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 of 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 individual 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.