

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

THE EFFECT OF SHARED EXPERIENCES ON MOOD

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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 including as: 1) an education tool for training individuals in human subjects research, 2) a basis for developing reviewer checklists/worksheets, and 3) a tool in designing research projects.

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CASE STUDY

SCENARIO/FACT PATTERN:

Experienced clinical psychologists at two different universities hypothesize that they can detect changes in the overall mood of college students based on whether the college football team wins or loses games. They propose to measure mood by analyzing changes in the proportion of positive vs. negative words in emails sent by students through their university email accounts. They have obtained the agreement of each university's IT departments to provide emails with the sending and receiving addresses "hashed," meaning that the actual email addresses are altered by an algorithm to create a code that is consistent for each email address but cannot be converted back to the original address. An automated algorithm would be used to analyze the words in the emails, meaning that no one on the research team would actually be reading the email, and therefore would not see any identifiable information contained in the body of the email.

The researchers recognize that student use of emails through their university account is only a small fraction of their electronic communications, but argue that the convenience of being able to obtain this anonymized data set makes it possible to test the hypothesis that attending a university with a successful football team boosts student moods, and that doing the analysis at two different universities will enhance the generalizability of the results.

In both universities, the athletic department sends out a text message with game results to all students with registered phone numbers, except for those who have opted out of receiving such text messages. To reduce variability in these messages, the researchers have obtained the agreement from each university's athletic departments to include certain consistent wording in these texts describing the wins

and losses: “Everyone at the university should be proud of the way the team played” for losses and “Everyone at the university should be proud of the way the team won” for wins.

The researchers originally proposed that the students did not need to be notified about this study because no identifiable email addresses would be obtained. However, one of the universities notified the investigator that she would be required to send an email to all student users of the email system describing the study and providing a way for them to opt out from having their emails analyzed. For consistency, the investigators now propose to use this process at both universities. However, the email will only say the purpose is to “analyze patterns in anonymized student emails” without specifically saying that positive and negative words will be counted or that the hypothesis is that the football team’s winning and losing will affect mood.

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DISCUSSION

Questions/Comments for the researcher:

- Is there sufficient justification for using “opt-out” consent, recognizing that some students will not read or fully understand the notification email? Does this plan adequately protect the rights and welfare of the students? Could the study practicably be carried out if student emails were only analyzed for students who affirmatively agreed to participate? What provisions are made for telling the students after the study is completed about their participation?
- Is there sufficient justification for not revealing the hypothesis that mood is linked to the football team’s performance and the standardization of the text messaging about wins and losses? Are the rights and welfare of the students adequately protected? Could the study practicably be carried out if the notification included information about the standardized text messages? Will students be informed about the incomplete disclosure, and if so, how and when?
- Will undergraduates who are minors (younger than 18 in many, but not all, states) be included? If not, how will they be screened out? If so, will parental permission be obtained or is a waiver requested?
- What are the protections for the electronic information as it is stored and analyzed on the researcher’s computers?
- Should the people to whom a student’s emails are sent be notified about the study and allowed to opt out, possibly by including a standard message accompanying every email from the student’s address?
- Will the researchers obtain any additional “hashed” information about the students, such as gender, class status, or whether they opted out of receiving text messages from the athletics department?
- Are any provisions needed for follow up of students whose emails reveal a plan to harm themselves or others? How would students be notified about these provisions?
- Is the algorithm for analyzing positive and negative words a reliable enough indicator of mood for the study to yield meaningful results?

REGULATORY, CULTURAL, & ETHICAL ISSUES:

- Alteration of consent: There are two proposed alterations in consent, first, that the purpose of the study will not be completely described, and second, that data will be analyzed from all students unless they actively request not to be included; that is, a lack of response is considered consent. In order to approve both proposals, the IRB must determine that the procedures in each case meet the criteria for an alteration of consent under 46.116(d) as follows: (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.
- Waiver of parental permission: If the researchers plan to include students who are minors, the IRB must make the same findings as above to approve either “opt-out” or no permission from parents or guardians. One common argument for waiver of parental permission for college students is that although they are technically minors, their parents have relinquished oversight of their daily lives and the students are expected to take on many adult responsibilities.
- Privacy protection: Does analysis of emails constitute an unacceptable invasion of privacy, even if the sender and receiver are anonymized and no human reads the emails?

Questions for the IRB:

- What additional institutional review and permissions are required?
- Should the IRB seek the opinion of students as part of the review of this study?
- Do the students need to be informed of the name of the other university where the study is being carried out?
- Are there adequate measures to prevent students from feeling pressure from the school to agree to participate?
- Are the researchers' measures for safeguarding the data sufficient?

RESOLUTION & DISCUSSIONS:

Risk/Benefit Analysis:

The main source of risk in this study is the invasion of privacy in analyzing emails and the potential breach of confidentiality if anyone other than the researchers gain access to the email data (for example, through loss of a laptop or hacking).

The research offers no direct benefit to the participants. Knowledge gained from the research may influence debates about the appropriate investment of university resources in athletic departments and possibly provisions for supporting the mood of the student body after athletic team losses.

Mitigation/Management of Risks:

This risk can be minimized by adequate provisions to obtain consent from the students and protect the data from inadvertent disclosure. The key decision, both for the IRB and for other university reviewers, is whether the altered (opt-out) consent process with incomplete disclosure of the hypothesis is in fact adequate.

Alternate Details:

- The researchers decide not to standardize the text messages from the athletic departments and then argue that this is not human subjects research because no interactions or interventions occur and no identifiable information is being obtained.
- An undergraduate doing thesis research under one of the investigators proposes to use his access to undergraduate directories to recruit students to "friend" him on Facebook and give permission for the research team to download and analyze their Facebook posts for positive and negative words during the course of the study.

Other Events:

- A student contacts the university president to object to the study, saying that she didn't read the email allowing her to opt out but that the university honor code should have required that only those giving active consent should have their emails analyzed.
- The algorithm used for "hashing" the email addresses is revealed to have a flaw that would allow someone with access to substantial computing power to back out the original email addresses.
- The football coach (who does know the purpose of the study) publicly reveals it and calls for all students to opt out of allowing their emails to be analyzed because he does not want the results of the study to put additional pressure to win on the members of the football team.

- When the students are debriefed about the hypothesis, the members of the basketball team object to basketball games being left out of the study.

REFERENCE(S)

Waiver of consent: 45 CFR [46.116](#)(c) and (d)

Waiver of documentation of consent: [45 CFR 46.117\(c\)](#)

DHHS regulations pertaining to the enrollment of minors (**[Subpart D](#)**)

OHRP Research with Children [FAQs](#)