again to administer a low-dose sedative (e.g., diazepam (Valium) or alprazolam (Xanax)) prior to undergoing the fMRI. How might this impact the study? Is this of increased concern since employees of the healthcare center may be enrolled?

Other events:

- During the formal mental health examination, as part of the pre-screening, an employee reveals that in the past he has thought about hurting himself. He has never attempted suicide and has never sought counseling; he is not currently prescribed any psychiatric medication and sees his primary care physician annually. The employee learns on a Friday afternoon that he does not qualify for the study and is upset. He is given a list of referral options, including suicide hotlines, etc. The PI learns from a co-worker on Monday that the employee attempted suicide over the weekend. What should the PI do, if anything?
- During the pre-screening a prospective subject, who happens to be a physician employee, misconstrues the questions about “smoking” and reports smoking marijuana recreationally on occasion. What should the PI do?
- An employee screens for the study, but does not qualify because he is prescribed an anti-depressant in an off-label capacity to treat his migraine headaches. His supervisor overhears him telling a co-worker that because he’s taking an anti-depressant he doesn’t qualify for the study. The supervisor begins to observe the employee’s behavior more carefully thinking he has a
mental health issue. Is this an IRB issue? Should or could the protocol and/or study consent form be altered to avoid a potential situation such as this, or decrease the likelihood of such an occurrence? Is a confidentiality issue such as this a potentially “foreseeable risk?”

- The clinician is administering the mental health examination to an employee who the clinician has previously treated clinically. The clinician knows the participant has not answered some of the questions truthfully. The clinician is duty bound to protect the employee’s privacy as a patient, but knows that some of the research screening data are incorrect. What should the clinician do?
- The cohort that regularly smokes and drinks alcohol is full, so an employee tells the study team that he does not smoke or drink alcohol, which is not accurate. One of the research assistants sees the individual’s information and knows it is not accurate. If she tells the PI it will be a breach of privacy and confidentiality; if she does not tell the PI it may compromise the integrity of the data. What should she do, if anything? What are her obligations, if any?

**Reference(s)**

45 CFR 46.111(b)
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111

45 CFR 46.116
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116

ADA 42 U.S.C. United States Code, 2011 Edition; Title 42 - The Public Health And Welfare; Chapter 126 - Equal Opportunity For Individuals With Disabilities
http://www2.ed.gov/about/offices/list/ocr/docs/hq9805.html

Age Discrimination act of 1975 (34 CFR Part 110)
A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF A SOCIAL ANTHROPOLOGY STUDY

AN ETHNOGRAPHIC STUDY OF THE ORGANIZATIONAL STRUCTURE OF OCCUPY BOSTON

By Hila Bernstein, MS

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 social anthropology graduate student proposes an ethnographic research study focused on the organizational structure and response to the legal and cultural challenges of Occupy Boston as the situation changes over time. Occupy Boston is a loosely organized group of activists of all ages who are camped out at Dewey Square in Boston.

The student investigator plans to begin his research by examining the content of online forums related to organizing and logistics. He plans to follow this with participant observation and semi-structured interviews covering: early stages of organization and current modes of operation, resource needs, handling of disputes, as well as the legal challenges they have faced and anticipate facing. The student investigator would like to conduct in-person interviews with 10 participants who are active in the group. He also plans to photograph and videotape activists’ activities, especially when police and local business owners engage with the Occupy residents. The researcher’s written proposal also mentions possibly comparing Occupy Boston with other Occupy sites across the country in the future.
AN ETHNOGRAPHIC STUDY OF THE ORGANIZATIONAL STRUCTURE OF OCCUPY BOSTON

DISCUSSION

Questions/Comments for the researcher:

- How many times do you anticipate visiting the site?
- Are the activists who will be recorded/photographed/videotaped the same activists you would like to interview?
- What interview questions may be answered in advance, and what questions must be answered on-site?
- What do you know about the age range of prospective participants? Will you interview anyone under 18? How will you know if anyone is a minor?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

45 CFR 46.116 General requirements for informed consent

“(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) The research could not practicably be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.”

45 CFR 46.117 Documentation of informed consent

“(c) 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.

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.”
45 CFR 46.101 (b) (2) Exemption

“(b) Unless otherwise required […], research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy [i.e., the Basic HHS Policy for Protection of Human Research Subjects]:

(2) Research involving the use of … interview procedures or observation of public behavior, unless:(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.”

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.”

Questions for the IRB:

• Is there risk to the researcher if he is observing police interaction? Does this impact the feasibility of collecting good data? Is the venue problematic (i.e., does it exacerbate this concern)?

• Should the safety of the researcher be considered? Is risk to the researcher under the IRB’s purview?

• What if the researcher is arrested? What if research data is confiscated? Is this a “scientific issue?” (Note: some IRBs take this into account, some don’t).

• Is this project journalism? Where is the line between research and journalism? Does the IRB have guidelines or policies that help guide this decision making process?

• What institutional policies may impact the review and conduct of this study?

• Is it appropriate to waive/alter elements of consent for the interviews? What about for the videos/photos?

• What creative ways could the researcher use technology for consent purposes?

• What measures will need to be taken to ensure privacy and confidentiality? What are the data safety concerns? Would a Certificate of Confidentiality or Privacy be an option?

• How does the risk/benefit analysis change if the participants in this study are already putting themselves at risk through their actions (which are not part of the research)? What additional risk does the research add?

Alternate Details:

• While reviewing the IRB application, the IRB staff member finds news reports that a homeless population, including those who are mentally ill, have been displaced from a recently closed
shelter and have taken up residence in the encampment. It is not clear whether all of them would be able to give informed consent.

- The researcher has become aware that legal trainings are being held periodically where those interested can learn about their rights and how to help others who may be arrested or detained. These trainings are not open to the media and are described as being for those who will become legal volunteers. The researcher proposes going to the training and writing about it by posing as an Occupy participant.

Other Events:

- Following initial approval of the study, the Boston Police Department (BPD) orders the site be cleared by all participants by 5 pm, two business days from now. The researcher has conducted interviews already, which have indicated that there are plans to barricade the site in order to resist entry by police. While videotaping and observing resistance activities (including more than passive resistance to the police) may be in the scope of the original application, the researcher plans to interview organizers about their specific plans and to conduct follow-up interviews of anyone who is arrested, jailed and/or prosecuted.

  - How does this impact the IRB’s review of the study?
  - What is the obligation of the researcher to inform the BPD?

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

Participants in the Occupy movement are a diverse group, and it may be difficult to predict what individuals may share or in what direction group activities may turn. It is also unclear what the responses from the greater community and the legal system may be. Further, the public nature of the activities of some protesters, amounting in some cases to civil disobedience, must be taken into account in considering the extent to which the research responses (as opposed to the underlying conduct) poses risk of civil or criminal liability or damage to the reputation of the subjects.

Mitigation/Management of Risks:

If the researcher will learn about or observe illegal activities, a Certificate of Confidentiality may be useful in protecting the identities of participants who disclose information that could put them at risk.

The researcher should discuss his intentions with participants prior to observations in non-public spaces, and prior to conducting interviews.

The researcher will need to be careful not to inadvertently identify participants in published materials or research data. It will be helpful to outline a thorough description of what will be done with videotapes. If identifiable video will be released publicly, participants must explicitly consent to their release. If the researcher does not need to identify participants, consider using pseudonyms or a code in the study files, and publishing information that does not identify participants.
**REFERENCE(s)**

45 CFR 46.101
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101

45 CFR 46.116
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116

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

NIH Certificates of Confidentiality Kiosk
http://grants.nih.gov/grants/policy/coc/

American Anthropological Association Statement on Ethnography and Institutional Review Boards
http://www.aaanet.org/stmts/irb.htm
A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF STUDENTS IN RESEARCH

ENROLLING STUDENTS INTO A RESEARCH STUDY ON ADJUSTING TO COLLEGE LIFE

By Cynthia Monahan, MBA, 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 faculty member researcher in the Psychology Department at University A is conducting a study on how students adjust to college life. Enrolled subjects will complete questionnaires at the beginning and end of either the fall or the spring semester. In addition, students will complete a weekly diary. The information that will be collected in the diary includes: exercise and eating habits, recreational activities, and mood (including questions about depression).

The inclusion criteria for this study are that a subject must be a current college student aged 18-25. The researcher would like to recruit students from University A as well as from surrounding universities/colleges. In addition, the researcher would like to recruit through the student pool in the Department of Psychology. The researcher will post an announcement on the electronic research recruitment system used by the university.

Psych 101 students are required to either participate in a research study or complete a similar project as part of their coursework. The alternative project involves writing a two-page report on an additional reading; students may select from a list of readings. It is expected that participation in the research study will take approximately one hour. The readings were selected to be comparable to the time commitment for study participation; the time required to complete the reading and report is expected to be approximately one hour.
Prior to scheduling the first study visit, subjects will be asked if they are currently enrolled into one of the researcher’s classes. If they indicate ‘yes’, they will be scheduled to meet with a co-investigator. In addition, the co-investigator will maintain the study records for these students.

There is no direct benefit to subjects for participating in this study. This research study is not funded.
ENROLLING STUDENTS INTO A RESEARCH STUDY ON ADJUSTING TO COLLEGE LIFE

DISCUSSION

Questions/Comments for the researcher:

• When will the investigator review responses to the questionnaire?
• If a subject indicates that he/she may be depressed, what is the plan for providing resources to the subject?
• How will the investigator ensure that the subjects are aged 18-25?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

The research plan must satisfy the regulations outlined in 45 CFR 46.111(b), namely:

“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.”

Consider the general requirements for informed consent outlined in 45 CFR 46.116:

“Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.” [Emphasis added]

Also consider if the research meets the criteria for a Waiver of Documentation of Consent [45 CFR 46.117(c)]:

“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:

• Is the schedule for reviewing responses appropriate for this study?
• Are there adequate safeguards in place for subjects who indicate depression?
• Is the data storage plan adequate?
• Does the consent form clearly state that there is no benefit to study participation and that participation will not affect the subject’s status as a student?

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

• Should research that involves students not be greater than minimal risk?
• Undue influence/coercion from faculty affects student participation; will students think that participating in research will affect them in a positive manner (higher grade, recommendations, etc.)? Or in a negative manner (lower grade)?

Mitigation/Management of Risks:

• Recruitment and consent procedures should be non-coercive
• If the researcher is to enroll from her class, a co-investigator (independent of the class) should consent subjects and collect study data; the researcher should not have access to this material during the grading period
• Recruitment should be non-coercive and be done through general announcement or central posting
• The plan for protecting privacy and maintaining confidentiality should be designed to minimize risks related to disclosure of information (e.g. all documents should be labeled with a code and not the subject’s name).
• Identify and enlist a student representative to serve on the IRB Committee
• When course credit or extra credit is given to students, students should be given options; the option should be comparable in terms of time, effort, and educational benefit
• The consent form should include, and make clear, that a student can withdraw at anytime and without penalty
• If materials ask about depressive symptoms, a detailed process for reviewing responses should be included in the research plan (e.g. when will answers be reviewed, who will review, etc.)
• If a subject indicates he/she has depressive symptoms, there should be a plan and mechanism for providing resources (e.g. student health services, clinic information, etc.)

Other Events:

During the screening visit, a potential subject incorrectly indicates that he is not a student in the Principal Investigator’s (PI) class; however, the subject is currently enrolled in the PI’s class. This error is not discovered until Visit 1 when the PI meets the student. Per the IRB-approved protocol, if the subject is a student in the PI’s class, a co-investigator must meet with that subject. At this time, the PI decides to go ahead and enroll the student into the study. The PI informs the IRB of this deviation. Should the subject be allowed to remain in the study? Are there additional protections that should be put in place for this student? Is there additional corrective action that should be required of the PI?

REFERENCE(s)

45 CFR 46
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111

OHRP Guidebook
http://www.hhs.gov/ohrp/archive/irb/irb_chapter6.htm
A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF TERRORISM RESEARCH

ASSESSING FACTORS THAT INFLUENCE A REFUGEE POPULATION’S ASSOCIATIONS WITH TERRORIST GROUPS

By Matt Stafford

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.

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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 sociologist has teamed up with a psychologist to conduct a long-term study of mental health and social group formation among Latin American refugees to the US. The research cohort will be comprised of adults who have fled violent conflicts in countries where known terror groups are believed to be actively recruiting.

A specific aim of this project is to determine what factors influence whether or not refugees are likely to accept, engage, or align themselves with terrorist groups in their post-conflict lives. The researchers will look at the impact of social, personal, experiential, and psychological factors, at both the group and individual level.

The study involves taking personal histories from subjects, asking them to recount traumatic encounters, and tell their refugee story. Subjects will be asked to complete standardized psychological evaluations at specific time points throughout the study and will be followed as they settle in new homes and communities. Subjects will also be invited to focus groups in convenient clusters post-resettlement and their social networks will be mapped through periodic in-person interviews.

An important aspect of the follow-up interviews will be to gauge changes in opinion regarding certain negative social groups (terrorists or terror-related groups). The research team will also assess personal anecdotes regarding interactions with agents of negative groups within their community as well as with the authorities.
Subjects will not be told the specific aims of the research, only that the purpose of the study is to learn the long-term social and psychological outcomes of refugee resettlement on post-conflict groups.

The researchers will recruit through flyers at refugee/immigration service agencies, local community centers, churches, grocery stores, etc.

This research is funded through a grant from the United Nations. Participants will receive a $25 gift card to a local supermarket chain at 12-month intervals for the duration of the research (based on continued engagement in the study).
ASSESSING FACTORS THAT INFLUENCE A REFUGEE POPULATION’S ASSOCIATIONS WITH TERRORIST GROUPS

DISCUSSION

Questions/Comments for the researcher:

- Will all materials be written/evaluated in English? Or available in translation?
- Are members of the research team trained in screening for depression and PTSD? Specifically among this cultural group?
- Who will facilitate the focus groups? Who will conduct the interviews?
- How often will psychological screenings occur? Who will evaluate and in how timely a manner?
- What are the risks of triggering episodes of anxiety or depression when asking subjects to re-live and recount traumatic experiences? What measures can be put in place to ameliorate this risk and/or to address observed instances of distress?
- Will participants be informed of the results of their psychological evaluations? Will follow-up care be offered if such need is indicated? What is the protocol for indications of suicidality?
- Could the fact that participants will be asked about terrorist groups be added to the consent form among a list of discussion topics as a way to avoid deception? If not, will participants be debriefed about the full intent of the study?
- How will the data be protected from being used in such a way that brings harm to participants?
- If subjects are loosely affiliated with and/or in proximity to terrorist groups who see them cooperating with researchers, might they be at risk of harm from these groups?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

45 CFR 46.116

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

American Psychological Association's (APA) Ethical Principles of Psychologists and Code of Conduct

§ 8.07 Deception in Research

(a) Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective non-deceptive alternative procedures are not feasible.

(b) Psychologists do not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress.
(c) Psychologists explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data.

§ 8.08 Debriefing
(a) Psychologists provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the psychologists are aware.
(b) If scientific or humane values justify delaying or withholding this information, psychologists take reasonable measures to reduce the risk of harm.
(c) When psychologists become aware that research procedures have harmed a participant, they take reasonable steps to minimize the harm.

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.

Questions for the IRB:
• Should individuals with signs of severe depression/PTSD be excluded from participation?
• What are the confidentiality risks? What risks are subjects exposing themselves to by opening up to the researchers?
  o Can a Certificate of Confidentiality be obtained to protect against compelled disclosure?
  o Does the use of focus groups introduce too much risk to individual privacy or safety?
• What are the reputational risks to the community?
• Does the partial disclosure of the research aims qualify as deception?
  o Does the research meet the criteria for a waiver of informed consent?
  o Is a waiver appropriate in this instance?
  o Would the information being withheld affect subjects’ willingness to participate?
• Might some of the participants become incarcerated during their participation? If so, Subpart C protections would need to be invoked.
• Is coercion a factor here?
  o Does the compensation offered qualify as coercion or undue influence?
  o Might a refugee population feel compelled to cooperate with the host country and its researchers out of intense gratitude or a sense of obligation?

Resolution & Discussions:
Risk/Benefit Analysis:
• Is it ethical not to fully disclose the purpose of the research to subjects?
• What are the risks to the subject population as a group?
• What are the risks to individual subjects within family/community groups?
• Is there an obligation to provide psychological counseling or other treatment/services to this research population?
• How can potentially coercive aspects of the study design/compensation be addressed?
• What benefits are there, if any to participants? Can a benefit be built in to the study somehow?

**Mitigation/Management of Risks:**

• Engage a community member in the planning and/or conduct of the research.
• Utilize a bi-directional consent procedure or other method to help ensure participants understand that their participation in the research is voluntary, and that they clearly understand any risks and benefits before agreeing to participate.
• Ensure that data is coded such that accidental disclosure will not place participants at risk of harm, embarrassment, threat to social standing, liberty, employability, etc.
• Obtain a Certificate of Confidentiality to protect the data from compelled disclosure.
• Ensure that interviewers and focus group leaders are trained to detect anxiety or depression reaching levels requiring evaluation and/or treatment, and have a plan in place (counseling, referral, etc.) to address such situations if they arise.

**Alternate Details:**

• The study adds an intervention designed to aid resettlement and engages participants in psychologically advantageous activities, such as gainful employment at a local charity.
• The investigator receives significant additional funding but in order to receive it they have to create a documentary film about the participants and their settlement in the area. Half of the participants have to agree to allow camera crews and interviews in their homes and workplaces.

**Other Events:**

• The investigator discovers that the primary computer where they enter study data has been tampered with and a key-logging device installed. It is unclear who did it, when it was done, and what study data may have been siphoned off prior to encryption of the data.
• The investigator sees a news alert on television, which mentions a study participant who was just interviewed two days prior, who is suspected of being involved in a terror plot and is currently the subject of a manhunt in the vicinity. The news alert warns that the alleged attack remains an imminent possibility and that anyone who has information should contact authorities.
• A study participant tells you the only reason they are participating in the study is to obtain a visa. What ethical dilemma does the researcher face?
REFERENCE(s)
45CFR46.116, General requirements for informed consent:  
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116

45CFR46, Subpart C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects:  
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc

NIH Certificates of Confidentiality Kiosk:  
http://grants2.nih.gov/grants/policy/coc/

HHS’s IRB Guidebook, Chapter 3 (see section on “Deception and Incomplete Disclosure”):  
http://www.hhs.gov/ohrp/archive/irb/irb_chapter3.htm#e2

Harvard Catalyst Community Engaged Research (CEnR) 101:  

An Annotated Bibliography on Cultural Competence in Research  
http://catalyst.harvard.edu/pdf/diversity/CCR-annotated-bibliography-10-12-10ver2-FINAL.pdf
A SOCIAL, BEHAVIORAL, & EDUCATION RESEARCH (SBER) CASE STUDY OF EDGES OF RESEARCH/IRB PURVIEW

AN EVALUATION OF AN EARLY INTERVENTION PROGRAM TO AMELIORATE PSYCHOSOCIAL EFFECTS OF TRAUMATIC BRAIN INJURY (TBI) IN COLLEGIATE ATHLETES

By: Lara N. Sloboda and Matt Stafford
with the SBER Subcommittee of Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program

OVERVIEW

The social, behavioral, and education 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:

Dr. Spikes, a sports medicine physician at a major research university with division I athletics program has partnered with a psychiatric clinician in the University’s Student Health Services department as well as a researcher in the Neuropsychology and Brain Sciences program to develop a multidisciplinary treatment program to lessen the long-term impact of post-concussion syndrome (PCS) caused by mild Traumatic Brain Injury (TBI). The study team intends to research the positive effects of the program on emotional adjustment, memory, and brain functioning.

Potential participants are those students actively involved in at least one Division I Varsity sport. The researchers intend to recruit participants in to the study based on referral by the coaching staff, team doctors and physicians, or athletic sports trainer. Sports staff will be instructed to provide the names of...
student athletes that suffer a concussion during a sporting event. Upon receipt of a potential participants' name, a member of the research team will contact the participant and set a meeting to conduct an in person prescreen interview which will include demographic items, questions regarding the incident that lead to the concussion, and questions regarding the student athlete’s diagnosis. This information will be confirmed through health records from Student Health Services. The prescreen interview will take place within 48 hours of the concussing event. The inclusion criteria for the study include being over the age of 18, having suffered a concussion during a NCAA sporting event and treated at the Sports Medicine clinic or Student Health Services with a diagnosis mild TBI (mTBI) as established by ICD-9 score. Students must be enrolled in college aged and not in their final semester at school. They must also confirm that there is no history of drug abuse or clinical depression. If deemed eligible, the participant will be presented with the consent form.

Researchers have planned four-week controlled aerobic intervention program to reduce ongoing symptoms. The program will include closely monitored physical activity, matched with physical conditioning, coordination exercises, visualization techniques, cognitive behavioral therapy to focus on motivation and anxiety, and medical education. The training will be conducted in 4 weekly group therapy and physical training sessions, coupled with daily monitoring during individual conditioning sessions.

At the beginning of the four-week intervention, participants will complete an in-person data collection session which will include basic memory and attention tasks, emotional quotient questionnaires, and psychosocial questions. The same tasks will be completed after the four-week intervention, and every six months until the participant graduates. To monitor the functional changes in the brain due to PCS, Functional Magnetic Resonance Imaging will be used at study time points to functional changes in the brain’s memory and executive function centers over time. Participants will complete basic working memory tasks. The scanning will help the researchers identify any structural changes in the brain as well as determine whether there is a relationship between symptoms reported pre- and post-intervention and the function of the brain during working memory tasks.

**Discussion**

*Questions/Comments for the researcher:*

- Will participants be able to provide the information needed for eligibility with 48 hours of the concussing event?
- If the research team is not referred to a potential participant immediately, will this affect the outcome of the study?
- Will the requirements for enrollment in to the study contradict the potential participants' doctor's orders?
- If participants are only referred by the coaching staff or Health Services, will their personal doctors be made aware of their enrollment in the research?
- Are there any exclusion criteria, including assessing whether an injury is too severe to be eligible?
- What is the justification for collecting health information both through self-report and student health records? Both carry risks (confidentiality around health information, putting the participant in a stressful situation post-concussion). Is there a reason why both are necessary?
• Is the participant able to consent to the study immediately following the concussion? Has the research team a means of identifying whether participants are able to consent, and if not, will the research team involve a Legally Authorized Representative?

• Will the research team be looking into academic performance? Will the time effort needed for the study affect the students’ work load and academic performance?

REGULATORY, ETHICAL, & CULTURAL ISSUES:

46.102 Definitions (in relevant part)

(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.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:
(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

List of categories (in relevant part):

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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.

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Email: regulatory@catalyst.harvard.edu

Traumatic Brain Injury in Collegiate Athletes
November 2018
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.

46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:
(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) 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.

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.

Massachusetts Mandated Reporter Laws

Child Abuse

M.G.L. c. 119 § 51A requires that nurses who have reasonable cause to believe that a child is suffering physical or emotional injury resulting from: (i) abuse inflicted which causes harm or substantial risk of harm to the child’s health or welfare, including sexual abuse; (ii) neglect, including malnutrition; (iii) physical dependence upon an addictive drug at birth; or (iv) being a sexually exploited child; or (v) being a human trafficking victim must immediately communicate with the Department of Children & Families (DCF) orally and, within 48 hours, submit a written report to DCF detailing the suspected abuse or neglect.

Any mandated reporter who fails to make required oral and written reports of witnessed or suspected child abuse and/or neglect shall be punished by a fine of up to $1,000. Any mandated reporter who willfully fails to report child abuse and/or neglect that resulted in serious bodily injury or death shall be punished by a fine of up to $5,000 and up to 2½ years in jail, and be reported to the person’s professional licensing authority. Whoever knowingly and willfully files a frivolous report shall be punished by: (i) a fine of not more than $2,000 for the first offense; (ii) imprisonment in a house of correction for not more than 6 months and a fine of not more than $2,000 for the second offense; and (iii) imprisonment in a house of correction for not more than 21/2 years and a fine of not more than $2,000 for the third and subsequent offenses.

Elder Abuse

M.G.L. c. 19A §15 requires that nurses who have reasonable cause to believe that an elderly person is suffering from or has died as a result of abuse to immediately make an oral report and submit a written
Elder abuse is defined as an act or omission which results in serious physical or emotional injury to an elderly person or financial exploitation of an elderly person; or the failure, inability or resistance of an elderly person to provide for himself or herself one or more of the necessities essential for physical and emotional well-being without which the elderly person would be unable to safely remain in the community. Forms of abuse include physical, sexual, emotional, neglect, financial exploitation, and self-neglect. However, no person is considered to be abused or neglected for the sole reason that such person is being furnished or relies upon treatment in accordance with the tenets and teachings of a church or religious denomination by a duly accredited practitioner thereof.

Mandated reporters who fail to make elder abuse reports when appropriate are subject to a fine up to $1,000. In addition, the law provides mandated reporters with immunity from any civil or criminal liability that otherwise could result from making a report, provided the reporter did not commit the abuse.

Abuse of a Disabled Person

M.G.L. c. 19C, § 10 requires that nurses who have reasonable cause to believe that a disabled person is abused must report the situation to the Disabled Persons Protection Commission (DPPC). Abuse of a disabled person includes acts of physical, sexual, emotional, verbal abuse and omission by a caregiver of a person with a physical disability between the ages of 18 and 59. Abuse of a disabled person under age 18 must be reported as child abuse and if older than 59 as elder abuse (see above). In addition to reporting suspected abuse and neglect, mandated reporters are also required to report to the DPPC all cases in which an individual with a disability has died, regardless of whether or not abuse or neglect is suspected.

Questions for the IRB:

- Does this study qualify for a waiver of documentation of consent and a Health Insurance Portability and Accountability (HIPAA) waiver?
- Who is conducting each aspect of the research? While there is a collaborative study team, who will be conducting the intervention? Does this individual have the training to be able to ensure the safety of the participants?
- Is there any control comparison in the study? The study is a within subjects design, but is there any reason to think that there will be measurable results over such a short duration?
- Are participants being asked to do too much following a brain injury? Are there ways to assess the effectiveness of this intervention in other ways?

Resolution & Discussions:

Risk/Benefit Analysis:

- Based on the details of the study, would the study need to go to full review? Do the research methods fall within the expedited review categories?
- The study methods add increased physical and mental stress for participants in recovery after a traumatic brain injury. The loud noises in the scanner as well as the audiotaped exercises could be a physical risk to participants during their recovery. The stress of the study due to the arduousness of the study requirements and mental exercises is a potential risk, as well as the added stress of the responsibility of being a participant.
- Involvement in the study has the potential to lead to a confirmation bias for the participants. It is possible that knowledge of their deficits would lead to the participants’ having a slower recovery.
- While also a potential benefit to the study, there is a concern that participants may not be able to return to their respective sports due to the results of the study, or the research team’s perception of their recovery. There is a possibility that participants who would normally have cleared their
institutions concussion protocol would be delayed in returning to their sport because of their performance in the research.

- For those athletes with the potential to be professional athletes, it is possible that the role in the research could affect their recruitment prospects.

**Mitigation/Management of Risks:**

- Risk of confidentiality could be decreased if participants were to self-disclose their concussion as opposed to being referred by the team doctor.
- The research team should create a protocol for assessing ability to consent and have a plan for inclusion of LARs if necessary.
- Research team members should be trained to identify severe signs of post-concussion symptomology so as to discontinue data collection or intervention should participants’ symptoms become too severe.

**Alternate Details:**

- In order to determine whether participants are eligible to return to sports, athletes will undergo an exertional test including running to determine if symptoms occur. They will also fill out a symptomology index. Only when symptoms are no longer present at baseline or after the exertional test will athletes be allowed to return to their sport.
- The study team determines that some participants will be allowed to return to sport earlier than the school’s concussion protocol usually allows if they agree to being in a concurrent research study, since clinic and coaches agree that the extra monitoring may make it safer to resume athletic activities. The concurrent study includes audio-taping the athletes reading a pre-determined script to monitor changes in speech patterns over time. The use of speech patterns will help the researchers identify any micro-changes in word usage which could be indicative of long-term mTBI damage leading to CTE.

**Other Events:**

- After being allowed to return to sport, a participant suffers another head injury. The research team determines that the participant should be removed from the study protocol because, having suffered two concussions in succession, the participant is no longer comparable to other participants.
- While enrolled in the study, a research participant is arrested for public intoxication and aggravated assault. Individuals known to the participant report that both drinking and aggressive behavior are not typical of this individual. The clinical psychiatrist indicates that the criminal proclivity is likely a side-effect of the concussion.

**Reference(s):**


45 CFR 46.102: [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102)


A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF MEDICATION ADHERENCE AND DESTIGMATIZING OPIOID RECOVERY SERVICES

By:
Amy Ben-Arieh, Matt Stafford with the SBER Subcommittee of Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program

OVERVIEW

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CASE STUDY

Piloting initiatives to overcome reluctance to utilize group-based recovery services for patients with Hepatitis C (HCV) and opioid use disorder.

SCENARIO/FACT PATTERN

Behavioral health clinicians at Big City Community Health Center (BCCCHC) are trying to improve outcomes for patients with HCV who have joined their addiction recovery and wellness service program. Services for those with substance use issues include: detox; counseling; education and case management; individual and group counseling; and harm reduction/recovery skills groups. While utilization of their detox treatment program has been high, group counseling and harm reduction/recovery skills group sessions have proven difficult to sustain. Engagement in these services by affected individuals and by their support group can be a crucial factor in reducing risk of relapse. Anecdotally, clinicians have noticed that consistent use of the group sessions seems to be associated with medication adherence and improved outcomes for patients with HCV. However, an initial quality improvement assessment revealed that patients found stigma associated with both substance use and HCV to be a barrier to both accessing and continuing to using the group sessions.

The clinicians would now like to further analyze the relationship between stigma, group service utilization, and medication adherence for HCV infected patients. To do this, they propose a two part study. First, they plan to hold a series of 3 focus groups (10 Subjects in each) who self-report HCV and opioid use. The groups will discuss why Subjects do or do not utilize or want to utilize the group services, in an effort to to further identify characteristics of the perceived stigma. They will also discuss what might help encourage...
those with HCV who use opioids to use the services, and ask them to help craft targeted affirming messages aimed at reducing stigma. Subjects will be passively recruited using flyers on the addiction recovery and wellness service floor of BCCHC. Eligibility will be confirmed during a screening interview when Subjects call in.

Once the messages are finalized (and IRB approved), they will then enroll 60 adults with treatment naïve HCV and documented opioid use disorder in a randomized trial. Investigators will compare service utilization and outcomes of those who receive standard appointment reminders to those who receive enhanced affirming messages and reminders. They plan to recruit from BCCHC’s online patient communication portal, seeking a HIPAA waiver to identify the eligible patient population, and then sending a letter co-signed by the potential subjects’ Primary Care Physician or Addiction and Recovery Specialist. Thirty subjects will receive standard messages, with 12 week course of a single pill/day HCV treatment regimen consistent with standard of care at BCCHC. Thirty Subjects will receive enhanced appt reminders, with the 12 week course of a single pill/day HCV treatment regimen. The pills will be in digital capsules to provide real-time verification of medication ingestion events and can be used to monitor medication adherence.

Digital pills are a radiofrequency emitter combined with a standard gelatin capsule that is compounded with a medication. Upon ingestion of the digital pill, the electro chemical gradient in the stomach will activate the emitter, signaling medication ingestion information to a wearable tech device (reader). The reader then stores encrypted ingestion data and sends it to a smartphone and cloud based server in real time. This data is then available for review by clinicians. The smart phones and readers will be provided by the study. Subjects may keep the smart phones upon completion of the study. The study will also cover the cost of the HCV medication.

In addition to regular care and optional group service utilization, Subjects will come in for 4 study visits (6 weeks, 12 weeks, 6 months, 1 year). Each visit will consist of a brief physical exam, drug test (blood), semi-structured interview, and quality of life survey. Investigators will combine this with review of the Subjects medical record for information regarding group service utilization, medication adherence, liver function, relapse, overdose, and general wellness at these time points.

**DISCUSSION**

**Questions/Comments for the researcher:**

- How will individuals be consented for participation in the focus groups?
- Considering that inclusion criteria for this group is opioid use disorder, how will you determine if a subject is able to consent to participate? Might the capacity for consent change over time? How should continued consent be assured and documented?
- Will the focus groups be audio recorded? When will audio recordings be transcribed? When will they be destroyed?
- Is information in the cloud and on the reader secure?
- What would happen if the reader or phone are hacked or stolen?
- Given the sensitive intersection of identities, and the understanding that they carry stigma, could a more private method of discussion achieve the same/similar aims without risk of outing?
- What are the protections for the electronic information as it is stored and analyzed on the cloud?
- If stigma is preventing this patient population from accessing group services, will passive recruitment be sufficient to get focus group Subjects?
- Is a letter in the patient portal the right way to make first contact?
- Who will be conducting the focus groups and/or study visits?
- Will monitoring adherence impact adherence in the control group?
- Will the content of the enhanced messages place subjects at risk?
REGULATORY, ETHICAL, AND CULTURAL ISSUES

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 Subjects 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 Subjects.

Waiver of Documentation of Consent (45 CFR 46.117) is permissible when:

- The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality. For example, for research on sensitive topics, such as domestic violence or illegal activities; OR
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online.
- Under the 2018 Common Rule, there is an additional requirement for the IRB approval of an informed consent documentation waiver request: Where the Subjects are members of a cultural group in which signing forms is not a normal/acceptable practice.

Questions for the IRB:

- What are the security/HIPAA concerns related to digital pill use?
- Does the institution need a BAA with the digital pill/cloud server/phone app company?
- Should age inclusion criteria be added?
- Should the study seek a Certificate of Confidentiality from the NIH (not an NIH funded study)?
- Should written consent for participation in the focus group be waived?
- Is provision of a smart phone and/or payment for this extremely expensive medication an undue inducement to participation?
- How might alterations to the study design lower risk to subjects?
- What are the procedural risks of this study?
- While the HCV medication is approved and standard of care, does combining with the digital pill make this an FDA regulated study? Are additional determinations required (e.g., non-significant risk)?
- What training should be required for the study staff responsible for facilitating the focus groups?
- What are the physical security details associated with the study smart phone and reader (e.g., storage of the device, access to it)?

RESOLUTION AND DISCUSSIONS

Risk/Benefit Analysis:

- What special challenges does this research pose for this population? Consider specifically: loss of confidentiality, disclosure of substance use disorder, disclosure of HCV, disclosure of seeking treatment, risk to insurability.
- Does the recruitment process pose unnecessary risks?

Mitigation/Management of Risks:

- Focus groups sessions should begin with a confidentiality reminder to all Subjects.
- Information provided to volunteers during recruitment, pre-screening, and enrollment should describe the nature of the questions that will be included in the semi-structured interview, quality of live survey, and asked in the focus group. Given the sensitivity of questions, Subjects must be free...
to skip questions on the survey, refuse to answer questions during the focus group, and may terminate participation at any time.

- Data must be collected through a HIPAA compliant web server then securely relayed to a cloud-based program. The cloud-based database must be hosted behind the secure firewall and accessed through BCCHC secure computers. Identifiers should not be linked to ingestion data captured by web server or the cloud-based program.
- Subjects may be having liver function and drug testing blood draws for clinical care at similar time points. Can this data be drawn from the medical record to prevent re-sticking/superfluous draws?

**ALTERNATE DETAILS:**

**Other Events:**

A recording device with the audio interviews is stolen.

Subject loses their phone.

**New Recruitment Strategy:**

Passive recruitment is insufficient, so the investigator submits an amendment seeking to give $5 gift cards to enrolled subjects who refer a potential Subject who completes screening (snowball/chain-recruitment).

**REFERENCE(S):**

45 CFR 46.117(c) [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117)

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

VIDEOCONFERENCEING FOR RESEARCH PURPOSES

By: Cynthia J. Monahan and Jennifer A. Graf
with the SBER Subcommittee of Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program

OVERVIEW

The social, behavioral, and education 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:

Standard care treatment of adults with depression commonly involves individual and/or group therapy sessions with a psychiatrist and/or psychologist/therapist and medication. Non-adherence to drug regimens is well documented in the literature among such patients. A treating psychiatrist at the local medical center believes that medication adherence can be improved by contacting patients between in-person sessions to confirm adherence; however, she does not believe that electronic mail (email) or telephone communication are the appropriate communication methods, as they eliminate non-verbal communication.

To test this hypothesis, she has submitted a research study to the hospital’s Institutional Review Board (IRB) for consideration that proposes to enroll her adult patients being treated for depression with prescription medication and in-office therapy sessions. Participants will be randomized to standard care (e.g., standard in-person therapy sessions and medication) or standard care plus a 15-minute videoconference check-in with patients between clinic visits. Those in the standard care group will be asked to bring their prescription medication bottle to the in-person therapy sessions so that the doctor or
a member of the study team can assess medication adherence. During each videoconference session she or a co-investigator will ask the subject to see the number of pills remaining in the prescription bottle and will ask some general wellness questions of the patient since the last in-person therapy session. The psychiatrist hypothesizes that those who are randomized to the standard care plus videoconference session will have greater medication adherence and will benefit from an additional opportunity for a brief face-to-face meeting. Videoconference check-in sessions will be scheduled at the same time in-person clinic therapy sessions are scheduled.

The protocol requires that subjects have a device that has videoconferencing capabilities and either a data plan or secure Wi-Fi, as participants are advised in the consent form that they should not videoconference with the study team on unsecure Wi-Fi. The protocol specifies that a member of the study team will use the telecommunications application Skype from a desktop computer in a private office in the outpatient psychiatry clinic at the hospital and that the videoconference session will be recorded.

Discussion

Questions/Comments for the researcher:

- The protocol does not address that subjects should only videoconference from a private location. How will the PI ensure privacy of communication or handle a situation if a subject is obviously videoconferencing from a public or non-private setting?
- What is the justification for recording the videoconference sessions?
- Where will the recorded videoconference sessions be stored, who will have access to them, and will they be available in the clinical record?
- What are the procedures if a study participant does not participate in the scheduled videoconference session?
- What procedures will be followed if the subject appears distressed or indicates s/he has not been adhering to the medication regimen?
- Will participants be paid for participation or receive payment to help defray any costs associated with the videoconferencing?
- If illegal behavior is tangentially observed during the videoconference session (e.g., drug paraphernalia is observed in the background at a home location) how will that be addressed by the study team?
- If a subject refuses to show the contents of the pill bottle to the researcher during the videoconference will this be reported to the IRB as an unanticipated problem?

Regulatory, Ethical, & Cultural Issues:

46.102 Definitions (in relevant part)

(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.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

*List of categories* (in relevant part):

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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.

46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:
(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes
in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) 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.

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.

**Massachusetts Mandated Reporter Laws**

**Child Abuse**

M.G.L. c. 119 § 51A requires that nurses who have reasonable cause to believe that a child is suffering physical or emotional injury resulting from: (i) abuse inflicted which causes harm or substantial risk of harm to the child’s health or welfare, including sexual abuse; (ii) neglect, including malnutrition; (iii) physical dependence upon an addictive drug at birth; or (iv) being a sexually exploited child; or (v) being a human trafficking victim must immediately communicate with the Department of Children & Families (DCF) orally and, within 48 hours, submit a written report to DCF detailing the suspected abuse or neglect.

Any mandated reporter who fails to make required oral and written reports of witnessed or suspected child abuse and/or neglect shall be punished by a fine of up to $1,000. Any mandated reporter who willfully fails to report child abuse and/or neglect that resulted in serious bodily injury or death shall be punished by a fine of up to $5,000 and up to 2½ years in jail, and be reported to the person’s professional licensing authority. Whoever knowingly and willfully files a frivolous report shall be punished by: (i) a fine of not more than $2,000 for the first offense; (ii) imprisonment in a house of correction for not more than 6 months and a fine of not more than $2,000 for the second offense; and (iii) imprisonment in a house of correction for not more than 2½ years and a fine of not more than $2,000 for the third and subsequent offenses.

**Elder Abuse**

M.G.L. c. 19A §15 requires that nurses who have reasonable cause to believe that an elderly person is suffering from or has died as a result of abuse to immediately make an oral report and submit a written report within forty-eight hours. Elder abuse is defined as an act or omission which results in serious physical or emotional injury to an elderly person or financial exploitation of an elderly person; or the failure, inability or resistance of an elderly person to provide for himself or herself one or more of the necessities essential for physical and emotional well-being without which the elderly person would be unable to safely remain in the community. Forms of abuse include physical, sexual, emotional, verbal abuse and omission by a caregiver of a person with a physical disability between the ages of 18 and 59. Abuse of a disabled person under age 18 must be reported as child abuse and if older than 59 as elder abuse (see above). In addition to reporting suspected abuse and neglect, mandated reporters are also required to report to the DPPC all
cases in which an individual with a disability has died, regardless of whether or not abuse or neglect is suspected.

Questions for the IRB:

- Is it acceptable that the PI will enroll her own patients as study participants?
- Does this study qualify for a waiver of documentation of consent and a Health Insurance Portability and Accountability (HIPAA) waiver?
- Should participants in the videoconference group be advised about the MA Mandated Reporter laws/requirements?
- Should a clinician (e.g., MD, PhD, RN, LCSW) conduct the videoconference session?
- Are there other institutional policies to consider (e.g., video communication policies, other Information Technology policies)?
- In addition to the IRB, should the Office of the General Counsel and an Information Technology expert review this study?
- Is Skype use permitted by institutional policies? Is it HIPAA compliant? Will subjects have to download this software? If so, are there end user license agreement (EULA) issues that need to be taken into consideration relative to the research? Is a contract between the medical center and Skype indicated?
- If the results suggest improved adherence, should the standard care arm receive the same intervention?
- If subjects experience increased adherence, what happens when the study ends? Will they just return to standard care? Should a transition plan be in place to help sustain adherence when the study ends?
- Should the PI obtain a Certificate of Confidentiality?
- Should the PI be required to supply iPADs or laptops to potential subjects who do not have access to these types of devices?
- Is the Skype interview being saved electronically? If so, how will privacy be protected and confidentiality be maintained?

Resolution & Discussions:

Risk/Benefit Analysis:

- While the study qualifies for expedited review, given the privacy issues and the possibility of self-incrimination, review by the convened IRB may be warranted.
- As participation in the study could potentially increase risk for self-disclosure of sensitive information or illegal behavior, the protocol should include a plan to discuss Wi-Fi security issues and the MA Mandated Reporter laws with prospective subjects about the potential implications of each. These conversations should be documented with a signed and dated memorandum to file.
- A person with appropriate training and experience should conduct the videoconference sessions given that a psychological wellbeing assessment will be conducted.
- A standard referral/escalation plan should be specified in the protocol in the event that behavior of concern is observed during a videoconference session. Furthermore, as part of the enrollment/consent process, a subject's permission to contact his/her treating psychiatrist/therapist should be documented in the event that notification is indicated.

**Mitigation/Management of Risks:**

- Do not record videoconference sessions.
- Given the potential vulnerability of the study population, require detailed criteria in the protocol to assess and document each subject’s capacity to consent.
- Create a standard script to be read to subject at the start of each videoconference session reminding them of secure Wi-Fi use requirements, self-incrimination risks, mandatory reporting requirements, etc.
- The protocol should have clear escalation procedures if during a videoconference session a subject is observed to be non-adherent to the medication regimen and indicates behavior/thoughts of self-harm, etc.

**Alternate Details:**

- What if the study population involved minors?
- What if this study is NIH-funded?

**Other Events:**

- The participant is videoconferencing with the study team at his private office at work. His supervisor in the adjacent office overhears the conversation because the walls are thin and raises study participation with the subject/employee.
- During a videoconference session with a subject the PI notices a disorderly home environment in the background. The PI asks the subject about it and knows that she and her husband are taking care of his elderly father. The PI has concerns about the care and wellbeing of the subject’s elderly farther in-law.
- During a videoconference session, an individual other than the subjects is observed doing something illegal or abusive?
- During a videoconference session, the investigator sees illegal drug supplies and guns. What is the responsibility of the PI?

**Reference(s):**

45 CFR 46.111-112:  
[http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111)

45 CFR 46.102:  
[http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102)

45 CFR 46.110:

45 CFR 46.116:

45 CFR 46.117:

Massachusetts Mandated Reporter Laws: