

Informed Consent

Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention.



In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing a treatment or procedure.

In turn, your patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.

This communications process, or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states. (For more information about ethical obligations, see the AMA's Code of Medical Ethics, contained in the [AMA PolicyFinder](#). Providing the patient relevant information has long been a physician's ethical obligation, but the legal concept of informed consent itself is recent. The first case defining informed consent appeared in the late 1950's. Earlier consent cases were based in the tort of battery, under which liability is imposed for unpermitted touching. Though battery claims occasionally occur when treatment is provided without consent, most consent cases generally center around whether the consent was "informed", i.e., whether the patient was given sufficient information to make a decision regarding his or her body and health care. Because informed consent claims, unlike battery claims, are based in negligence, they generally are covered by liability insurance.

To protect yourself in litigation, in addition to carrying adequate liability insurance, it is important that the communications process itself be documented. Good documentation can serve as evidence in a court of the law that the process indeed took place. A timely and thorough documentation in the patient's chart by the physician providing the treatment and/or performing the procedure can be a strong piece of evidence that the physician engaged the patient in an appropriate discussion. A well-designed, signed informed consent form may also be useful, but an overly broad or highly detailed form actually can work against you. Forms that serve mainly to satisfy all legal requirements (stating for example that "all material risks have been explained to me") may not preclude a patient from asserting that the actual disclosure did not include risks that the patient unfortunately discovered after treatment. At the other extreme, listing all of the risks may not be wise either. A comprehensive listing will be difficult for the patient to understand and any omission from the list will likely be presumed undisclosed. If you are using a form that contains a list, consider, with your attorney, inserting language indicating

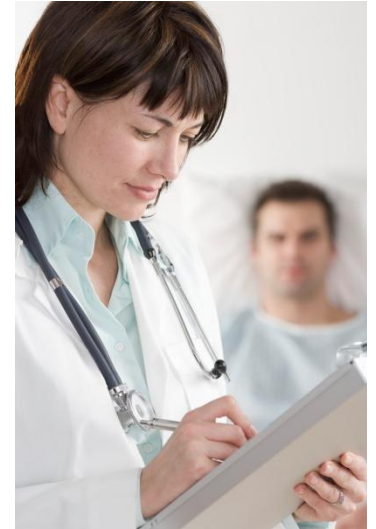
that the list is not exclusive (such as "included, but not limited to") before the list begins. Medicare participating physicians must also be cognizant of CMS's requirements for informed consent.

Again, this is general knowledge you can use when you ask for further information and advice from qualified attorneys and/or other professional consultants. If you need a referral to a qualified attorney, please contact your state medical society.

Below from "Medical Records Documentation" RM topic for ProHealth/Argus/PMN Physicians

Document informed consent discussions carefully

Although a signed consent form technically is evidence of a patient's consent to a surgery or invasive procedure, litigants often claim - and juries believe - they did not read or understand the lengthy form they signed, or that they signed it because they were told the procedure would be canceled if they did not. Even in states in which a signed consent form is *prima facie* evidence that a patient gave an informed consent, a consent form alone may lack credibility unless it is backed up by a physician's handwritten or dictated note in the office or hospital record that verifies informed consent was obtained. Defense attorneys recommend that physicians document their informed consent discussions with a note similar to this: "The patient was advised of the purpose, benefits and significant risks of this procedure, including but not limited to bleeding, infection, (damage to adjacent structures or organs) (other specific, common risks). Alternative treatments and their risks, and the risks of non-treatment also were discussed. The patient's questions were answered. (S)he appears to understand the risks of the procedure and gives his/her informed consent." Defense attorneys further suggest that physicians indicate in the note who else (spouse, relative) was present during the informed consent discussion with the patient.



Important Note: Physicians should document informed consent discussions with patients in their office progress note, a History and Physical report, or a consultation report, **but not in an operative or procedure report**, which are dictated **after** the surgery or procedure. If problems occur, notes about **pre-operative** discussions of complications or potentially adverse outcomes in these **after-the-fact** reports appear self-serving and may lack credibility in court.

Physicians are encouraged to ask patients to sign a plain-language consent form for elective and non-emergency office surgery at the time the procedure is discussed. Include statements on the form for the patient to validate, such as: "Dr. (name) has explained to my satisfaction the purpose, benefits and alternatives to this procedure, the significant risks, and the consequences of not having the procedure. The doctor answered my questions and I wish to proceed."

Document "informed refusal" discussions

Several states require physicians to inform patients who refuse medically essential surgery or diagnostic tests if there are potentially deleterious consequences to their decision. Informed refusal, if it is properly documented, protects physicians from liability for decisions the patient has made after being informed of the risks. A brief chart note such as: "Patient refuses test [or procedure]; explained risks of refusing treatment and degree of urgency, and patient understands," generally suffices.

Contact MIEC's Loss Prevention Department for a *Claims Alert* with state specific information on informed consent and informed refusal.