

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

VIDEOCONFERENCING FOR RESEARCH PURPOSES

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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, 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:

- 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>

45 CFR 46.102:

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

45 CFR 46.110:

Prior to January 19, 2018: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.110>; January 19, 2018 and later: <https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf>

45 CFR 46.116:

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116>

45 CFR 46.117:

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.117>

Massachusetts Mandated Reporter Laws:

<http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/nursing/complaint-resolution/mandatory-abuse-reporting.html>