ETHICAL GUIDELINES FOR CLINICAL INVESTIGATION
(Adopted by House of Delegates, American Medical Association, Nov. 30, 1966)

At the 1966 Annual Convention of its House of Delegates, the American Medical Association endorsed the ethical principles set forth in the 1964 Declaration of Helsinki of the World Medical Association concerning human experimentation. These principles conform to and express fundamental concepts already embodied in the Principles of Medical Ethics of the American Medical Association.

The following guidelines, enlarging on these fundamental concepts, are intended to aid physicians in fulfilling their ethical responsibilities when they engage in the clinical investigation of new drugs and procedures.

1. A physician may participate in clinical investigation only to the extent that his activities are a part of a systematic program competently designed, under accepted standards of scientific research, to produce data which is scientifically valid and significant.

2. In conducting clinical investigation, the investigator should demonstrate the same concern and caution for the welfare, safety and comfort of the person involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation.

3. In clinical investigation primarily for treatment —
   A. The physician must recognize that the physician-patient relationship exists and that he is expected to exercise his professional judgment and skill in the best interest of the patient.
   B. Voluntary consent must be obtained from the patient, or from his legally authorized representative if the patient lacks the capacity to consent, following: (a) disclosure that the physician intends to use an investigational drug or experimental procedure, (b) a reasonable explanation of the nature of the drug or procedure to be used, risks to be expected, and possible therapeutic benefits, (c) an offer to answer any inquiries concerning the drug or procedure, and (d) a disclosure of alternative drugs or procedures that may be available.

   i. In exceptional circumstances and to the extent that disclosure of information concerning the nature of the drug or experimental procedure or risks would be expected to materially affect the health of the patient and would be detrimental to his best interests, such information may be withheld from the patient. In such circumstances such information shall be disclosed to a responsible relative or friend of the patient where possible.

   ii. Ordinarily, consent should be in writing, except where the physician deems it necessary to rely upon consent in other than written form because of the physical or emotional state of the patient.

   iii. Where emergency treatment is necessary and the patient is incapable of giving consent and no one is available who has authority to act on his behalf, consent is assumed.

4. In clinical investigation primarily for the accumulation of scientific knowledge —
   A. Adequate safeguards must be provided for the welfare, safety and comfort of the subject.
   B. Consent, in writing, should be obtained from the subject, or from his legally authorized representative if the subject lacks the capacity to consent, following: (a) a disclosure of the fact that an investigational drug or procedure is to be used, (b) a reasonable explanation of the nature of the procedure to be used and risks to be expected, and (c) an offer to answer any inquiries concerning the drug or procedure.
   C. Minors or mentally incompetent persons may be used as subjects only if:
      i. The nature of the investigation is such that mentally competent adults would not be suitable subjects.
      ii. Consent, in writing, is given by a legally authorized representative of the subject under circumstances in which an informed and prudent adult would reasonably be expected to volunteer himself or his child as a subject.
   D. No person may be used as a subject against his will.