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.

We encourage you to reproduce and use these materials freely. In doing so, we require that you acknowledge Harvard Catalyst as the publisher and that you give appropriate credit to the individual authors. For additional information, visit http://catalyst.harvard.edu/about/citingsupport.html.

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 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.

Visit: http://catalyst.harvard.edu/programs/regulatory/sber.html
Email: regulatory@catalyst.harvard.edu

Illegal Behaviors
V1 May 2014
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 group 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 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.

Questions/Comments for the researcher:
• Is a focus group 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 group 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 group (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, ETHICAL, & CULTURAL 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 they 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 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 group 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.

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
http://www.gpo.gov/fdsys/pkg/FR-2013-01-17/pdf/2012-31341.pdf and

The National Advisory Council on Drug Abuse (NACDA) Guidelines for Substance Abuse Research Involving Children and Adolescents