



## A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF RESEARCH ON ILLEGAL BEHAVIORS

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

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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:**

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 from 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

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

<http://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/childrens-online-privacy-protection-rule>

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

<http://www.drugabuse.gov/funding/clinical-research/nacda-guidelines-substance-abuse-research-involving-children-adolescents> and <http://www.drugabuse.gov/sites/default/files/pdf/nacdaguidelines.pdf>.