INTRODUCTION

The American Nurses' Association in establishing a Commission on Nursing Research publicly reaffirmed the nursing profession's obligation to support the advancement of scientific knowledge toward the achievement of improved nursing practice and better patient care. In taking this step the organization accepted a commitment to support two sets of human rights. One set is concerned with the rights of qualified nurses (those with research preparation to engage in research and to have access to resources necessary for implementing scientific investigations. The other deals with the human rights of all persons who are recipients of health care services or are participants in research performed by investigators whose studies impinge on the patient care provided by nurses. The need for the establishment of human rights guidelines for nurses came as a result of social and technical changes that altered nursing and nursing practice.

In the twentieth century, nurses engage in a variety of activities that impinge upon the rights of other human beings. Some nurses participate as investigators in organized research utilizing animals or human beings as subjects of study. Other nurses are employed in work settings in which clinical medical activities and technical procedures have moved into the domain of the unusual or extraordinary. Probably the majority of nurses continue to perform activities that are usual and expected according to the norms of accepted practice, but increasingly the borderline between usual and expected and "experimental” clinical practices is becoming blurred. As the scope of nursing practice has increased in complexity, nursing as a profession has had an increased concern with the human rights of all persons who are recipients of nursing services or are participants in clinical research.

The relationship of trust between patient and nurse has always been an essential element of the professional code of ethics. In research, the relationship of trust between subject and investigator requires that the investigator assumes special obligations to safeguard the subject in several ways. The subject needs to be assured that his rights will not be violated without his voluntary and informed consent. Secondly, the investigator guarantees that no risk, discomfort, invasion of privacy, or threat to personal dignity beyond that initially stated in describing the subject's role in the study will be imposed without further permission being obtained. Finally, the subject is assured that if he does not wish to participate in the study, he will neither be subjected to harrassment nor will the quality of his care be influenced by this decision.

The members of the ANA Commission on Nursing Research believe that each individual has the right of self-determination concerning what will be done to his person. The members also believe that each practitioner of nursing has an obligation to endorse and support self-determination as a moral and legal right of the individual. The responsibilities attendant to safeguarding the rights of other people must be freely
accepted by nurses whether their roles be practitioners, educators, or researchers.

Changing Scope of Responsibility

The scope of nurses' responsibilities in relation to human rights issues has gradually extended in response to continued professional dialogue, public debate, and legal testing of individual cases. Some substantive areas such as death and dying, population control, genetic engineering, and manipulation of behavior are emerging already as significant social issues and problems in nursing practice. Consequent ramifications regarding "informed consent" by the individual involve both practitioners and researchers when invasion of privacy, dehumanization, and risk are potentially present. Furthermore, health as a national resource or public good involves new social and scientific dimensions when decisions regarding the use of scarce resources such as hemodialysis and transplants must be made.

The ethical standards and guidelines established at any given time by the nursing profession need to be sufficiently flexible to be applicable to new issues as they emerge under the influence of science or technology. Clear standards and flexible guidelines are essential if science and social values are to change and develop together in relative harmony rather than in conflict. To be effective such guidelines must also clearly delineate and specify the circumstances under which they apply. The guidelines that follow attempt to specify several important entities: the type of activities that are involved; the rights that are to be protected; the persons to be safeguarded; and mechanisms necessary to ensure that protection is adequate.

ETHICAL GUIDELINES

Nursing Activities and Ethical Issues

The need for protection of human rights potentially involves all activities that go beyond the established and accepted practices of the professional group involved. In health care practice, the need for protection of human rights is of singular importance for any and all activities when the focus is not specifically directed toward meeting the needs of the individual patient or subject. The development and refinement of scientific knowledge in nursing will increasingly involve nurses in clinical investigations with an emphasis on furthering knowledge rather than specifically on meeting patients' needs. Other nurses in their roles as practitioners in hospitals and other institutional settings can find themselves engaged in clinical research developed and implemented by practitioners in other fields. In both cases, ethical concerns about the potential violations of human rights become crucial whenever new and untried techniques and procedures are to be used and
when the probable outcomes are unknown or doubtful.

Whenever nurses perform activities that are components of clinical research (whether directed by physicians, nurses, or other investigators), the need for protection of human rights must extend to the practitioners who are expected to participate in new and untried practices as well as to the subjects who are recipients of them. The concept of informed consent applies not only to subjects per se but also to any workers who are expected as part of their daily work to implement activities that potentially or actually carry risk for others or have uncertain outcomes.

Implementation of this guideline implies the need for written statements about conditions of employment and any special expectations about work performance above and beyond that usually expected of a person occupying the position of nurse. In advance of such employment, nurses need to know if they will be expected to provide medicines, treatments, and other procedures as part of double blind investigations. They need to know in advance if the work requires them to function as data-collectors for research in addition to their roles as nurses engaged in the delivery of patient care services. Conditions of employment must also provide for the option of not participating in clinical research if these work expectations are not spelled out in advance of employment.

Stated in a more general way, conditions of employment in settings in which clinical and/or other research is in progress need to be spelled out in detail for all potential workers. As a corollary, it follows that anyone employed in work that carries the potential risk to others needs to be advised as to the types of risks involved, the ways of recognizing when risk is present, and the proper actions to take to counteract harmful effects and unnecessary danger.

Human Rights

Right to Freedom from Intrinsic Risk of Injury

In situations in which the nature of the activities or research design exposes an individual to increased possibility of emotional, social, or physical injury, the degree of risk needs to be estimated and specified by the principal investigator or his designate. It is incumbent upon all practitioners to recognize that risk is potentially present in all situations when novel and untried procedures are involved and there is little if any data upon which to predict outcomes. The primary problem faced by the investigator or practitioner is prediction of the extent of risk to the individual in comparison to the potential clinical benefit to him and/or the humanitarian importance of the knowledge to be gained.

In all instances, the prospective subject must be given all relevant information prior to participation in activities that go beyond established and accepted procedures necessary to meet his personal needs. By virtue of their calling, practitioners in the health professions seek to protect individuals under their care from arbitrary physical or mental suffering. Nurses must be increasingly vigilant in their concern for subjects and patients who by reason of their situation and/or illness are not able to protect themselves effectively from externally imposed threat or injury. They must also be sensitive to the tendency toward exploitation of
"captive" populations such as students, patients in institutions, and prisoners.

Right of Privacy and Dignity

Human beings vary in their values and judgments about what is considered invasion of privacy and a threat to dignity through demeaning or dehumanizing conditions. The investigator cannot presume to decide for the other person on this matter of privacy and dignity. Consequently all proposals, investigative instruments, protocols, and techniques to be used in the particular activities need to be specified and discussed with the prospective subject and with any workers who are expected to participate in the activity as subjects, as data-collectors, or as both.

Consideration must be given to the development of safeguards such that no unanticipated physical, psychological, or social disadvantage accrues to subjects either during the study or as a result of dissemination of the findings. If the subject agrees voluntarily to share certain specific information about himself which he may or may not choose to divulge to others in a different context, then the investigator must provide assurance that the subject's anonymity will be protected. Specific prior consent must be obtained whenever the plan of a study or a report of findings sacrifices subject anonymity or confidentiality.

Special mechanisms for safeguarding the confidentiality of information must be developed whenever the information will not always remain under the control of the investigator. Potentially demeaning or dehumanizing conditions merit special consideration from both practitioners and investigators inasmuch as they are in many instances difficult to specify and to protect against. Health care practitioners need to be aware that violations involving human dignity have many potential long range repercussions when significant values of the individual are involved.

Subjects

The persons for whom human rights guidelines apply include all individuals involved in the activities described before. When activities are supported either directly or indirectly by government and other funding resources, the persons to whom these guidelines apply include the following groups: patients; outpatients; donors of organs, tissues, and services; informants; normal volunteers including students; and volunteers in groups with limited civil freedom. The latter classification refers to prisoners, residents or clients in institutions for the mentally ill and mentally retarded, and persons subject to military discipline, all of whom tend easily to fall into the class of captive audience and population vulnerable to exploitation.

The choice of minors and groups with limited civil freedom as research subjects can be justified, in most instances, only if there are benefits that will accrue in the future to them or to others in similar situations or classes. Strict standards governing the use of minors and other groups (including the unborn and the dead) lacking the capacity to give informed consent are being established with increasing frequency by various government statutes and regulations.
Society's Obligation and the Public Good

In a democratic society the rights of the individuals are of necessity counterbalanced by actions and activities designed for the common good of collective man. Established public health practices such as the immunization of children against diphtheria and pertussis and the chlorination of public water supplies to prevent epidemics of water-borne disease are examples of societal actions in which personal rights gave way to collective rights for the benefit of society as a whole. These and many other public health practices came into being as a result of research seeking ways to treat and control disease.

Advancement of knowledge about health and health-promoting practices is also of value to society as a whole. So too is knowledge about patient responses and adaptations to illness and the effects of different nursing interventions on these responses and adaptations. Just as nurses have an obligation to protect the human rights of patients, so do they also have an obligation to support the accrual of knowledge that broadens the scientific underpinnings of nursing practice and the delivery of nursing services. Professional responsibility includes a recognition that research by qualified nurses is a resource in need of support and encouragement.

MECHANISMS FOR PROTECTION OF RIGHTS

Assurance--Informed Consent

To safeguard the basic human rights of self-determination, consent to participate in research or unusual clinical activities must be obtained from the prospective subject or his legal representative. Free and informed consent is expected to incorporate the following entities: an explanation of the study, the procedures to be followed, and their purposes; a description of physical risk or discomfort, any invasion of privacy, and any threat to dignity; and the methods used to protect anonymity and to insure confidentiality. The subject needs also to receive a description of any benefits to the subject and/or to the development of new knowledge that potentially might be expected. In instances in which control groups are utilized and therapeutic measures, such as drugs, withheld, appropriate alternative procedures that might be advantageous for the subject need to be discussed with him.

In addition to making available explicit information, an offer to discuss or answer additional questions must be made. The investigator also must inform the subject that he is free to discontinue participation in the activity at any time that he wishes to do so. If subjects are patients of other practitioners, the investigator has an obligation to discuss the proposed study with that individual prior to its inception and
to negotiate support for its successful completion.

Subsequent to having all of the above information, the person's consent must be voluntarily given without overt or covert coercion being used and without deception being practiced upon the subject. Should the research design require some degree of concealment of the true purpose of methodology of the study, the design must also provide for subsequent disclosure of the nature of the concealment and the rationale for incorporating secrecy as part of the procedure.

On some occasions, a research design involves procedures or possible outcomes that may impinge upon the rights of someone related to the subject, such as a spouse or parent. In such cases the informed consent of that individual must also be obtained.

The informed consent of parents or legal guardians must be obtained for investigations that involve minors or individuals judged to be legally incompetent to handle their own affairs. In instances in which these subjects have the capacity to comprehend the implications of the proposed activity, they should also be asked to give their consent. In this case, consent supplements rather than supplants that of the parent or other legal agent.

As part of any study protocol, documentation of the procedures to be followed in obtaining informed consent is expected. If written consent is not to be obtained, justification of the omission must be provided. Since the investigator carries the major responsibility for insuring that the rights of the subject are protected, he must throughout the course of the investigation and thereafter scrupulously adhere to the mutual agreement (whether oral or written) contracted with each subject.

Assurance--Institutions and Agencies

There is increasing public support for systematic accountability to insure that unintentional professional and/or investigator bias does not overtly or covertly deny individuals their rights. In almost all circumstances, either the professional nurse or the prospective subject is under the aegis of an institution or agency, and the institution is responsible for establishing and maintaining procedures to safeguard human rights. In most instances, the protective mechanism takes place through a committee judged competent to review projects and other activities that involve human subjects. Membership on the review committee should be representative of all occupational groups (including practicing nurses) whose members are likely to be involved either directly or indirectly in the implementation of the activities or projects undertaken.

In most institutions, the committee is responsible for an initial and continuing review and approval of each activity deemed necessary for review. The review is designed to determine and assure that subject rights have been protected, that the procedures proposed for obtaining informed consent are adequate, that appropriate records are maintained regarding the selection, participation, and protection of subjects, and that circumstances they may or do adversely affect the rights or the welfare of individual subjects are reviewed and acted upon appropriately. In addition, when projects are supported by government funds, the institution must also provide for appropriate professional attention in case the subject suffers physical,
psychological, or other injury as a result of participation in the particular activity. In some institutions investiga-
tors must also explain how and when identifying data are to be destroyed when the study has been
completed.

There are investigational areas in which, by the nature of the data used and the manipulations applied
to it, consent by subjects is not required. This ruling would apply to stored data, information, tissue, body
fluids, or other materials obtained in the course of routine, professional or clinical observations and
activities, and collection does not involve any increased risk to the subject. According to societal values
as represented by the federal government, however, use of any of these items for many research, training,
and service purposes may present psychological, sociological, or legal risks to the subject or his authorized
representative. Determination of whether such risks are involved and whether the use of the materials is
within the scope of the original consent is a responsibility of the institution through its established review
committee.

In clinical studies that involve hospital or other institutional staff in addition to the research team, special
precautions are needed to safeguard the human rights of these employees. If the research design requires
actions by persons who are not regular members of the research staff (such as nurses assigned to a clinical
unit), steps must be taken to insure that these persons are informed about the procedures and activities
expected of them. Responsibility for obtaining informed consent to participate in research belongs to the
principal investigator and must not be delegated to regular employees of the institution for the sake of
convenience. So that all members of the institutional staff can know that research is in progress, a copy
of the patient's (consumer's) signed consent form should be attached as part of that patient's (consumer's)
hospital record.

To monitor the utilization of both patients and nursing personnel in research and other special activities,
a list of all research projects approved by the institutional review committee must be sent routinely to
nursing and other departments that are likely to be involved in the implementation of the studies.
Conversely, to safeguard the overutilization of patients and nursing personnel in research and other special
projects and to provide a mechanism for approving research and special activities within the departments
of nursing, organized nursing services have responsibility to develop and enforce written policies and
guidelines governing these matters with special attention to protection of the rights of prospective subjects.
Guidelines designed to protect human subjects against violation of their rights must incorporate explicit
directions for protecting the highly vulnerable individuals who for one or more reasons have difficulty in
providing informed consent. High risk individuals include but may not be limited to those who are illiterate,
lack command of the English language (or other primary language), do not recognize their right to refuse
participation without jeopardizing their care, or for some reason are unable to comprehend instructions or
directions.

The institution also has responsibility to formulate mechanisms and procedures for the reporting of events
in which human rights are violated. Such mechanisms and procedures need to be brought to the attention
of all members of the staff and all consumers of services. The mechanism of reporting should be such that
the rights of the person reporting the event also are not violated.
Assurance--Professions

Increased use of hospitals and health care facilities for clinical and other research means that practicing nurses in many institutions are knowingly or unknowingly serving as participants in research designed and implemented by others. Increased educational opportunity for nurses has produced a corps of nurse researchers who are actively engaged in scientific study. Yet stereotyped images of nurses and nursing have in some settings obstructed active participation by nurses on institutional committees for review of research. The profession of nursing through its organization, the American Nurses’ Association, has an obligation to publicly support the inclusion of nurses as regular members of the institutional review committees and to make this policy known through written statements of policy.

Because nurses in practice encounter many patients whose rights can unknowingly or inadvertently be violated, the profession of nursing through its national organization carries additional responsibility for the development of written policies and guidelines governing the rights of human subjects to guide nurses at many different levels of practice in formulating policies and procedures pertaining to these matters in their own jurisdictions. The professional nurse's responsibility for protecting the rights of human subjects requires that mechanisms be established whereby violations of rights can be reported and actions taken to countermand the violations. The profession of nursing through its organization at the state level has responsibility to develop mechanisms whereby grievances of nurses may be reported and redressed when these nurses have knowledge of violation of human rights.

PERSONAL RESPONSIBILITY

In order for nursing to fulfill its professional obligations in a rapidly changing society, each nurse must develop an awareness of the issues and a framework for dealing effectively with emerging human rights problems. Ethical issues frequently involve conflicting values, and in many individual cases ethical standards are not specified in sufficient clarity to allow for unambiguous decision-making. As knowledgeable participants in healthcare practice and research, professional nurses should involve themselves in institutional policy making and review committee activities.

As knowledgeable participants, nurses need also to become informed about various legal parameters affecting practitioner-client relationships. With respect to human rights, legal accountability focuses upon evidence that the professional practitioner or researcher has not failed his/her responsibility by either intentionally or unintentionally withholding relevant information that might have altered the patient or subject’s decision. Knowledge about the changing scope of nursing responsibility and the emerging ethical issues affecting all practitioners in health care today is a necessary requirement for professional nursing practice in which accountability for the protection of human rights of consumers is accepted.