RESEARCH ETHICS
Cases and Materials

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Research Involving Human Subjects
The Administration of Alcohol

The study of alcohol use, abuse, and dependence is a major national research priority. Alcohol abuse and dependence is associated with devastating personal and social consequences. It is currently the third most prevalent public health problem in the United States. Alcohol use is associated with approximately one-half of all automobile accidents, homicides, rapes, acts of family violence, and child molestations. Costs to the U.S. economy are estimated to exceed $120 billion annually.

To help us understand more fully the factors that influence alcohol consumption and abuse and the factors that may mediate how a particular individual may be affected by alcohol, a large number of studies examine the effects of alcohol by administering alcohol to human subjects in a laboratory setting. The research focuses primarily on the question of whether alcohol actually reduces cardiovascular stress reactivity, thereby acting as a potential reinforcer of drinking behavior in stressful situations. (There is disagreement among researchers as to whether alcohol produces a true physiological stress-reduction effect or whether some subjects experience pronounced stress reactivity when intoxicated.) The secondary purpose of the research is to identify the factors that might cause alcohol to reduce the reaction to stress in some individuals and those factors that might cause alcohol to increase reactions to stress in other persons. Identification of these factors may lead to the identification of characteristics that are related to an increased likelihood of alcohol abuse.

The following cases describe experiments in which alcohol is administered to a subject and various measures of the individual's responsivity to alcohol are measured. All of the cases employ a similar experimental protocol, but differ with respect to (1) the subjects' characteristics and (2) the information collected from the subjects. Each scenario involves the use of "mild" stress induction, a commonly used methodology that poses minimal risk to participating subjects.

The ethical issues presented in the cases in this chapter pertain to the use of experimental procedures that pose a risk of harm to subjects. In working through the cases, pay attention to defining the nature of the (potential) harm, the procedures that might be employed to reduce or eliminate the risk of harm, the reasonableness of the research in view of the potential harms, and the
unique conceptual issues presented by the problem of identifying the degree of risk posed by the research.

The cases involve various methods through which a group of investigators plan to recruit participants in an alcohol study. The experimental procedure is first described, followed by each of three recruitment scenarios and questions for discussion.

Methodological Background

A widely used experimental approach to research such as this is to study various groups of individuals whose level of overall risk for alcohol abuse varies. The basic rationale behind such an approach is that the factors that might lead to alcohol abuse, which, in this case, might be related to a greater sensitivity to the reinforcing effects of alcohol, are more likely to be found in groups at greater risk. Individuals are assumed to be at greater risk for alcohol abuse if they possess a characteristic or are a member of a group that is associated with greater prevalence of alcohol abuse than is found in the general population. Described below are some characteristics (e.g., a history of previous alcohol abuse) and groups (e.g., males) associated with increased risk for abuse.

Note both that there are different risk factors as well as varying degrees of risk. In general, the more risk factors an individual possesses, the greater the overall level of risk. For example, one risk factor is being male. Males exhibit two to three times the levels of alcohol abuse as do females. Thus, at any given point in time, the average male has a 7.5 percent chance of developing serious alcohol problems within three months. Another risk factor is age. In general, young adults (between 18 and 30 years of age) have higher prevalence rates of alcohol problems than do older adults. The risk that a younger adult will experience alcohol problems is close to 13 percent (20 percent for men and 6 percent for women). Another risk factor, which appears to be present only in males, is being the child of an alcoholic parent. Sons of alcoholic parents have been estimated to have a risk level upwards of 35 percent. Another risk factor is having a history of alcohol- and drug-related problems. Such individuals have a risk level of approximately 50 percent. In this case, mediating factors relevant to the risk prediction are the length and severity of the earlier problem, as well as amount of time that has elapsed since the earlier period of substance abuse. A person who has had a long history of relatively severe substance abuse in the recent past is at a greater risk for current problems. There are a number of widely used and high-quality substance abuse screening instruments and diagnostic interviews available to researchers conducting drug and alcohol research.
The Experimental Alcohol Administration Procedure  
(Applicable to Each Recruitment Scenario)

Researchers at a midwestern university are conducting an experiment examining the effects of alcohol on stress. Following recruitment, each subject is scheduled for the test session. Upon arrival for the session, subjects read a description of the experimental procedure, sign a consent form, and have their IDs checked to ensure that they are 21 years of age or older. During the consent process, subjects are provided with a full description of the purpose of the study. Subjects are then assessed for mood (using standard measures), and resting heart rate levels are taken. A stress-inducement procedure is administered, during which heart rate activities continue to be recorded. Subjects then rest for a period of time until they are completely relaxed (i.e., their heart rate returns to pre-stress levels). Subjects then drink enough alcohol to bring their blood alcohol level up to 0.10 percent, the legal limit for intoxication in most states. The stress-inducement procedure is administered once again, and subjects' reaction is recorded. After the testing, subjects remain in the laboratory until their blood alcohol level drops to less than 0.02 percent.

Recruitment Scenario 1

Subjects are recruited for the study through an advertisement placed in the university's student newspaper. The ad reads as follows: "Volunteers needed for an alcohol research project. Must be over 21 years of age. Call 555-2121." When prospective subjects call, they are asked their age and whether they have ever had any problems with alcohol. If a subject reports being over 21 years old and as having had no prior problems with alcohol, he or she is scheduled to come into the laboratory for the experiment. The experiment consists of the Alcohol Administration Procedure, described above.

Questions for Discussion

1. Does this recruitment method present any ethical problems?
2. Suppose the investigators decide to offer a monetary reward for participating in the research. Would such a reward be relevant to your analysis of Question 1?
3. Suppose the study excluded anyone who has never consumed alcohol. Would this restriction affect your analysis of Question 1?
4. Are there any potential risks of harm inherent in the administration procedure that should be disclosed during the consent process? Are there risks of harm that make the study unacceptable, even if the risks are disclosed? If so, is there any way to reduce or eliminate these risks?
5. Are there any gender-dependent risks that need to be considered (i.e., are there risks for men that don’t exist for women or vice versa)?

6. How should the consent form be worded?

7. Suppose the study reveals that the subject is an alcoholic or is at risk for alcohol abuse. Does the investigator have an obligation to inform the subject? Suppose that this information is revealed at the screening stage, so that the subject is ineligible to participate. What should the subject be told?

Recruitment Scenario 2

The researchers now recruit persons who are the offspring of alcoholic parents through various groups such as ACOA (Adult Children of Alcoholics) and AL-ANON (family members of alcoholics). A postcard is sent to members of the local chapters of these two organizations soliciting their participation. The postcard reads as follows: “We are seeking to recruit volunteers to participate in an alcohol research project. Participants must be over 21 years of age. For more information, please call 555-2121.”

As in Recruitment Scenario 1, when prospective subjects call, they are asked their age and whether they have ever had any problems with alcohol. If a subject reports being over 21 years old and as having had no prior problems with alcohol, he or she is scheduled to come into the laboratory for the experiment. The experiment consists of the Alcohol Administration Procedure, described above. The only difference between the subjects recruited in this scenario and those recruited for Scenario 1, is that these subjects have a higher risk of developing alcohol problems in the future (statistically speaking), by virtue of being a member of a group with a higher prevalence of alcohol problems.

For this scenario, more extensive interviews are conducted prior to admitting subjects to the study. Each subject is interviewed before the alcohol administration procedure begins to obtain detailed information about the history of alcohol use and abuse, both their own history and that of their family members. In addition, subjects are asked to provide detailed personal information about themselves and their family members.

Questions for Discussion

1. Does this recruitment method present any ethical problems? Explain. How does this scenario differ from Recruitment Scenario 1? Is it more or less ethically problematic? Why?

2. If any additional risks are presented by this experiment as compared with the previous one, what might be done to reduce these risks?

3. Would your assessment of the case differ if the subjects had no history of alcohol abuse, but reported recreational use of other mood altering drugs? Why? What are the important issues to consider here?
4. Suppose the subjects, who are offspring of alcoholics, had a history of drug abuse (as opposed to recreational drug use) or alcohol abuse as well. What ethical issues are presented by including them in the study?

5. What types of conceptual issues may cloud the ethical decision making process about the inclusion of the kinds of subjects described in these cases (i.e., no personal history of alcohol problems, family history of alcohol problems but no personal history, family history and personal history, personal history of drug abuse, recreational drug use, drug abuse)?

6. Suppose the study reveals that the subject is an alcoholic or appears to be in the early stages of alcohol abuse. Does the investigator have an obligation to inform the subject? Does the investigator have any obligations to the subject's family members to communicate to them information learned through the study that may have implications for their health or welfare?

7. Suppose that you are a member of the university's human subjects committee and are reviewing the investigator's protocol. What stipulations might you make concerning the consent process, screening, and debriefing procedures?

Recruitment Scenario 3

The same researchers want to conduct the same experiment with alcoholic subjects. Subjects are recruited using advertisements in a local community newspaper. The ad reads as follows: "Heavy drinkers needed to volunteer for alcohol research studies. Call 555-2121."

Questions for Discussion

1. Does this recruitment method present any ethical problems? Explain. How does this scenario differ from Recruitment Scenarios 1 and 2? Is it more or less ethically problematic? Why?

2. What are the potential risks, if any, inherent in this study? What might be done to reduce these risks? Should such a study be done? Why or why not?

3. Suppose the investigators decide to offer a monetary incentive to participate in the research. Would such a payment be relevant to your analysis of Question 1? Explain.

Recruitment Scenario 4

Suppose that previously conducted research indicates that certain aspects of an alcoholic's response to alcohol may predict his or her response to different pharmacological and physiological treatments for alcohol dependence. A group of investigators want to take this research further by pinning down the specific predictors.

Instead of advertising for subjects, the investigators team up with several
alcohol treatment centers and recruit subjects as they come in for treatment. Recruitment into the study takes place before enrollment in the treatment center. There is no screening procedure; persons seeking treatment for alcohol dependence are presumed to qualify for participation. Persons who agree to participate are tested using the Alcohol Administration Procedure described above and are then put on different treatment regimens, depending on the nature of their physiological response to the alcohol administration. Treatment is provided by the treatment center.

Questions for Discussion

1. Does this recruitment method present any ethical problems? Explain. How does this scenario differ from Recruitment Scenarios 1, 2, and 3? Is it more or less ethically problematic? Why?

2. Recall that the results of the Alcohol Administration Procedure are hypothesized to be predictors of successful treatment, but that they have not yet been proven to be so. According to the study design, treatment decisions will be made based on this hypothesis. Is this fact important to a decision whether to allow the study to go forward? Would it make a difference to you if the subject's response to the alcohol administration procedure actually did predict which treatment would be successful?

3. When subjects agree to participate in the study, to what are they giving their consent? The alcohol administration procedure? Treatment for alcohol dependency? What happens if a subject changes his or her mind about receiving treatment at the clinic?

4. Suppose the researchers just wanted to examine the nature of the subjects' reaction to alcohol, but there was no relationship between the research and application of the findings to treatment for alcoholism. Are there any ethical concerns involved in administering alcohol to alcohol dependent individuals for research purposes? Does the proposed recruitment method (recruiting subjects at an alcohol treatment clinic) raise ethical concerns? Explain.

Note

1. The prevalence of alcoholism in women at any given point in time is approximately 2.5 percent, while men have a prevalence rate of about 7–8 percent. The rate of alcoholism in the general population is about 5 percent.

References

The Ethics of Deception in Research

One fundamental principle underlying the ethical conduct of research involving human subjects is respect for persons. This principle is the basis for the requirement that prior to becoming research subjects, prospective participants must give their free, voluntary, and informed consent to participation. As part of providing consent, subjects must be informed of the purposes of the research, the risks and benefits of participating, and various other kinds of information.  

Psychological research, however, sometimes includes elements of deception. That is, subjects are not given an opportunity to provide their informed consent to participation before the investigator collects the data. Examples of deception in research include covert observation (where the subject is unaware that research is being conducted and the investigator merely observes the subjects' activities), participant observation (where the subject is unaware that research is being conducted and the investigator interacts with the subject), and research in which the subject knows that he or she is participating in research but the nature of the research is not fully revealed to the subject prior to the agreement to participate.

Legitimate uses of deceptive research practices are situations in which the research cannot be conducted unless the subject is kept in the dark about the purposes of the research. The federal regulations governing research involving human subjects allow deceptive research to be conducted so long as:

1. the research involves no more than minimal risk to the subjects;
2. the rights and welfare of the subjects will not be affected;
3. the research cannot practicably be carried out without the deception; and
4. where appropriate, subjects are provided pertinent information about the research after participating in the research.  

In addition, when approving research involving human subjects, institutional review boards (IRBs) consider not only the legitimacy of the consent process the investigator proposes to use, but also the acceptability of the risks to which
subjects will be exposed. In reviewing the acceptability of risks, the IRB looks to see whether risks to subjects are minimized (by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk), and whether risks to subjects are reasonable in relation to any anticipated benefits to subjects. This latter criterion (often referred to as the risk/benefit ratio) includes an evaluation by the IRB of the importance of the knowledge that may reasonably be expected to result from the research.

We present here a series of cases designed to explore the ethical questions raised by the conduct of research that includes elements of deception. The cases consist of descriptions of a group of social psychology experiments that were conducted in the late 1960s. All but one are concerned with the conditions under which subjects will act responsibly in a social situation. (The exception examines whether or not a subject will interact with strangers in a playful activity.) When considering these cases, readers should note that the studies were conducted nearly 20 years before the regulations on human subjects were adopted.

Case 1: Lost in the Subway

This study took place in the subways of New York City. A situation was prearranged between two experimenters where one experimenter, E-1, posed as a bystander, and the other, E-2, as an individual who was lost in the subway. Both staged a scene in front of an unwitting subway rider, S, who was randomly selected as a subject. E-1 stood or sat near S. E-2, in the guise of looking like he was lost, approached and asked S whether the subway was going uptown or downtown. E-1 cut in and gave the wrong answer—if the subway was going uptown, he replied “downtown” and vice versa. The dilemma for the subject (S) was whether he or she should give the right information, correcting the bystander. Variations of the situation were tried where both S and E-1 were asked (rather than S alone), or E-1 was addressed directly. The dependent measure was whether the subject (S) actually corrected E-1. (Adapted from Latane and Darley 1970: 21–22.)

Questions for Discussion

1. Does this experiment present any ethical problems? If so, what are they? Would your answer be the same if the experimenters had waited in the station and recorded actual situations of people asking directions?
2. Should the experimenter be required to obtain informed consent from the subjects? If so, is there any way of obtaining consent?
3. Should the subject be debriefed following the experiment? If yes, how?
4. Are the subject’s rights being violated? If so, how?
5. Might S have been harmed as a result of being chosen as a subject? If so, how?
6. Is the social importance of the experiment relevant to your answers? If so, explain.

**Case 2: To Frisbee or Not to Frisbee**

This study was concerned with assessing the factors that might promote interaction among previously unorganized groups or strangers in public places. The following situation was staged: A girl sat on a bench in the waiting room at Grand Central Station. Soon another girl sat on a bench facing her. They pretended to recognize each other and began a conversation. One girl had been shopping and announced that she had just bought a Frisbee. The other girl asked to see it, and the first girl threw it to her. They then began to toss it back and forth. Apparently by accident, the Frisbee was thrown to a third person; the reaction of the third person (a confederate or plant of the researchers), was the independent variable of the study. The third person either enthusiastically joined in throwing the Frisbee or accused the two girls of being childish and dangerous and kicked the Frisbee back across the gap. Whichever of these two variations occurred, the two girls continued throwing the Frisbee back and forth and eventually threw it to one of the real bystanders (an actual experimental subject) seated on the benches. They continued this until all the bystanders on the two facing benches had been tried. A bystander was counted as participating in the activity if he or she returned the Frisbee at least twice. The percentage of bystanders who joined in the Frisbee fest was the dependent measure of the study. (Adapted from Latane and Darley 1970: 25.)

**Questions for Discussion**

1. Does this experiment present any ethical problems? If so, what are they? If the researchers observed and recorded an actual situation of someone trying to involve bystanders in a game of Frisbee, would your answer be the same? Is that approach to collecting this kind of data feasible?
2. Should the experimenter be required to obtain informed consent from the bystander subjects? If so, is there any way of obtaining consent?
3. Should the subjects be debriefed following the experiment? If yes, how?
4. Are the subjects' rights being violated? If so, how?
5. Could any harm come to any of the bystanders as a result of the attempt to draw them into the game?
6. Is this experiment more or less problematic than in Case 1 in the subway? Why?
7. Is the social importance of the experiment relevant to your answer? If so, explain.
Case 3: The Lady in Distress

In this study, male subjects were asked to participate in a questionnaire survey, purportedly being conducted by the Consumer Testing Bureau, a market research organization "interested in testing the market appeal of a number of adult games and puzzles" in exchange for a modest sum of money. As they filled out the questionnaires, they were exposed to an emergency. They were tested alone, with a friend, or with a stranger (co-subjects), and their responses were observed.

Upon arrival for his appointment, the subject was met by an attractive and vivacious young woman (secretary) who showed him to the testing room and gave him the questionnaire to fill out. While he answered the questionnaire, the secretary said that she had a few things to do next door in her office, but would return in ten or 15 minutes to give further instructions. The office door was open and easily accessible from the testing room. While the subject (and co-subjects) worked on their questionnaires they heard the secretary moving around in the next office and opening and closing drawers. After a couple of minutes, they heard a loud crash and a scream as the chair fell over. "Oh, my God, my foot... I... I... can't move... it. Oh, my ankle. I... can't... can't... get... this thing off... me." The secretary moaned for about a minute longer, getting gradually more subdued and controlled. This whole sequence was pre-recorded on high fidelity tape, but the subject (and co-subjects), next door, had no way of knowing that. The main dependent variable of the study was the type of response made to the emergency and the length of time before that response was made. (Adapted from Latane and Darley 1970: 57-58.)

Questions for Discussion

1. Does this experiment present any ethical problems? If so, what are they? If the experimenters had merely observed situations of bystanders' response to situations involving the distress of others, would your answer be the same? Is that approach feasible?

2. Should the experimenter be required to obtain informed consent from the subjects concerning the deception? If so, is there any way of obtaining consent?

3. Should the subjects be debriefed following the experiment? If so, how? What should be said to subjects? Should there be different debriefings for those who did and those who did not come to the woman's aid?

4. Are the subjects' rights being violated? If so, how?

5. Could the subjects be harmed as a result of their inclusion in the study? If so, how?
6. Is this experiment any more or less problematic than Case 1 (in the subway) or Case 2 (with the Frisbee)? Why?
7. Is the social importance of the research relevant to your answer? If so, explain.

Case 4: The Hand in the Till

In this experiment, male undergraduates witnessed a (staged) theft while waiting for an interview. In one condition, each subject was the sole witness; in another, two subjects were present. Male college freshmen were asked to volunteer to participate in an interview for a modest sum of money. After arriving for their interviews, the subjects were greeted by an attractive female receptionist and directed toward a waiting room. Among the subjects was a short, clean-cut, conservatively dressed student. This participant (C) was an confederate of the experimenter.

All of the subjects were told that they would be individually interviewed by a team of experts from the Institute for the Study of Consumer Practices on the reactions of college students to the urban environment of New York City. They were also told that since the interviews were running behind schedule, they would be paid in advance.

When paying the subjects, the receptionist pulled several large and small bills out of an envelope in full view of all subjects. To emphasize the presence of the large amount of money in the envelope, she asked the subjects if anyone had change for a fifty. After paying the subjects, she put the remainder of the money (between $50 and $200 dollars) back in the envelope and placed the envelope on top of the desk. Shortly afterward, she left the room to speak to an interviewer.

Just after the receptionist left the room, C walked over to the desk and pretended to fumble with a magazine lying on top of the desk. Seemingly trying to hide his actions but in full view of the other, real, subject(s), C then took the cash from the envelope, picked up the magazine, and returned to his seat. He did not say anything. If a subject questioned him about taking the money, he either ignored the comment, continuing to leaf through his magazine, or innocently answered, "I don't know what you are talking about."

A couple of minutes later, the receptionist returned. At this point in time, the subjects could report the crime and confront C directly. After about half a minute, the receptionist sent C to his "interview." The subjects now had an opportunity to report the theft without directly confronting C.

Finally, each subject was called into his interview. If the subject did not tell the interviewer then, the deceptions and purposes of the experiment were explained. The dependent variable of interest was the proportion of subjects reporting the theft spontaneously to the receptionist or the interviewer. (Adapted from Latane and Darley 1970: 70-71.)
Questions for Discussion

1. Does this experiment present any ethical problems? If so, what are they? Can this experiment be conducted without the use of deception? Is there an alternative research design that would be less problematic (assuming you find it problematic)?

2. Should the experimenter be required to obtain informed consent from the subjects concerning the deception? If so, is there any way to obtain consent?

3. Should the subjects be debriefed? If so, how? What should be said to a subject who did not reveal the theft to the experimenters at any point when he had the opportunity to do so?

4. Are the subjects' rights being violated? If so, how?

5. Could participating in this project as an actual subject pose any harm to the individual? If so, what would that harm be?

6. Is this experiment any more or less problematic than Case 1 (in the subway), Case 2 (with the Frisbee), or Case 3 ("The Lady in Distress")? Why?

7. Is the social importance of the experiment relevant to your answer? If so, explain.

Case 5: The Stolen Beer

In this study, two experimenters posed as robbers to conduct a field study examining factors that affect the likelihood that individuals will report crimes they have witnessed. The experimenters were husky young men who would enter a corner store singly or in a pair when some unwitting customers (subjects) were present. They would ask the cashier at the checkout counter: "What is the most expensive imported beer that you carry?" The cashier, in cahoots with the experimenters, would reply, "Heineken. I'll go back and see how much we have." Leaving the experimenters in the front of the store, the cashier would disappear into the rear to look for the Heineken. After waiting for a minute, the experimenters would pick up a case of beer near the front of the store and, remarking out loud, "They'll never miss this," walk out of the front door. The robberies were always staged when there were either one or two potential subjects in the store, and the timing was arranged so that one or both subjects would be at the checkout counter at the time when the experimenters entered. Although occasionally the two subjects had come in together, more usually they were strangers. When the cashier returned from the rear of the store, he came back to the checkout counter and resumed waiting on the subjects at the counter. After a minute, if nobody had spontaneously mentioned the theft, he casually inquired, "Hey, what happened to that man (those men) who was (were) in here? Did you see him (them) leave?" The dependent vari-
ables of interest were whether the subjects reported the stolen case of beer, and the time taken to do so. (Adapted from Latane and Darley 1970: 75-76.)

**Questions for Discussion**

1. Does this experiment present any ethical problems? If so, what are they? Is there an alternative research design that would be less problematic (assuming you find it problematic)?

2. Should the experimenter be required to obtain informed consent from the subjects prior to the experiment? If so, is there any way to obtain consent without biasing the data?

3. Should the subjects be debriefed? If so, how? What should be said to a subject who did not reveal the theft to the clerk at any point of opportunity?

4. Are the subjects' rights being violated? If so, how?

5. Could any harm come to the subjects of this study? If so, what?

6. Is this experiment more or less problematic than the experiment in Case 1 (in the subway); Case 2 (with the Frisbee), Case 3 ("The Lady in Distress"), or Case 4 ("The Hand in the Till")? Why?

**Notes**


2. Ibid., 116 (d).

3. Ibid., 111(a) (1) and (2).

4. All of the cases are excerpted from a report of a series of experiments contained in Latane and Darley 1970: 21-22, 25, 57-58, 70-71, 75-76. Adapted by permission of Prentice-Hall, Inc., Englewood Cliffs, NJ.

5. Since the checkout counter was 20 feet from the front door, there were no direct attempts to stop the robberies.

**References**
