CONTENTS CHAPTER 7 ETHICS OF RESEARCH

7 ETHICS OF RESEARCH

> *Experimentation was originally sanctioned by natural science. There it is performed on inanimate objects, and raises no moral problems. But as soon as animate, feeling beings become the subjects of experiment, . . . this innocence of the search for knowledge is lost and questions of conscience arise. Hans Jonas*

Syphilis had become a public health problem in the United States during the first decades of the 20th century. People who contracted this highly contagious and much dreaded disease faced dismal life prospects. The lucky ones experienced symptoms only temporarily, shortly after contracting the disease. The unlucky ones could look forward to prolonged illness, blindness, arthritis, dementia, and premature death. After the spirochete that causes the disease was discovered in 1905, fear of the syphilis germ grew along with general support for treatment programs that prevented its worst symptoms and rendered it noninfectious. It was with great hope of bringing syphilis under control that the physician-scientists of the United States Public Health Service began six pilot treatment programs in the South in the 1930s (Dilanni, 1993).

Macon County, Alabama, was selected as a treatment site for this program. Most of its poverty-stricken residents were black sharecroppers, among the poorest of the poor, who welcomed the medical treatment that the government offered them. Unfortunately, the funds available for the treatment program soon ran out; those involved in the planning had underestimated the expense of the lengthy course of injections that was then the only therapy available for treating the disease. The program came to an abrupt halt, despite the fact that many people had received less than the full series of injections needed for a cure and some had not been treated at all.

It was at this point that the scientists of the Public Health Service made a decision that would be momentous for the people of Macon County and for the future of research ethics. Although there were no funds to continue treating the patients, they thought that something of value still might be garnered from the project. So in the fall of 1932, they began a six-month research project designed to study "the

effects of untreated syphilis in the Negro male." They reasoned that the men would not be treated in the six-month period anyway, so they wouldn't be harmed by the research and the results of this project might discredit the popular and dangerous myth that syphilis is not a fatal disease in African Americans.

The researchers enlisted the aid of the Tuskegee Institute, a local college, founded by Booker T. Washington in 1881 to educate freed slaves and their descendants, that had the staff and facilities needed to do the required medical testing and the respect of Macon County's residents. The officials at Tuskegee agreed to do the testing in the hope of improving the future treatment prospects of the region's residents.

Four hundred men in the late stages of the disease were recruited for the study. The men were told only that they had "bad blood," a euphemism that they might have understood to mean anything from anemia to syphilis, and offered "special free treatment" for it. In fact, they received no treatment, only X-rays, blood tests, physical exams, and extremely painful and dangerous spinal taps, which were used only to study the effects of the disease.

In this first phase of the research, the investigators were able to demonstrate that syphilis had the same physical consequences for the residents of Macon County as it had for other groups. Encouraged by these results, they decided to continue the research beyond the initial six-month period. The study had changed from a short-term to a long-term study of the progression of untreated syphilis. At this point, two hundred more men were recruited to serve as controls.

A COMPARATIVE STUDY OF TREATED AND UNTREATED CASES

R. A. VONDERLEHR, M.D.

TALIAFERRO CLARK, M.D.

O. C. WENGER, M.D.

AND

J. R. HELLER JR., M.D.

Assistant Surgeon General, Medical Director (Retired), Surgeon, and Assistant Surgeon, Respectively, United States Public Health Service

WASHINGTON, D. C.

A determination of the effectiveness of treatment in preventing the transmission of syphilis is one of the basic problems in the control of this disease. Second in importance to it is the effect which treatment has in preventing late and crippling manifestations. The administration of adequate treatment in early syphilis is recognized as the most important factor in the prevention both of communicable relapse and of the early complications so detrimental to the health of the individual patient. As the result of surveys of a few years ago in southern rural areas it was learned that a considerable portion of the infected Negro population remained untreated during the entire course of syphilis. Such individuals seemed to offer an unusual opportunity to study the untreated syphilitic patient from the beginning of the disease to the death of the infected person. An opportunity was also offered to compare this process, uninfluenced by modern treatment, with the results attained when treatment has been applied.

First published report of the Tuskegee syphilis study: *Journal of the American Medical Association* (1936).

For the next 40 years, the research participants suffered through annual tests masquerading as treatment, including the painful spinal taps. To keep up the appearance of treatment, three kinds of pills, all placebos, were given to the men. In exchange for their continued participation and for permitting autopsies to be performed on them when they died, each man was paid $35 to $50 "life insurance," just enough to give him a decent burial.

The researchers never told the men that they had syphilis, and none received treatment. In fact, the investigators enlisted the aid of other

government agencies to prevent them from being diagnosed and treated elsewhere. Early on it became clear that the disease was devastating the subjects. By 1936, 75% of the test group suffered from complications of the disease; 50% were experiencing cardiovascular problems; and a third had neurological damage. By 1972, 128 of the participants had died of syphilis or syphilis-related complications, 40 of their wives had contracted the disease, and 19 children had been infected at birth (Associated Press, 1997).

Despite its horrific nature, the study was never a secret. Its results were published periodically in leading journals and even reported to Congress. The research continued long after the discovery of penicillin, the wonder drug that cures syphilis even in its late stages. It even went on through large government efforts to eradicate the disease. Finally, in 1972, 40 years after it began, Pete Buxton, an epidemiologist who worked for the Centers for Disease Control, passed information about the study on to the press. When the public learned about the research, a government investigation began and the study was halted. In the end, the survivors of this experiment were paid less than $38,000 each in compensation in an out-of-court settlement. On May 16, 1997, President Clinton apologized to the 8 elderly survivors of this shameful government-sponsored research.

In the 1930s, when the Tuskegee syphilis study began, there were no laws or formal codes of conduct to protect research subjects. At that time, physician researchers, who are bound by the Hippocratic oath to bring no harm to their patients, were trusted to take care of the people who participated in their research. Studies like Tuskegee demonstrated that in some cases that trust was misplaced.

When the abuses of human subjects in this and other medical studies became the focus of public attention in the 1970s, the result was widespread debate about the proper treatment of participants in research and legislative action to prevent future abuses. As a consequence, scientists who conduct research on people today have federal regulations to guide their work. These regulations now have the authority of law, and mechanisms are in place to ensure compliance.

In this chapter, we discuss the current ethical guidelines for human and animal research of the American Psychological Association (APA). Our presentation here focuses on ethical guidelines related to the design and conduct of research. Ethical issues involved in the analysis and communication of research results will be taken up in Chapter 13, Communicating Research. As we shall see, developments in medicine have played a critical role in shaping the ethical standards of research psychologists. But because the risks to research subjects differ in medicine and psychology, there also are important differences in their ethical requirements.

The men in the Tuskegee syphilis study had been subjected to incalculable abuse. They had been tricked into participating in research disguised as treatment, denied information about its nature and risks, lied to about the benefits they would receive from it, subjected to excruciating pain and the continuing ravages of a deadly and infectious disease—all in the name of science. Ironically, while this was going on, the United States government had been involved in developing the Nuremberg Code, the first internationally accepted code of ethics for medical research. The Nuremberg Code specifically prohibited each of the violations of human subjects committed by the scientists involved in the Tuskegee syphilis study.

7.1 The Nuremberg Code

In 1945 a military tribunal of American judges met at Nuremberg, Germany, to decide the fate of 23 Nazi doctors on trial for their involvement in atrocious medical experiments on concentration camp inmates during World War II. The tribunal learned of experiments in which people were exposed to extremely high altitudes to study their endurance; experiments in which parts of people's bodies were deliberately frozen; experiments in which healthy people were infected with malaria, epidemic jaundice, and spotted fever to test treatments and vaccines, or merely to keep a virus alive for future experimentation; and experiments in which people were poisoned so that researchers could study the effects at autopsy (Katz, 1972). In these experiments, the torture and death of the research participants were part of the research plan.

The 23 defendants were found guilty of war crimes and crimes against humanity. Despite their arguments to the contrary, the court judged the defendants to have violated certain fundamental principles that they believed define what is legal, moral, and ethical conduct of medical researchers toward human participants in research. The judges argued that only "certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally." These "bounds" were spelled out in 10 principles for medical research, now known as the Nuremberg Code.

The Nuremberg Code, which is presented in its entirety in Box 1, provided the first widely accepted ethical guidelines for medical experimentation on humans. The code has since served as the prototype for many other ethical codes for research, including those of the U.S. federal government and the APA.

BOX 1 THE NUREMBERG CODE

The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical, and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or

person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4.The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him that a continuation of the

experiment is likely to result in injury, disability, or death to the experimental subject.

7.1.1 Informed Consent

The concentration camp inmates had no choice about whether to participate in the medical experiments. They were at the mercy of their captors. It was to prevent such coercion in future research that the judges at Nuremberg formulated their first principle, *the principle of informed consent*. It reads: The voluntary consent of the human subject is absolutely essential.

This principle requires that before the decision to participate in research is made, potential subjects must be fully informed about the "nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected"; and any effects upon health or person that could result from their involvement. Subjects must be free to withdraw from the study at any time.

In conducting their research at Tuskegee, the Public Health Service doctors clearly violated this fundamental principle. The participants in that research thought that they were being treated for "bad blood." They did not know that they were in a research study at all, nor were they told of the risks associated with their participation. For their part, the investigators of the Tuskegee study claimed that their research was not comparable to the experiments conducted by the Nazis and therefore that the Nuremberg Code was not relevant to it.

Most medical researchers since the Nuremberg trials have agreed on the validity of informed consent as a guiding principle for research (Katz, 1972). When controversy has arisen in medicine, it usually has been over questions of how the principle should be interpreted and applied, not over the principle itself. One problem is that the procedures used to solicit participation may affect the sense of freedom experienced by potential subjects. Variations in who discusses the research with them, who asks for their participation, in what ways, and under what circumstances can all be important. Another problem in applying the principle is that many life circumstances can threaten people's perceived freedom of choice. Subjects recruited in business may see little choice in whether to be a

part of research, since they may believe that their job security depends upon participating. Dying patients may be willing to undergo extreme risks; they may see the research as providing their only hope for recovery. Prisoners may believe that their cooperation in risky experimental procedures will affect the length or conditions of their imprisonment. Clients of human service agencies may believe that the services they receive depend upon their involvement in the research. Prisoners or other inmates may be unduly swayed by monetary inducements, since even small sums of money can materially change institutional life for them.

A separate question is how best to protect subjects who are incapable of clearly understanding the nature of an experiment or of making decisions for themselves; that is, how should informed consent be obtained in the case of children, mental patients, severely retarded people, and psychotherapy patients whose intense involvement with their therapists might jeopardize a reasoned consideration of whether they should take part in research conducted by them? More generally, how can we ensure that failures of communication and of understanding are avoided?

Finally, there are differences of opinion about how the principle of informed consent should be applied outside the context of medical experimentation. How should it be applied in psychology, where physical risks are rare? Many psychological studies could not be conducted if the principle of informed consent was strictly followed; complete informed consent would require the experimenter to reveal in full the intent of the research, perhaps even its hypotheses. The effects of such full disclosure would prevent unambiguous interpretation of the results and seriously compromise the value of research. The question of how to apply the principle of informed consent in behavioral research was not resolved at Nuremberg.

7.1.2 Risk/Benefit Analysis

A second basic ethical requirement of the Nuremberg Code is that, before conducting research, there should be a careful assessment of whether the *risks* of the research are justified by its *potential fruitfulness* for society. All unnecessary risks should be scrupulously avoided and precautions should be taken to protect participants from even the remote possibility of injury or disability. Research should be

undertaken only when the risks of physical and mental damage and suffering "do not exceed that determined by the humanitarian importance of the problem to be solved by the experiment."

To decide for or against research using this principle, the importance of the research must be assessed. Gauging this can be difficult because there are no agreed-upon standards for what qualifies as important research. Differences of opinion are common. Some scientists look at immediate or potential applications in assessing the value of research. Others regard a contribution to knowledge as sufficient justification for research, even when no potential applications of its findings seem likely.

Assessing the nature and extent of the risks in research also can be difficult. Katz (1972) distinguished *three types of risk* that can arise in research with human participants: *interference with bodily integrity, interference with psychological integrity,* and *interference with self-determination and privacy.* In the Nazi experiments and in the Tuskegee study, interference with bodily integrity was certain. Pain and death were expected. Neither the psychological distress nor the right of participants to determine their own destinies entered into the deliberations of the researchers.

Although risks of physical injury are a major concern in medical research, other sorts of risk are more likely in psychology. Psychological research involves physical dangers only occasionally, for example, in drug or stress research, or in sleep or food deprivation experiments. Threats of death or physical disability are rare in psychological research. Threats to psychological well-being and privacy are more common. To illustrate the controversy that can arise over the extent and nature of research risks in psychology let's look at an experiment conducted by Stanley Milgram (1963). Milgram, who was concerned with the claim of the Nazi researchers that they had only been following orders, decided to test whether people in this country would blindly obey an authority. Milgram asked his subjects, who had been recruited through an advertisement, to shock another "subject" (actually an accomplice of the experimenter who received no shocks) whenever the subject made a mistake on a learning task. Facing the participants was a shock generator with 30 switches, each apparently increasing the shock by 15 volts and delivering shocks

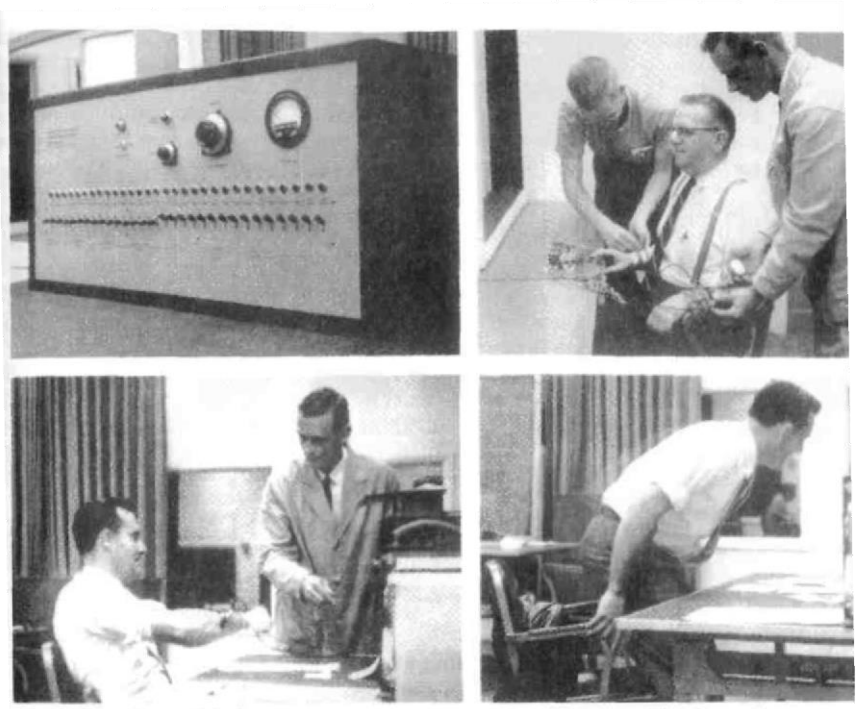
ranging in intensity from 15 to 450 volts. Each time the "learner" made an error, the "teacher," the actual subject, was told to increase the shock level one notch. Milgram gave the teachers a real 45-volt shock so that they could experience how painful it was.

Milgram was surprised to find that 87% of the participants continued to shock the learner after he kicked loudly on the wall of the room where he was strapped into the electric chair and stopped answering any of the teacher's questions. Two-thirds delivered 450 volts, the highest level of shock. Although subjects continued to obey the experimenter, they did so with great tension. One "mature and initially poised businessman" was "reduced to a twitching, stuttering wreck, who was rapidly approaching a point of nervous collapse" (Milgram, 1963, p. 377).

The public disclosure of Milgram's experiment led to debate over the ethics of exposing people to deceptive and stressful procedures in research. Milgram's critics claimed that the psychological distress experienced by his subjects, both during and after their participation, could not be justified by the importance of the problem and that his subjects also had to live, after the experiment, with the painful knowledge of what they had been willing to do in the name of science. They also argued that by conducting this experiment Mil-gram had exploited his subjects' trust (Baumrind, 1964).

Milgram (1964) countered these claims with reports from participants collected in postexperimental interviews. Many said that they were glad to have been involved and that they knew themselves better because of it. In response, Milgram's critics argued that experimenters should not be in the business of providing such disturbing insights to participants and that the statements of Milgram's subjects most likely reflected only their need to believe that something of value came from this painful experience.

In addition to threats to psychological well-being, psychologists also must be sensitive to potential threats to the anonymity and reputation of research participants. Special care must be taken to avoid such risks when observing



The photo at the top left shows the shock generator used by the "teacher" in Milgram's experime the top right photo, electrodes are attached to the "learner;" the pictures at the bottom show a "te getting a sample electric shock (left) and refusing to continue (right).

people's behavior in private places or in institutional settings; in deciding whether to give researchers access to confidential records of inmates or clients; and in reaching conclusions about whether or not to collect data about people from third parties who might learn confidential information (e.g., about their mental or legal status) during the questioning (Kelman, 1977).

7.2 The Need For Legislative Change

Although the guidelines set forth at Nuremberg were widely accepted, in the decades following World War II several more medical experiments that violated the Nuremberg Code's most fundamental principles came to light. These experiments were conducted in the United States, the country responsible for the Nuremberg Code, by well-respected scientists, with financial support from the federal government. The moral outrage that resulted from the public disclosure of these studies led to legislative action that has shaped current research practice in medicine and psychology.

In 1966, Henry Beecher, an American physician, reported on 22 experiments that he believed violated both the principle of informed consent and the Nuremberg Code's injunction against risking the health and well-being of research participants. In one study, retarded children were injected with the hepatitis virus so that a controlled test of the effectiveness of a vaccine could be conducted. In another, elderly hospital patients were injected with live cancer cells to study their immune reactions. They were told that they would be receiving "some cells" but no mention was made of cancer. Beecher claimed that the 22 studies in his report were a small fraction from a list he had compiled reviewing one prestigious medical journal in a single year.

Several ethically controversial research studies in the behavioral sciences, in addition to Milgram's, also came to light in the decades following World War II. The violation of the right to privacy was at issue in the Wichita jury study of 1954. This study was conducted by law professors who were interested in studying federal jury deliberations by secretly recording them. Although the prior consent of the judge and the opposing lawyers was sought, the consent of the jurors was not (Diener & Crandall, 1978).

In 1970, four years after Beecher's report, Laud Humphreys published observations he collected secretly while he acted as "watchqueen" in a public rest room where homosexual encounters regularly took place. Humphreys copied down the men's license plate numbers, found out where they lived, and a year later collected more information from them by carrying out a phony health survey.

The ethics of a simulated prison experiment conducted by Philip Zimbardo and his students (Haney, Banks, & Zimbardo, 1973) also aroused concern. The experiment, which was to have gone on for two weeks, had to be called off after only a few days because Zimbardo found the students who were role-playing guards becoming frighteningly sadistic toward the students who had been assigned, purely by chance, to the role of prisoners.

Prompted by such revelations, in 1973 Congress established the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. The mandate of the commission,

the majority of whose members were from outside the health professions, was to "provide a public review of the ethical and legal problems of human subjects research" (Veatch, 1989, p. 15). Two documents resulted from their work: *the Belmont Report,* a statement on the basic values that they believed ought to underlie research on human subjects, and *new federal regulations* to provide the means for ensuring that these values are upheld in research. We will consider each of these in turn.

7.3 BELMONT REPORT

The Belmont Report, which is reprinted in Appendix A, was the result of nearly four years of monthly meetings by members of the National Commission as well as four days of deliberations that took place at the Smithsonian Institution's Belmont Conference Center in 1976. Over these years, the commissioners worked to identify the basic values behind "the many particular ethical prescriptions and evaluations of human actions" (National Commission, 1979, p. 3—4) in previous codes of ethical conduct for research. Among the documents they studied were the Nuremberg Code, the federal regulations then in effect for research on human subjects, and the APA's 1972 code of conduct for research. When their analyses were complete, the commissioners articulated *three fundamental values,* which they believed are essential for researchers to uphold in studies with human participants. They are: (1) *respect,* (2) *beneficence,* and (3) *justice.*

7.3.1 Respect

The first principle of the Belmont Report requires investigators to respect the autonomy of human participants in research. This value preserves the right of subjects to make their own decisions about the activities in which they will be involved, and if they are incapable of such autonomous decision making, to be protected from harm. This principle requires researchers to give potential subjects sufficient information about the study initially to allow them to make an informed and free choice about whether to participate, and once the study begins to decide whether to continue. Those with diminished capacities of self-determination, who cannot capably make decisions for themselves, must be protected from harm.

Respect is the value underlying the Nuremberg Code's principle of informed consent and, in the case of persons judged incapable of self-determination, its requirement to protect research participants from unnecessary physical and mental suffering and from "even the remote possibility of injury, disability, or death."

7.3.2 Beneficence

The second principle of the Belmont Report, the principle of beneficence, is the requirement that researchers treat participants in such a way as to secure their well-being. Beneficence requires researchers, first, to follow the injunction of the Nuremberg Code and the Hippocratic oath to "do no harm" and, second, to "maximize possible benefits and minimize possible harms" to participants in research (National Commission, 1979, p. 4).

The principle of beneficence goes beyond the Nuremberg Code's requirement that researchers weigh the humanitarian importance of research against its risks to assert that research should aim at benefiting the participants themselves, not just humanity. Based on this principle, placebo control groups now are controversial in medical research. Although many researchers continue to assign control subjects to an inactive placebo group or to a waiting list in treatment studies, some medical researchers believe that such control subjects instead should receive the best alternative to the treatment being tested; should the new treatment prove more effective than the alternative, they believe, it should be made available to all participants in the study (Rothman & Michels, 1994).

7.3.3 Justice

The third principle of the Belmont Report is the requirement that researchers treat subjects justly by distributing the benefits and harms associated with research equitably. "An injustice occurs," according to the commissioners, "when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly" (National Commission, 1979, p. 5). When people are subjected to the risks of research but reap none of its benefits, as they were in the Nazi experiments and in the Tuskegee syphilis study, and as poor ward patients were in countless medical experiments in the 19th and early 20th centuries, they are being treated unjustly.

The powerful rarely serve in psychological experiments. Members of minority groups, the poor, those with special health care needs, and others perceived as vulnerable do. Injustice occurs whenever such subjects are "systematically selected simply because of their easy availability, their compromised position, or their manipulability rather than for reasons directly related to the problem being studied" (National Commission, 1979, p. 5).

The *principle of justice* adds to the Nuremberg Code the requirement of fairness in the distribution of benefits and burdens of research through the avoidance of biased selection and unfair treatment of participants.

7.4 Code of Federal Regulations For The Protection Of Human Subjects

The federal regulations formulated by the National Commission in conjunction with the National Research Act were designed to implement the principles of the Belmont Report through specific behavioral guidelines and procedures for research. The intent of the regulations was to remove the ambiguities of previous codes by mandating specific procedures for researchers and to shift some of the burden of ethical decision making from the individual researcher, who has a personal stake in it, to committees representing the views of the broader community. The new regulations also provided a mechanism for preventing and correcting questionable ethical practices in research.

The regulations require that *Institutional Review Boards (IRBs)*, committees that review proposed research to ensure that it complies with federal regulations, be established. Such IRBs must include at least one member not affiliated with the institution to represent community views. Box 2 gives the criteria that IRBs are to use in evaluating research.

The first task of the IRB is to ensure that risks to human subjects are minimized and reasonable in relation to the benefits they derive from their participation. If the research involves more than minimal risk, IRBs also ensure that the regulations for acquiring informed consent are followed and documented appropriately, and that procedures for

recruiting participants are equitable. Procedures for applying for IRB approval of research, including the documentation of informed consent, are discussed more fully in Chapter 12, Planning the Study.

Although the federal regulations incorporate the principles of the Nuremberg Code, they differ from that code in allowing research on human subjects to be done without informed consent when three conditions are met: (1) the research involves no more than *minimal risk* to subjects; (2) subjects' rights or welfare will not be interfered with; and (3) the research could not be carried out without such a waiver.

BOX 2 EXCERPTS FROM HEALTH AND HUMAN SERVICES POLICY FOR PROTECTION OF HUMAN RESEARCH SUBJECTS, CODE OF FEDERAL REGULATIONS, REVISED AS OF OCTOBER 1, 1994

Criteria for IRB approval of research

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which 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. . . . The IRB should not consider possible long-range effects of applying knowledge gained in the research ... 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 take into account 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 [the law].
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by [the law].
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.

(b) 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.

A study involves *minimal risk* when "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (Office for Protection from Research Risks, 1994, p. 119)

This relaxing of the informed consent requirement enables psychologists to do certain kinds of low-risk research that would not be possible if informed consent procedures were mandatory. One common type of research in social psychology, for example, involves the naturalistic observation of people's behavior in public places. The APA notes that in such research "the experience of the participants is not affected by the research, and there are no direct positive or negative effects on them" (APA, 1982, p. 37). Because the behavior being observed is public, and the subjects are anonymous and their involvement minimal, no threats to their privacy or self-determination are involved either.

7.5 AMERICAN PSYCHOLOGICAL ASSOCIATION (APA) CODE OF CONDUCT FOR RESEARACH

The APA's code of ethics for research, first published in 1973, has since been revised, most recently in 1992. As you can see from studying Box 3, where the current version is reprinted, the code owes much to the Nuremberg Code and the Belmont Report. In addition, it requires psychologists to comply with federal and state regulations governing behavioral research. What is unique about this code is that it was based not only on past codes and government guidelines but also on input from APA members about specific research practices that were of ethical concern to them and extensive discussion by psychologists.

BOX 3 AMERICAN PSYCHOLOGICAL ASSOCIATION CODE OF CONDUCT FOR RESEARCH (STANDARDS FOR PLANNING AND CONDUCTING RESEARCH ON HUMAN SUBJECTS), 1992

6.06 Planning Research

(a) Psychologists design, conduct, and report research in accordance with recognized standards of scientific competence and ethical research.

(b) Psychologists plan their research so as to minimize the possibility that results will be misleading.

(c) In planning research, psychologists consider its ethical acceptability under the Ethics Code. If an ethical issue is unclear, psychologists seek to resolve the issue through consultation with institutional review boards, animal care and use committees, peer consultations, or other proper mechanisms.

(d) Psychologists take reasonable steps to implement appropriate protections for the rights and welfare of human participants, other persons affected by the research, and the welfare of animal subjects.

6.07 Responsibility

(a) Psychologists conduct research competently and with due concern for the dignity and welfare of the participants.

(b) Psychologists are responsible for the ethical conduct of research conducted by them or by others under their supervision or control.

(c) Researchers and assistants are permitted to perform only those tasks for which they are appropriately trained and prepared.

(d) As part of the process of development and implementation of research projects, psychologists consult those with expertise concerning any special population under investigation or most likely to be affected.

6.08 Compliance with Law and Standards

Psychologists plan and conduct research in a manner consistent with federal and state law and regulations, as well as professional standards governing the conduct of research, and particularly those standards governing research with human participants and animal subjects.

6.09 Institutional Approval

Psychologists obtain from host institutions or organizations appropriate approval prior to conducting research, and they provide accurate information about their research proposals. They conduct the research in accordance with the approved research protocol.

6.10 Research Responsibilities

Prior to conducting research (except research involving only anonymous surveys, naturalistic observations, or similar research), psychologists enter into an agreement with participants that clarifies the nature of the research and the responsibilities of each party.

6.11 Informed Consent to Research

(a) Psychologists use language that is reasonably understandable to research participants in obtaining their appropriate informed consent (except as provided in Standard 6.12, Dispensing With Informed Consent). Such informed consent is appropriately documented.

(b) Using language that is reasonably understandable to participants, psychologists inform participants of the nature of the research; they inform participants that they are free to participate or to decline to participate or to withdraw from the research; they explain the foreseeable consequences of declining or withdrawing; they inform

participants of significant factors that may be expected to influence their willingness to participate (such as risks, discomfort, adverse effects, or limitations on confidentiality, except as provided in Standard 6.15, Deception in Research); and they explain other aspects about which the prospective participants inquire.

(c) When psychologists conduct research with individuals such as students or subordinates, psychologists take special care to protect the prospective participants from adverse consequences of declining or withdrawing from participation.

(d) When research participation is a course requirement or opportunity for extra credit, the prospective participant is given the choice of equitable alternative activities.

(e) For persons who are legally incapable of giving informed consent, psychologists nevertheless (1) provide an appropriate explanation, (2) obtain the participant's assent, and (3) obtain appropriate permission from a legally authorized person, if such substitute consent is permitted by law.

6.12 Dispensing with Informed Consent

Before determining that planned research (such as research involving only anonymous questionnaires, naturalistic observations, or certain kinds of archival research) does not require the informed consent of research participants, psychologists consider applicable regulations and institutional re, view board requirements, and they consult with colleagues as appropriate.

6.13 Informed Consent in Research Filming or Recording

Psychologists obtain informed consent from research participants prior to filming or recording them in any form, unless the research involves simply naturalistic observations in public places and it is not anticipated that the recording will be used in a manner that could cause personal identification or harm.

6.14 Offering Inducements for Research Participants

(a) In offering professional services as an inducement to obtain research participants, psychologists make clear the nature of the services, as well as the risks, obligations, and limitations. . . .

(b) Psychologists do not offer excessive or inappropriate financial or other inducements to obtain research participants, particularly when it might tend to coerce participation.

6.15 Deception in Research

(a) Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's prospective scientific, educational, or applied value and that equally effective alternative procedures that do not use deception are not feasible.

(b) Psychologists never deceive research participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences.

(c) Any other deception that is an integral feature of the design and conduct of an experiment must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research. (See also Standard 6.18, Providing Participants With Information About the Study.)

6.26 *Sharing and Utilizing Data*

Psychologists inform research participants of their anticipated sharing or further use of personally identifiable research data and of the possibility of unanticipated future uses.

6.17 Minimizing Invasiveness

In conducting research, psychologists interfere with the participants or milieu from which data are collected only in a manner that is warranted by an appropriate research design and that is consistent with psychologists' roles as scientific investigators.

6.18 Providing Participants With Information About the Study

(a) Psychologists provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and psychologists attempt to correct any misconceptions that participants may have.

(b) If scientific or humane values justify delaying or withholding this information, psychologists take reasonable measures to reduce the risk of harm.

6.19 Honoring Commitments

Psychologists take reasonable measures to honor all commitments they have made to research participants.

The APA's ethical standards for research agree with the Nuremberg Code in stating that it is the obligation of the researcher to obtain subjects' informed and voluntary consent to participate in research when there are risks to their physical or psychological integrity. Participants must be informed of "all features of the research that reasonably might influence their willingness to participate" and any other aspects of the research about which they inquire. The decision to participate must be made without coercion, informed consent must be fully documented, and subjects must be informed that they are free to terminate their involvement in the research at any time.

For those legally incapable of giving informed consent, whether because of age or disability, psychologists are required to explain the study as fully as possible, obtain potential subjects' agreement to participate, and seek the informed consent of their legal representatives (see the discussion of consent forms in Chapter 12, Planning the Study).

Research participants also must be informed about any anticipated sharing or further use of data gathered from them in which they might be-identified, as well as any possibility of unanticipated future uses of data collected from them (e.g., by depositing it in an archive). The APA guidelines are based on the idea that people have a right to privacy which must be protected by psychologists who conduct research. Participants must decide for themselves whether personally identifiable data can be shared with others.

As we have said, the federal regulations allow researchers to waive the requirement of informed consent under certain circumstances. The APA guidelines permit some research to be conducted without informed consent and even allow researchers to misinform subjects when methodological considerations require it and when the risks to participants are negligible. *Deception* is not discussed in the federal guidelines, although it is not ruled out.

Deception was common in behavioral research some decades ago; but current APA standards require that deception be used only as a last resort, and only when the problem is important and no alternative

procedures (e.g., simulation or role-playing techniques) are available. They also specify that "psychologists never deceive research participants about significant aspects" of the research "that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences."

The opinions of responsible professionals vary on the question of whether and to what extent deception should be permissible in psychological research. Some researchers believe that deception is harmful and never ethically justified, since it violates the principle of informed consent and destroys the nature of the researcher-participant relationship by violating the participant's trust. Other psychologists believe that deception in experiments, which usually is very mild, is harmless, since its effects are transitory, and in specific cases, they argue, the importance of the research justifies the minimal loss of human dignity that might be entailed. Keith-Spiegal and Koocher (1985) summarize the kinds of suggestions that researchers have developed to help make deception more acceptable to subjects. One of these is giving participants the option of removing their data from the study if they wish to do so.

Although the APA guidelines allow deception under certain circumstances, they also state that gaps in participants' understanding of the study should be removed when data collection is complete. Explanations then should be given for why there was no informed consent and/or why the deception was used (see Chapter 12, Planning the Study). Although such *debriefing* is intended to restore the nature of the researcher-participant relationship to its preresearch status, it is difficult for researchers to know whether this has been successful. Participants who have been lied to during the experiment may not believe researchers when they tell the truth at the end of an experiment, and in the future such subjects may suspect deception in research even when none is" present.

7.6 Ethics In Animal Research

So far, we have discussed the ethics of research involving human participants, but this is only one part of research ethics in psychology. Animals are used in about 7 to 8% of psychology's experiments; of these animal studies, most involve rodents and birds (90%) and about

5% use primates (APA, 1994). The genes, environment, and experience of animal subjects can be controlled and experimental conditions manipulated to a greater extent than is possible with human participants.

The benefits of psychological research with animals are less well known than the medical ones, but they are many and important. Research with animals has led to important insights that have greatly improved people's lives.

To give just a few examples, principles of learning and behavior acquired from animal studies have resulted in new educational methods, life-enhancing treatments for disorders like enuresis, and lifesaving treatments for disorders like anorexia (Miller, 1985). Studies done on primate communication have inspired improved strategies for communicating with retarded children (APA, 1994). In behavioral medicine, animal research has yielded important advances in rehabilitating victims of stroke, brain injury, and neurological damage (Miller, 1985).

Despite the benefits to people and animals themselves of animal studies, the ethics of such research has been a continuing concern of scientists and members of the general public for the past two hundred years. And feelings on this issue have often run high.

In the first decades of the 19th century, the pioneering physiological researchers Francoise Magendie and Claude Bernard aroused moral outrage by conducting surgical procedures on live unanaesthetized animals. These men ran private research laboratories and conducted public demonstrations of surgery for their livelihood. Although Magendie and Bernard justified such practices by saying that animals lack consciousness and feel no pain, other scientists who witnessed these demonstrations disagreed, calling them unnecessary and cruel (Orlans, 1993).

The antivivisectionists who were active in Magendie's day wanted to eliminate or reduce surgery done on animals for scientific research or for purposes of demonstration. Their main method was to read scientific publications and expose studies that they judged to be cruel, trivial, and repetitive. Psychologists did not escape their attention. Early in the 20th century, John Watson, the father of behaviorism, was

severely criticized in the popular press for surgically depriving rats of their sense modalities to learn how their ability to run mazes would be affected (Dewsbury, 1990).

Public concern over animal experimentation continued throughout the century. The beginning of what has been called the animal rights movement can be traced to 1975 when Peter Singer published his popular and controversial book *Animal Liberation*. In it, Singer argued that the exploitation of animals in research reflects an attitude of speciesism, analogous to racism or sexism, which he defined as "a prejudice or attitude of bias toward the interests of members of one's own species and against those of members of other species" (Singer, 1975, p. 7). Singer's book led to widespread political action to end cruelties in animal farming and the use of animals in testing chemicals and beauty products in industry. It also led to organized protests against animal research in medicine and psychology.

After the publication of Singer's book, many animal rights organizations, varying in size and strategies, sprang up in the United States and other countries. These include *People for the Ethical Treatment of Animals (PETA);* the *Animal Liberation Front (ALF); Ethics and Animals,* an association of philosophers; the *Animal Legal Defense Fund,* an association of attorneys; and *Psychologists for the Ethical Treatment of Animals*.

The late 1970s and 1980s ushered in demonstrations and sit-ins and other peaceful methods of protesting animal research, as well as a variety of more violent and militant strategies. Radical animal rights groups began infiltrating research labs, destroying data and equipment, bombing and setting fire to buildings, and removing research subjects. Acting in part as a response to publicity raised by the animal rights activists, in the mid-1980s Congress passed the amendments to the Animal Welfare Act, to which we now turn.

7.6.1 Animal Welfare Act of 1985

In 1985, experimental procedures came under the Animal Welfare Act and thereafter were regulated by the Office for Protection from Research Risks (OPRR) at the National Institutes of Health (NIH), the same office that oversees human subjects research. As of 1985, research proposals that involve subjecting animals to pain must be

reviewed by an *Institutional Animal Care and Use Committee (IACUC),* pronounced *"I,* a cook." IACUCs must include a scientist, a veterinarian, and at least one member who is not affiliated with the institution to represent community views on the care and treatment of animal subjects. The job of the IACUC, as described by Holden, is "to judge whether the experimental design is sufficient to yield important new knowledge, whether the animal model selected is appropriate (or whether nonanimal alternatives exist), the adequacy of procedures for pain control and euthanasia, environmental conditions, and qualifications for personnel" (Holden, 1987, p. 880).

The 1985 amendments to the Animal Welfare Act also required for the first time that the environment of primates promote their psychological well-being. Jane Goodall, author of *The Chimpanzees of Gombe* (1986), had lobbied for such legislation, arguing that because of the similarity of primates to humans, chimpanzees "should be provided with a rich and stimulating environment" and the company of caretakers "selected for their understanding of animal behavior and their compassion and respect for, and dedication to, their charges" (Goodall, 1987, p. 577). Psychologists have been active in research investigating the types of living conditions best suited for that purpose (see Novak & Petto, 1991).

As a result of these changes in the federal regulations, proposals for research involving animals now are evaluated to determine whether they are likely to yield important new knowledge. The research problem should be important; there should be a reasonable prospect that the study will generate the knowledge being sought; and needless repetition of procedures must be avoided. To accomplish this, researchers must select the most appropriate animal for the research, as well as the best experimental procedures and instruments, based on a firm grounding in the literature of animal research.

7.6.2 APA Code of Conduct: Care and Use of Animals in Research

The APA regulations on the ethical treatment of animals in research, reprinted in Box 4, require psychologists to comply with federal, state, and local regulations, to treat animal subjects humanely, and to make every effort

BOX 4 APA STANDARD 6.20: CARE AND USE OF ANIMALS IN RESEARCH, 1992

(a) Psychologists who conduct research involving animals treat them humanely.

(b) Psychologists acquire, care for, use, and dispose of animals in compliance with current federal, state, and local laws and regulations, and with professional standards.

(c) Psychologists trained in research methods and experienced in the care of laboratory animals supervise all procedures involving animals and are responsible for ensuring appropriate consideration of their comfort, health, and humane treatment.

(d) Psychologists ensure that all individuals using animals under their supervision have received instruction in research methods and in the care, maintenance, and handling of the species being used, to the extent appropriate to their role.

(e) Responsibilities and activities of individuals assisting in a research project are consistent with their respective competencies.

(f) Psychologists make reasonable efforts to minimize the discomfort, infection, illness, and pain of animal subjects.

(g) A procedure subjecting animals to pain, stress, or privation is used only when an alternative procedure is unavailable and the goal is justified by its prospective scientific, educational, or applied value.

(h) Surgical procedures are performed under appropriate anesthesia; techniques to avoid infection and minimize pain are followed during and after surgery.

(i) When it is appropriate that the animal's life be terminated, it is done rapidly, with an effort to minimize pain, and in accordance with accepted procedures.

"to minimize the discomfort, infection, illness, and pain of animal sub jects." As of 1992, the regulations specify that psychologists can subject animals to pain, stress, or privation only when there are no alternative procedures and when the research is of sufficient "scientific, educational, or applied value" to justify such procedures. According to the APA's statistics, few behavioral studies involve pain, stress, or privation to animal subjects (APA, 1994). *+

When pain is involved, the APA code requires that every effort be made to reduce the animals' suffering. One way to do this is to choose

procedures for research that are the least painful and least invasive. Specialists in animal behavior should be consulted to ensure that the best animal species is selected for the research. Species differ in their appropriateness as models for studying particular phenomena. They also vary in the amount of discomfort that a particular procedure will produce in them; the age of the animal also can make a difference. Observations of animals in the wild might replace laboratory experiments. Whenever possible, positive incentives should be used in place of deprivation.

A second strategy is to reduce the number of animals involved in research to a minimum and, when appropriate, to search for alternatives to animal subjects. Power analyses can be used to determine the minimum number of animals needed for meaningful statistical testing (see Chapter 6), and research designs can be selected that require the fewest subjects. In the future, the availability of animal clones may increase the precision of experiments and reduce the number of animals needed in research. Occasionally it has been possible for nonanimal models to substitute for animals. Some experiments on predation, for example, have used lifelike models in place of animal prey. Finally, when appropriate, post hoc (after the fact) analyses of data gathered on people who have experienced the conditions of interest might be considered.

The debates on the ethics of animal research in the past two centuries have been characterized by extremes of opinion and passion on both sides. At one extreme are animal rights advocates who argue that all animal research should be abolished, disregarding the benefits of such research to people and animals. At the other are those researchers who believe that the interests of humans should take precedence over any concerns about animal welfare. Most researchers today would take a position somewhere in the middle and almost all would acknowledge the moral obligation of researchers to treat animal subjects with compassion.

The changes in the law and in the thinking of scientists and nonscientists alike about the ethics of animal research that have taken place in the past decades have been nothing short of revolutionary. One can only imagine how a scientist in Magendie's day would react to the following statement made by the editors of *Animal*

Behaviour, one of today's most prestigious journals of animal behavior:

> To stop, to think and to weigh up the value of the research against all of the costs for the animals involved before anything is done to them at all should be part and parcel of any scientific inquiry. (Dawkins & Gosling, 1992, p. 1)

7.7 Final Comments

Although guidelines and committees are an indispensable aid to ethical decision making, it is not necessary to rely exclusively on such external standards in making judgments about the ethics of research. There is a simple strategy that anyone, including you, can use as a check in considering the ethics of specific research techniques. It is to put yourself in the place of the people who will be participating in the research and then decide whether you would be willing to be treated in precisely the same way as you plan to treat them. If you conclude that you would, you can rest assured that the research most likely is ethically sound.

Of course, you recognize this simple and powerful principle as the *golden rule,* a guide to moral conduct that your parents and teachers taught you as a child. Indeed, the golden rule is a principle of right conduct in all the major religions of our time (Seldes, 1972, pp. 432-4).

In Buddhism:

Hurt not others in ways that you yourself would find hurtful. (UdanaVarga: 5, 18).

In Christianity:

All things whatsoever ye would that men should do to you, do ye even so to them: for this is the Law and the Prophets. (Matthew: 7,12)

In Confucianism:

Tsze-kung asked, saying: "Is there one word which may serve as a rule of practice for all one's life?" The Master said, "Is not Reciprocity such a word? What you do not want done to yourself, do not do to others." (Confucius: *Analects)*

In Islam:

No one of you is a believer until he desires for his brother that which he desires for himself. (Sunnah)

In Judaism:

What is hateful to you, do not to your fellow-men. That is the entire Law; all the rest is commentary. (Talmud: Shabbat, 31 a)

This principle also appears as the central prescription in a classic treatise in philosophy. Immanuel Kant, the 18th-century philosopher, called it the *categorical imperative* and claimed it to be the only moral rule needed to live the good life. The categorical imperative reads:

> Act as if the principle on which your action is based were to become by your will a universal law of nature. (Kant, 1785; cited in *Microsoft Encarta*, 1994)

Finally, this principle also is central in the thinking of people who have suffered abuse at the hands of researchers. Eva Mozes Kor, a survivor of the Nazi medical experiments on twins, for example, offered the following guideline for scientists to use in designing and conducting studies with human participants (Kor, 1992, p. 8):

> Treat the subjects of your experiments in the manner that you would want to be treated if you were in their place.

Charles Pollard, a survivor of the Tuskegee syphilis study, described his feelings after learning of the deadly deception that had been practiced on him for over 40 years in similar terms. He remembers muttering some curse words to himself and thinking:

> I wouldn't have did them like that.

7.8 Key Terms

Tuskegee syphilis study

Trial of Nazi doctors at Nuremberg

Nuremberg Code

Principle of informed consent

Milgrams's obedience study

Wichita jury study

Zimbardo's prison experiment

Belmont Report

Principles of respect, beneficence, and justice

Institutional Review Board (IRB

Code of federal regulations for the protection of human subjects

APA Code of Conduct for Research Speciesism

Institutional Animal Care and Use Committee (IACUC)

APA Code: Care and use of animals in research

7.9 Key People

Stanley Milgram

Henry Beecher

Laud Humphreys

Philip Zimbardo

Françoise Magendie and Claude Bernard

Peter Singer

7.10 Review Questions

1. Describe the purpose, procedures, and duration of the Tuskegee syphilis study.

2. Why were charges brought against the Nazi doctors on trial at Nuremberg?

3. What are the two most fundamental principles of the Nuremberg Code?

4. What problems are encountered by medical and psychological researchers in applying the principle of informed consent?

5. According to the Nuremberg Code, under what conditions should research involving risks to subjects be undertaken?

6. According to Katz, what three types of risk can arise in research with human participants?

7. Describe the purpose, procedures and results of Milgram's obedience experiment.

8. What were the ethical problems Milgram's critics saw in his experiment? What was Milgram's reply to his critics?

9. What types of violations of research ethics did Beecher find in the medical literature?

10. What were the ethical problems in Humphreys's study of gay men?

11. According to the Belmont Report, what three fundamental values must be upheld in research with human participants?

12. Describe how research should be done to be in accord with the following principles:

a) respect

b) beneficence,

c) justice.

13. In what way does the principle of beneficence go beyond the Nuremberg Code?

14. What is the purpose of the Institutional Review Board?

15. Under what conditions do the federal regulations permit research on human subjects without informed consent?

16. What is the definition of “minimal risk” in the federal regulations for human research?

17. According to APA guidelines, how should a participant’s right to privacy affect procedures in research?

18. What is the APA position on deception in psychological research?

19. What proportion of psychological research involves animals?

20. What are some benefits to people that have resulted from psychological research on animals?

21. What is the job of the IACUC?

22. What are the concerns addressed in the APA Code of Conduct for Animal Research?

23. What strategies can be used to reduce the number of animals in research?

24. Explain Kant’s categorical imperative.