

Many ethical codes have sections regarding informed consent. A few are included here.

The Nuremberg Code, element 1 is:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

The Belmont Report has the following principle:

Respect for persons incorporates at least two ethical convictions; first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

The World Medical Association Declaration of Helsinki (Ottawa):

§22 Informed consent

Unless otherwise specified in this Declaration, each potential subject must be adequately and objectively informed about the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. Potential subjects must be made aware of all reasonable alternatives to those procedures or interventions that are performed with the intent and reasonable probability of providing direct health-related benefit to the subjects. There must be no coercion, constraint, duress, unjustified deception or undue influence. Material inducements should be limited to reimbursement for out-of-pocket expenses and normal levels of compensation for time, inconvenience or discomfort. The subject should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participate at any time without jeopardizing his or her medical care and without loss of any other benefits to which he or she is entitled.

§23 The investigator's responsibilities

The investigator is responsible for assuring the adequacy of informed consent from or on behalf of each subject. Although the investigator may delegate another appropriately qualified person to obtain consent from prospective subjects, the responsibility for assuring that adequate consent has been accomplished remains with the investigator. When obtaining informed consent, the investigator should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In some cases of this type, it may be preferable if the informed consent were to be obtained by a qualified person who is either not engaged in the investigation, independent of the dependent relationship, or both.

§24 Documentation of informed consent

In most research the subject's informed consent should be documented in writing. The requirement for written documentation may be waived by the research ethics committee in certain circumstances such as when the research involves only slight risk, when the procedures to be used are customarily used in the practice of medicine without documentation of consent, or when a signed consent document would create an unwarranted risk of a breach of the subject's confidentiality.

§25 Waiver of consent

When permitted by applicable law, the requirement for informed consent may be waived by the independent research ethics committee. Such waiver may be appropriate in research that presents little or no threat to the rights and welfare of research subjects as exemplified by use of anonymous tissue samples for research purposes and in certain other types of research in such fields as epidemiology and policy evaluation. It may also be justified in research in emergency situations in

which patient-subjects have temporary or enduring loss of decisional capacity and interventions or procedures must be initiated before informed consent can be obtained from patient-subjects or their legally authorized representatives. In the latter case the research ethics committee may require special procedures to protect the rights and welfare of the research subjects.

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