

## ***AMA Code of Medical Ethics***

### ***7.1.2 Informed Consent in Research***

Informed consent is an essential safeguard in research. The obligation to obtain informed consent arises out of respect for persons and a desire to respect the autonomy of the individual deciding whether to volunteer to participate in biomedical or health research. For these reasons, no person may be used as a subject in research against his or her will.

Physicians must ensure that the participant (or legally authorized representative) has given voluntary, informed consent before enrolling a prospective participant in a research protocol. With certain exceptions, to be valid, informed consent requires that the individual have the capacity to provide consent and have sufficient understanding of the subject matter involved to form a decision. The individual's consent must also be voluntary.

A valid consent process includes:

- (a) Ascertaining that the individual has decision-making capacity.
- (b) Reviewing the process and any materials to ensure that it is understandable to the study population.
- (c) Disclosing:
  - (i) the nature of the experimental drug(s), device(s), or procedure(s) to be used in the research;
  - (ii) any conflicts of interest relating to the research, in keeping with ethics guidance;
  - (iii) any known risks or foreseeable hazards, including pain or discomfort that the participant might experience;
  - (iv) the likelihood of therapeutic or other direct benefit for the participant;
  - (v) that there are alternative courses of action open to the participant, including choosing standard or no treatment instead of participating in the study;
  - (vi) the nature of the research plan and implications for the participant;
  - (vii) the differences between the physician's responsibilities as a researcher and as the patient's treating physician.
- (d) Answering questions the prospective participant has.
- (e) Refraining from persuading the individual to enroll.
- (f) Avoiding encouraging unrealistic expectations.
- (g) Documenting the individual's voluntary consent to participate.

Participation in research by minors or other individuals who lack decision-making capacity is permissible in limited circumstances when:

- (h) Consent is given by the individual's legally authorized representative, under circumstances in which informed and prudent adults would reasonably be expected to volunteer themselves or their children in research.
- (i) The participant gives his or her assent to participation, where possible. Physicians should respect the refusal of an individual who lacks decision-making capacity.
- (j) There is potential for the individual to benefit from the study.

In certain situations, with special safeguards in keeping with ethics guidance, the obligation to obtain informed consent may be waived in research on emergency interventions.

*AMA Principles of Medical Ethics: I,III,V*