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

ENROLLING STUDENTS INTO A RESEARCH STUDY ON ADJUSTING TO COLLEGE LIFE

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OVERVIEW

The social, behavioral, and educational research (SBER) case studies provide education and guidance on how to identify and mitigate risks associated with SBER. These studies may be used by both IRB administrators and investigators when reviewing and designing research studies that involved SBER components.

Case studies follow a standard format that includes: 1) a fact pattern, 2) regulatory, cultural, and ethical issues, and 3) a risk/benefit analysis and risk management options. This format was created to allow for flexibility in applying the case studies.

By identifying common themes, linking them directly to federal regulations and guidance, and outlining risk mitigation options, the case studies can be used in a variety of ways, which include: 1) as an education tool for training individuals in human subjects research, 2) as a basis for developing reviewer checklists/worksheets, and 3) as a tool in designing research projects.

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CASE STUDY

SCENARIO/FACT PATTERN:

A 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.
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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