CHAPTER 3

Research Ethics and Research Proposals

Journal Link
Driving While Impaired

Let's begin with a thought experiment (or a trip down memory lane, depending on your earlier exposure to this example). One spring morning as you are drinking coffee and reading the newspaper, you notice a small ad for a psychology experiment at the local university. "Earn money and learn about yourself," it says. Feeling a bit bored with your job as a high school teacher, you call and schedule an evening visit to the lab.

WE WILL PAY YOU $45 FOR ONE HOUR OF YOUR TIME

Persons Needed for a Study of Memory

Research That Matters, Questions That Count

You are driving on the highway at about 3 p.m. on a Friday when you see a police officer standing by his squad car, lights flashing. The officer motions you to pull off the road and stop in an area marked off with traffic cones. You are both relieved and surprised when someone in plain clothes working with the police officer then walks over to your car and asks if you would consent to be in a survey. You then notice two large signs that say NATIONAL ROADSIDE SURVEY and VOLUNTARY SURVEY. You are offered $10 to provide an oral fluid sample and answer a few additional questions on drug use.

This is what happened to 10,909 U.S. motorists between July 20 and December 1, 2007, at sites across the United States. Those who agreed to the oral fluid collection were also offered an additional $5 to complete a short alcohol and drug-use disorder questionnaire. Before they drove off, participants were also offered a $50 incentive for providing a blood sample. Drivers who were found to be too impaired to be able to drive safely (blood alcohol level above .05) were given a range of options, including switching with an unimpaired passenger, getting a free ride home, or spending a night in a local motel (at no expense to them). None were arrested or given citations and no crashes occurred in relation to the study. Those younger than 21 years and those who were pregnant were given informational brochures because of the special risk they face if they consume alcohol.

John H. Lacey and others from the Pacific Institute for Research and Evaluation, C. Debra Furr-Holden from Johns Hopkins University, and Amy Berning from the National Highway Traffic Safety Administration (NHTSA, which funded the study) reported the procedures for this survey in a 2011 article in the *Evaluation Review.* The survey explained that all data collected were maintained as anonymous, so no research participants could be linked to their survey.

The 2007 National Roadside Survey identified 10.5% of the drivers as using illegal drugs and 3% as having taken medications.

What is your initial reaction to these research procedures, involving collaboration with the police, diversion of drivers, and measurement of substance abuse?

1. The institute's institutional review board (IRB) reviewed all staff training and operational procedures and a human subjects protection training module was used to prepare interviewers for the roadside encounters. Do you think human subjects were protected? How about the procedures with impaired drivers?
2. What types of persons do you think should have been on the IRB at this research institute when the study was reviewed?
3. Do you think that the potential benefits of this study for improving policies about impaired driving would outweigh concerns about interference with individuals' activities?

In this chapter, you will learn about standards and procedures for the protection of human subjects in research. By the end of the chapter, you will have a much firmer basis for answering the questions I have posed. After you finish the chapter, test yourself by reading the 2011 *Evaluation Review* article at the *Investigating the Social World* study site and completing the related interactive exercises for Chapter 3 at edge.sagepub.com/schutt8e.

Lacey, John H., Tara Kelley-Baker, Robert B. Voas, Eduardo Romano, C. Debra Furr-Holden, Pedro Torres, and Amy Berning. 2011. "Alcohol- and Drug-Involved Driving in the United States: Methodology for the 2007 National Roadside Survey." *Evaluation Review* 35:319–353.

You arrive at the assigned room at the university, ready for an interesting hour or so, and are impressed immediately by the elegance of the building and the professional appearance of the personnel. In the waiting room, you see a man dressed in a lab technician's coat talking to another visitor—a middle-aged fellow dressed in casual attire. The man in the lab coat turns and introduces himself and explains that as a psychologist, he is interested in the question of whether people learn things better when they are punished for making a mistake.

He quickly convinces you that this is a very important question for which there has been no adequate answer; he then explains that his experiment on punishment and learning will help answer this question. Then he announces, "I'm going to ask one of you to be the teacher here tonight and the other one to be the learner."

"The experimenter" [as we'll refer to him from now on] says he will write either *teacher* or *learner* on small identical slips of paper and then asks both of you to draw out one. Yours says teacher.

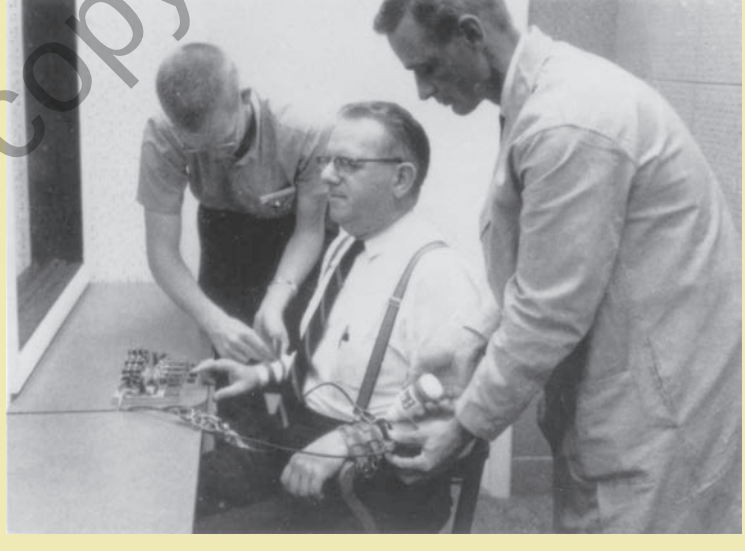
The experimenter now says, in a matter-of-fact way, "All right. Now the first thing we'll have to do is to set the learner up so that he can get some type of punishment."

He leads you both behind a curtain, sits the learner down, attaches a wire to his left wrist, and straps both his arms to the chair so that he cannot remove the wire (see Exhibit 3.1). The wire is connected to a console with 30 switches and a large dial on the other side of the room. When you ask what the wire is for, the experimenter says he will demonstrate. He then asks you to hold the end of the wire, walks back to the control console, flips several switches, and focuses his attention on the dial. You hear a clicking noise, see the dial move, and then feel an electric shock in your hand. The shock increases and the dial registers more current when the experimenter flips the next switch on the console.

"Oh, I see," you say. "This is the punishment. Couldn't it cause injury?" The experimenter explains that the machine is calibrated so that it will not cause permanent injury, but acknowledges that when it is turned up all the way it is very, very painful and can result in severe, although momentary, discomfort.

Now you walk back to the other side of the room (so that the learner is behind the curtain) and sit before the console. The experimental procedure has four simple steps: (1) You read aloud a series of word pairs, such as *blue box, nice day, wild duck,* and so on. (2) You read one of the first words from those pairs and a set of four words, one of which contains the original paired word. For example, you might say, "blue: sky ink box lamp." (3) The learner states the word that he thinks was paired with the first word you read ("blue"). If he gives a correct response, you compliment him and move on to the next word. If he makes a mistake, you flip a switch on the console. This causes the learner to feel a shock on his wrist. (4) After each mistake, you are to flip the next

Exhibit 3.1 **Learner Strapped in Chair With Electrodes**

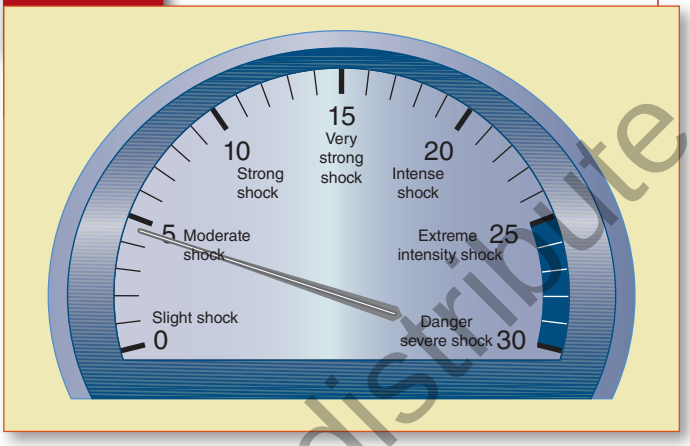


Source: From the film *OBEDIENCE*. Copyright © 1968 by Stanley Milgram, copyright renewed 1993 by Alexandra Milgram and distributed by Alexander Street Press.

switch on the console, progressing from left to right. You note that there is a label corresponding to every fifth mark on the dial, with the first mark labeled *slight shock,* the fifth mark labeled *moderate shock,* the tenth *strong shock,* and so on through *very strong shock, intense shock, extreme intensity shock,* and *danger: severe shock.*

You begin. The learner at first gives some correct answers, but then he makes a few errors. Soon you are beyond the fifth mark (moderate shock) and are moving in the direction of more and more severe shocks. You recall having heard about this experiment and so you know that as you turn the dial, the learner's responses increase in intensity from a grunt at the tenth mark (strong shock) to painful groans at higher levels, anguished cries to "get me out of here" at the extreme intensity shock levels, to a deathly silence at the highest level. You also know that as you proceed and indicate your discomfort at administering the stronger shocks, the experimenter will tell you, "The experiment requires that you continue," and occasionally, "It is absolutely essential that you continue." Now, please note on the meter in Exhibit 3.2 the most severe shock that you would agree to give to the learner.

Exhibit 3.2 Shock Meter



Source: From the film *OBEDIENCE*. Copyright © 1968 by Stanley Milgram, copyright renewed 1993 by Alexandra Milgram and distributed by Alexander Street Press.

Milgram's obedience experiments: Experiments begun in 1960 at Yale University by psychologist Stanley Milgram to determine the likelihood of people following orders from an authority despite their own sentiments; widely cited as helping to understand the emergence of phenomena such as Nazism and mass cults.

You may very well recognize that this thought experiment is a slightly simplified version of **Milgram's obedience experiments**, begun at Yale University in 1960. Did you know that Stanley Milgram also surveyed Yale undergraduates and asked them to indicate at what level they would terminate their "shocks"? The average (mean) maximum shock level predicted by the Yale undergraduates was 9.35, corresponding to a strong shock. Only one student predicted that he would provide a stimulus above that level, but only barely so, for he said he would stop at the very strong level. Responses were similar from nonstudent groups who were asked the same question.

What was the actual average level of shock administered by the 40 New Haven adults who volunteered for the experiment? A shock level of 24.53, or a level higher than extreme intensity shock and just short of danger: severe shock. Of Milgram's original 40 subjects, 25 (62.5%) complied with the experimenter's demands, all the way to the top of the scale (originally labeled simply as *XXX*). And lest you pass this result off as simply the result of the subjects having thought that the experiment wasn't "real," we hasten to point out that there is abundant evidence from the subjects' own observed high stress and their subsequent reports that many subjects really believed that the learner was receiving actual, hurtful shocks.

Are you surprised by the subjects' responses? By the Yale undergraduates' predictions of so many compassionate responses? By your own response? (I leave it to you to assess how accurately you predicted the response you would have given if you had been an actual subject.) Do you think the results of this experiment tell us about how people behave in the real world?

Of course, my purpose in introducing this small "experiment" is not to focus attention on the prediction of obedience to authority; instead, I want to introduce the topic of research ethics by encouraging you to think about research from the standpoint of the people who are the participants in social science research. I will refer to Milgram's (1963) famous research on obedience throughout this chapter because it is fair to say that this research ultimately had as profound an influence on the way social scientists think about research ethics as it had on the way they understand obedience to authority.

Every social scientist needs to consider how to practice his or her discipline ethically. Whenever we interact with other people as social scientists, we must give paramount importance to the rational concerns and

Video Link
Milgram's Experiment

emotional needs that will shape their responses to our actions. Ethical research practice begins here, with the recognition that our research procedures involve people who deserve as much respect for their well-being as we do for ours.

2 Historical Background

Concern with ethical practice in relation to people who are in some respect dependent, whether as patients or research subjects, is not a new idea. Ethical guidelines for medicine trace back to Hippocrates in 5 BC Greece (Hippocratic Oath, n.d.) and the American Medical Association (AMA) adopted the world's first formal professional ethics code in medicine in 1847 (AMA 2011). Human subjects protections issues were widely discussed during the experiments that identified the cause of yellow fever in 1900 and 1901 (http://virtualmentor.ama-assn.org/2009/04/mhst1-0904.html). Current AMA ethical principles include respecting patient rights, maintaining confidentiality, and regarding "responsibility to the patient as paramount" (AMA 2011). Yet the history of medical practice makes it clear that having an ethics code is not sufficient to ensure ethical practice, at least when there are clear incentives to do otherwise.

Nuremberg War Crime Trials: The International Military Tribunal held by the victorious Allies after World War II in Nuremberg, Germany, that exposed the horrific medical experiments conducted by Nazi doctors and others in the name of "science."

Tuskegee Study of Untreated Syphilis in the Negro Male: U.S. Public Health Service study of the "natural" course of syphilis that followed 399 low-income African American men from the 1930s to 1972, without providing them with penicillin after this was discovered as treating the illness. The study was stopped after it was exposed in 1972, resulting in an out-of-court settlement and then, in 1997, an official public apology by President Bill Clinton.

A defining event occurred in 1946, when the **Nuremberg War Crime Trials** exposed the horrific medical experiments conducted by Nazi doctors and others in the name of "science." Almost 20 years later, Milgram's research on obedience also generated controversy about participant protections (Perry 2013:37). As late as 1972, Americans learned from news reports that researchers funded by the U.S. Public Health Service had followed 399 low-income African American men in the **Tuskegee Study of Untreated Syphilis in the Negro Male** since the 1930s, collecting data to study the "natural" course of the illness (Exhibit 3.3) (http://www.tuskegee.edu/about_us/centers_of_excellence/bioethics_center/about_the_usphs_syphilis_study.aspx). At the time, there was no effective treatment for the disease, but the men were told they were being treated for "bad blood," whether they had syphilis or not. Participants received free medical exams, meals, and burial insurance but were not asked for their consent to be studied. What made this research study, known as the Tuskegee Syphilis Experiment, so shocking was that many participants were not informed of their illness and, even after penicillin was recognized as an effective treatment in 1945 and in large-scale use by 1947, the study participants were not treated. The research was only ended after the study was exposed. In 1973, congressional hearings began, and in 1974, an out-of-court settlement of $10 million was reached; it was not until 1997 that President Bill Clinton made an official apology (CDC 2009).

Audio Link
Research Ethics

These and other widely publicized abuses made it clear that formal review procedures were needed to protect research participants. The U.S. government created a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and charged it with developing guidelines (Kitchener & Kitchener 2009:7). The commission's 1979 ***Belmont Report*** (Department of Health, Education, and Welfare 1979) established three basic ethical principles for the protection of human subjects:

Belmont Report: Guidelines developed by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979 for the protection of human subjects.

Respect for persons: The ethical principle of treating persons as autonomous agents and protecting those with diminished autonomy in research involving human subjects that was included in the *Belmont Report*.

- **Respect for persons:** treating persons as autonomous agents and protecting those with diminished autonomy
- **Beneficence:** minimizing possible harms and maximizing benefits
- **Justice:** distributing benefits and risks of research fairly

Exhibit 3.3 Tuskegee Syphilis Experiment

Source: Tuskegee Syphilis Study Administrative Records. Records of the Centers for Disease Control and Prevention. National Archives—Southeast Region (Atlanta).

The Department of Health and Human Services and the Food and Drug Administration then translated these principles into specific regulations that were adopted in 1991 as the **Federal Policy for the Protection of Human Subjects**. This policy has shaped the course of social science research ever since, and you will have to consider it as you design your own research investigations. Professional associations such as the American Sociological Association (ASA), university review boards, and ethics committees in other organizations also set standards for the treatment of human subjects by their members, employees, and students, although these standards are all designed to comply with the federal policy. This section introduces these regulations.

Beneficence: The ethical requirement of minimizing possible harms and maximizing benefits in research involving human subjects that was included in the *Belmont Report*.

Justice: The ethical principle of distributing benefits and risks of research in research involving human subjects fairly that was included in the *Belmont Report*.

Federal Policy for the Protection of Human Subjects: Specific regulations adopted in 1991 by the Department of Health and Human Services and the Food and Drug Administration that were based on the principles of the *Belmont Report*.

Code of Ethics: Professional code of the American Sociological Association for the treatment of human subjects by members, employees, and students, designed to comply with federal policy and revised in 1997.

2 Ethical Principles

The ASA, like other professional social science organizations, has adopted, for practicing sociologists, ethical guidelines that are more specific than the federal regulations are. Professional organizations may also review complaints of unethical practices when asked.

The ***Code of Ethics*** of the ASA (1999) is summarized on the ASA website (http://www.asanet.org/about/ethics.cfm); the complete text of the code is also available at this site. The general principles articulated in the code are intended to

guide professional practice in diverse settings, while some of the specific standards focus specifically on the protection of human subjects in research.

According to the general principles, sociologists should be committed in their work to high levels of competence, to practicing with integrity, and to maintaining responsibility for their actions. They must also respect the rights, dignity, and diversity of others, including research participants, as well as be socially responsible to their communities and use research to contribute to the public good. The following sections discuss the most important implications of these principles for the conduct of research, including the protection of human subjects.

Achieving Valid Results

Commitment to achieving valid results is the necessary starting point for ethical research practice. Simply put, we have no business asking people to answer questions, submit to observations, or participate in experimental procedures if we are simply seeking to verify our preexisting prejudices or convince others to take action on behalf of our personal interests. The pursuit of objective knowledge about human behavior—the goal of validity—motivates and justifies our investigations and gives us some claim to the right to influence others to participate in our research. Knowledge is the foundation of human progress as well as the basis for our expectation that we, as social scientists, can help people achieve a brighter future. If we approach our research projects objectively, setting aside our personal predilections in the service of learning a bit more about human behavior, we can honestly represent our actions as potentially contributing to the advancement of knowledge.

Encyclopedia Link
Ethical Codes

Milgram made a strong case in his 1963 article and 1974 book on the obedience experiments that he was committed to achieving valid results—to learning how and why obedience influences behavior. He tied his motivations directly to the horror of the Holocaust, to which the world's attention had been drawn once again by the capture and trial of Adolf Hitler's mastermind of that genocide, Adolf Eichmann (Perry 2013:210). In Milgram's (1963) own words,

> It has been reliably established that from 1933–45 millions of innocent persons were systematically slaughtered on command. . . . Obedience is the psychological mechanism that links individual action to political purpose. It is the dispositional cement that binds men to systems of authority . . . for many persons obedience may be a deeply ingrained behavior tendency. . . . Obedience may [also] be ennobling and educative and refer to acts of charity and kindness, as well as to destruction. (p. 371)

Milgram (1963) then explains how he devised experiments to study the process of obedience in a way that would seem realistic to the subjects and still allow "important variables to be manipulated at several points in the experiment" (p. 372). According to Milgram, every step in the experiment was carefully designed to ensure that subjects received identical stimuli and that their responses were measured carefully. The experiment's design also reflected what had become in the preceding 30 years a tradition in social psychology of laboratory experiments that used deception to create different believable conditions for participants (Perry 2013:31–35).

Milgram (1963:377) made every effort to convince readers that "the particular conditions" of his experiment created the conditions for achieving valid results. These particular conditions included the setting for the experiment at Yale University, its purported "worthy purpose" to advance knowledge about learning and memory, and the voluntary participation of the subject as well as of the learner—as far as the subject knew. Milgram then tested the importance of some of these "particular conditions" (e.g., the location at Yale) in replications of the basic experiment (Milgram 1965).

However, not all social scientists agreed that Milgram's approach could achieve valid results. Milgram's first article on the research, "Behavioral Study of Obedience," was published in 1963 in the *Journal of Abnormal and Social Psychology*. In the next year, the *American Psychologist* published a critique of the experiment's methods and ethics by the psychologist Diana Baumrind (1964). Her critique begins with a rejection of the external validity—the generalizability—of the experiment, because

> The laboratory is unfamiliar as a setting and the rules of behavior ambiguous. . . . Therefore, the laboratory is not the place to study degree of obedience or suggestibility, as a function of a particular experimental condition. [And so,] the parallel between authority-subordinate relationships in Hitler's Germany and in Milgram's laboratory is unclear. (pp. 421–423)

Milgram (1964) quickly published a rejoinder in which he disagreed with (among other things) the notion that it is inappropriate to study obedience in a laboratory setting: "A subject's obedience is no less problematical because it occurs within a social institution called the psychological experiment" (p. 850).

Milgram (1974:169–178) also argued in his later book that his experiment had been replicated in other places and settings with the same results, that there was considerable evidence that the subjects had believed that they actually were administering shocks, and that the "essence" of his experimental manipulation—the request that subjects comply with a legitimate authority—was also found in the dilemma faced by people in Nazi Germany, soldiers at the My Lai massacre in Vietnam, and even the cultists who drank poison in Jonestown, Guyana, at the command of their leader, Jim Jones (Miller 1986:182–183).

Baumrind (1985) was still not convinced. In a follow-up article in *American Psychologist*, she argued that "far from illuminating real life, as he claimed, Milgram in fact appeared to have constructed a set of conditions so internally inconsistent that they could not occur in real life" (p. 171). Although Milgram died in 1984, the controversy did not. A recent review of the transcripts and interviews with many participants raises additional concerns about the experiment's validity (Perry 2013). Milgram understated the "experimenter's" efforts to get the subjects to comply, he overstated the subjects' level of obedience, he never publicized one condition in which most subjects refused to give strong shocks when the "learner" was a friend, and he didn't acknowledge that even those classified as "obedient" were looking for a way to get out of the experiment. His claim that the results were replicated in similar experiments around the world was only partially true, and it seems clear from the transcripts and interviews that the aura created by the location at Yale University and the emphasis on a contribution to "science" influenced many participants.

Do you agree with Milgram's assumption that obedience could fruitfully be studied in the laboratory? Do you find merit in Baumrind's criticism? Are you troubled by the new evidence that Milgram may have presented his evidence selectively, to make his conclusions as convincing as possible? Will your evaluation of the ethics of Milgram's experiments be influenced by your answers to these questions? Should our ethical judgments differ depending on whether we decide that a study provides valid information about important social psychological processes? Should it matter that a 2005 replication of Milgram's experiment (with less severe "shocks") for ABC TV supported Milgram's conclusions (Perry 2013:275–279)?

I can't answer these questions for you, but before you dismiss them as inappropriate when we are dealing with ethical standards for the treatment of human subjects, bear in mind that both Milgram and his strongest critic at the time, Baumrind, buttressed their ethical arguments with assertions about the validity (or invalidity) of the experimental results. It is hard to justify *any* risk for human subjects, or even *any* expenditure of time and resources, if our findings tell us nothing about human behavior.

Audio Link
Milgram's Experiment

Interactive Exercises Link
Ethical Issues

Honesty and Openness

The scientific concern with validity requires, in turn, that scientists be open in disclosing their methods and honest in presenting their findings. In contrast, research distorted by political or personal pressures to find particular outcomes or to achieve the most marketable results is unlikely to be carried out in an honest and open fashion. To assess the validity of a researcher's conclusions and the ethics of their procedures, you need to know exactly how the research was conducted. This means that articles or other reports must include a detailed methodology section, perhaps supplemented by appendixes containing the research instruments, or websites or an address where more information can be obtained.

Milgram presented his research in a way that would signal his adherence to the goal of honesty and openness. His initial 1963 article included a detailed description of study procedures, including the text of

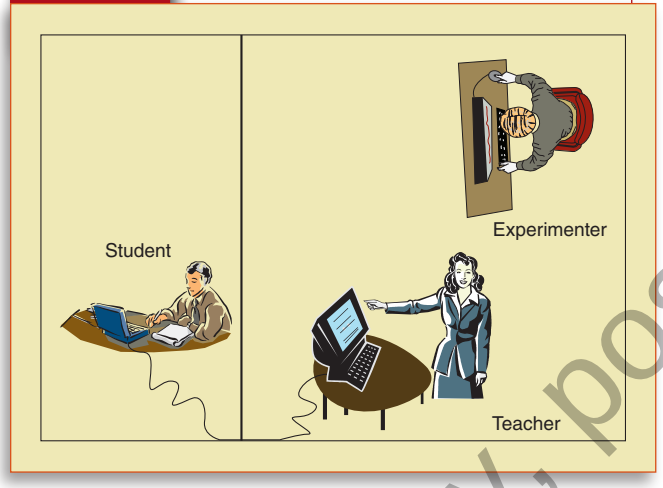
Journal Link
Intensive Rehabilitation Supervision Program

Research|Social Impact Link
Research Ethics

the general introduction to participants, the procedures involved in the learning task—the "shock generator," the administration of the "sample shock," the shock instructions and the preliminary practice run, the standardized feedback from the "victim" and from the experimenter—and the measures used. Many more details, including pictures, were provided in Milgram's (1974) subsequent book (Exhibit 3.4).

The act of publication itself is a vital element in maintaining openness and honesty. Others can review and question study procedures and so generate an open dialogue with the researcher. Although Milgram disagreed sharply with Baumrind's criticisms of his experiments, their mutual commitment to public discourse in journals widely available to social scientists resulted in a more comprehensive presentation of study procedures and a more thoughtful discourse about research ethics. Almost 50 years later, this commentary continues to inform debates about research ethics (Cave & Holm 2003).

Exhibit 3.4 Diagram of Milgram Experiment



Source: Northern Illinois University Department of Psychology, http://www3.niu.edu/acad/psych/Millis/History/2004/milgram2.gif

The latest significant publication in this open dialogue about Milgram's work actually challenges his own commitment to the standard of openness and honesty. Gina Perry's (2013) *Behind the Shock Machine: The Untold Story of the Notorious Milgram Psychology Experiments* reveals many misleading statements about participants' postexperiment debriefing, about adherence to the treatment protocol, about the extent of participants' apparent distress, and about the extent of support for his favored outcome.

Openness about research procedures and results thus goes hand in hand with honesty in research design and in research reporting. Despite this need for openness, some researchers may hesitate to disclose their procedures or results to prevent others from building on their ideas and taking some of the credit or, as may have occurred with Milgram, to make their procedures seem more acceptable or their findings more impressive. You might have heard of the long legal battle between a U.S. researcher, Robert Gallo, and a French researcher, Luc Montagnier, about how credit for discovering the AIDS virus should be allocated. Although a public dispute such as this one is unusual—even more unusual was its resolution through an agreement announced by then U.S. President Ronald Reagan and then French Prime Minister Jacques Chirac (Altman 1987)—concerns with priority of discovery are common. Scientists are like other people in their desire to be first. Enforcing standards of honesty and encouraging openness about research are the best solutions to these problems (as exemplified by the chronology of discovery that Gallo and Montagnier jointly developed as part of the agreement).

Conflict of interest: When a researcher has a significant financial stake in the design or outcome of his or her own research.

Conflicts of interest may occur when a researcher has a significant financial stake in the design or outcome of the research. Receiving speaking fees, consulting fees, patents or royalties, and other financial benefits as a result of the way in which a research project is designed or the results that it obtains creates a pressure to distort decisions and findings in one's (financial) favor. Both federal research funding agencies and journal editors require disclosure of possible conflicts of interest so that others can scrutinize the extent to which these conflicts may have lessened researchers' honesty and openness (Fisher & Anushko 2008:96–97). Unfortunately, experimental research suggests that disclosure does not reduce trust in advice from people who have disclosed a conflict of interest (Humphries 2011:K3). In fact, researchers can be unduly motivated by concerns about their publication records and career prospects even without explicit financial inducements.

Protecting Research Participants

Several standards concerning the treatment of human subjects are emphasized in federal regulations and the ethical guidelines adopted by many professional social science organizations:

- Research should cause no harm to subjects.
- Participation in research should be voluntary, and therefore subjects must give their informed consent to participate in the research and researchers must disclose their identity.
- Researchers should avoid deception, except in limited circumstances.
- Anonymity or confidentiality must be maintained for individual research participants unless it is voluntarily and explicitly waived.
- Consider the uses of a research project so that its benefits outweigh any foreseeable risks.

Each of these standards became a focus of debate about Milgram's experiments, so we will return frequently to that debate to keep our discussion realistic. We will also refer frequently to the ASA code to keep our treatment current. You will soon realize that there is no simple answer to the question: What is (or isn't) ethical research practice? The issues are just too complicated and the relevant principles too subject to different interpretations. But, I do promise that by the time you finish this chapter, you will be aware of the major issues in research ethics and be able to make informed, defensible decisions about the ethical conduct of social science research.

Journal Link
Written Consent

Avoid Harming Research Participants

Although this standard may seem straightforward, it can be difficult to interpret in specific cases and harder yet to define in a way agreeable to all social scientists. Does it mean that subjects should not be harmed psychologically as well as physically at all? That they should feel no anxiety or distress whatsoever during the study or only after their involvement ends? Should the possibility of any harm, no matter how remote, deter research?

Before we address these questions with respect to Milgram's experiments, a verbatim transcript of one session will give you an idea of what participants experienced (Milgram 1965:67):

150 volts delivered.	You want me to keep going?
165 volts delivered.	That guy is hollering in there. There's a lot of them here. He's liable to have a heart condition. You want me to go on?
180 volts delivered.	He can't stand it! I'm not going to kill that man in there! You hear him hollering? He's hollering. He can't stand it. . . . I mean who is going to take responsibility if anything happens to that gentleman? *[The experimenter accepts responsibility.]* All right.
195 volts delivered.	You see he's hollering. Hear that. Gee, I don't know. *[The experimenter says: "The experiment requires that you go on."]* I know it does, sir, but I mean—hugh—he don't know what he's in for. He's up to 195 volts.
210 volts delivered.	
225 volts delivered.	
240 volts delivered.	

This experimental manipulation generated "extraordinary tension" (Milgram 1963:377):

> Subjects were observed to sweat, tremble, stutter, bite their lips, groan and dig their fingernails into their flesh. . . . Full-blown, uncontrollable seizures were observed for 3 subjects. One . . . seizure so violently convulsive that it was necessary to call a halt to the experiment [for that individual]. (p. 375)

An observer (behind a one-way mirror) reported, "I observed a mature and initially poised businessman enter the laboratory smiling and confident. Within 20 minutes he was reduced to a twitching, stuttering wreck, who was rapidly approaching a point of nervous collapse" (Milgram 1963:377).

From critic Baumrind's (1964:422) perspective, this emotional disturbance in subjects was "potentially harmful because it could easily effect an alteration in the subject's self-image or ability to trust adult authorities in the future." Milgram (1964) quickly countered,

> Momentary excitement is not the same as harm. As the experiment progressed there was no indication of injurious effects in the subjects; and as the subjects themselves strongly endorsed the experiment, the judgment I made was to continue the experiment. (p. 849)

When Milgram (1964:849) surveyed participants in a follow-up, 83.7% endorsed the statement that they were "very glad" or "glad" "to have been in the experiment," 15.1% were "neither sorry nor glad," and just 1.3% were "sorry" or "very sorry" to have participated (p. 849). Interviews by a psychiatrist a year later found no evidence "of any traumatic reactions" (p. 849)—although he did not disclose that of 780 initial participants, only 140 were invited for an interview and only 32 of those accepted the invitation (Perry 2013:217). After these later revelations, Milgram's (1977:21) subsequent argument that "the central moral justification for allowing my experiment is that it was judged acceptable by those who took part in it" rings hollow.

Milgram (1963) also reported that he attempted to minimize harm to subjects with postexperimental procedures "to assure that the subject would leave the laboratory in a state of well being" (p. 374). He said that a friendly reconciliation was arranged between the subject and the victim, and an effort was made to reduce any tensions that arose as a result of the experiment, but it turns out that his "dehoaxing" was normally very brief and did not disclose the deception to most participants. Most participants did not receive a letter informing them of the nature of the experiment until almost a year had passed (Milgram 1964:849; Perry 2013:72, 84).

Baumrind (1964:422) was unconvinced even without knowing of these later revelations: "It would be interesting to know what sort of procedures could dissipate the type of emotional disturbance just described [citing Milgram 1964]."

In a later article, Baumrind (1985:168) dismissed the value of the self-reported "lack of harm" of subjects who had been willing to participate in the experiment—although noting that still 16% did *not* endorse the statement that they were "glad" they had participated in the experiment. Baumrind (1985:169) also argued that research indicates most introductory psychology students (and some students in other social sciences) who have participated in a deception experiment report a decreased trust in authorities as a result—a tangible harm in itself.

Many social scientists, ethicists, and others concluded that Milgram's procedures had not harmed the subjects and so were justified for the knowledge they produced, but others sided with Baumrind's criticisms (Miller 1986:88–138; Perry 2013:269). Perry's (2013:77–78) recent investigation found even more evidence of psychological harm, including feelings of shame that had persisted since the experiment. The experimental records also reveal that debriefing never occurred for some participants and was very limited for almost all (Perry 2013:76–84). Most were not told after the experiment that the shocks were fake; the usual "dehoaxing" consisted of the "learner" reassuring the "teacher" that the shocks he had received were not harmful.

Video Link
Zimbardo's Prison Experiment

What is your opinion of the possibility for harm at this point? Does Milgram's debriefing process relieve your concerns? Are you as persuaded by the subjects' own endorsement of the experiment as was Milgram?

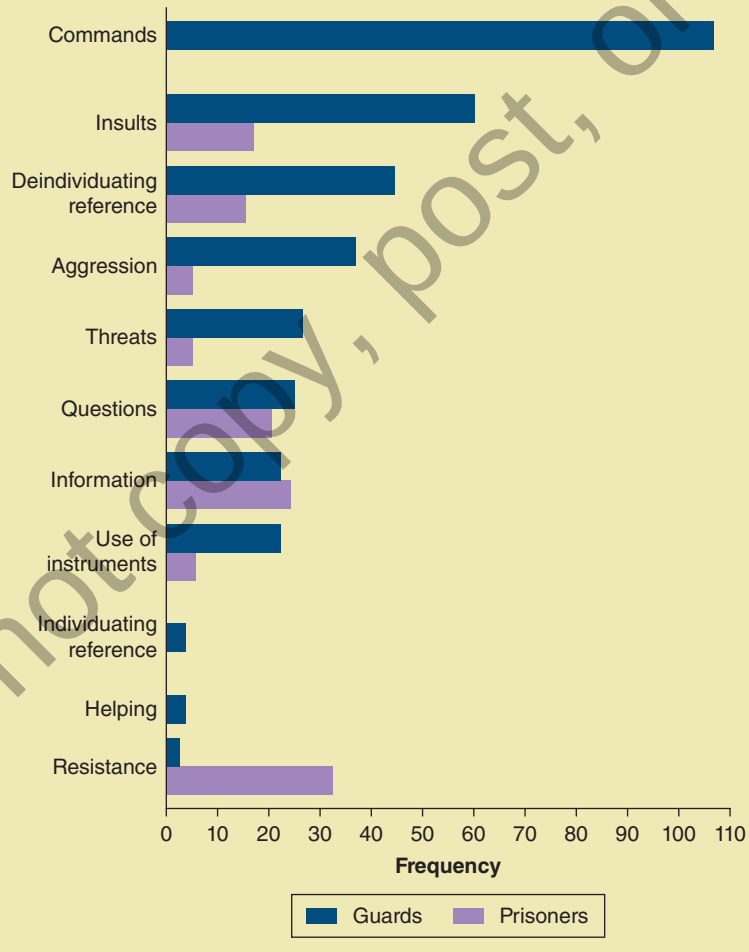
What about possible harm to the subjects of the famous prison simulation study at Stanford University (Haney, Banks, & Zimbardo 1973)? The study was designed to investigate the impact of social position on behavior—specifically, the impact of being either a guard or a prisoner in a prison, a "total institution." The researchers selected apparently stable and mature young male volunteers and asked them to sign a

contract to work for 2 weeks as a guard or a prisoner in a simulated prison. Within the first 2 days after the prisoners were incarcerated by the "guards" in a makeshift basement prison, the prisoners began to be passive and disorganized, while the guards became "sadistic"—verbally and physically aggressive (Exhibit 3.5). Five "prisoners" were soon released for depression, uncontrollable crying, fits of rage, and, in one case, a psychosomatic rash. Instead of letting things continue for 2 weeks as planned, Philip Zimbardo and his colleagues terminated the experiment after 6 days to avoid harming the subjects.

Through discussions in special postexperiment encounter sessions, feelings of stress among the participants who played the role of prisoner seemed to be relieved; follow-up during the next year indicated no lasting negative effects on the participants and some benefits in the form of greater insight.

Would you ban such experiments because of the potential for harm to subjects? Does the fact that Zimbardo's and Milgram's experiments seemed to yield significant insights into the effect of a social situation on human behavior—insights that could be used to improve prisons or perhaps lessen the likelihood of another holocaust—make any difference (Reynolds 1979:133–139)? Do you believe that this benefit outweighs the foreseeable risks?

Exhibit 3.5 **Chart of Guard and Prisoner Behavior**



Source: Adapted from *The Lucifer Effect* by Philip G. Zimbardo. Copyright 2007 by Philip G. Zimbardo, Inc. Used by permission of Random House, Inc., and Random House Group Ltd.

Zimbardo's prison simulation study: Famous prison simulation study at Stanford University by psychologist Philip Zimbardo designed to investigate the impact of social position on behavior—specifically, the impact of being either a guard or a prisoner in a "total institution"; widely cited as demonstrating the likelihood of emergence of sadistic behavior in guards.

Well-intentioned researchers may also fail to foresee all the potential problems. Milgram (1974:27–31) reported that he and his colleagues were surprised by the subjects' willingness to carry out such severe shocks. In **Zimbardo's prison simulation study**, all the participants signed consent forms, but how could they have been fully informed in advance? The researchers themselves did not realize that the study participants would experience so much stress so quickly, that some prisoners would have to be released for severe negative reactions within the first few days, or that even those who were not severely stressed would soon be begging to be released from the mock prison. If this risk was not foreseeable, was it acceptable for the researchers to presume in advance that the benefits would outweigh the risks? And are you concerned, like Arthur Miller (1986), that real harm "could result from *not doing* research on destructive obedience" (p. 138) and other troubling human behaviors?

Obtain Informed Consent

The requirement of informed consent is also more difficult to define than it first appears. To be informed, consent must be given by the persons who are competent to consent, have consented voluntarily, are fully informed about the research and know who is conducting the research, and have comprehended what they have been told (Reynolds 1979). Yet you probably realize, as Baumrind (1985) did, that because of the inability to communicate perfectly, "full disclosure of everything that could possibly affect a given subject's decision to participate is not possible, and therefore cannot be ethically required" (p. 165).

Research|Social Impact Link
Informed Consent

Obtaining informed consent creates additional challenges for researchers. The researcher's actions and body language should help convey his or her verbal assurance that consent is voluntary. The language of the consent form must be clear and understandable to the research participants and yet sufficiently long and detailed to explain what will actually happen in the research. Consent Forms A (Exhibit 3.6) and B (Exhibit 3.7) illustrate two different approaches to these trade-offs.

Exhibit 3.6 Consent Form A

University of Massachusetts Boston
Department of Sociology
(617) 287-6250

Dear _____:

The health of students and their use of alcohol and drugs are important concerns for every college and university. The enclosed survey is about these issues at UMass/Boston. It is sponsored by University Health Services and the PRIDE Program (Prevention, Resources, Information, and Drug Education). The questionnaire was developed by graduate students in Applied Sociology, Nursing, and Gerontology.

You were selected for the survey with a scientific, random procedure. Now it is important that you return the questionnaire so that we can obtain an unbiased description of the undergraduate student body. Health Services can then use the results to guide campus education and prevention programs.

The survey requires only about 20 minutes to complete. Participation is completely voluntary and anonymous. No one will be able to link your survey responses to you. In any case, your standing at the University will not be affected whether or not you choose to participate. Just be sure to return the enclosed postcard after you mail the questionnaire so that we know we do not have to contact you again.

Please return the survey by November 15th. If you have any questions or comments, call the PRIDE program at 287-5680 or Professor Schutt at 287-6250. Also call the PRIDE program if you would like a summary of our final report.

Thank you in advance for your assistance.

Russell K. Schutt, PhD
Professor and Chair

Exhibit 3.7 Consent Form B

Research Consent Form for Social and Behavioral Research

Dana-Farber/Harvard Cancer Center

BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates OPRS 11-05

Protocol Title: ASSESSING COMMUNITY HEALTH WORKERS' ATTITUDES AND KNOWLEDGE ABOUT EDUCATING COMMUNITIES ABOUT CANCER CLINICAL TRIALS

DF/HCC Principal Research Investigator / Institution: Dr. Russell Schutt, PhD / Beth Israel Deaconess Medical Center and Univ. of Massachusetts, Boston

DF/HCC Site-Responsible Research Investigator(s) / Institution(s): Lidia Schapira, MD / Massachusetts General Hospital

Interview Consent Form

A. INTRODUCTION

We are inviting you to take part in a research study. Research is a way of gaining new knowledge. A person who participates in a research study is called a "subject." This research study is evaluating whether community health workers might be willing and able to educate communities about the pros and cons of participating in research studies.

It is expected that about 10 people will take part in this research study.

An institution that is supporting a research study either by giving money or supplying something that is important for the research is called the "sponsor." The sponsor of this protocol is National Cancer Institute and is providing money for the research study.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of the research study, alternatives to participation, and your rights as a research subject. The decision to participate is yours. If you decide to participate, please sign and date at the end of the form. We will give you a copy so that you can refer to it while you are involved in this research study.

If you decide to participate in this research study, certain questions will be asked of you to see if you are eligible to be in the research study. The research study has certain requirements that must be met. If the questions show that you can be in the research study, you will be able to answer the interview questions.

If the questions show that you cannot be in the research study, you will not be able to participate in this research study.

Page 1 of 6

DFCI Protocol Number: 06-085	Date DFCI IRB Approved this Consent Form: January 16, 2007
Date Posted for Use: January 16, 2007	Date DFCI IRB Approval Expires: August 13, 2007

(Continued)

Exhibit 3.7 Continued

Research Consent Form for Social and Behavioral Research

Dana-Farber/Harvard Cancer Center

BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates OPRS 11-05

We encourage you to take some time to think this over and to discuss it with other people and to ask questions now and at any time in the future.

B. WHY IS THIS RESEARCH STUDY BEING DONE?

Deaths from cancer in general and for some specific cancers are higher for black people compared to white people, for poor persons compared to nonpoor persons, and for rural residents compared to non-rural residents. There are many reasons for higher death rates between different subpopulations. One important area for changing this is to have more persons from minority groups participate in research about cancer. The process of enrolling minority populations into clinical trials is difficult and does not generally address the needs of their communities. One potential way to increase participation in research is to use community health workers to help educate communities about research and about how to make sure that researchers are ethical. We want to know whether community health workers think this is a good strategy and how to best carry it out.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. Instead of being in this research study, you have the following option:

- Decide not to participate in this research study.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the research starts (screening): After signing this consent form, you will be asked to answer some questions about where you work and the type of community health work you do to find out if you can be in the research study.

If the answers show that you are eligible to participate in the research study, you will be eligible to participate in the research study. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

After the screening procedures confirm that you are eligible to participate in the research study: You will participate in an interview by answering questions from a questionnaire. The interview will take about 90 minutes. If there are questions you prefer not to answer we can skip those questions. The questions are about the type of work you do and your opinions about participating in research. If you agree, the interview will be taped and then transcribed. Your name and no other information about you will be associated with the tape or the transcript. Only the research team will be able to listen to the tapes.

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DFCI Protocol Number: 06-085	Date DFCI IRB Approved this Consent Form: January 16, 2007
Date Posted for Use: January 16, 2007	Date DFCI IRB Approval Expires: August 13, 2007

Research Consent Form for Social and Behavioral Research

Dana-Farber/Harvard Cancer Center

BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates OPRS 11-05

Immediately following the interview, you will have the opportunity to have the tape erased if you wish to withdraw your consent to taping or participation in this study. You will receive $30.00 for completing this interview.

After the interview is completed: Once you finish the interview there are no additional interventions.

…

N. DOCUMENTATION OF CONSENT

My signature below indicates my willingness to participate in this research study and my understanding that I can withdraw at any time.

_____ _____

Signature of Subject or Legally Authorized Representative — Date

_____ _____

Person obtaining consent — Date

To be completed by person obtaining consent:

The consent discussion was initiated on _____ (date) at _____ (time.)

☐ A copy of this signed consent form was given to the subject or legally authorized representative.

For Adult Subjects

☐ The subject is an adult and provided consent to participate.

☐ The subject is an adult who lacks capacity to provide consent and his/her legally authorized representative:

- ☐ gave permission for the adult subject to participate
- ☐ did not give permission for the adult subject to participate

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DFCI Protocol Number: 06-085	Date DFCI IRB Approved this Consent Form: January 16, 2007
Date Posted for Use: January 16, 2007	Date DFCI IRB Approval Expires: August 13, 2007

Consent Form A was approved by my university IRB for a mailed survey about substance abuse among undergraduate students. It is brief and to the point.

Consent Form B reflects the requirements of an academic hospital's IRB (I have only included a portion of the six-page form). Because the hospital is used to reviewing research proposals involving drugs and other treatment interventions with hospital patients, it requires a very detailed and lengthy explanation of procedures and related issues, even for a simple interview study such as mine with Dr. Schapira. You can probably imagine that the requirement that prospective participants sign such lengthy consent forms can reduce their willingness to participate in research and perhaps influence their responses if they do agree to participate (Larson 1993:114).

Debriefing: A researcher's informing subjects after an experiment about the experiment's purposes and methods and evaluating subjects' personal reactions to the experiment.

As in Milgram's study, experimental researchers whose research design requires some type of subject deception try to get around this problem by withholding some information before the experiment begins, but then debriefing subjects at the end. In a **debriefing**, the researcher explains to the subjects what happened in the experiment and why, and then responds to their questions. A carefully designed debriefing procedure can help the research participants learn from the experimental research and grapple constructively with feelings elicited by the realization that they were deceived (Sieber 1992:39–41). However, even though debriefing can be viewed as a substitute, in some cases, for securing fully informed consent before the experiment, debriefed subjects who disclose the nature of the experiment to other participants can contaminate subsequent results (Adair, Dushenko, & Lindsay 1985). Apparently for this reason, Milgram provided little information in his "debriefing" to participants in most of his experiments. It was only in the last two months of his study that he began to provide more information, while still asking participants not to reveal the true nature of the experimental procedures until after the study was completely over (Perry 2013:76, 84). Unfortunately, if the debriefing process is delayed, the ability to lessen any harm resulting from the deception is also reduced.

For a study of the social background of men who engage in homosexual behavior in public facilities, Laud Humphreys (1970) decided that truly informed consent would be impossible to obtain. Instead, he first served as a lookout—a "watch queen"—for men who were entering a public bathroom in a city park with the intention of having sex. In a number of cases, he then left the bathroom and copied the license plate numbers of the cars driven by the men. One year later, he visited the homes of the men and interviewed them as part of a larger study of social issues. Humphreys changed his appearance so that the men did not recognize him. In ***Tearoom Trade***, his book on this research, Humphreys concluded that the men who engaged in what were viewed as deviant acts were, for the most part, married, suburban men whose families were unaware of their sexual practices. But debate has continued ever since about Humphreys's failure to tell the men what he was really doing in the bathroom or why he had come to their homes for the interview. He was criticized by many, including some faculty members at the University of Washington who urged that his doctoral degree be withheld. However, many other professors and some members of the gay community praised Humphreys for helping normalize conceptions of homosexuality (Miller 1986:135).

Tearoom Trade: Study by sociologist Laud Humphreys of men who engage in homosexual behavior in public facilities, including subsequent later interviews in their homes after recording their license plate numbers; widely cited in discussions of the need for informed consent to research.

If you were to serve on your university's IRB, would you allow this research to be conducted? Can students who are asked to participate in research by their professor be considered able to give informed consent? Do you consider *informed consent* to be meaningful if the true purpose or nature of an experimental manipulation is not revealed?

The process and even possibility of obtaining informed consent must consider the capacity of prospective participants to give informed consent. Children cannot legally give consent to participate in research; instead, they must in most circumstances be given the opportunity to give or withhold their *assent* to participate in research, usually by a verbal response to an explanation of the research. In addition, a child's legal guardian must give written informed consent to have the child participate in research (Sieber 1992). There are also special protections for other populations who are likely to be vulnerable to coercion—prisoners, pregnant women, persons with mental disabilities, and educationally or economically disadvantaged persons. Would you allow

research on prisoners, whose ability to give informed consent can be questioned? What special protections do you think would be appropriate?

Obtaining informed consent also becomes more challenging in collectivist communities in which leaders or the whole group are accustomed to making decisions for individual members. In such settings, usually in non-Western cultures, researchers may have to develop a relationship with the community before individuals can be engaged in research (Bledsoe & Hopson 2009:397–398).

Subject payments create another complication for achieving the goal of informed consent. Although payments to research participants can be a reasonable way to compensate them for their time and effort, payments also serve as an inducement to participate. If the payment is a significant amount in relation to the participants' normal income, it could lead people to set aside their reservations about participating in a project—even though they may harbor those reservations (Fisher & Anushko 2008:104–105).

Avoid Deception in Research, Except in Limited Circumstances

Deception: Used in social experiments to create more "realistic" treatments in which the true purpose of the research is not disclosed to participants, often within the confines of a laboratory.

Deception occurs when subjects are misled about research procedures to determine how they would react to the treatment if they were not research subjects. Deception is a critical component of many social psychology experiments, partly because of the difficulty of simulating real-world stresses and dilemmas in a laboratory setting. The goal is to get subjects "to accept as true what is false or to give a false impression" (Korn 1997:4). In Milgram's (1964) experiment, for example, deception seemed necessary because the subjects could not be permitted to administer real electric shocks to the "stooge," yet it would not have made sense to order the subjects to do something that they didn't find to be so troubling. Milgram (1992:187–188) insisted that the deception was absolutely essential, although the experimental records indicate that some participants figured out the deception (Perry 2013:128–129).

The results of many other social psychological experiments would be worthless if subjects understood what was really happening to them while the experiment was in progress. The real question: Is this sufficient justification to allow the use of deception?

Gary Marshall and Philip Zimbardo (1979:971–972) sought to determine the physiological basis of emotion by injecting student volunteers with adrenaline, so that their heart rates and sweating would increase, and then placing them in a room with a student "stooge" who acted silly. The students were told that they were being injected with a vitamin supplement to test its effect on visual acuity (Korn 1997:2–3). Jane Allyn Piliavin and Irving Piliavin (1972:355–356) staged fake seizures on subway trains to study helpfulness (Korn 1997:3–4). If you were a member of your university's IRB, would you vote to allow such deceptive practices in research? What about less dramatic instances of deception in laboratory experiments with students like yourself?

Do you believe that deception itself is the problem? Elliot Aronson and Judson Mills's (1959) study of the severity of initiation to groups is a good example of experimental research that does not pose greater-than-everyday risks to subjects, but still uses deception. This study was conducted at an all-women's college in the 1950s. The student volunteers who were randomly assigned to the "severe initiation" experimental condition had to read a list of embarrassing words. I think it's fair to say that even in the 1950s, reading a list of potentially embarrassing words in a laboratory setting and listening to a taped discussion were unlikely to increase the risks to which students are exposed in their everyday lives. Moreover, the researchers informed the subjects that they would be expected to talk about sex and could decline to participate in the experiment if this requirement would bother them. None dropped out.

To further ensure that no psychological harm was caused, Aronson and Mills (1959) explained the true nature of the experiment to the subjects after the experiment. The subjects did not seem perturbed: "None of the Ss [subjects] expressed any resentment or annoyance at having been misled. In fact, the majority were intrigued by the experiment, and several returned at the end of the academic quarter to ascertain the result" (p. 179).

Are you satisfied that this procedure caused no harm? Do you react differently to Aronson and Mills's debriefing than you did to Milgram's debriefing? The minimal deception in the Aronson and Mills experiment,

coupled with the lack of any ascertainable risk to subjects plus a debriefing, satisfies the ethical standards for research of most social scientists and IRBs, even today.

What scientific, educational, or applied value would make deception justifiable, even if there is some potential for harm? Who determines whether a nondeceptive intervention is "equally effective"? (Miller 1986:103). Baumrind (1985:167) suggested that personal "introspection" would have been sufficient to test Milgram's hypothesis and has argued subsequently that intentional deception in research violates the ethical principles of self-determination, protection of others, and maintenance of trust between people, and so can never be justified. How much risk, discomfort, or unpleasantness might be seen as affecting willingness to participate? When should a postexperimental "attempt to correct any misconception" caused by deception be deemed sufficient?

Can you see why an IRB, representing a range of perspectives, is an important tool for making reasonable, ethical research decisions when confronted with such ambiguity? Exhibit 3.8 shows a portion of the complex flowchart developed by the U.S. Department of Health and Human Services to help researchers decide what type of review will be needed for their research plans. Any research involving deception requires formal human subjects review.

Maintain Privacy and Confidentiality

Maintaining privacy and confidentiality is another key ethical standard for protecting research participants, and the researcher's commitment to that standard should be included in the informed consent agreement (Sieber 1992). Procedures to protect each subject's privacy—such as locking records and creating special identifying codes—must be created to minimize the risk of access by unauthorized persons. However, statements about confidentiality should be realistic: Laws allow research records to be subpoenaed and may require reporting of child abuse; a researcher may feel compelled to release information if a health- or life-threatening situation arises and participants need to be alerted. Also, the standard of confidentiality does not apply to observation in public places and information available in public records.

Certificate of Confidentiality: A certificate issued to a researcher by the National Institutes of Health that ensures the right to protect information obtained about high-risk populations or behaviors—except child abuse or neglect—from legal subpoenas.

Health Insurance Portability and Accountability Act (HIPAA): A congressional act passed in 1996 that creates stringent regulations for the protection of health care data.

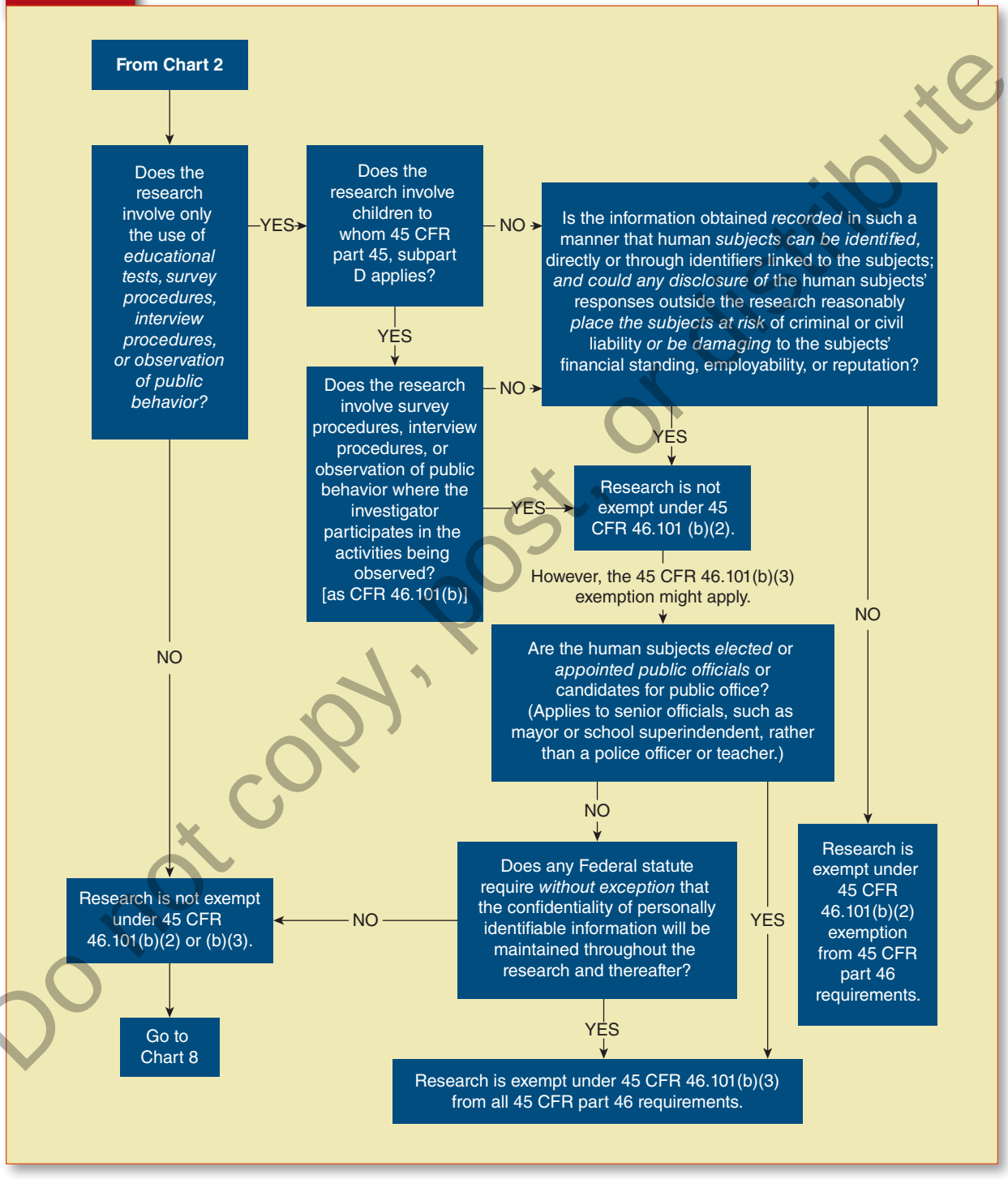
There is one exception to some of these constraints: The National Institutes of Health (NIH) can issue a **Certificate of Confidentiality** to protect researchers from being legally required to disclose confidential information. This is intended to help researchers overcome the reluctance of individuals engaged in illegal behavior to sign a consent form or to risk exposure of their illegal activities (Sharma 2009:426). Researchers who are focusing on high-risk populations or behaviors, such as crime, substance abuse, sexual activity, or genetic information, can request such a certificate. Suspicions of child abuse or neglect must still be reported, and in some states, researchers may still be required to report such crimes as elder abuse (Arwood & Panicker 2007).

The **Health Insurance Portability and Accountability Act (HIPAA)** passed by Congress in 1996 created more stringent regulations for the protection of health care data. As implemented by the U.S. Department of Health and Human Services in 2000 (revised in 2002), the HIPAA Final Privacy Rule applies to oral, written, and electronic information that "relates to the past, present or future physical or mental health or condition of an individual." The HIPAA rule requires that researchers have valid authorization for any use or disclosure of "protected health information" (PHI) from a health care provider. Waivers of authorization can be granted in special circumstances (Cava, Cushman, & Goodman 2007).

Consider Uses of Research So That Benefits Outweigh Risks

Scientists must also consider the uses to which their research is put. Although many scientists believe that personal values should be left outside the laboratory, some feel that it is proper—even necessary—for scientists to concern themselves with the way their research is used.

Exhibit 3.8 U.S. Department of Health and Human Services Human Subjects Decision Flowchart 4: For Tests, Surveys, Interviews, Public Behavior Observation



Source: Department of Health and Human Services.

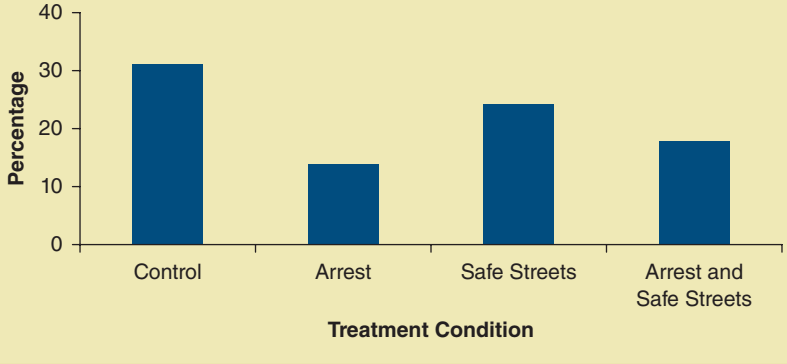
Milgram made it clear that he was concerned about the phenomenon of obedience precisely because of its implications for people's welfare. As you have already learned, his first article (Milgram 1963) highlighted the atrocities committed under the Nazis by citizens and soldiers who were "just following orders." In his more comprehensive book on the obedience experiments (Milgram 1974), he also argued that his findings shed light on the atrocities committed in the Vietnam War at My Lai, slavery, the destruction of the American Indian population, and the internment of Japanese Americans during World War II. Milgram makes no explicit attempt to "tell us what to do" about this problem. In fact, as a dispassionate social scientist, Milgram (1974) tells us, "What the present study [did was] to give the dilemma [of obedience to authority] contemporary form by treating it as subject matter for experimental inquiry, and with the aim of understanding rather than judging it from a moral standpoint" (p. xi).

Yet it is impossible to ignore the very practical implications of Milgram's investigations, which Milgram took pains to emphasize. His research highlighted the extent of obedience to authority and identified multiple factors that could be manipulated to lessen blind obedience (e.g., encouraging dissent by just one group member, removing the subject from direct contact with the authority figure, and increasing the contact between the subject and the victim). It is less clear how much Milgram's laboratory manipulation can tell us about obedience in the very different historical events to which he generalized his conclusions, but its conclusions still have potentially great benefits for society.

The evaluation research by Lawrence Sherman and Richard Berk (1984) on police response to domestic violence provides an interesting cautionary tale about the uses of science. As you recall from Chapter 2, the results of this field experiment indicated that those who were arrested were less likely to subsequently commit violent acts against their partners. Sherman (1993) explicitly cautioned police departments not to adopt mandatory arrest policies based solely on the results of the Minneapolis experiment, but the results were publicized in the mass media and encouraged many jurisdictions to change their policies (Binder & Meeker 1993; Lempert 1989). We now know that the original finding of a deterrent effect of arrest did not hold up in many other cities where the experiment was repeated, so it is not clear that the initial changes in arrest policy were beneficial. Sherman (1992:150–153) later suggested that implementing mandatory arrest policies might have prevented some subsequent cases of spouse abuse, but this does not change the fact that these policies were often ineffective.

Given the mixed findings from the replications of Sherman and Berk's experiment, do you think that police policy should be changed in light of JoAnn Miller's (2003) analysis of victims' experiences and perceptions concerning their safety after the mandatory arrest experiment in Dade County, Florida? Miller found that victims reported experiencing less violence after their abuser had been arrested (and/or assigned to a police-based counseling program called Safe Streets) (Exhibit 3.9). Should this Dade County finding be publicized in the popular press, so it could be used to improve police policies? What about the results of the other replication studies?

Exhibit 3.9 Victim Reports of Violence Following Police Intervention



Source: Miller, JoAnn. 2003. "An Arresting Experiment: Domestic Violence Victim Experiences and Perceptions." *Journal of Interpersonal Violence* 18:695–716. Based on table 1.

Social scientists who conduct research on behalf of specific organizations may face additional difficulties when the organization, instead of the researcher, controls the final report and the publicity it receives. If organizational leaders decide that particular research results are unwelcome, the researcher's desire to have the findings used appropriately and reported fully can conflict with contractual obligations. Researchers can often anticipate such dilemmas in advance and resolve them when the contract for research is negotiated—or they may simply decline a particular research opportunity altogether. But, often, such problems come up only after a report has been drafted, or the problems are ignored by a researcher who needs to have a job or needs to maintain particular personal relationships. These possibilities cannot be avoided entirely, but because of them, it is always important to acknowledge the source of research funding in reports and to consider carefully the sources of funding for research reports written by others.

The potential of withholding a beneficial treatment from some subjects also is a cause for ethical concern. The Sherman and Berk (1984) experiment required the random assignment of subjects to treatment conditions and thus had the potential of causing harm to the victims of domestic violence whose batterers were not arrested. The justification for the study design, however, is quite persuasive: The researchers didn't know before the experiment which response to a domestic violence complaint would be most likely to deter future incidents (Sherman 1992). The experiment provided what seemed at first to be clear evidence about the value of arrest, so it can be argued that the benefits outweighed the risks.

2 The Institutional Review Board

Federal regulations require that every institution that seeks federal funding for biomedical or behavioral research on human subjects have an **institutional review board (IRB)** that reviews research proposals involving human subjects—including data about living individuals. According to federal regulations [45 CFR 46.102(d)], research is "a systematic investigation . . . designed to develop or contribute to generalizable knowledge," and according to the Department of Health and Human Services (DHHS) [45 CFR 46.102 (f)], a human subject is "a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or just identifiable private information." The IRB determines whether a planned activity is research or involves human subjects.

Institutional review board (IRB): A group of organizational and community representatives required by federal law to review the ethical issues in all proposed research that is federally funded, involves human subjects, or has any potential for harm to human subjects.

IRBs at universities and other agencies apply ethical standards that are set by federal regulations but can be expanded or specified by the institution's IRB and involve all research at the institution irrespective of the funding source (Sieber 1992:5, 10). The IRB has the authority to require changes in a research protocol or to refuse to approve a research protocol if it deems human subjects protections inadequate. Consent forms must include contact information for the IRB, and the IRB has the authority to terminate a research project that violates the procedures the IRB approved or that otherwise creates risks for human subjects. The **Office for Protection From Research Risks, National Institutes of Health** monitors IRBs, with the exception of research involving drugs (which is the responsibility of the federal Food and Drug Administration).

Office for Protection From Research Risks, National Institutes of Health: The office in the U.S. Department of Health and Human Services (DHHS) that provides leadership and supervision about the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by HHS, including monitoring IRBs.

To promote adequate review of ethical issues, the regulations require that IRBs include at least five members, with at least one nonscientist and one from outside the institution (Speiglman & Spear 2009:124). The IRB must also include members from both sexes, diverse backgrounds, and multiple professions. When research is reviewed concerning vulnerable populations, such as prisoners, the IRB must include a member having experience with and knowledge about that vulnerable population. Sensitivity to community attitudes and training in human subjects protection procedures is also required (Selwitz, Epley, & Erickson 2013).

Every member of an institution with an IRB—including faculty, students, and staff at a college or university—must submit a proposal to their IRB before conducting research with identifiable people. The IRB

proposal must include research instruments and consent forms, as applicable, as well as enough detail about the research design to convince the IRB members that the potential benefits of the research outweigh any risks (Speiglman & Spear 2009:124). Most IRBs also require that researchers complete a training program about human subjects, usually the Collaborative Institutional Training Initiative (CITI) at the University of Miami (https://www.citiprogram.org/). CITI training is divided into topical modules ranging from history, ethical principles, and informed consent to vulnerable populations, Internet-based research, educational research, and records-based research. Each IRB determines which CITI training modules researchers at its institution must complete.

In the News

Research in the News

WHAT WOULD AN IRB SAY?

Former New York City Mayor Michael Bloomberg and his health commissioner Thomas Frieden unilaterally moved New Yorkers to a lower salt diet. While numerous research experiments have attempted to find a relationship between low salt diets and improved health, there have been no conclusive results. But New York City administrators required restaurants to impose a cap on salt intake.

For Further Thought

1. Is it ethical to base public policies on ambiguous research results? What about if the results are definitive? Should these restaurants be using informed consent forms?
2. Could you imagine a real social experiment in New York restaurants to test the value of lowering salt in foods? What steps might an IRB require?

News Source: Tierney, John. 2009. "Public Policy That Makes Test Subjects of Us All." *The New York Times,* April 7: D1.

Researcher Interview Link
Institutional Review Boards

Although the IRB is the responsible authority within the institution, many research proposals do not have to be reviewed by the full board (Hicks 2013). Some proposals, including many developed by social scientists, may be exempt from review because they involve very low perceived risk: research about educational procedures in an educational setting, a survey that does not collect information that could be harmful to respondents if it were disclosed, or analysis of existing records that are not individually identifiable. However, the decision of whether a research project is *exempt* from IRB review must be made by an official designated by the institution to screen applications—typically one or more representatives of the IRB.

Many research proposals that do not meet the criteria for exemption but still pose only minimal risk to human subjects may be given an *expedited* review by IRB representatives (often an IRB administrator and the IRB chair), rather than being sent to a hearing at a meeting of the full IRB. According to the regulations (DHHS 2009),

1. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

2. The categories in this list apply regardless of the age of subjects, except as noted.
    a. The expedited review procedure may not be used where identification of the subjects or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
    b. The expedited review procedure may not be used for classified research involving human subjects.
    c. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—used by the IRB.
    d. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

The categories of research that can be considered for expedited review include collection of biological specimens and some medical data for research purposes by noninvasive means; collection of data from voice, video, digital, or image recordings made for research purposes; and research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies (DHHS 2009).

Many projects must be reviewed before the full IRB (Speiglman & Spear 2009:125–126). An IRB must ensure that several specific standards are met by research projects that it reviews either on an expedited basis or in a full board review (Hicks 2013):

1. Risks to subjects are minimized: (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment the IRB should consider the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

In addition, 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.

The IRB may also serve as the privacy board that ensures researchers' compliance with the HIPAA. In this capacity, the IRB responds to requests for waivers or alterations of the authorization requirement under the privacy rule for uses and disclosures of protected health information (PHI) in research. Researchers seeking to collect or use existing HIPAA data must provide additional information to the IRB about their plans for using the health information.

A proposed research project that does not meet these standards will have to be revised to increase human subjects protections or it will be rejected.

CAREERS AND RESEARCH

Kristen Kenny, Research Compliance Specialist

Kristen Kenny comes from a long line of musicians and artists and was the first in her family to graduate from college. Kenny majored in filmmaking and performance art at the Massachusetts College of Art and soon started working on small films and in theater doing everything from set design, hair, and make-up to costume design and acting. The arts have their fair share of interesting characters; this was the beginning of Kenny's training in dealing with a variety of difficult personalities and learning how to listen and how to react.

After years of working a variety of jobs in the entertainment field, Kenny found herself working as a receptionist in the music industry, a hotbed of difficult personalities, contracts, and negotiations. Within a year, Kenny had been promoted to assistant talent buyer for small clubs and festivals in the Boston area. This job helped Kenny develop the skill of reading dense contract documents and being able to identify what contractual clause language stays and what gets deleted. Eventually the music industry started to wane and Kenny was laid off, but a friend at a local hospital who was in dire need of someone who could interpret volumes of documents and deal with bold personalities asked her to apply for a job as their IRB administrator. Kenny had no idea what an IRB was, but she attended trainings and conferences to learn the IRB trade. Three years later, Kenny was asked to join the Office of Research and Sponsored Programs at the University of Massachusetts Boston as the IRB administrator.

Now, as a research compliance specialist II, Kenny maintains the IRB and other regulatory units and has developed a training curriculum and program for the Office of Research and Sponsored Programs. And if you look hard enough you can find her clothing and fabric designs on eBay, Etsy, and her own website.

2 Social Research Proposals

Now that you have an overview of the research process and a basic understanding of IRB requirements, it is time to introduce the process of writing a research proposal. A research proposal is the launching pad for a formal research project, and it serves the very important function of forcing a researcher to set out a problem statement and a research plan—to think through the details of what you are trying to accomplish and how you will go about that—as well as to think through procedures for the protection of human subjects. So whether you must write a proposal for a professor, a thesis committee, an organization seeking practical advice, or a government agency that funds basic research, you should approach the requirement as a key step toward achieving your goals. Just writing down your ideas will help you see how they can be improved, and almost any feedback will help you refine your plans.

Each chapter in this book includes a section, "Developing a Research Proposal," with exercises that guide you through the process of proposal writing. This section introduces the process of proposal writing as well as these special end-of-chapter exercises. It also provides a schematic overview of the entire research process. You will want to return to this section frequently so you will remember "where you are" in the research process as you learn about particular methods in the remaining chapters.

Research proposals often have five sections (Locke, Spirduso, & Silverman 2000:8–34):

- *An introductory statement of the research problem,* in which you clarify what it is that you are interested in studying
- *A literature review,* in which you explain how your problems and plans build on what has already been reported in the literature on this topic
- *A methodological plan,* detailing just how you will respond to the particular mix of opportunities and constraints you face
- *An ethics statement,* identifying human subjects issues in the research and how you will respond to them in an ethical fashion
- *A statement of limitations,* reviewing the potential weaknesses of the proposed research design and presenting plans for minimizing their consequences

You will also need to include a budget and project timeline, unless you are working within the framework of a class project.

When you develop a research proposal, it will help to ask yourself a series of questions such as those in Exhibit 3.10; see also Gregory Herek (1995). It is easy to omit important details and to avoid being self-critical while rushing to put a proposal together. However, it is even more painful to have a proposal rejected (or to receive a low grade). It is better to make sure the proposal covers what it should and confronts the tough issues that reviewers (or your professor) will be sure to consider.

The series of questions in Exhibit 3.10 can serve as a map to subsequent chapters in this book and as a checklist of decisions that must be made throughout any research project. The questions are organized in five sections, each concluding with a checkpoint at which you should consider whether to proceed with the research as planned, modify the plans, or stop the project altogether. The sequential ordering of these questions obscures a bit the way in which they should be answered: not as single questions, one at a time, but as a unit—first as five separate stages and then as a whole. Feel free to change your answers to earlier questions on the basis of your answers to later questions.

We will learn how to apply the decision checklist with an example from a proposal focused on a public health care coordination program. At this early point in your study of research methods, you may not recognize all the terms in this checklist. Don't let that bother you now because my goal is just to give you a quick overview of the decision-making process. Your knowledge of these terms and your understanding of the decisions will increase as you complete each chapter. Your decision-making skills will also improve if you complete the "Developing a Research Proposal" exercises at the end of each chapter.

Case Study: Evaluating a Public Health Program

Exhibit 3.11 provides excerpts from the research proposal I submitted to our IRB as part of an evaluation of a public health program for low-income residents funded by the U.S. Centers for Disease Control and the Massachusetts Department of Public Health (DPH) (Schutt 2011a). Appendixes included consent forms, research instruments, and the bibliography.

As you can see from the excerpts, I proposed to evaluate a care coordination program for low-income uninsured and underinsured Massachusetts residents (before universal health care). The proposal included

Exhibit 3.10 Decisions in Research

Problem Formulation (Chapters 1–3)

1. Developing a research question
2. Assessing researchability of the problem
3. Consulting prior research
4. Relating to social theory
5. Choosing an approach: Deductive? Inductive? Descriptive?
6. Reviewing research guidelines and ethical standards

Checkpoint 1
Alternatives:

- Continue as planned.
- Modify the plan.
- Stop. Abandon the plan.

Research Validity (Chapters 4–6)

7. Establishing measurement validity:
   - How should concepts be defined?
   - What measures are available and what measures must be developed?
   - How can reliability and validity be assessed?
   - Is authenticity an important goal and how can it be assessed?
8. Establishing generalizability:
   - Was a representative sample used?
   - Are the findings applicable to particular subgroups?
   - Does the population sampled correspond to the population of interest?
9. Establishing causality:
   - What is the possibility of experimental or statistical controls?
   - How to assess the causal mechanism?
   - What is the causal context?
10. Determining the data required: Longitudinal or cross-sectional?
11. Determining the units of analysis: Individuals or groups?
12. Determining the major possible sources of causal invalidity

Checkpoint 2
Alternatives:

- Continue as planned.
- Modify the plan.
- Stop. Abandon the plan.

Research Design (Chapters 7, 8, 10, 12–15)

13. Choosing a research design and procedures: Experimental? Survey? Participant observation? Historical, comparative? Evaluation research? Secondary data analysis? Mixed methods?
14. Specifying the research plan: Type of surveys, observations, etc.
15. Determining secondary analysis and availability of suitable data sets
16. Choosing a causal approach: Idiographic or nomothetic?
17. Assessing human subjects protections

Checkpoint 3
Alternatives:

- Continue as planned.
- Modify the plan.
- Stop. Abandon the plan.

Data Analysis (Chapters 9, 11)

18. Choosing an analytic approach:

- Identifying statistics and graphs for describing data
- Identifying relationships between variables
- Deciding about statistical controls
- Testing for interaction effects
- Evaluating inferences from sample data to the population
- Developing a qualitative analysis approach

Checkpoint 4
Alternatives:

- Continue as planned.
- Modify the plan.
- Stop. Abandon the plan.

Reporting Research (Chapter 16)

19. Clarifying research goals and prior research findings
20. Identifying the intended audience
21. Developing tables and charts
22. Organizing the text
23. Reviewing research limitations

Checkpoint 5
Alternatives:

- Complete the research!
- Modify the plan.
- Stop. Abandon the plan.

a lengthy literature review, a description of the population and the sampling procedure, measures to be used in the survey, and the methods for conducting phone interviews as well as in-person interviews with a subset of the sample. Required sections for the IRB also included a statement of risks and benefits, procedures for obtaining informed consent, and means for maintaining confidentiality. A HIPAA compliance statement was included because of the collection of health-related data.

Let's review the issues identified in Exhibit 3.10 as they relate to the public health proposal. The research question concerned the effectiveness of a care coordination program involving the use of patient navigators—an evaluation research question [Question 1]. This problem certainly was suitable for social research, and it was one that was feasible with the money DPH had committed [2]. Prior research demonstrated clearly that the program had potential but also that this approach had not previously been studied [3]. The treatment approach was connected to theories about health care disparities [4] and, given prior work and uncertainties in this area, mixed methods involving both a deductive, hypothesis-testing approach and an inductive, exploratory approach was called for [5]. I argued to the IRB that our plan protected human subjects and took each research guideline into account [6]. So it seemed reasonable to continue to develop the proposal (Checkpoint 1).

Exhibit 3.11 An IRB Proposal for a Program Evaluation

Evaluation of the Coordinated Care Program

Rationale

Inadequate personal resources, knowledge, and service opportunities limit the access of low income and minority populations to health care services. . . . four types of barriers to effective service delivery in interviews with Latina women . . . additional systemic barriers of provider bias and poor quality of care. Many public health agencies have adopted programs designed to overcome these barriers and thus to reduce disparities in health care services and, ultimately, outcomes.

The Massachusetts Department of Public Health began a Coordinated Care Program in 2006 in order to improve identification of health needs among low income uninsured and underinsured residents and to increase the effectiveness of health services for this population. . . .

The purpose . . . is to investigate patient experience with the program, including subjective outcomes of the program and the bases of these outcomes. . . .

Program Background

Congress funded the National Breast and Cervical Cancer Early Detection Program (Breast and Cervical Cancer Mortality Prevention Act of 1990) to improve the rate of screening, testing and referral to treatment for low income uninsured and underinsured women at risk of breast and cervical cancer . . .

Patient navigation is designed to overcome barriers to treatment, while coordinated care is intended to improve treatment benefits, so the combination of both elements in one program should improve treatment outcomes.

The first patient navigation program appeared to reduce average stage at diagnosis among cancer patients. . . .

Care coordination is an important property of health care systems as well as a key aspect of patients' experience of health care. . . .

The emphases on coordinated care and on patient navigation may not always be complementary. . . . Programs offering patient navigation and care coordination have not typically been combined together due to their different disease foci: cancer for patient navigation and chronic illness for care coordination. The MA CCP program thus provides a unique opportunity to study the effect of combining these two different types of programs and examining their value for a very diverse and historically underserved population.

HIPAA Compliance Information

. . . No information about health conditions will be reported in a way that could be linked to any particular client.

Methodology

. . . Data will be collected with a statewide phone survey of a representative sample and through in-person interviews with a small number of clients at six of the 17 program delivery sites.

The phone survey is to result in a total sample of 400 interviews. One thousand clients will be sent an informational letter about the survey, indicating that they may receive a call. Cases will be selected randomly from the initial sampling frame and called to determine study eligibility. Phone calls will be repeated up to 20 times in order to make contact. Questions S0-S4 (in the attached questionnaire) will serve as the screening questions. . . . The phone survey instrument will be translated into Spanish and Portuguese. . . .

Questions in the phone survey instrument are designed to identify relation to the health center and patient navigator, ethnic and linguistic background and some other sociodemographic characteristics, current health status, including levels of depression and anxiety, use of health services, perceived barriers to the use of health services, and satisfaction with health services. . . .

A sample of 30 clients will be selected for more intensive interviews about program experience and orientations. . . . For those clients who consent, the in-person interviews will be recorded and transcribed. The resulting textual data will be coded and analyzed with the assistance of qualitative analysis software . . .

Human Participants Information

Participant Data

The client database maintained by the Massachusetts Care Coordination Program identifies . . . active clients. . . .

Risks and Benefits

Participation in the Client Survey involves a minimal risk of loss of confidentiality. In addition, the probability and magnitude of harm or discomfort anticipated from responding to the Client Survey items is no greater than what would ordinarily be encountered in daily life, that is, minimal risk. Although the only direct benefit to survey participants is the opportunity to express their perceptions of and satisfaction with . . . case management, the information gained may be helpful to case managers and other health care providers. The societal benefit is having objective data on which to base effective models of case management. The potential benefits of the proposed survey outweigh the minimal risk for individual survey participants.

Informed Consent and Confidentiality

The . . . phone survey interviewer will inform the clients that the survey is voluntary and explain procedures to be followed (the respondent can stop at any time; can skip any question she does not want to answer). The script for the telephone interview is in the Appendix. [P]hone interviewers and other staff adhere to strict confidentiality requirements. Identifying information will be used only for client contact and no personal identifiers will be maintained in the phone survey database. The phone survey ID numbers will be stored in a locked file with a list that links them to an identifier in the DPH CCP healthcare database. This linked list will allow subsequent matching in Stage III of data from the phone survey with data from CCP records about health outcomes. Signed consent forms for client in-person interviews will be stored in a locked cabinet. A list linking identification numbers and names of staff who were interviewed will be available only to the Principal Investigator. All in-person interviews will be taped and transcribed and records will also be stored in a locked cabinet and on password-protected computers. . . . Consent forms will include consent for the interview, consent for taping, and consent for follow-up.

Measures were to include structured survey questions to measure many variables and open-ended questions to allow exploration of barriers to care [7]. Use of a representative sample of the population of program recipients would increase the generalizability of the findings, although I was limited to interviews in English, Spanish, and Portuguese even though we knew there were a small number of recipients who spoke other languages [8]. The problem was well suited to a survey design [9] and could be adequately addressed with cross-sectional data [10], involving individuals [11]. The design left several sources of causal invalidity, including the possibility that persons who received the most services from patient navigators were those who had more resources and so were more healthy [12]. It seemed that I would be able to meet basic criteria for validity (Checkpoint 2).

A survey design was preferable because this was to be a study of a statewide population, but I did include a qualitative component so that I could explore orientations [13, 14]. Because the effectiveness of the program strategy had not been studied before in this type of population, I could not propose doing a secondary data analysis or meta-analysis [15]. I sought only to investigate causation from a *nomothetic* perspective, without attempting to show how the particular experiences of each participant may have led to their outcome [16]. The study design was low-risk and included voluntary participation; the research design seemed ethical [17] (Checkpoint 3). Standard statistical tests were proposed as well as some analysis of qualitative data [18] (Checkpoint 4). My goal was to use the research as the basis for several academic articles, as well as a report to the agency [19, 20]. I had reviewed the research literature carefully [21], but as is typical in most research proposals, I did not develop the research reporting plans any further [22, 23] (Checkpoint 5).

If your research proposal will be reviewed competitively, it must present a compelling rationale for funding. You should not overstate the importance of the research problem that you propose to study (see the first section of this chapter). If you propose to test a hypothesis, be sure that it is one for which there are plausible alternatives. You want to avoid focusing on a "boring hypothesis"—one that has no credible alternatives, even though it is likely to be correct (Dawes 1995:93).

A research proposal also can be strengthened considerably by presenting results from a pilot study of the research question. This might have involved administering the proposed questionnaire to a small sample, conducting a preliminary version of the proposed experiment with a group of students, or making observations over a limited period in a setting like that proposed for a qualitative study. My original proposal to the DPH was strengthened by my ability to build on a prior study I had conducted in the agency 10 years previously. Careful presentation of the methods used in the pilot study and the problems that were encountered will impress anyone who reviews the proposal.

Don't neglect the procedures for the protection of human subjects. Even before you begin to develop your proposal, you should find out what procedure your university's IRB requires for the review of student research proposals. Follow these procedures carefully, even if they require that you submit your proposal for an IRB review. No matter what your university's specific requirements are, if your research involves human subjects, you will need to include in your proposal a detailed statement that describes how you will adhere to these requirements.

By the book's end, in Chapter 16, you will have attained a much firmer grasp of the various research decisions outlined in Exhibit 3.10.

2 Conclusions

The extent to which ethical issues are a problem for researchers and their subjects varies dramatically with the type of research design. Survey research, in particular, creates few ethical problems. In fact, researchers from Michigan's Institute for Survey Research interviewed a representative national sample of adults some years ago and found that 68% of those who had participated in a survey were somewhat or very interested in participating in another; the more times respondents had been interviewed, the more willing they were to participate again. Presumably, they would have felt differently if they had been treated unethically (Reynolds 1979:56–57). Conversely, some experimental studies in the social sciences that have put people in uncomfortable or embarrassing situations have generated vociferous complaints and years of debate about ethics (Reynolds 1979; Sjoberg 1967).

The evaluation of ethical issues in a research project should be based on a realistic assessment of the overall potential for harm and benefit to research subjects rather than an apparent inconsistency between any particular aspect of a research plan and a specific ethical guideline. For example, full disclosure of "what is really going on" in an experimental study is unnecessary if subjects are unlikely to be harmed. Nevertheless, researchers should make every effort to foresee all possible risks and to weigh the possible benefits of the research against these risks. Researchers should consult with individuals with different perspectives to develop a realistic risk–benefit assessment and should try to maximize the benefits to, as well as minimize the risks for, subjects of the research (Sieber 1992:75–108).

Ultimately, these decisions about ethical procedures are not just up to you, as a researcher, to make. Your university's IRB sets the human subjects protection standards for your institution and will require that researchers—and even, in most cases, students—submit their research proposals to the IRB for review. So, I leave you with the instruction to review the human subjects guidelines of the ASA or other professional association in your field, consult your university's procedures for the conduct of research with human subjects, and then proceed accordingly.

You can now also understand why human subjects protections should be considered as a vital part of any research proposal. You are ready to begin evaluating and designing the particulars of a research project.

Key Terms

Belmont Report 68
Beneficence 69
Certificate of Confidentiality 82
Code of Ethics (American Sociological Association) 69
Conflict of interest 72
Debriefing 80
Deception 81
Federal Policy for the Protection of Human Subjects 69
Health Insurance Portability and Accountability Act (HIPAA) 82
Institutional review board (IRB) 85
Justice 69
Milgram's obedience experiments 67
Nuremberg War Crime Trials 68
Office for Protection From Research Risks, National Institutes of Health 85
Respect for persons 68
Tearoom Trade 80
Tuskegee Study of Untreated Syphilis in the Negro Male 68
Zimbardo's prison simulation study 76

Highlights

- Stanley Milgram's obedience experiments led to intensive debate about the extent to which deception could be tolerated in social science research and how harm to subjects should be evaluated.
- Egregious violations of human rights by researchers, including scientists in Nazi Germany and researchers in the Tuskegee syphilis study, led to the adoption of federal ethical standards for research on human subjects.
- The 1979 *Belmont Report* developed by a national commission established three basic ethical standards for the protection of human subjects: (1) respect for persons, (2) beneficence, and (3) justice.
- The Department of Health and Human Services adopted in 1991 the Federal Policy for the Protection of Human Subjects. This policy requires that every institution seeking federal funding for biomedical or behavioral research on human subjects have an institutional review board to exercise oversight.
- Current standards for the protection of human subjects require avoiding harm, obtaining informed consent, avoiding deception except in limited circumstances, maintaining privacy and confidentiality, and ensuring that the benefits of research outweigh foreseeable risks.
- The American Sociological Association's general principles for professional practice urge sociologists to be committed in their work to high levels of competence, to practicing with integrity, and to maintaining responsibility for their actions. They must also respect the rights, dignity, and diversity of others, including research participants, as well as be socially responsible to their communities and use research to contribute to the public good.
- Scientific research should maintain high standards for validity and be conducted and reported in an honest and open fashion.
- Effective debriefing of subjects after an experiment can help reduce the risk of harm resulting from the use of deception in the experiment.
- Writing a research proposal is an important part of preparing for research. Key decisions can be viewed as checkpoints that will shape subsequent stages. Proposals may need to be submitted to the university IRB for review before the research begins.

Discussion Questions

1. Should social scientists be permitted to conduct replications of Milgram's obedience experiments? Zimbardo's prison simulation? Can you justify such research as permissible within the current ASA ethical standards? If not, do you believe that these standards should be altered to permit Milgram-type research?
2. How do you evaluate the current ASA ethical code? Is it too strict or too lenient, or just about right? Are the enforcement provisions adequate? What provisions could be strengthened?
3. Why does unethical research occur? Is it inherent in science? Does it reflect "human nature"? What makes ethical research more or less likely?
4. Does debriefing solve the problem of subject deception? How much must researchers reveal after the experiment is over as well as before it begins?
5. What policy would you recommend that researchers such as Sherman and Berk (1984) follow in reporting the results of their research? Should social scientists try to correct misinformation in the popular press about their research or should they just focus on what is published in academic journals? Should researchers speak to audiences such as police conventions to influence policies related to their research results?

Practice Exercises

1. Pair up with one other student and read the article by John Lacey and others, or another from the Research That Matters vignettes in the preceding two chapters. One of you should criticize the research in terms of its adherence to each of the ethical principles for research on human subjects, as well as for the authors' apparent honesty, openness, and consideration of social consequences. Be generally negative but not unreasonable in your criticisms. The other one of you should critique the article in the same way but from a generally positive standpoint, defending its adherence to the five guidelines, but without ignoring the study's weak points. Together, write a summary of the study's strong and weak points, or conduct a debate in the class.
2. Investigate the standards and operations of your university's IRB. Review the IRB website, record the composition of the IRB (if indicated), and outline the steps that faculty and students must take to secure IRB approval for human subjects research. In your own words, distinguish the types of research that can be exempted from review, that qualify for expedited review, and that require review by the full board. If possible, identify another student or a faculty member who has had a proposal reviewed by the IRB. Ask them to describe their experience and how they feel about it. Would you recommend any changes in IRB procedures?
3. Choose one of the four "Ethical Issues" lessons from the opening menu for the Interactive Exercises. Review issues in ethical practice by reading the vignettes and entering your answers when requested. You have two chances to answer each question.
4. Also from the book's study site, at edge.sagepub.com/schuttisw8e, choose the Learning From Journal Articles option. Read one article based on research involving human subjects. What ethical issues did the research pose and how were they resolved? Does it seem that subjects were appropriately protected?

Ethics Questions

1. Lacey and his collaborators in the National Roadside Survey (2011), described in the Research That Matters vignette, conducted a purely descriptive study of the prevalence of impaired driving. What if they had sought to test the impact of conducting such traffic stops on the subsequent likelihood of drivers drinking (or drugging) and driving? If this had been their goal, they might have proposed conducting the traffic stops at randomly determined locations, while

conducting surveys without a test for impaired driving at other randomly determined locations as their control condition. They could then have followed up a year later to see if those in the traffic stop group were less likely to have been arrested for DUI. The results of such a study could help devise more effective policies for reducing driving under the influence. Do you think an IRB should approve a study like this with a randomized design? Why or why not?

2. Milgram's research on obedience to authority has been used to explain the behavior of soldiers charged with intentionally harming civilians during armed conflicts, both on the battlefield and when guarding prisoners of war. Do you think social scientists can use experiments such as Milgram's to learn about ethical behavior in the social world in general? What about in situations of armed conflict? Consider in your answers Perry's discoveries about aspects of Milgram's research that he did not disclose.

Web Exercises

1. The Collaborative Institutional Training Initiative (CITI) offers an extensive online training course in the basics of human subjects protections issues. Go to the public access CITI site at www.citiprogram.org/rcrpage.asp?affiliation=100 and complete the course in social and behavioral research. Write a short summary of what you have learned.
2. The U.S. Department of Health and Human Services maintains extensive resources concerning the protection of human subjects in research. Read several documents that you find on its website, www.hhs.gov/ohrp, and write a short report about them.
3. Read the entire ASA *Code of Ethics* at the website of the ASA Ethics Office, www.asanet.org/images/asa/docs/pdf/CodeofEthics.pdf. Discuss the difference between the aspirational goals and the enforceable rules.

Video Interview Questions

Listen to the researcher interview for Chapter 3 at edge.sagepub.com/schutt8e.

1. What are the key issues that an institutional review board (IRB) evaluates in a research proposal?
2. What are some challenges that an IRB faces? How does Dr. Nestor suggest that these challenges can be resolved?

SPSS Exercises

1. Consider three variables in the GSS2012 survey: helpblk, income06, and owngun. Review the corresponding variable labels in the "Variable View" in the GSS2012x or GSS2012a file so that you know what questions were used to measure these variables. Are there any ethical issues involved in asking these questions? Do you imagine that some respondents would be more likely to give untruthful answers to these questions? Explain your answers.
2. Imagine that you are invited by a friend of a friend to speak to members of a fundamentalist church about the implications of the latest General Social Survey for persons of faith. Suppose that you believe in "a woman's right to choose" and in "free speech." Examine the cross-tabulation between fundamentalist beliefs and support for the right to abortion after a rape and support for allowing an anti-religionist to speak (Analyze→ Descriptive Statistics→ Crosstabs→ (Rows=abrape, spkath; Columns=fund; Cells/Percentages=columns). How will the relationship between fundamentalist beliefs and these political attitudes affect your speech? Why or why not?

Developing a Research Proposal

The following steps add to the very critical first steps identified in Exhibit 3.10 that you have already completed in the research proposal exercises for Chapters 1 and 2:

1. Identify each of the elements of your planned research that might be of concern to an IRB. These could include procedures for drawing a sample, inclusion of particular questions in a survey, or openness about procedures in an experiment.
2. Write an annotated list for the application to the IRB in which you explain how you will ensure that your research adheres to each relevant ASA standard.
3. Draft a consent form to be administered to your research participants when they enroll in your research. Use underlining and marginal notes to indicate where each standard for informed consent statements is met.