Sage Research Methods

Planning Ethically Responsible Research

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Research Ethics and IRBs

1.1 ETHICS IN SOCIAL AND BEHAVIORAL RESEARCH

Ethics (from the Greek ethos, “character”) is the systematic study of value concepts...“good,” “bad,” “right,” “wrong”...and the general principles that justify applying these concepts.

Thus, the ethics of social research¹ is not about etiquette; nor is it about considering the poor hapless subject² at the expense of science or society. Rather, we study ethics to learn how to make social research “work” for all concerned. The ethical researcher creates a mutually respectful, win-win relationship with the research population; this is a relationship in which subjects are pleased to participate candidly, and the community at large regards the conclusions as constructive. Public policy implications of the research are presented in such a way that public sensibilities are unlikely to be offended and backlash is unlikely to occur.

In contrast, an ethically insensitive researcher may leave the research setting in pandemonium. The ensuing turmoil may harm the researcher, his or her institution, and even the cause he or she seeks to promote, as suggested by the following fictionalized case, adapted from an actual study.³

Case 1.1: Working at Cross-Purposes. A researcher sends bilingual research assistants to interview poor Chicano families in Texas about their attitudes toward their children's school. The purpose of her research is to gather information that will help local schools meet the needs of children from families that have recently moved there. Unbeknown to the researcher, many of those interviewed are illegal aliens, who suspect that the research is connected with the U. S. Immigration authorities. They fabricate many of their answers to hide their illegal status here, and they are especially careful to reveal nothing about their children's needs or problems with the school. Others in that community carefully avoid the researcher, thus ruining the random sampling design.

A better scientist would have understood that community-based research cannot be planned or conducted unilaterally, and that culturally sensitive approaches are required. He or she would have enlisted community leaders in formulating the research procedures, trained appropriate members of the community to assist with conducting the interviews, and closely supervised the entire process, as exemplified in Case 1, Part III (page 77) and discussed in Chapter 11.
Research designs and procedures that result in failure to treat subjects with respect are likely to yield misleading, inconclusive, or biased results. Yet, enlightened self-interest does not come easily to social scientists because they have been trained, typically, to focus on their predetermined research agenda and to ignore the perceptions and expectations of their subjects and of society at large. This “get data” mentality often produces invalid data.

Selective perception plays an important role in the judgment of scientists who are involved in the intense and demanding enterprise of research. When a researcher is narrowly focused on completing a research project, it is easy to overlook some of the interests and perspectives of the research participants and of society at large. In settings where social scientists have unilateral power to conduct research, they may appear to get away with insensitivity to the perceptions and expectations of their subjects, but they do not. Insensitive researchers themselves become an integral part of the stimulus array; thus, it should come as no surprise that their subjects often respond with lies and subterfuge. Clearly, sound ethics and sound methodology go hand in hand.

Scientists, themselves, (e.g., Kelman, 1968; Vinacke, 1954) have critically examined some of the ethically questionable assumptions and practices of social research and recommended changes, but it was the federal government that finally brought these issues most forcibly to our attention. In 1974 the federal government mandated the establishment of Institutional Review Boards (IRBs) at all universities that accept funding from the Department of Health and Human Services (DHHS). The role of the IRB is to examine all proposals for research involving human subjects to determine whether the rights and welfare of the subjects are adequately protected. Before starting research, the investigator submits a protocol to the IRB. The protocol describes the proposed research and the arrangements that have been made to ensure that the project adheres to sound ethical and scientific principles.

The wise researcher uses the protocol as a guide for improving the research design and procedures. Chapter 2 briefly introduces the elements of a typical research protocol and directs attention to those parts of this book that will guide the researcher through each part of the protocol.

### 1.2 WHAT IS AN IRB?

An IRB, or Human Subjects Committee, is a committee mandated by the National Research Act, Public Law
93-348, to be established within each university or other organization that conducts biomedical or behavioral research involving human subjects and receives federal funding for research involving human subjects. The purpose of the IRB is to review all proposals for human research before the research is conducted to ascertain whether the research plan has adequately included the ethical dimensions of the project. The administration of IRBs by the DHHS is conducted by the Office for Protection from Research Risks (OPRR), except for drug-related research, which is administered by the Federal Drug Administration. OPRR is an office within the National Institutes of Health. That office answers any queries from local IRBs, provides information to assist IRBs in their functioning, receives and investigates complaints about research practices, investigates the functioning of local IRBs, as necessary, and recommends sanctions against institutions not in compliance with the law. Institutions not in compliance with the law may lose any federal funding of their programs, including funding of student programs (e.g., federal financial aid to students).

1.3 HOW FEDERAL REGULATIONS AND IRBs CAME ABOUT

Until the past two centuries, people in many cultures considered any kind of research on humans, or even on human cadavers, to be sinful, since they conceived of the spirit and soul as residing in the body. These religious views about research involving humans largely disappeared with the rise of biomedical research in the 1700s. Research on human subjects gradually gained wide acceptance. However, by the middle of the twentieth century the ethical fallibility of well-meaning scientists was recognized.

The world also came to recognize that atrocities could be committed in the name of science. After World War II, it was learned that Nazi scientists had used prisoners in brutal medical experiments, without the slightest regard for their lives, and had contributed nothing to science in the process. These crimes were investigated at the Nuremberg trials of Nazi war criminals. One consequence of these trials was the development of the Nuremberg Code of research involving humans, which emphasized that scientists must have the informed consent of any human participants in research. Katz (1972) presents a detailed discussion of the origins of political concern about use of human subjects in research.

In the United States, the next significant step in examining research ethics occurred during the 1970s, when the U.S. Congress created the National Commission for the Protection of Human Subjects in Biomedical and
Behavioral Research. From 1974 to 1977, the National Commission conducted hearings on ethical problems in human research. On the basis of these hearings and long deliberations, the Commission formulated certain principles and recommendations concerning human research.

The most troubling cases that came to the attention of the National Commission concerned the involvement of human subjects in biomedical research, where concern for human life was sometimes overshadowed by concern for enrolling subjects, completing the research, or using the most rigorous design. To accomplish their scientific objectives, biomedical scientists have at times concealed from subjects circumstances relevant to the subjects' well-being. The following case illustrates how scientific zeal can interfere with ethical sensibilities:

Case 1.2: The Tuskegee Syphilis Study. A study was begun in 1932 to determine the course of syphilis from inception to death. Poor black men were recruited and offered thorough annual examinations and health care in return for serving as subjects in this study. Much information had already been gathered by 1943, when penicillin was identified as a cure for syphilis. However, the subjects were not told of the discovery of an effective treatment for syphilis and the study was allowed to continue until 1972, when an oversight committee finally recognized what was being done and halted the study (Heller, 1972). The details of this case are told in the book Bad Blood (Jones, 1982).

The problems that the National Commission observed in the social and behavioral sciences were not of this magnitude, but they were similar in character. In social science research prior to 1973, informed consent was rarely sought and subjects were rarely debriefed or desensitized (restored to an emotional condition at least as good as that with which they had entered the study) after research was performed. In some instances, electric shock was used as a punishing stimulus.

Deception was a standard and unquestioned social research technique, and the assumption seemed to be that subjects neither suspected deception nor could be harmed by it. In retrospect, we see that the harm, while subtle, was manifold. By the 1960s many of the people who participated in research (typically college subjects) actually expected deception and produced different results than unsuspecting subjects; see Diener and Crandall (1978, pp. 80-85) for discussion. Naturally, nondeceptive studies also become suspect in the minds of research participants; hence, even the data from studies not employing deception were tainted by the attitudes of subjects expecting to be deceived. Ironically, research validity was being jeopardized by the very procedures thought to promote validity.
Another prevalent problem in the social sciences was invasion of privacy. Social scientists typically study persons who are relatively powerless to refuse (students, the elderly, minority populations), rather than persons who are in a position to limit scientists' access to them...precisely because it is inconvenient, difficult, and even impossible to study the powerful. Like deception, invasion of privacy is not only disrespectful of human subjects but also a cause of invalid data. Those who cannot refuse to participate have a secret weapon available for the protection of their privacy and autonomy...they can lie. Unfortunately, the real harm goes deeper than this apparent game of cat and mouse between investigator and subject. The reputation of social science itself becomes tainted. Consider the following commentary by journalist Nicholas von Hoffman (1970), which appeared in the Washington Post:

We are so preoccupied with defending our privacy against insurance investigators, dope sleuths, counter-espionage men, divorce detectives and credit checkers that we overlook the social scientists behind the hunting blinds who’re also peeping into what we thought were our most private and secret lives. But there they are, studying us, taking notes, getting to know us, as indifferent as everybody else to the feeling that to be a complete human involves having an aspect of ourselves that's unknown.

Von Hoffman's remarks were about sociologist Laud Humphreys, whose research on “tearoom trade” raises the most difficult of all questions for social scientists: What if there seems to be no way to do an important study without wronging someone?

Case 1.3: Tearoom Trade. The public, as well as law-enforcement authorities, tend to hold simplistic stereotypes about men who commit impersonal sexual acts in public rest rooms. As a consequence, “tearoom sex," as fellatio in public rest rooms is called, used to account for the majority of “homosexual” arrests in the United States. Laud Humphreys, then a doctoral candidate in sociology at Washington University, sought to learn what kinds of men seek quick, impersonal sexual gratification and what motivates them to do so.

Humphreys gathered some of his data by stationing himself in “tearooms" and assuming the role of "watchqueen," the individual who keeps watch and coughs when a police car stops nearby or a stranger approaches. He played that role faithfully while observing hundreds of acts of fellatio. He gained the confidence of some of the men he observed, disclosed to them his role as a scientist, and persuaded them to tell him about the rest of their lives and about their motives for engaging in tearoom trade; but those who were willing to talk openly with him tended to be among the better ed-
ucated members of the tearoom trade. To avoid socioeconomic class bias, Humphreys secretly followed some of the other men he observed and recorded the license numbers of their cars, which he then surreptitiously matched with Department of Motor Vehicle data to obtain names and addresses. Carefully disguised, Humphreys appeared at their homes a year later and claimed to be a health service interviewer. He interviewed them about their marital status, employment, and so on. Most of these interviews developed into quite personal discussions in which the men disclosed a great deal. Humphreys was aware that his data could be subpoenaed, an eventuality that probably would have led to the arrest of his subjects; he claims to have guarded the data with great care.

Humphreys' findings destroyed stereotypes: Fifty-four percent of his subjects were married and lived with their wives; superficial analysis would suggest that they were exemplary citizens who had satisfactory marriages. Most of these married men did not think of themselves either as bisexual or as homosexual. The marriages of these men were important to them, but were marked with tension. Most of these men or their wives were Catholic, and since the birth of their last child, conjugal relations had been rare, in most cases for reasons connected with family planning. Their alternative source of sexual gratification had to be quick, inexpensive, and impersonal. It could not entail involvement that would threaten their already unstable marriage, or jeopardize their most important asset, their standing as father of their children. They wanted some form of orgasm-producing action that was less lonely than masturbation and less involving than a love relationship. Only about 14% of Humphreys' subjects were members of the gay community and interested primarily in homosexual relations (Humphreys, 1970).

The gay community praised Humphreys' research for dispelling myths and stereotypes. Police departments in some cities responded to the knowledge he produced by ceasing to raid public rest rooms. Many social scientists have applauded Humphreys' research. The Society for the Study of Social Problems chose Humphreys' book for its prestigious annual C. Wright Mills Award. But for others, the study raised some very difficult questions: Is it ever justifiable to act contrary to the interests of subjects in order to obtain valuable knowledge? Does the importance of Humphreys' research justify spying on people and later visiting their homes and families and interviewing them under false pretexts?

Today, a study such as Humphreys' probably would be conducted differently. There are now legal mechanisms for protecting data from subpoena, as well as an emphasis on keeping data in anonymous form if feasible (see Chapter 6). While deception is not entirely ruled out, there is now a strong sentiment against
the kinds of deception Humphreys employed (see Chapter 7). For respectful, straightforward approaches to subjects (see Chapter 4). For sensitive use of interview skills to learn about personal matters (see Chapter 11). Using an honest approach, sophisticated interview skills, and assurance of confidentiality, social scientists typically are able to obtain even the most personal information from respondents. Current approaches to research on persons with HIV infection (e.g., Melton, Levine, Koocher, Rosenthal, & Thompson, 1988; see Case 11.1) and on the sexual practices of persons at high risk for AIDS (McKusick, Wiley, & Coates, 1986) attest to the recent advances in social research methodology. Today researchers work with their IRB to develop ethically acceptable procedures.

## 1.4 HOW IRBs WORK

IRBs consist of five or more members, sometimes including the IRB administrator. The members are required by law to have:

[V]arying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. (45 CFR 46.107, 1981)

The IRB meets periodically to review research protocols submitted by members of that institution and persons intending to do research at that institution. A research protocol of the kind that is submitted to an IRB is a description of the research and of the steps that will be taken to treat subjects respectfully and to reduce any risks involved. See Chapters 2 and 12 for a discussion of protocols. Ideally, the IRB administrator is available to researchers to answer questions and provide information about the IRB. The administrator receives protocols, sends them out for review, calls IRB meetings, and communicates the IRB's concerns or its approvals of protocols.

Human research, as it pertains to IRBs, refers to any study of persons that is a systematic investigation to develop generalizable knowledge. Administrative data gathering that has no scientific purpose is normally not reviewed by IRBs. Classroom demonstrations of research, done solely for pedagogical purposes, are not
reviewed by IRBs. There is also a category of exempt research for which the federal government does not insist on IRB review; see Title 45 CFR Part 46.101 for exemptions. Most university IRBs, however, either do not exempt any scientific research from review, or else require that the investigator send a description of the research plan to the IRB to ascertain whether it is, indeed, exempt.

*Investigators wishing to do human research should acquaint themselves with the requirements of their IRB at the time they begin planning their research.* The IRB administrator can provide investigators with a statement of the requirements of that particular IRB, and of the federal government, concerning human research. While federal regulations outline the general procedures of IRBs, each IRB is responsible for developing its own specific policy statement.

A research protocol may be reviewed by either the full membership or an appropriate subgroup. A protocol must be submitted sufficiently far in advance of scheduled IRB meetings so that members can review it; the IRB administrator can provide information about the review schedule. Those who must begin their research by a particular time should submit their protocols well in advance.

When submitting research proposals under a deadline to a funding agency, it is usually possible to submit a preliminary protocol to the IRB and obtain a letter to the funding agency, stating that the research idea has been approved by the IRB and that a final protocol will be reviewed after the investigator has completed pilot testing and has worked out procedural details. The agency will not release funding until notified by the IRB that the final protocol has been approved.

In the review process, one or more of the reviewers may phone the investigator to clarify questions concerning the protocol. At that time, any problems reviewers have with the protocol can often be resolved. In any event, the investigator will receive a formal letter from the IRB (a) approving the protocol; (b) requesting changes or inquiring about problems; (c) approving the protocol, contingent on the investigator’s making specified changes or solving certain problems to the satisfaction of the IRB; or (d) not approving the protocol. Protocols are rarely disapproved outright.

## 1.5 IS PILOT TESTING REVIEWED BY THE IRB?

*Pilot testing* refers to informal investigation with one or a few individuals to “fine tune” research procedures until they are satisfactory. For example, when a survey instrument is developed, it typically is tested on a few
people and modified various times before it is satisfactory. These people typically are acquaintances of the investigator (e.g., students or colleagues) who have agreed to help with the study. Adequately performed pilot testing also provides an ideal opportunity to discover whether the interests and needs of subjects are adequately met.

Neither fine tuning a questionnaire nor testing equipment or a procedure with the help of a few acquaintances requires IRB review. However, most pilot studies...that is, exploratory studies to determine whether further research might be worthwhile...do require IRB review, as does the pilot testing of a risky procedure. A reviewer in doubt about whether review is required for a pilot activity should check with his or her IRB.

1.6 WHY IRBs HAVE BEEN CONTROVERSIAL

The knowledge required to design research that is both scientifically valid and respectful of human subjects is still not adequately taught in many methodology courses today. Some scientists do not know how to do research that is in compliance with federal regulations. Others find it difficult to describe their research in terms that IRBs readily understand. Not surprisingly, some of these scientists find themselves in an adversarial relationship with their IRB and accuse the federal government of abridging the freedom of science.

IRBs are not perfect, either. An IRB that is unprepared to assist scientists in developing the most acceptable research procedures can only say what is unacceptable...hardly a popular enterprise! When that occurs, the scientist must become an effective ethical problem solver, and be able to communicate about that process with the IRB.

Finally, by establishing a decentralized review system, the federal government has not only given each IRB much autonomy in the interpretation of the regulations but also permits each to add requirements of its own. Thus different IRBs might decide the same case quite differently.

1.7 WHAT IF YOU THINK YOUR IRB MAY DISAPPROVE YOUR PROTOCOL?

Researchers who are aware that their intended research is ethically sensitive must educate themselves about
the problems likely to be encountered. They should consult with several sources of information:

1. Scientists who have recently conducted related research.
2. Experts in the pertinent field. For example, if one wants to study the effects of caffeine on various kinds of learning, but realizes that some people have extreme physical reactions to caffeine, the appropriate person to consult may be the campus physician. Similarly, if one wishes to study abused children and is concerned about how they will respond to the intended questionnaire, an appropriate consultant would be a clinical psychologist who treats abused children.
3. Key members of one's own IRB.
4. IRB, A Review of Human Subjects Research, an excellent bimonthly journal that covers issues of concern to IRBs and scientists and is available in most university libraries or IRB offices.

In any event, the investigator who undertakes sensitive research must investigate possible risks and learn how to decrease or avoid them. The investigator then describes, in the protocol, the details of the consultation that has occurred, what has been learned about the nature of the possible risks, and what procedures have been selected to minimize those risks. Relevant literature should be discussed and cited.

The IRB may need to be educated. If so, the researcher should provide that needed education and not be adversarial. IRBs have heavy workloads and tire of arrogant colleagues. Besides, they have the last word.

NOTES

1. For the sake of brevity, the term social research will be used from here on in place of social and behavioral research.
2. Many have argued that the term research participant is more respectful than the term subject. For some purposes I would agree. For the purposes of this book, however, I would prefer to use a term that continually reminds the reader that the person being studied typically has less power than the researcher and must be accorded the protections that render this inequality morally acceptable.
3. The illustrative cases presented in this book include: (a) cases based on published work; (b) cases based on personal communication; and (c) actual cases known to the author, in which anonymity and deliberate alteration of details are appropriate.

4. The federal regulations governing the protection of human subjects are set forth in Title 45 Code of Federal Regulations (CFR) Part 46. A copy of the federal regulations of human research can be obtained through any university's research office or reference librarian, or from the Office for Protection From Research Risk, National Institutes of Health, Building 31, 9000 Rockville Pike, Bethesda, MD 20892; phone (301) 496-8101.

5. Privacy refers to the ability of persons to control intrusions into their personal life; confidentiality is an extension of the concept of privacy and refers to agreements governing what may be done with information about oneself. The implications of privacy and confidentiality for research planning are discussed extensively in Chapters 5 and 6.

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