



## 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

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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 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 2<sup>nd</sup> or 3<sup>rd</sup> 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:
  - The decision to participate (or not) will have no bearing on employment status or performance reviews, or result in preferential treatment,
  - The information collected will not affect current or future employment,
  - 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 suspect 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)

<http://www2.ed.gov/policy/rights/reg/ocr/edlite-34cfr110.html>