

# Informed Consent

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**Myth:** A satisfactory informed consent process should include all the information that a reasonable physician believes is important to communicate.

**Fact:** A satisfactory informed consent process requires disclosure of pertinent information that a reasonable patient believes would be important to know.

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## History of Informed Consent

The foundations for the ethical duty implicit in the concept of informed consent to medical treatment originate from the Greek Hippocratic Oath to "...use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing" [1]. Most of the internationally recognized movements for standards and regulation of informed consent occurred in response to events such as human experimentation during the Holocaust and the Tuskegee syphilis study. Legal and ethical standards for informed consent in treatment versus research have evolved separately. *Research* consents are directed by federal and international governmental agencies. The parameters for adequate informed consent for *treatment* have been addressed by the judicial system via individual lawsuits. Over time, a body of law has grown with standards for disclosure and required elements of conduct by physicians in the realm of patient care. [2-4] The information in this FactFinder pertains to informed consent for *treatment*, not clinical trials.

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## Six Elements of the AMA Guidelines for Informed Consent [5]

- 1) The patient must be given a diagnosis.
- 2) The patient must have the capacity to make the relevant decision.
- 3) The medical provider must disclose information on the treatment in question, including the expected benefits and risks, and the likelihood (or probability) that the benefits and risks will occur.
- 4) The patient must be presented with alternatives to proposed treatment, the alternative treatment risks, and the risk of refusing treatment.
- 5) The patient must comprehend the relevant information.
- 6) The patient must voluntarily grant consent, without coercion or duress.

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## Reasonable Patient

The elements of a satisfactory informed consent process depend on the thought process of a "reasonable patient." The European Union and half of the states in the U.S. have adopted a standard that views the informed consent communication process from the patient's perspective. This standard requires the provider to disclose information about the risks, benefits, and alternatives of a proposed treatment that an objective patient would find necessary in making an intelligent decision as to whether to proceed with the treatment [6-9]. This standard thus eliminates the assumed physician beneficence and relies on patient autonomy and self-determination. Material facts of risks may include common minor risks with little or no long-term effect as well as rare events that may have considerable long-term sequela.

The practical methods of obtaining an appropriate informed consent have never been explicitly codified. Rather, legal precedents have arisen piecemeal from malpractice cases. The following represent important points to consider.

- In some jurisdictions, the duty to have the informed consent *discussion* cannot be delegated to anyone other than the physician himself/herself [9,10]. This is distinct from who may obtain the *signed consent form*, which may be delegated to ancillary personnel. Documentation of the *discussion* should be performed by a provider involved with performing the procedure [11-14]. The physician is liable if the consent session is incomplete or ineffective. It is not sufficient to state that “the risks and benefits were discussed” without further description of the specifics.
- The record of obtaining informed consent is best documented in the office or hospital notes sometime prior to the day of the procedure [9]. There is generally no need for a witness to the one-on-one discussion [10,12].
- The informed consent *document* (distinct from the documentation of the informed consent *discussion*) is generally signed and witnessed at the treating facility and the treating physician need not be present.
- The use of decision aids—written, electronic, audiovisual, or web-based—may improve the decision-making process [15,16].
- Physicians must answer truthfully if a patient asks questions about the number of similar procedures the physician has performed and their success rates [17].
- Interpreters should be knowledgeable and unbiased [18].
- Disclosures: The physician must advise patients during the consent process of involved personnel and their respective roles, including residents, students, and equipment representatives. It is particularly important for patients to know if residents or students will be performing portions of a procedure [19]. The law mandates disclosure of a physician’s financial conflict(s) of interest, since the law presumes that there is potential for undue influence on that physician’s medical judgment. Examples include referral to a laboratory, an ambulatory surgery center, or a radiology service in which the physician has ownership. There may also be disclosure requirements if the physician has a commercial interest in the use of a new device or technique [20].

- Patients may withdraw consent at any time during a procedure, and the physician must then engage in a new informed consent (or informed refusal) discussion [21].
- Failure to obtain consent: The legal ramifications of failure to obtain a proper informed consent may result in charges of battery [22,23] or negligent nondisclosure [24].

Rare exceptions to informed consent may include emergency [13], incompetency [3], therapeutic privilege, and waiver. These exceptions may be especially important in critically ill patients and reflect a balance of autonomy and society’s interest in the promotion of health [5].

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## Conclusions and Recommendations

- Physicians have an ethical and legal duty to provide timely and accurate information to patients concerning their treatment options, to decide what facts about a procedure should be presented, and to determine how detailed the discussion with a patient should be in order to meet the “reasonable patient” benchmark.
- Physicians are responsible for understanding state and federal regulations on informed consent, including but not limited to, pertinent disclosures, use of competent interpreters, as well as the issue of who can obtain consent, which differs among states.
- Physicians should disclose to the patient conflicts of interest, if any.
- An estimate of the benefits and risks of treatment options should be an integral part of the doctor/patient informed consent discussion, and documentation should reflect the details of that discussion.
- Physicians should construct a process of consent *discussion* and *signing* that affirms patient autonomy, conforms to the AMA Guidelines, and facilitates informed choice and shared decision-making.

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