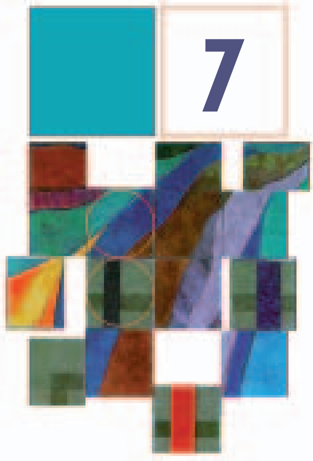
PART 3

Designs for Nursing Research



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Designing Ethical Research

This part of the textbook presents materials relating to the planning and design stage of empirical research. Ethical concerns permeate every aspect of the design of a study and the execution of the design. Therefore, before discussing techniques of research design, we present in this chapter major ethical principles that must be considered in developing research plans.

The proliferation of research has led to growing concerns about the protection of the rights of study participants. Ethical concerns are especially prominent in the field of nursing because the line of demarcation between what constitutes the expected practice of nursing and the collection of research information has become less distinct as research by nurses increases. Furthermore, ethics can create particular challenges to nurse researchers because ethical requirements sometimes conflict with the need to produce evidence of the highest possible quality for practice.

THE NEED FOR ETHICAL GUIDELINES

When humans are used as study participants—as they usually are in nursing research—care must be exercised in ensuring that the rights of those humans are protected. The requirement for ethical conduct may strike you as so self-evident as to require no further comment, but the fact is that ethical considerations have not always been given adequate attention. In this section, we consider some of the reasons that ethical guidelines became imperative.

Historical Background

As modern, civilized people, we might like to think that systematic violations of moral principles within a research context occurred centuries ago rather than in recent times, but this is not the case. The Nazi medical experiments of the 1930s and 1940s are the most famous example of recent disregard for ethical conduct. The Nazi program of research involved the use of prisoners of war and racial "enemies" in numerous experiments designed to test the limits of human endurance and human reaction to diseases and untested drugs. The studies were unethical not only because they exposed these people to permanent physical harm and even death but because subjects could not refuse participation.

Some recent examples of ethical transgressions have also occurred in the United States. For instance, between 1932 and 1972, a study known as the Tuskegee Syphilis Study, sponsored by the U.S. Public Health Service, investigated the effects of syphilis among 400 men from a poor

African-American community. Medical treatment was deliberately withheld to study the course of the untreated disease. Another well-known case of unethical research involved the injection of live cancer cells into elderly patients at the Jewish Chronic Disease Hospital in Brooklyn, without the consent of those patients. Even more recently, it was revealed in 1993 that U.S. federal agencies had sponsored radiation experiments since the 1940s on hundreds of people, many of them prisoners or elderly hospital patients. Many other examples of studies with ethical transgressions—often much more subtle than these examples—have emerged to give ethical concerns the high visibility they have today.

Ethical Dilemmas in Conducting Research

Research that violates ethical principles is rarely done specifically to be cruel or immoral, but more typically occurs out of a conviction that knowledge is important and potentially life-saving or beneficial to others in the long run. There are research problems in which participants' rights and study demands are put in direct conflict, posing **ethical dilemmas** for researchers. Here are examples of research problems in which the desire for rigor conflicts with ethical considerations:

1. *Research question:* How empathic are nurses in their treatment of patients in the intensive care unit (ICU)?
   Ethical dilemma: Ethics require that participants be cognizant of their role in a study. Yet if the researcher informs nurses participating in this study that their degree of empathy in treating ICU patients will be scrutinized, will their behavior be "normal?" If the nurses' usual behavior is altered because of the known presence of research observers, the findings will not be valid.
2. *Research question:* What are the coping mechanisms of parents whose children have a terminal illness?
   Ethical dilemma: To answer this question, the researcher may need to probe into the psychological state of the parents at a vulnerable time in their lives; such probing could be painful and even traumatic. Yet knowledge of the parents' coping mechanisms might help to design more effective ways of dealing with parents' grief and anger.
3. *Research question:* Does a new medication prolong life in patients with cancer?
   Ethical dilemma: The best way to test the effectiveness of an intervention is to administer the intervention to some participants but withhold it from others to see if differences between the groups emerge. However, if the intervention is untested (e.g., a new drug), the group receiving the intervention may be exposed to potentially hazardous side effects. On the other hand, the group *not* receiving the drug may be denied a beneficial treatment.
4. *Research question:* What is the process by which adult children adapt to the day-to-day stresses of caring for a terminally ill parent?
   Ethical dilemma: In a qualitative study, which would be appropriate for this research question, the researcher sometimes becomes so closely involved with participants that they become willing to share "secrets" and privileged information. Interviews can become confessions—sometimes of unseemly or even illegal or immoral behavior. In this example, suppose a participant admitted to physically abusing an adult parent—how does the researcher respond to that information without undermining a pledge of confidentiality? And, if the researcher divulges the information to appropriate authorities, how can a pledge of confidentiality be given in good faith to other participants?

As these examples suggest, researchers involved with human participants are sometimes in a bind. They are obligated to advance knowledge and develop the highest-quality evidence for practice, using the best methods available; however, they must also adhere to the dictates of ethical rules that have been developed to protect human rights. Another type of dilemma arises from the fact that nurse researchers may be confronted with conflict-of-interest situations, in which their expected behavior as nurses comes into conflict with the expected behavior of researchers (e.g., deviating from a standard research protocol to give needed assistance to a patient). It is precisely because of such conflicts and dilemmas that **codes of ethics** have been developed to guide the efforts of researchers.

Codes of Ethics

During the past four decades, largely in response to the human rights violations described earlier, various codes of ethics have been developed. One of the first internationally recognized efforts to establish ethical standards is referred to as the **Nuremberg Code**, developed after the Nazi atrocities were made public in the Nuremberg trials. Several other international standards have subsequently been developed, the most notable of which is the **Declaration of Helsinki**, which was adopted in 1964 by the World Medical Association and then later revised, most recently in 2000.

Most disciplines have established their own code of ethics. The American Nurses' Association (ANA) put forth a document in 1995 entitled *Ethical Guidelines in the Conduct, Dissemination, and Implementation of Nursing Research* (Silva, 1995). Box 7-1 presents the nine ethical principles outlined in that document. The American Sociological Association published a revised *Code of Ethics* in 1997. Guidelines for psychologists were published by the American Psychological Association (1992) in *Ethical Principles of Psychologists and Code of Conduct*. Although there is considerable overlap in the basic principles articulated in these documents, each deals with problems of particular concern to their respective disciplines.

In the United States, an important code of ethics was adopted by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978). The commission, established by the National Research Act (Public Law 93–348), issued a report in 1978 that served as the basis for regulations affecting research sponsored by the federal government. The report, sometimes referred to as the *Belmont Report*, also served as a model for many of the guidelines adopted by specific disciplines. The *Belmont Report* articulated three primary ethical principles on which standards of ethical conduct in research are based: beneficence, respect for human dignity, and justice.

TIP: The following websites offer information about various codes of ethics and ethical requirements for government-sponsored research:

U.S. federal policy for the protection of human subjects, from the Office of Human Research Protections (OHRP): http://ohrp.osophs.dhhs.gov

Canadian policies, from the Tri-Council Policy Statement of the Natural Sciences and Engineering Research Council of Canada (NSERC): http://www.nserc.ca/programs/ethics/english

American Psychological Association: http://www.apa.org/ethics/code.html

American Sociological Association: http://www.asanet.org/members/ecoderev.html

THE PRINCIPLE OF BENEFICENCE

One of the most fundamental ethical principles in research is that of **beneficence**, which encompasses the maxim: Above all, do no harm. Ethical Principle 2 of the ANA guidelines addresses beneficence. Most researchers consider that this principle contains multiple dimensions.

Freedom From Harm

Study participants can be harmed in a variety of ways, including harm that is physical (e.g., injury, fatigue), psychological (e.g., stress, fear), social (e.g., loss of friends), and economic (e.g., loss of wages). Researchers should strive to minimize all types of harm and discomfort and to achieve insofar as possible a balance between the potential benefits and risks of being a participant.

Clearly, exposing study participants to experiences that result in serious or permanent harm is unacceptable. Research should be conducted only

BOX 7.1 Ethical Principles in Nursing Research

THE INVESTIGATOR . . .

1. Respects autonomous research participants' capacity to consent to participate in research and to determine the degree and duration of that participation without negative consequences.
2. Prevents harm, minimizes harm, and/or promotes good to all research participants, including vulnerable groups and others affected by the research.
3. Respects the personhood of research participants, their families, and significant others, valuing their diversity.
4. Ensures that the benefits and burdens of research are equitably distributed in the selection of research participants.
5. Protects the privacy of research participants to the maximum degree possible.
6. Ensures the ethical integrity of the research process by use of appropriate checks and balances throughout the conduct, dissemination, and implementation of the research.
7. Reports suspected, alleged, or known incidents of scientific misconduct in research to appropriate institutional officials for investigation.
8. Maintains competency in the subject matter and methodologies of his or her research, as well as in other professional and societal issues that affect nursing research and the public good.
9. Involved in animal research maximizes the benefits of the research with the least possible harm or suffering to the animals.

From Silva, M. C. (1995). *Ethical guidelines in the conduct, dissemination, and implementation of nursing research* (pp. v–vi). Washington, DC: American Nurses' Association.

by qualified people, especially if potentially dangerous technical equipment or specialized procedures are used. Ethical researchers must be prepared to terminate the research if there is reason to suspect that continuation would result in injury, death, disability, or undue distress to study participants. When a new medical procedure or drug is being tested, it is almost always advisable to experiment with animals or tissue cultures before proceeding to tests with humans. (Ethical guidelines relating to the treatment of animal subjects should be consulted for research on animals; see, for example, the American Psychological Association's *Guidelines for ethical conduct in the care and use of animals* at http://www.apa.org/science/anguide.html.)

Example of risk reduction:
Varda and Behnke (2000) studied the effect of the timing of an initial bath (1 hour versus 2 hours after birth) on newborn temperature. To minimize risks, the researchers excluded all infants with conditions (e.g., infection, fetal distress, hypoglycemia) that could predispose them to temperature instability.

Although protecting human beings from physical harm may be straightforward, the psychological consequences of participating in a study are usually subtle and thus require close attention and sensitivity. For example, participants may be asked questions about their personal views, weaknesses, or fears. Such queries might lead people to reveal sensitive personal information. The point is not that researchers should refrain from asking questions but rather that they need to be aware of the nature of the intrusion on people's psyches. Researchers can avoid or minimize psychological harm by carefully phrasing questions, by having **debriefing** sessions that permit participants to ask questions or air complaints after data are collected, and, in some situations, by making referrals to appropriate health, social, or psychological services.

Example of referrals:
In the study by Polit, London, and Martinez (2001) of the health of nearly 4000 poor women in 4 major cities, the 90-minute interviews covered such sensitive topics as substance abuse, depression, parenting stress, and domestic violence. Each interviewer had an information sheet with contact information for local service providers who could assist with any issue about which a participant mentioned a need for help.

The need for sensitivity may be greater in qualitative studies, which often involve in-depth exploration into highly personal areas. In-depth probing may actually expose deep-seated fears and anxieties that study participants had previously repressed. Qualitative researchers, regardless of the underlying research tradition, must thus be especially vigilant in anticipating such problems.

Example of an issue of risk in a qualitative study:
Caelli (2001) conducted a phenomenological study to illuminate nurses' understandings of health, and how such understandings translated into nursing practice. One participant, having explored her experience of health with the researcher over several interview sessions, resigned from her city hospital job as a result of gaining a new recognition of the role health played in her life.

Freedom From Exploitation

Involvement in a research study should not place participants at a disadvantage or expose them to situations for which they have not been prepared. Participants need to be assured that their participation, or information they might provide, will not be used against them in any way. For example, a person describing his or her economic circumstances to a researcher should not be exposed to the risk of losing Medicaid benefits; a person reporting drug use should not fear exposure to criminal authorities.

Study participants enter into a special relationship with researchers, and it is crucial that this relationship not be exploited. Exploitation may be overt and malicious (e.g., sexual exploitation, use of subjects' identifying information to create a mailing list, and use of donated blood for the development of a commercial product), but it might also be more subtle. For example, suppose subjects agreed to participate in a study requiring 30 minutes of their time and that the researcher decided 1 year later to go back to them, to follow their progress or circumstances. Unless the researcher had previously explained to participants that there might be a follow-up study, the researcher might be accused of not adhering to the agreement previously reached and of exploiting the researcher—participant relationship.

Because nurse researchers may have a nurse—patient (in addition to a researcher—participant) relationship, special care may need to be exercised to avoid exploiting that bond. Patients' consent to participate in a study may result from their understanding of the researcher's role as *nurse*, not as *researcher.*

In qualitative research, the risk of exploitation may become especially acute because the psychological distance between investigators and participants typically declines as the study progresses. The emergence of a pseudotherapeutic relationship is not uncommon, which imposes additional responsibilities on researchers—and additional risks that exploitation could inadvertently occur. On the other hand, qualitative researchers typically are in a better position than quantitative researchers to *do good*, rather than just to avoid doing harm, because of the close relationships they often develop with participants. Munhall (2001) has argued that qualitative nurse researchers have the responsibility of ensuring that the "therapeutic imperative of nursing (advocacy) takes precedent over the research imperative (advancing knowledge) if conflict develops" (p. 538).

Benefits From Research

People agree to participate in research investigations for a number of reasons. They may perceive that there are some direct personal benefits. More often, however, any benefits from the research accrue to society in general or to other individuals. Thus, many individuals may participate in a study out of a desire to be helpful. Researchers should strive insofar as possible to maximize benefits and to communicate potential benefits to participants.

The Risk/Benefit Ratio

In designing a study, researchers must carefully assess the risks and benefits that would be incurred. The assessment of risks and benefits that individual participants might experience should be shared with them so that they can evaluate whether it is in their best interest to participate. Box 7-2 summarizes the major risks and benefits of research participation. In evaluating the anticipated **risk/benefit ratio** of a study design, researchers might want to consider how comfortable they would feel if their own family members were participating in the study.

The risk/benefit ratio should also be considered in terms of whether the risks to participants are commensurate with the benefit to society and the nursing profession in terms of the quality of evidence produced. The general guideline is that the degree of risk to be taken by those participating in the research should never exceed the potential humanitarian benefits of the knowledge to be gained. Thus, the selection of a significant topic that has the potential to improve patient care is the first step in ensuring that research is ethical.

All research involves some risks, but in many cases, the risk is minimal. **Minimal risk** is defined as risks anticipated to be no greater than those ordinarily encountered in daily life or during routine physical or psychological tests or procedures. When the risks are not minimal, researchers must proceed with caution, taking every step possible to reduce risks and maximize benefits. If the perceived

BOX 7.2 Potential Benefits and Risks of Research to Participants

MAJOR POTENTIAL BENEFITS TO PARTICIPANTS

- Access to an intervention that might otherwise be unavailable to them
- Comfort in being able to discuss their situation or problem with a friendly, objective person
- Increased knowledge about themselves or their conditions, either through opportunity for introspection and self-reflection or through direct interaction with researchers
- Escape from normal routine, excitement of being part of a study
- Satisfaction that information they provide may help others with similar problems or conditions
- Direct monetary or material gains through stipends or other incentives

MAJOR POTENTIAL RISKS TO PARTICIPANTS

- Physical harm, including unanticipated side effects
- Physical discomfort, fatigue, or boredom
- Psychological or emotional distress resulting from self-disclosure, introspection, fear of the unknown, discomfort with strangers, fear of eventual repercussions, anger or embarrassment at the type of questions being asked
- Social risks, such as the risk of stigma, adverse effects on personal relationships, loss of status
- Loss of privacy
- Loss of time
- Monetary costs (e.g., for transportation, child care, time lost from work)

risks and costs to participants outweigh the anticipated benefits of the study, the research should be either abandoned or redesigned.

In quantitative studies, most of the details of the study are usually spelled out in advance, and therefore a reasonably accurate risk/benefit ratio assessment can be developed. Qualitative studies, however, usually evolve as data are gathered, and it may therefore be more difficult to assess all risks at the outset of a study. Qualitative researchers thus must remain sensitive to potential risks throughout the research process.

THE PRINCIPLE OF RESPECT FOR HUMAN DIGNITY

Respect for human dignity is the second ethical principle articulated in the *Belmont Report*. This principle, which includes the right to self-determination and the right to full disclosure, is covered in the ANA guidelines under principles 1 and 3.

The Right to Self-Determination

Humans should be treated as autonomous agents, capable of controlling their own activities. The principle of **self-determination** means that prospective participants have the right to decide voluntarily whether to participate in a study, without risking any penalty or prejudicial treatment. It also means that people have the right to ask questions, to refuse to give information, to ask for clarification, or to terminate their participation.

A person's right to self-determination includes freedom from coercion of any type. **Coercion** involves explicit or implicit threats of penalty from failing to participate in a study or excessive rewards from agreeing to participate. The obligation to protect people from coercion requires careful thought when the researcher is in a position of authority, control, or influence over potential participants, as might often be the case in a nurse—patient relationship. The issue of coercion may require scrutiny even when there is not a preestablished relationship. For example, a generous monetary incentive (or **stipend**) offered to encourage the participation of an economically disadvantaged group (e.g., the homeless) might be considered mildly coercive because such incentives may place undue pressure on prospective participants; its acceptability might have to be evaluated in terms of the overall risk/benefit ratio.

TIP: Stipends used to increase the rate of participation in a study appear to be especially effective when the group under study is difficult to recruit or when the study is time-consuming or tedious. Stipends range from $1 to hundreds of dollars, but most are in the $10 to $25 range. Federal agencies that sponsor research sometimes do not allow the payment of an outright stipend but will allow reimbursement of certain expenses (e.g., for participants' travel, child care, or lunch money).

The Right to Full Disclosure

The principle of respect for human dignity encompasses people's right to make informed, voluntary decisions about study participation, which requires full disclosure. **Full disclosure** means that the researcher has fully described the nature of the study, the person's right to refuse participation, the researcher's responsibilities, and likely risks and benefits. The right to self-determination and the right to full disclosure are the two major elements on which informed consent is based. Procedures for obtaining informed consent from participants are discussed later in this chapter.

Although full disclosure is normally provided to participants before they begin a study, there is often a need for further disclosure at a later point, either in debriefing sessions or in written communications. For example, issues that arise during the course of data collection may need to be clarified, or participants may want aspects of the study explained once again. Some researchers offer to send participants summaries of the research findings after the information has been analyzed. In qualitative studies, the consent process may require an ongoing negotiation between researchers and participants.

Issues Relating to the Principle of Respect

Although most researchers would, in the abstract, endorse participants' right to self-determination and full disclosure, these standards are sometimes difficult to adhere to in practice. One issue concerns the inability of some individuals to make well-informed judgments about the risks and benefits of study participation. Children, for example, may be unable to give truly informed consent. The issue of groups that are vulnerable within a research context is discussed later in this chapter.

Another issue is that full disclosure can sometimes create two types of bias: first, a bias resulting if subjects provide inaccurate information, and second, a bias resulting if a representative sample is not recruited. Suppose we were studying the relationship between high school students' substance abuse and their absenteeism from school; we hypothesize that students with a high rate of absenteeism are more likely to be substance abusers than students with a good attendance record. If we approached potential participants and fully explained the purpose of the study, some students might refuse to participate, and nonparticipation would be selective; those least likely to volunteer for such a study might well be students who are substance abusers—the very group of primary interest. Moreover, by knowing the research question, those who do participate might not give candid responses. In such a situation, full disclosure could undermine the study.

One technique that researchers sometimes use in such situations is **covert data collection** or **concealment**—the collection of information without participants' knowledge and thus without their consent. This might happen, for example, if a researcher wanted to observe people's behavior in a real-world setting and was concerned that doing so openly would result in changes in the very behavior of interest. The researcher might choose to obtain the information through concealed methods, such as by observing through a one-way mirror, videotaping with hidden equipment, or observing while pretending to be engaged in other activities. As another example, hospital patients might unwittingly become participants in a study through researchers' use of existing hospital records. In general, covert data collection may be acceptable as long as risks are negligible and participants' right to privacy has not been violated, and if the researcher has arranged to debrief participants about the nature of the study subsequent to data collection. Covert data collection is least likely to be ethically acceptable if the research is focused on sensitive aspects of people's behavior, such as drug use, sexual conduct, or illegal acts.

A more controversial technique is the use of deception. **Deception** can involve deliberately withholding information about the study, or providing participants with false information. For example, in studying high school students' use of drugs we might describe the research as a study of students' health practices, which is a mild form of misinformation.

The practice of deception is problematic ethically because it interferes with participants' right to make a truly informed decision about personal costs and benefits of participation. Some people argue that deception is never justified. Others, however, believe that if the study involves minimal risk to subjects and if there are anticipated benefits to the profession and society, then deception may be justified to enhance the validity of the findings. The ANA guidelines offer this advice about deception and concealment:

> The investigator understands that concealment or deception in research is controversial, depending on the type of research. Some investigators believe that concealment or deception in research can never be morally justified. The investigator further understands that before concealment or deception is used, certain criteria must be met: (1) The study must be of such small risk to the research participant and of such great significance to the advancement of the public good that concealment or deception can be morally justified. . . . (2) The acceptability of concealment or deception is related to the degree of risks to research participants. . . . (3) Concealment or deception are used only as last resorts, when no other approach can ensure the validity of the study's findings. . . . (4) The investigator has a moral responsibility to inform research

> participants of any concealment or deception as soon as possible and to explain the rationale for its use. (Silva, 1995, p. 10, Section 4.2).

Another issue relating to the principle of respect that has emerged in this new era of electronic communications concerns the collection of data from people over the Internet. For example, some researchers are analyzing the content of messages posted to chat rooms or on listserves. The issue is whether such messages can be used as data without the authors' permission and their informed consent. Some researchers believe that anything posted electronically is in the public domain and therefore can be used without consent for purposes of research. Others, however, feel that the same ethical standards must apply in cyberspace research and that electronic researchers must carefully protect the rights of individuals who are participants in "virtual" communities. Schrum (1995) has developed some ethical guidelines for use by such researchers. As one example, she advocates that researchers, before collecting electronic data, negotiate their entry into an electronic community (e.g., a chat room) with the list owner. Sixsmith and Murray (2001) also warn researchers that obtaining consent from list moderators does not necessarily mean that every member of the listserve or chat room has provided consent. Researchers should periodically remind members of the on-line group of their presence at the site.

THE PRINCIPLE OF JUSTICE

The third broad principle articulated in the *Belmont Report* concerns justice. Justice, which includes participants' right to fair treatment and their right to privacy, is covered in the ANA guidelines under principles 4 and 5.

The Right to Fair Treatment

Study participants have the right to fair and equitable treatment before, during, and after their participation in the study. Fair treatment includes the following features:

- The fair and nondiscriminatory selection of participants such that any risks and benefits will be equitably shared; participants should be selected based on research requirements and not on the vulnerability or compromised position of certain people
- Respect for cultural and other forms of human diversity
- The nonprejudicial treatment of those who decline to participate or who withdraw from the study after agreeing to participate
- The honoring of all agreements between researchers and participants, including adherence to the procedures described to them and payment of any promised stipends
- Participants' access to research personnel at any point in the study to clarify information
- Participants' access to appropriate professional assistance if there is any physical or psychological damage
- Debriefing, if necessary, to divulge information withheld before the study or to clarify issues that arose during the study
- Courteous and tactful treatment at all times

The Right to Privacy

Virtually all research with humans involves intruding into personal lives. Researchers should ensure that their research is not more intrusive than it needs to be and that participants' privacy is maintained throughout the study.

Participants have the right to expect that any data they provide will be kept in strictest confidence. This can occur either through anonymity or through other confidentiality procedures. **Anonymity** occurs when even the researcher cannot link participants to their data. For example, if questionnaires were distributed to a group of nursing home residents and were returned without any identifying information on them, responses would be anonymous. As another example, if a researcher reviewed hospital records from which all identifying information (e.g., name, address, social security number, and so forth) had been expunged, anonymity would again protect participants' right to privacy. Whenever it is possible to achieve anonymity, researchers should strive to do so.

Example of anonymity: Thomas, Stamler, Lafrenier, and Dumala (2001) used the Internet to gather data from an international sample of women about their perceptions of breast health education and screening. A website with a questionnaire was established. No identifying information was sought from respondents, and so their anonymity was guaranteed.

When anonymity is impossible, appropriate **confidentiality procedures** need to be implemented. A promise of confidentiality is a pledge that any information participants provide will not be publicly reported in a manner that identifies them and will not be made accessible to others. This means that research information should not be shared with strangers nor with people known to the participants (e.g., family members, physicians, other nurses), unless the researcher has been given explicit permission to share it.

Researchers can take a number of steps to ensure that breaches of confidentiality do not occur, including the following:

- Obtain identifying information (e.g., name, address) from participants only when essential.
- Assign an identification (ID) number to each participant and attach the ID number rather than other identifiers to the actual data.
- Maintain identifying information in a locked file.
- Restrict access to identifying information to a small number of people on a need-to-know basis.
- Enter no identifying information onto computer files.
- Destroy identifying information as quickly as practical.
- Make research personnel sign confidentiality pledges if they have access to data or identifying information.
- Report research information in the aggregate; if information for a specific participant is reported, take steps to disguise the person's identity, such as through the use of a fictitious name.

TIP: Researchers who plan to collect data from study participants on multiple occasions (or who use multiple data forms that need to be connected) might believe that anonymity is not possible. However, a technique that has been successfully used is to have participants themselves generate an ID number. They might be instructed, for example, to use their birth year and the first three letters of their mother's maiden names as their ID code (e.g., 1946CRU). This code would be put on every form participants complete, but researchers would not know participants' identities.

Qualitative researchers may need to take extra steps to safeguard the privacy of their participants. Anonymity is almost never possible in qualitative studies because researchers typically become closely involved with participants. Moreover, because of the in-depth nature of qualitative studies, there may be a greater invasion of privacy than is true in quantitative research. Researchers who spend time in the home of a participant may, for example, have difficulty segregating the public behaviors that the participant is willing to share from the private behaviors that unfold unwittingly during the course of data collection. A final issue is adequately disguising participants in research reports. Because the number of respondents is small, qualitative researchers may need to take considerable precautions to safeguard identities. This may mean more than simply using a fictitious name—it may also mean not sharing detailed information about informants' characteristics, such as their occupation and diagnosis.

TIP: Qualitative researchers may have to slightly distort identifying information in their reports, or provide fairly general descriptions. For example, a 49-year-old antique dealer with ovarian cancer might be described as "a middle-aged cancer patient who works in retail sales" to avoid identification that could occur with the more detailed description.

INFORMED CONSENT

Prospective participants who are fully informed about the nature of the research and its potential risks and benefits are in a position to make rational decisions about participating in the study. **Informed consent** means that participants have adequate information regarding the research, are capable of comprehending the information, and have the power of free choice, enabling them to consent to or decline participation voluntarily. This section discusses procedures for obtaining informed consent.

The Content of Informed Consent

Fully informed consent involves communicating the following pieces of information to participants:

1. *Participant status.* Prospective participants need to understand clearly the distinction between *research* and *treatment*. They should be told which health care activities are routine and which are implemented specifically for the study. They also should be informed that data they provide will be used for research purposes.
2. *Study goals.* The overall goals of the research should be stated, in lay rather than technical terms. The use to which the data will be put should be described.
3. *Type of data.* Prospective participants should be told the type of data that will be collected.
4. *Procedures.* Prospective participants should be given a description of the data collection procedures, and of the procedures to be used in any innovative treatment.
5. *Nature of the commitment.* Information should be provided regarding participants' estimated time commitment at each point of contact, and the number of contacts within specified timeframes.
6. *Sponsorship.* Information on who is sponsoring or funding the study should be noted; if the research is part of an academic requirement, this information should be shared.
7. *Participant selection.* Researchers should explain how prospective participants were selected for recruitment, and how many people will be participating.
8. *Potential risks.* Prospective participants should be informed of any foreseeable risks (physical, psychological, social, or economic) or discomforts that might be incurred as a result of participation, and any efforts that will be taken to minimize risks. The possibility of unforeseeable risks should also be discussed, if appropriate. If injury or damage is possible, treatments that will be made available to participants should be described. When risks are more than minimal, prospective participants should be encouraged to seek the advice of others before consenting.
9. *Potential benefits.* Specific benefits to participants, if any, should be described, as well as information on possible benefits to others.
10. *Alternatives.* If appropriate, researchers should provide information about alternative procedures or treatments that might be advantageous to participants.
11. *Compensation.* If stipends or reimbursements are to be paid (or if treatments are offered without fee), these arrangements should be discussed.
12. *Confidentiality pledge.* Prospective participants should be assured that their privacy will at all times be protected. If anonymity can be guaranteed, this should be noted.
13. *Voluntary consent.* Researchers should indicate that participation is strictly voluntary and that failure to volunteer will not result in any penalty or loss of benefits.
14. *Right to withdraw and withhold information.* Prospective participants should be told that even after consenting they have the right to withdraw from the study and to refuse to provide any specific piece of information. Researchers may, in some cases, need to provide participants with a description of circumstances under which researchers would terminate the overall study.
15. *Contact information.* The researcher should provide information on whom participants could contact in the event of further questions, comments, or complaints.

In some qualitative studies, especially those requiring repeated contact with the same participants, it is difficult to obtain a meaningful informed consent at the outset. Qualitative researchers do not always know in advance how the study will evolve.

Because the research design emerges during the data collection and analysis process, researchers may not know the exact nature of the data to be collected, what the risks and benefits to participants will be, or how much of a time commitment they will be expected to make. Thus, in a qualitative study, consent is often viewed as an ongoing, transactional process, referred to as **process consent**. In process consent, the researcher continually renegotiates the consent, allowing participants to play a collaborative role in the decision-making process regarding ongoing participation.

Example of informed consent: Wilde (2002) studied the experience of living with a long-term urinary catheter in a community-dwelling sample of adults. Fourteen men and women were recruited for this phenomenological study. Full informed consent was obtained before each interview, and reaffirmed as interviews continued.

Comprehension of Informed Consent

Consent information is normally presented to prospective participants while they are being recruited, either orally or in writing. A written notice should not, however, take the place of spoken explanations. Oral presentations provide opportunities for greater elaboration and for participant questioning.

Because informed consent is based on a person's evaluation of the potential risks and benefits of participation, it is important that the critical information not only be communicated but understood. Researchers must assume the role of teacher in communicating consent information. They should be careful to use simple language and to avoid jargon and technical terms whenever possible; they should also avoid biased language that might unduly influence the person's decision to participate. Written statements should be consistent with the participants' reading levels and educational attainment. For participants from a general population (e.g., patients in a hospital), the statement should be written at about seventh or eighth grade reading level.

For studies involving more than minimal risk, researchers need to make special efforts to ensure that prospective participants understand what participation will involve. In some cases, this might involve testing participants for their comprehension of the informed consent material before deeming them eligible for participation.

Documentation of Informed Consent

Researchers usually document the informed consent process by having participants sign a **consent form**. In the United States, federal regulations covering studies funded by government agencies require written consent of human subjects, except under certain circumstances. In particular, when the study does not involve an intervention and data are collected anonymously (or when existing data from records or specimens are used and identifying information is not linked to the data), regulations requiring written informed consent do not apply.

The consent form should contain all the information essential to informed consent, as described earlier. Prospective participants (or their legally authorized representative) should have ample time to review the written document before signing it. The document should also be signed by the researcher, and a copy should be retained by both parties. An example of a written consent form used in a study of one of the authors is presented in Figure 7-1. The numbers in the margins correspond to the types of information for informed consent outlined earlier. (Note that the form does not indicate how subjects were selected, because this is implied in the study purpose, and prospective participants knew they were recruited from a support group for mothers of multiples.)

TIP: In developing a consent form, the following guidelines might prove helpful:

1. Organize the form coherently so that prospective participants can follow the logic of what is being communicated. If the form is complex, use headings as an organizational aid.
2. Use a large enough font so that the form can be easily read, and use spacing that avoids making the document appear too dense. Make the form as attractive and inviting as possible.

[redacted]

FIGURE 7.1 Example of an informed consent form.

3. In general, simplify. Use clear and consistent terminology, and avoid technical terms if possible. If technical terms are needed, include definitions.
4. If possible, use a **readability formula** to estimate the form's reading level, and make revisions to ensure an appropriate reading level for the group under study. There are several such formulas, the most widely used being the FOG Index (Gunning, 1968), the SMOG index (McLaughlin, 1969), and the Flesch Reading Ease score and Flesch-Kincaid grade level score (Flesch, 1948). Specialized software (e.g., RightWriter) is available, and some word-processing software (e.g., Microsoft Word) also provides readability information.
5. Test the form with people similar to those who will be recruited, and ask for feedback.

If the informed consent information is lengthy, researchers whose studies are funded by U.S. government agencies have the option of presenting the full information orally and then summarizing essential information in a **short form**. If a short form is used, however, the oral presentation must be witnessed by a third party, and the signature of the witness must appear on the short consent form. The signature of a third-party witness is also advisable in studies involving more than minimal risk, even when a long and comprehensive consent form is used.

For studies that are not government sponsored, researchers should err on the side of being conservative. They should implement consent procedures that fully adhere to the principle that prospective participants can make good decisions about participation only if they are fully informed about the study's risks and benefits.

TIP: When the primary means of data collection is through a self-administered questionnaire, some researchers opt not to obtain written informed consent because they assume **implied consent** (i.e., that the return of the completed questionnaire reflects voluntary consent to participate). This assumption, however, may not always be warranted (e.g., if patients feel that their treatment might be affected by failure to cooperate with the researcher).

VULNERABLE SUBJECTS

Adherence to ethical standards is often straightforward. However, the rights of special vulnerable groups may need to be protected through additional procedures and heightened sensitivity. **Vulnerable subjects** (the term used in U.S. federal guidelines) may be incapable of giving fully informed consent (e.g., mentally retarded people) or may be at high risk of unintended side effects because of their circumstances (e.g., pregnant women). Researchers interested in studying high-risk groups should become acquainted with guidelines governing informed consent, risk/benefit assessments, and acceptable research procedures for such groups. In general, research with vulnerable subjects should be undertaken only when the risk/benefit ratio is low or when there is no alternative (e.g., studies of childhood development require child participants).

Among the groups that nurse researchers should consider as being vulnerable are the following:

- *Children.* Legally and ethically, children do not have the competence to give informed consent. Usually, the informed consent of children's parents or legal guardians should be obtained. However, it is appropriate—especially if the child is at least 7 years of age—to obtain the child's assent as well. **Assent** refers to the child's affirmative agreement to participate.

  If the child is developmentally mature enough to understand the basic information involved in informed consent (e.g., a 13-year-old), it is advisable to obtain written consent from the child as well, as evidence of respect for the child's right to self-determination. Lindeke, Hauck, and Tanner (2000) and Broome (1999) provide excellent guidance regarding children's assent and consent to participate in research. The U.S. government has issued special regulations for the additional protection of children as study participants (see Code of Federal Regulations, 1991, Subpart D).
- *Mentally or emotionally disabled people.* Individuals whose disability makes it impossible for them to weigh the risks and benefits of participation and make an informed decision (e.g.,

people affected by mental retardation, senility, mental illness, or unconsciousness) also cannot legally or ethically provide informed consent. In such cases, researchers should obtain the written consent of a legal guardian. Researchers should, however, be aware of the fact that a legal guardian may not necessarily have the person's best interests in mind. In such cases, informed consent should also be obtained from someone whose primary interest is the person's welfare. As in the case of children, informed consent or assent from prospective participants themselves should be sought to the extent possible, in addition to guardians' consent.

- *Severely ill or physically disabled people.* For patients who are very ill or undergoing certain treatments, it might be necessary to assess their ability to make reasoned decisions about study participation. For example, Higgins and Daly (1999) described a process they used to assess the decisional capacity of mechanically ventilated patients. Another issue is that for certain disabilities, special procedures for obtaining consent may be required. For example, with deaf participants, the entire consent process may need to be in writing. For people who have a physical impairment preventing them from writing or for participants who cannot read and write, alternative procedures for documenting informed consent (such as audiotaping or videotaping consent proceedings) should be used.
- *The terminally ill.* Terminally ill people who participate in the study can seldom expect to benefit personally from the research, and thus the risk/benefit ratio needs to be carefully assessed. Researchers must also take steps to ensure that if the terminally ill participate in the study, the health care and comfort of these individuals are not compromised. Special procedures may be required for obtaining informed consent if they are physically or mentally incapacitated.
- *Institutionalized people.* Nurses often conduct studies with hospitalized or institutionalized people. Particular care may be required in recruiting such people because they often depend on health care personnel and may feel pressured into participating or may feel that their treatment would be jeopardized by their failure to cooperate. Inmates of prisons and other correctional facilities, who have lost their autonomy in many spheres of activity, may similarly feel constrained in their ability to give free consent. The U.S. government has issued specific regulations for the protection of prisoners as study participants (see Code of Federal Regulations, 1991, Subpart C). Researchers studying institutionalized groups need to emphasize the voluntary nature of participation.
- *Pregnant women.* The U.S. government has issued stringent additional requirements governing research with pregnant women and fetuses (Code of Federal Regulations, 1991, Subpart B). These requirements reflect a desire to safeguard both the pregnant woman, who may be at heightened physical and psychological risk, and the fetus, who cannot give informed consent. The regulations stipulate that a pregnant woman cannot be involved in a study unless the purpose of the research is to meet the health needs of the pregnant woman and risks to her and the fetus are minimized or there is only a minimal risk to the fetus.

Example of research with a vulnerable group: Anderson, Nyamathi, McAvoy, Conde, and Casey (2001) conducted a study to explore perceptions of risk for human immunodeficiency virus infection/acquired immunodeficiency syndrome among adolescents in juvenile detention. The researchers obtained approval to conduct the study from the presiding judge, the detention facility, and a human subjects committee at their own institution. They structured their protocols to assure teens that their participation would be voluntary and would influence neither the duration of their detention nor their adjudication process. The data were collected in spaces that provided privacy for sound and afforded visual surveillance by probation staff.

It should go without saying that researchers need to proceed with extreme caution in conducting research with people who might fall into two or more vulnerable categories, as was the case in this example.

EXTERNAL REVIEWS AND THE PROTECTION OF HUMAN RIGHTS

Researchers may not be objective in assessing risk/benefit ratios or in developing procedures to protect participants' rights. Biases may arise as a result of the researchers' commitment to an area of knowledge and their desire to conduct a study with as much rigor as possible. Because of the risk of a biased evaluation, the ethical dimensions of a study should normally be subjected to external review.

Most hospitals, universities, and other institutions where research is conducted have established formal committees and protocols for reviewing proposed research plans before they are implemented. These committees are sometimes called *human subjects committees*, *ethical advisory boards*, or *research ethics committees*. If the institution receives funds from the U.S. government to help pay for the costs of research, the committee likely will be called an **Institutional Review Board (IRB).**

TIP: If the research is being conducted within an institution or with its help (e.g., assistance in recruiting subjects), you should find out early what the institution's requirements are regarding ethical issues, in terms of its forms, procedures, and review schedules.

Federally sponsored studies (including fellowships) are subject to strict guidelines for evaluating the treatment of human participants. Before undertaking such a study, researchers must submit research plans to the IRB, and must also go through a formal IRB training process. The duty of the IRB is to ensure that the proposed plans meet the federal requirements for ethical research. An IRB can approve the proposed plans, require modifications, or disapprove the plans. The main requirements governing IRB decisions may be summarized as follows (Code of Federal Regulations, 1991, §46.111):

- Risks to participants are minimized.
- Risks to participants are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result.
- Selection of participants is equitable.
- Informed consent will be sought, as required.
- Informed consent will be appropriately documented.
- Adequate provision is made for monitoring the research to ensure participants' safety.
- Appropriate provisions are made to protect participants' privacy and confidentiality of the data.
- When vulnerable subjects are involved, appropriate additional safeguards are included to protect their rights and welfare.

Example of IRB approval:
Jones, Bond, Gardner, and Hernandez (2002) studied the family planning patterns of immigrant Hispanic women in relation to their acculturation to American culture. The researchers sought and obtained approval for the study from the IRB of both a university and a medical center.

Many research projects require a full IRB review. For a full review, the IRB convenes meetings at which most IRB members are present. An IRB must have five or more members, at least one of whom is not a researcher (e.g., a member of the clergy or a lawyer may be appropriate). One IRB member must be a person who is not affiliated with the institution and is not a family member of a person who is affiliated. To protect against potential biases, the IRB cannot comprise entirely men, women, or members from a single profession.

For certain kinds of research involving no more than minimal risk, the IRB can use expedited review procedures, which do not require a meeting. In an **expedited review**, a single IRB member (usually the IRB chairperson or a member designated by the chairperson) carries out the review. Examples of research activities that qualify for an expedited IRB review, if they are deemed to be minimal-risk, include (1) the collection of blood samples in amounts not exceeding 550 ml in an 8-week period, from healthy, nonpregnant adults weighing at least 110 pounds; and (2) research on individual or group characteristics or behavior or "research employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies" (*Federal Register* notice cited in Code of Federal Regulations, 1991, §46.110).

The federal regulations also allow certain types of research to be totally exempt from IRB review. These are studies in which there are no apparent risks to human participants. The website of the Office of Human Research Protections, in its policy guidance section, includes decision charts designed to clarify whether a study is exempt from the federal regulations.

TIP: Not all research is subject to federal guidelines, and so not all studies are reviewed by formal committees. Nevertheless, researchers must ensure that their research plans are ethically sound and are encouraged to seek outside advice on the ethical dimensions of a study before it gets underway. Advisers might include faculty members, the clergy, representatives from the group being asked to participate, or advocates for that group.

BUILDING ETHICS INTO THE DESIGN OF THE STUDY

Researchers need to give careful thought to ethical requirements during the planning of a research project and to ask themselves continually whether planned safeguards for protecting humans are sufficient. They must persist in being vigilant throughout the implementation of the research plans as well, because unforeseen ethical dilemmas may arise during the conduct of the study. Of course, a first step in doing ethical research is to scrutinize the research questions to determine whether they are clinically significant and whether it is feasible to undertake the study in a manner that conforms to ethical guidelines.

The remaining chapters of the book offer advice on how to design studies that yield high-quality evidence for practice. Methodologic decisions about rigor, however, must factor in ethical considerations. Here are some examples of the kinds of questions that might be posed in thinking about various aspects of study design:

Research design:	• Will participants get allocated to different treatment groups fairly? • Will research controls add to the risks participants will incur? • Will the setting for the study be selected to protect against participant discomfort?
Intervention:	• Is the intervention designed to maximize good and minimize harm? • Under what conditions might a treatment be withdrawn or altered?
Sample:	• Is the population defined so as to unwittingly and unnecessarily exclude important segments of people (e.g., women, minorities)? • Is the population defined in such a way that especially high-risk people (e.g., unstable patients) could be excused from the study? • Will potential participants be recruited into the study equitably?
Data collection:	• Will data be collected in such a way as to minimize respondent burden? • Will procedures for ensuring confidentiality of data be adequate? • Will data collection staff be appropriately trained to be sensitive and courteous?
Reporting:	• Will participants' identities be adequately protected?

TIP: As a means of enhancing both individual and institutional privacy, research reports frequently avoid giving explicit information about the locale of the study. For example, the report might say that data were collected in a

200-bed, private, for-profit nursing home, without mentioning its name or location.

Once the study procedures have been developed, researchers should undertake a self-evaluation of those procedures to determine if they meet ethical requirements. Box 26-15 in Chapter 26 provides some guidelines for such a self-evaluation.

RESEARCH EXAMPLES

Because researchers usually attempt to report research results as succinctly as possible, they rarely describe in much detail the efforts they have made to safeguard participants' rights. (The absence of any mention of such safeguards does not, of course, imply that no precautions were taken.) Researchers are especially likely to discuss their adherence to ethical guidelines for studies that involve more than minimal risk or when the people being studied are a vulnerable group. Two research examples that highlight ethical issues are presented in the following sections.

Research Example from a Quantitative Study

Willson, McFarlane, Lemmy, and Malecha (2001) conducted a study to evaluate whether abused women's use of the police reduced further violence. The study sought to describe the extent of violence and homicide danger experienced by women before and after filing assault charges against an intimate through the police department.

After obtaining approval for conducting the study from the agency (a special family violence unit in a large metropolitan police department) and the researchers' IRB, the researchers sought to interview a consecutive sample of women who met study criteria (18 years of age or older, English speaking) and who attempted to file assault charges during a 1-month period in 1998. Investigators approached prospective participants and explained the study purpose, research protocols, administration time, and follow-up schedules. Women were paid a $20 stipend for each completed interview. Both verbal and written consent was obtained from a sample of 90 women.

The researchers took care to protect the women's rights during data collection. Data were obtained confidentially in private interview rooms. The women were assigned an ID number to maintain confidentiality. The subjects' safety was ensured for follow-up interviews by establishing a convenient, private, and safe time for the 3- and 6-month follow-up interviews. A total of 83 women completed all three rounds of interviews.

The researchers found that women seeking police help had significantly reduced threats of abuse, actual experiences of abuse, and perceived danger of being killed than before.

Research Example From a Qualitative Study

Wackerbarth (1999) undertook an in-depth study designed to describe the dynamics of caretaker decision making. Wackerbarth's study focused on understanding the decision process among family caregivers of persons with dementia. A local chapter of the Alzheimer's Association mailed out 100 preinterview questionnaires with an introductory letter from the director of the chapter. Caregivers interested in participating in the study mailed back a completed consent form and the preinterview questionnaire. From the pool of 80 caregivers who returned the questionnaire, 28 were selected to be interviewed. The sample was carefully selected to represent a broad viewpoint for developing a decision-making model.

Wackerbarth's article carefully explained the attention that was paid to participants' rights in this study: (1) the study objectives and methods were described orally and in writing to ensure that they were understood; (2) an informed consent form, which highlighted the voluntary nature of participation and indicated the safeguards that would be taken to protect their confidentiality, was signed before data collection began; (3) all preinterview questionnaires, tape recordings, and interview transcripts were kept in a locked file cabinet; (4) no identifying information was appended to study materials; and (5) participants were asked to review written materials and to give permission before publication of quotes and study findings.

On the basis of the interviews, Wackerbarth developed a model charting the caregiving experience over time, and documented decisions made to maintain tolerable situations. The model captured the intrapersonal struggle driving the decision-making efforts of caregivers who care for family members with dementia.

SUMMARY POINTS

- Because research has not always been conducted ethically, and because of the genuine **ethical dilemmas** researchers often face in designing studies that are both ethical and methodologically rigorous, **codes of ethics** have been developed to guide researchers.
- The three major ethical principles incorporated into most guidelines are beneficence, respect for human dignity, and justice.
- **Beneficence** involves the protection of participants from physical and psychological harm, protection of participants from exploitation, and the performance of some good.
- In deciding to conduct a study, researchers must carefully weigh the **risk/benefit ratio** of participation to individuals and also the risks to participants against potential benefits to society.
- **Respect for human dignity** involves the participants' **right to self-determination**, which means participants have the freedom to control their own activities, including study participation.
- Respect for human dignity also encompasses the **right to full disclosure,** which means that researchers have fully described to prospective participants their rights and the full nature of the study. When full disclosure poses the risk of biased results, researchers sometimes use **covert data collection** or **concealment** (the collection of information without the participants' knowledge or consent) or **deception** (either withholding information from participants or providing false information). If deception or concealment is deemed necessary, extra precautions should be used to minimize risks and protect other rights.
- **Justice** includes the **right to fair treatment** (both in the selection of participants and during the course of the study) and the **right to privacy**. Privacy can be maintained through **anonymity** (wherein not even researchers know participants' identities) or through formal **confidentiality procedures** that safeguard the information participants provide.
- **Informed consent** procedures, which provide prospective participants with information needed to make a reasoned decision about participation, normally involve signing a **consent form** to document voluntary and informed participation. In qualitative studies, consent may need to be continually renegotiated with participants as the study evolves, through **process consent**.
- **Vulnerable subjects** require additional protection. These people may be vulnerable because they are not able to make a truly informed decision about study participation (e.g., children); because their circumstances make them believe free choice is constrained (e.g., prisoners); or because their circumstances heighten the risk of physical or psychological harm (e.g., pregnant women, the terminally ill).
- External review of the ethical aspects of a study by a human subjects committee or **Institutional Review Board (IRB)** is highly desirable and may be required by either the agency funding the research or the organization from which participants are recruited.
- In studies in which risks to participants are minimal, an **expedited review** (review by a single member of the IRB) may be substituted for a full board review; in cases in which there are no anticipated risks, the research may be exempted from review.
- Researchers are always advised, even in the absence of an IRB review, to consult with at least one external adviser whose perspective allows an objective evaluation of the ethics of a proposed study.
- Researchers need to give careful thought to ethical requirements throughout the study's planning and implementation and to ask themselves continually whether safeguards for protecting humans are sufficient.

STUDY ACTIVITIES

Chapter 7 of the *Study Guide to Accompany Nursing Research*: *Principles and Methods*, *7th edition*, offers various exercises and study suggestions for reinforcing concepts presented in this chapter. In addition, the following study questions can be addressed:

1. Point out the ethical dilemmas that might emerge in the following studies:
   a. A study of the relationship between sleeping patterns and acting-out behaviors in hospitalized psychiatric patients
   b. A study of the effects of a new drug treatment for diabetic patients
   c. An investigation of an individual's psychological state after an abortion
   d. An investigation of the contraceptive decisions of high school students at a school-based clinic
2. For each of the studies described in question 1, indicate whether you think the study would require a full IRB review or an expedited review, or whether it would be totally exempt from review.
3. For the study described in the research example section (Willson et al., 2001), prepare an informed consent form that includes required information, as described in the section on informed consent.

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