

look for descriptions of events and things (cross-sectional), may follow individuals into the future to describe events as they occur (prospective), or may describe what exists today (cross-sectional).

Ethical Issues in Nursing Research

For many nursing students, the first personal contact with research will be when they invite patients to participate in a study or when they help with data collection. With nursing studies dealing primarily with human participants, there is a concern for protecting individuals from any harmful effects that might result from participation in a study. As nurses engage in various research activities, it is important that the profession operate from a sound ethical knowledge base. For example, adequate protection of research subjects may cause a delay in the proposed schedule or a change in the research design. Regardless, maintaining the safety and human rights of human participants must be the priority at all times.

Developing Professional Guidelines

To help you, nursing has developed guidelines to ensure the protection of human participants while research is conducted. The basic documents that have been used to develop guidelines are based on the articles of

the Nuremberg Code (1947)⁷ and the Declaration of Helsinki (1964).⁸ The articles of the Nuremberg Code serve as a standard against which to measure the individual rights of subjects participating in experimental and clinical research.

Historical Events That Helped Shape Guidelines for Human Participant Protection

Before World War II, few guidelines were available to ensure the protection of human participants participating in research. Although Germany was the most scientifically and technologically advanced country during World War II, the Nazi Party exploited people's trust in the medical community and public health by performing unethical experiments on populations they discriminated against. For example, in one series of experiments, Air Force pilots were placed in vacuum chambers that could duplicate the low air pressure and anoxia (lack of oxygen) at altitudes over 65,000 feet. The German Air Force was interested in understanding if pilots could survive at extremely high altitudes, only to find that over 40 percent of the pilots died as a result of anoxia and ruptured lungs. The German Air Force was also involved in investigating survival times after pilots parachuted into cold water. Pilots were immersed for hours in tubs of ice water; others were fed nothing for days but saltwater. Still others were kept outside at subfreezing temperatures for hours. Finally, at several concentration camps, Polish women were shot and slashed on the legs. Wounds were stuffed with glass, dirt, and various bacteria cultures and sewn shut. The infected wounds were then treated with experimental anti-infective agents. In all instances, no attempts were made to relieve the tremendous suffering caused by these experiments. It was not uncommon for one out of every four individuals to die as a result of their involvement in the experiments.⁹

Nuremberg Code

As a result of the horrifying acts and unethical medical research experiments conducted by Nazi doctors in the name of science, the Nuremberg Trials took place. Several U.S. judges who presided over the final judgment in the Nuremberg Trials were instrumental in developing the Nuremberg Code. The code was developed in 1947 to address protection of human participants and basic principles of ethical behavior. Sections of the Nuremberg Code are presented in Table 2.1. Articles within the code emphasize adequate protection of subjects from risk or harm, the right to withdraw from experimentation, and adequate qualifications of those conducting research.⁷

Declaration of Helsinki

In 1964, the World Medical Association met in Finland and developed guidelines for physicians conducting research. In addition to reiterating

TABLE 2.1 Sections of the Nuremberg Code⁷

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results . . . and not random or unnecessary.
3. The experiment should be based on . . . [prior knowledge] and the anticipated results should justify the experiment.
4. The experiment should . . . avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur, except where the experimental physicians also serve as subjects.
6. The degree of risk should never exceed . . . the importance of the problem to be solved.
7. Proper preparations should be made and adequate facilities provided to protect subjects against possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons.
9. During the course of treatment, the human subject should be able to bring the experiment to an end.
10. During the course of treatment the scientist must be prepared to terminate the experiment if he or she has probable cause . . . that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

aspects of the Nuremberg Code, the Declaration of Helsinki outlined two categories of research: research that has a therapeutic value for subjects and research that does not have direct therapeutic value for subjects.

The essence of the Declaration was the need for subjects to be informed of the benefits of the study before consenting to participate in the research. Subjects also were to be informed when their participation could be harmful or of little value to them.⁸ The Declaration also allowed legal guardians to grant permission to enroll subjects in research and recommended written consent be given.

Even after the Nuremberg Code was established and informed consent laws were rewritten, protection of human participant rights was far from guaranteed. The Centers for Disease Control and Prevention conducted studies in the rural South to determine the prevalence of syphilis among blacks while exploring the possibilities of treatment. Tuskegee, a town in Macon County, Alabama, was found to have the highest incidence of syphilis among six counties.

The Tuskegee Syphilis Study

In 1932, the U.S. Public Health Service (USPHS) began an experiment in Tuskegee, Alabama. The study included 400 black sharecroppers

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diagnosed with syphilis and 200 black men who did not have syphilis. The study, known as the Tuskegee Syphilis Study, began in 1932 and ended in 1972. The study design called for the selection of black men with syphilis who were between 25 and 60 years of age. Subjects were randomly assigned into two groups, 400 men with untreated syphilis and 200 men without syphilis. As the study began, difficulties arose in recruiting subjects. Consequently, the men were told they were ill and would be offered free treatment. The USPHS did not inform subjects that they were part of a research study on syphilis. Instead, they were told they were being treated for "bad blood."

In 1933, the USPHS decided to continue with the study and treat subjects with mercurial ointment, a noneffective drug. This occurred in the face of findings in every textbook that clearly advocated treating patients who had syphilis, even in the disease's latent stages. By 1936, first reports were out that men with syphilis developed more complications than did the control group. By 1946, the death rate for men with untreated syphilis was twice as high as for the control group. In 1955, it was likewise reported that more than 30 percent of those autopsied had died directly from advanced syphilitic lesions of the cardiovascular or central nervous system.^{10,11} After the study ended, those men who had syphilis, along with their wives and children who had contracted the disease, were given free antibiotics and lifetime medical care. However, the damage to their health, as well as their trust in the medical research community, was beyond repair. In a formal White House ceremony in 1997, President Clinton apologized to subjects and their families who participated in the Tuskegee Study and called for a renewed emphasis on research ethics.

The Willowbrook Study

The Willowbrook State School on Staten Island, New York, was the focus of unethical research from the 1950s to 1970. The purpose of the Willowbrook Study was to determine the period of infectivity of infectious hepatitis. Subjects were mentally handicapped children who were given either intramuscular or oral doses of hepatitis B virus. If parents wished to admit their child to the school, they were required to sign their child on as a study participant. Parents gave consent for the administration of the hepatitis B virus, but they were not told of the serious consequences, such as flu-like symptoms, skin rashes, and liver damage. During the 20-year investigation, Willowbrook closed its doors to new admissions because of overcrowding, yet the research ward continued to admit new residents. Administrators at Willowbrook believed they were conducting ethical research in a category called "natural experiments." The question whether the Willowbrook experiment was an ethical "study in nature" has been debated for years. The belief was that if there was no cure or treatment for a particular disease, then observing its course with the informed consent of participants is a study of nature.¹¹

The Crisis at Johns Hopkins University

In April 2001, a 24-year-old healthy volunteer and technician at Johns Hopkins Asthma and Allergy Center consented to participate in a study. The purpose of the study was to gain a better understanding of the pathophysiology of asthma, specifically the mechanism of airway hyperresponsiveness. The study was based on the hypothesis that in normal individuals, lung inflation protects the airways from obstruction through a neural mechanism that might be lacking or impaired in people with asthma.¹²

The protocol involved healthy subjects inhaling a ganglionic blocker, hexamethonium. If ganglionic blockage suppressed the protective effects of deep inspiration on the airways, it would suggest that neural mechanisms helped the airways stay open. Hexamethonium was chosen because it blocks neurotransmission. The drug had been used to treat hypertension, but it was removed from the U.S. market in 1972 after the Food and Drug Administration (FDA) found it was ineffective.¹²

In the consent form, hexamethonium was described as "a medication that has been used during surgery, as part of anesthesia; that is capable of stopping some nerves in your airways from functioning for a short period." The section on risks stated that hexamethonium "may reduce your blood pressure and make you feel dizzy, especially when you stand up." The consent document was later criticized as having "failed to indicate that inhaled hexamethonium was experimental and not approved by the FDA" and because it was referred to as "medication."¹²

The 24-year-old volunteer was the third subject to receive hexamethonium. Mild shortness of breath and cough developed in the first subject, resolving over a period of about 8 days. The second subject received hexamethonium while the first subject still had symptoms. The 24-year-old volunteer inhaled 1 gm of hexamethonium on May 4, 2001, and developed a cough. On May 9, the volunteer was hospitalized with fever, hypoxemia, and abnormalities on a chest x-ray. By May 12, progressive dyspnea had developed, and the volunteer was transferred to the intensive care unit. On June 2, the volunteer died as a result of progressive hypotension and multiorgan failure.¹²

The crisis at Johns Hopkins University led to several reviews of clinical research. These reviews were conducted by internal and external review committees convened by the university, the FDA, and the U.S. Office for Human Research Protections. After the death of the volunteer, Johns Hopkins temporarily suspended all studies involving healthy volunteers.

Other Scandals Regarding Unethical Research Studies

Beecher,¹³ a well-known Harvard anesthesiologist, describes a series of unethical research studies conducted at major medical institutions across the country. The article makes it clear how widespread the problems really were. All of these studies reinforce the important need for

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institutional review boards (IRBs) to review studies conscientiously and for researchers to act ethically. Rothman¹⁴ cautions researchers not to take advantage of subjects in particular social predicaments because they will become accomplices to the problem, not observers of it. As laid out here, the reader should be struck by the very recent examples of experiments gone terribly wrong, as well as the horrifying examples from Nazi Germany.

Developing Guidelines for Clinical Nursing Research

The articles of the Nuremberg Code and Declaration of Helsinki are prototypes for the development of guidelines for conducting research in nursing. The American Nurses Association (ANA) and American Association of Colleges of Nursing (AACN) have developed two documents that provide such direction. In a position statement from the ANA titled *Education for Participation in Nursing Research* and a position statement from AACN titled *Nursing Research*,^{15,16} general research competencies expected of graduates from associate, baccalaureate, and graduate degree programs in nursing are outlined (see Chapter 1). In *Human Rights Guidelines for Nurses in Clinical and Other Research*,¹⁷ the principles in the Nuremberg Code are emphasized and directed toward voluntary participation of subjects, protection of human participants, and informed consent. This document focuses on the rights of participants who are involved in research, along with ethical issues within clinical nursing research settings. A summary of this document is presented in Table 2.2. Adhering to these guidelines reduces the chance of violating the rights of subjects. Key points addressed in the document are summarized in Figure 2.2.

Protecting Human Rights

The guidelines presented in Table 2.2 provide nurses with principles intended to safeguard human rights. The researcher must consider these guidelines at every stage of the research process, from selecting and defining the problem, to selecting a research design and collecting data, to interpreting and publishing the results. **Human rights** involves the protection of human participants participating in research; the term refers to the following three rights outlined in the ANA guidelines:¹¹

1. Right to freedom from injury
2. Right to privacy and dignity
3. Right to anonymity and confidentiality

Right to Freedom From Injury

A basic responsibility of all researchers is to protect participants from harm while they are participating in a study. Participants have the right not to incur physical or emotional injury as a result of participating. If there is a possibility that any injury could occur, subjects need to know

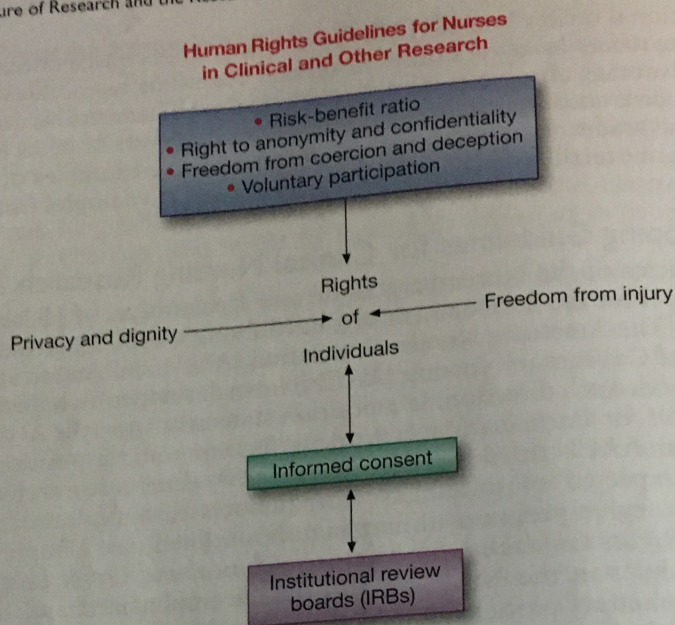


Fig 2•2 American Nurses' Association guidelines for protecting human rights.

TABLE 2.2 Summary of Guidelines for Protecting the Rights of Human Subjects

1. If research participation (medical, nursing, or other) is a condition of employment, nurses must be informed in writing of the nature of activity involved in advance of employment, and if this is not done, nurses must be given the opportunity to not participate in research. Potential risks to others must be clarified in advance of research as must ways to identify risks and counteract potential harm.
2. *Freedom from risk of injury or harm.* Researchers must estimate risk and benefit involved, and subjects must be informed of any potential mental or physical risk as well as personal benefit. Participants must be informed of procedures or activities that extend beyond personal need. Nurses must carefully monitor sources of potential risk of injury and protect subjects who are particularly vulnerable as a result of illness or members of captive groups (e.g., prisoners, students, institutionalized patients, and the poor).
Right to privacy and dignity. All proposals, instruments, and procedures involved in the research activity must be discussed with prospective subjects and others participating in the project so that they may make an informed decision about whether to participate.

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TABLE 2.2 Summary of Guidelines for Protecting the Rights of Human Subjects—cont'd

- Right to anonymity.* The researcher must describe to prospective subjects the methods that protect the identity of subjects and the information that will be obtained under privileged conditions.
3. Guidelines for protecting human rights apply to all individuals involved in a research activity. The use of subjects with limited civil freedom can usually only be justified when there is a predicted benefit to them or others in similar circumstances.
 4. Nurses have an obligation to protect human rights and a professional responsibility to support research that broadens the scientific knowledge base of nursing for the practice and delivery of service.
 5. Voluntary informed consent to participate in research must be obtained from all prospective subjects or their legal representatives.
 6. Nurses have an obligation to serve on institutional review boards to review the ethical implications of proposed and ongoing research. All studies that involve gathering data from humans, animals, or charts should be reviewed by health-care professionals and community representatives.

Source: Adapted from American Nurses' Association: Human Rights Guidelines for Nurses in Clinical and Other Research. American Nurses' Association, Kansas City, MO, 1985, used with permission.

an estimate of the extent of such injury before giving their consent. Providing participants with an estimate of the potential risks in relation to the potential benefits is called the **risk-benefit ratio**. Two factors emerge when attempting to ensure the right to freedom from injury:

1. Ability of the benefit to justify participants' exposure to involved risks
2. The participants' vulnerability

The risks to participants must be justified by the potential benefit to the individual (in the case of clinical research) or to society (in the case of knowledge produced). In short, *the benefits should exceed the risks*. Even then, however, a cancer patient's risks of increased side effects from multiple chemotherapeutic agents may not always be justified by advancing society's knowledge of cancer treatment.

The risk-benefit ratio remains a primary objective standard by which we can judge the ethics of certain research procedures. Calculating this ratio involves naming and weighing the benefits, as well as considering the following:

1. How important is the research?
2. How serious are the risks to human participants involved in the research?

In any case, if potential for harm exists, whether physiological or psychological, the researcher must explain how the risks will be minimized. Participants must be fully aware of the risks along with benefits associated with the study.⁹

Vulnerable Research Participants Needing Protection

Federal regulations impose additional requirements upon institutional review boards when protecting the welfare of particularly vulnerable subjects. **Vulnerable research participants** are those persons who are relatively or absolutely incapable of protecting their own interests and unable to provide meaningful informed consent. The ability to provide informed consent means a person has the mental capacity to understand the information provided, to appreciate how it is relevant to their particular circumstance, and to make a reasonable decision about participation in the study.

The Office for Human Research Protections (OHRP) is the agency responsible for setting policies and regulations regarding the protection of the rights, welfare, and well-being of subjects participating in research. A list of vulnerable research subjects needing protection is provided in Table 2.3. In general, special regulations allow IRBs to approve research that is of minimal risk or that will benefit subjects directly. In addition, research involving persons whose mental capacity to consent is questionable requires careful consideration to ensure that each person is provided additional safeguards for his or her safety and welfare. Refer to the OHRP Web site (www.hhs.gov/ohrp) for specific policies and regulations supporting research involving vulnerable subjects.

Right to Privacy and Dignity

The type of data collected may be highly sensitive in regard to the subjects' privacy and dignity. Many questionnaires or surveys require

TABLE 2.3 Vulnerable Research Subjects

Children
Cognitively impaired
Elderly
Human fetuses
Mentally incapacitated
Neonates
Prisoners
Sedated or unconscious (comatose) patients
Students and employees
Terminally ill patients

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subjects to provide data such as income, marital status, personal activities, opinions and beliefs, and attitudes. In addition, the use of cameras, one-way mirrors, tape recorders, diaries, and patient records may easily be construed as an invasion of privacy. Participant observation is frequently used as a method to collect data in qualitative research studies. Such an approach may not be clearly understood by subjects. In all instances, the researcher is obligated to make sure that subjects clearly understand all procedures, the type of data being collected, and the data collection methods, so that they can make an informed decision about participating in a study.

Right to Anonymity and Confidentiality

Closely related to protecting privacy and dignity is the right of subjects to remain anonymous and to be assured of confidentiality. The researcher must plan carefully to consider handling, storage, and reporting of data. **Anonymity** refers to keeping participants nameless⁹ and limiting access to information that is gathered about subjects. Anonymity can be facilitated by using code numbers for subjects' identity to prevent others from linking reported information with them. A master code list should be kept locked up, with access to the data limited to those who are intimately involved in the research. In anonymity, even the researcher cannot link the data to the subject.

Confidentiality refers to protecting data by not divulging information that is gathered or learned in caring for a patient without that individual's permission to do so.^{9,15} This right is extremely important when the information may carry a stigma, such as a diagnosis of HIV or AIDS, evidence of domestic violence, or a prison record.

Ensuring the Protection of Human Rights

Several procedures can be used to ensure protection of human rights, such as procedures for obtaining informed consent and review of study protocols by an ethics committee, often referred to as an institutional review board.

Key Elements of Informed Consent

A basic responsibility of researchers is to ensure that potential subjects understand the implications of participating in a research study and recognize that they have the freedom to decide whether they want to participate. The idea that individuals have the right to decide for themselves is referred to as the principle of self-determination, which is central to the process of informed consent.

Key elements of informed consent are (1) providing potential subjects with sufficient information about participating in a research study and (2) assuring them that participation is voluntary and can be withdrawn at any time without negative consequences. The language is kept

simple to make sure that all subjects understand the meaning of informed consent.

Participants give informed consent before participating in a study by signing a written consent form, which is also signed and dated by the researcher and a witness. The researcher discusses the proposed research study with subjects to provide feedback in response to their questions, concerns, or both. Consent forms should be divided into sections with headings. Medical jargon should be avoided for purposes of clarity and readability; sentences should be short, margins should be reasonably wide, and the pages should not be overcrowded with too much text. An example of a consent form is shown in Figure 2.3. The following information should be conveyed to potential subjects:

1. Title of the study
2. Personnel engaged in the study (e.g., principal investigator, coinvestigator(s), research assistants)
3. Invitation to participate in the study (e.g., "You are invited to participate in a research study"; not "requested," "chosen," or "eligible")
4. Reason the particular person is being invited to participate
5. Clear description of the purpose of the study
6. Detailed description of procedures of the study (e.g., descriptions of what will actually occur; how much time is required of the subject; whether hospitalization will be required and whether it will always, sometimes, or never be required as part of the subject's standard care; how much and how often blood will be drawn, if applicable)
7. Potential risks to subjects, including psychological, social, and physical risks (e.g., explanation of steps that will be taken to protect against risks; estimation of likelihood of occurrence, severity, and duration of potential risks, if applicable)
8. Potential benefits of the study (e.g., identification of desired benefit to society, the risk-benefit ratio, statement of whether there are direct subject benefits)
9. Economic considerations (e.g., whether subjects will incur any additional expenses as a result of participation)
10. Confidentiality considerations (e.g., explanation of steps that will be taken to ensure the confidentiality of information that is obtained during the course of the study, such as who will have access to the data and when the data and specimens will be destroyed)
11. Freedom of subjects to ask questions and withdraw from the study at any time without penalty

Some research subjects may be unwilling or unable to sign a consent form. For example, the elderly may be wary of signing forms, and other

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**University of Massachusetts Medical Center
Committee for the Protection of Human Subjects in Research
Consent to Participate in a Research Project**

Title: Patient Empowerment Program for People with Diabetes
Principle Investigator: James A. Fain, PhD, RN, BC-ADM, FAAN

Research Subject's Name _____ Date: _____

PURPOSE

You are invited to volunteer for a research study. You have been chosen to take part in this study because you have diabetes. The main objective is to see if a program that helps develop skills and self-awareness in the areas of goal setting, problem solving, stress management, coping, and motivation would be beneficial to patients with diabetes. The purpose of this study is to try to find an effective way to prepare patients with diabetes to make decisions.

It is important for you to know that your participation is entirely voluntary. You may decide not to take part in or quit the study at any time, without any penalty. You will be told about any new information or changes in the study that might affect your participation.

To take part in this study you must agree to participate in an outpatient educational program. The program will take place weekly for 2 hours and last a total of six (6) weeks. Each session will involve a brief presentation of key concepts related to the topic; completion of self-assessment worksheets; and small group discussions. You will be encouraged to bring a spouse, family member, or friend to each session.

PROCEDURES

If you agree to participate in this study, you will be invited to an orientation session where a discussion about the program along with sample worksheets will be presented. You will be asked to complete several questionnaires along with giving us permission to access your medical records to obtain the most recent glycosylated hemoglobin level which was performed as a routine procedure during your treatment at the diabetes clinic. In addition, at the end of 6 weeks, you will be asked to complete the questionnaires a second time along with giving us permission to access once again your glycosylated hemoglobin levels. Questions throughout the program will focus on exploring life satisfactions, coping with diabetes, addressing daily stresses, and setting priorities.

Not everyone in the study will initially participate in the program. You will either be assigned to attend the program (experimental group) or not attend (comparison group). At the conclusion of the program, all those individuals who did not attend the program will be asked to complete the questionnaires a second time. After that time, the program will be provided for all those individuals who did not initially participate in the program.

RISKS

We can foresee few risks that might occur if you decide to participate in this study. A minor risk is the possibility that certain questions regarding anxiety, stress, and feelings toward diabetes may arouse psychologically distressing emotions. If this is the case, you will be able to speak to a member of the research team or staff within the clinic.

BENEFITS

There is no promise or guarantee of any medical benefits to you resulting from your participation in this study. However, you might have a better insight into your own values, goals, and needs as they relate to living with diabetes. In addition, your participation may help others with diabetes in the future as a result of knowledge gained from this research.

ALTERNATIVES

Your standard treatment will be the same whether or not you decide to be in the study. However, the educational program is not presently available for study.

COSTS

There will be no additional cost to you from being in this research study. Patients will not be charged for any materials used in this research study.

CONFIDENTIALITY

Your research records will be confidential. In all records of the study you will be identified by a code number and your name will be known only to the researchers. Your name will not be

Fig 2•3 Example of an adult consent form.

(Continued)

**University of Massachusetts Medical Center
Committee for the Protection of Human Subjects in Research
Consent to Participate in a Research Project (continued)**

used in any reports or publications of this study. Once again, your participation in this study is entirely voluntary. You may withdraw from the study at any time.
Please feel free to ask any questions you may have about the study or about your rights as a research subject. If other questions occur to you later, you may contact James A. Fain, PhD, RN, BC-ADM, FAAN, the Principle Investigator, at (508) 856-5661. If at any time during or after the study, you would like to discuss the study or your research rights with someone who is not associated with the study, you may contact the Administrative Coordinator for the Committee for the Protection of Human Subjects in Research at UMMC, (508) 856-4261. Consent to Participate in the Research Project, H-2895 entitled "Patient Empowerment Program for People with Diabetes."

Subject's Name _____

P.I. Name _____

The purpose and procedures of this research project have been explained to me and I understand them. I have been told about all the predictable discomfort, risks, and benefits that might result, and I understand them. I agree to participate as a subject in this research project. I understand that I may end my participation at any time.

Subject's Signature Date: _____

NAME: (print) _____

Relationship to Subject: _____

Witness Signature: _____

Date: _____

NAME: (print) _____

Fig 2•3—cont'd

individuals may have certain physical handicaps preventing them from being able to sign. The researcher needs to decide the best way possible to document permission. In some cases, an audiotaped or videotaped recording may be used to present information and obtain verbal consent. In the case of children, a parent or legal guardian must sign the consent form. Children (individuals under 18 years of age) are not considered legally competent to provide informed consent. When children are involved in a study, the researcher should obtain informed consent of the parent or legal guardian as well as assent of the child. Assent of a child refers to a child's affirmative agreement to participate in a research study. Failure of the child to object, however, cannot be construed as assent. An example of a child's assent form is shown in Figure 2.4.

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**University of Massachusetts Medical Center
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Consent to Participate in a Research Project entitled:**

**Multidimensional Sense of Humor in School-Aged Children:
A Pilot Study**

Child's Name (print)

Date

Parent/Guardian Consent: The purpose and procedures of this research project, the predictable risks, and the benefits that my child may experience have been explained to me. Alternatives to my child's participation in this study have also been discussed. I have read and understand this consent form. I voluntarily consent to my child's participation in this study. I understand that my child and I may end our participation at any time.

Parent/Legal Guardian Signature

Date

Parent/Legal Guardian Signature (print)

Date

Child Assent: My parent/legal guardian has explained this study to me. We have Dr. Fain's telephone number and can call Dr. Fain at any time if we have any further questions. I have decided to do this study even though I know I do not have to.

Child's Signature

Fig 2•4 Examples of child's assent form.

Institutional Review Boards

In addition to ensuring that subjects give voluntary informed consent to participate in a study, most institutions and funding agencies have a mechanism for reviewing research proposals. As mentioned earlier, IRBs are review groups responsible for ensuring that researchers do

not engage in unethical behavior or conduct poorly designed research studies.

The major responsibility of an IRB is to review research proposals at convened meetings to ensure that federal guidelines are followed. Proposals submitted to IRBs are reviewed in detail. The IRB ensures that the researcher is not violating rights of human participants. Lawyers, lay persons, and clergy often serve on IRBs to deal with nonscientific issues. Feasibility of conducting a study, however, is outside the realm of the IRB. The IRB also reviews the procedures for selecting subjects, ensuring voluntary informed consent, clearly written descriptions, and confidentiality. The decision to approve, modify, or disapprove a proposal must be made by a majority of IRB members.

Some categories of research may qualify for an expedited review, such as when the use of noninvasive procedures is routine or if a study consists of surveys, interviews, or studies of existing records, provided that the data are collected in such a way that subjects cannot be identified and the study does not deal with sensitive issues. In the case of an expedited review, the chairperson and at least one other member of the IRB review the proposal. The advantage of an expedited review is that it is usually completed in less time than that required for a full IRB review.

Evaluating Evidence for the Protection of Human Rights

Most research reports provide only a sentence or two concerning review by an appropriate committee. Excerpt 2.5 displays an example of what is usually written in research reports regarding protection of human rights. Without a detailed explanation of data collection procedures, a number of issues can be raised as to the ethical acceptability of a given study. The information presented in Table 2.4 can help the researcher evaluate the protection of human rights in research reports. Nurses at all levels typically find themselves involved in carrying out research activities. As patient advocates, nurses must make an effort to verify the nature of a study and whether the study has been reviewed by an IRB. When human rights are violated, the nurse must report the concern to both the researcher and the IRB. Similarly, the nurse should not assume that the rights of subjects have been adequately addressed unless the exact nature of protection has been specified. It is incorrect to assume that the rights of subjects and the process of informed consent have been handled adequately unless the procedures are clearly articulated.

Training Program: Protecting Human Research Participants

The National Institutes of Health (NIH) require that all individuals receiving a NIH award must successfully complete an educational program reviewing issues (e.g., key historical events, ethical principles, informed consent, role of institutional review boards) that impact guidelines on human participant protection in research.

Understand

TABLE 2.4

Criteria for Evaluation

1. Is the research significant or important? Is the design sound?
2. Is the research likely to maximize benefits to subjects and society?
3. Is the selection of subjects ethically appropriate for the research?
4. Is there evidence of informed consent?
5. Is there evidence of deception?
6. Have subjects given informed consent when appropriate?
7. Is informed consent a legal guarantee of a subject's rights or her or his or her own?
8. Is there evidence of a report by the subjects?
9. Is there evidence of independent review by a board or committee?