



Informed Consent

What is 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. It is a process in which a fully informed patient can participate in choices about their health care. It originates from the legal and ethical right the patient has to direct what happens to their body and from the ethical duty of the physician to involve the patient in their health care.

Informed consent is a physician's *non-delegable* duty. The most important goal of informed consent is that the patient has an opportunity to be an informed participant in their health care decisions. It is generally accepted that complete informed consent includes a discussion of the following elements:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The relevant 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;
- The risks and benefits of not receiving or undergoing a treatment or procedure;
- Assessment of the patient's understanding; and
- The acceptance of the intervention by the patient

This communication 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. In Texas, the "Consent Statute" (Chapter 74, Subchapter C, Sections 74.101-74.107, of the Texas Civil Practices and Remedies Code) provides that, for a patient to recover against a provider for lack of informed consent, the patient must show that the provider was negligent in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent.

The Texas Medical Disclosure Panel ("Panel") was established in 1977 to provide physicians and other health care providers with guidelines for informed consent, both as to the risks and hazards that should be disclosed to the patient and the form of the disclosure. The Panel is required to prepare separate lists of medical treatments and surgical procedures that require disclosure of specific risks and hazards and those treatments that do not. List A sets out the treatments and procedures that the Panel has determined require a disclosure of



specific risks and hazards when obtaining informed consent. For each List A treatment or procedure, the Panel has identified the specific risks and hazards that should be disclosed in obtaining informed consent for that treatment or procedure. List B_ treatments and procedures are those that the Panel has determined do not require any disclosure of specific risks or hazards associated with the treatment or procedure. In addition, the Panel has established the form in which the disclosure of risks and hazards for treatments and procedures identified by the Panel must be made: *Disclosure and Consent Forms: Medical & Surgical Procedures; Radiation Therapy; Hysterectomy*.

When documenting informed consent for List B procedures, the Panel recommends listing the risks that the provider believes are associated with the treatment or procedure along with a statement to the effect that “*no disclosure of specific risks is required by the Panel*”. If the provider complies with the procedures established by the Panel, the Consent Statute provides a “rebuttable presumption” that the provider was not negligent in obtaining informed consent.

To protect yourself in litigation, it is important that the communication process itself be documented. Good documentation can serve as evidence in a court of law that the process indeed took place. Timely and thorough documentation in the patient’s chart by the physician indeed took place. 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 in the patient in an appropriate discussion. Some examples of documenting this are: “Risk/benefits/alternatives discussed with patient/family and patient wishes to proceed”. Again the signed forms are really the culmination of a dialogue required to foster the patient’s informed participation in the clinical decision. For a wide range of decisions, written consent is neither required nor needed, but some meaningful discussion is needed. For hospital based procedures, we recommend documentation of the communication process in the admitting History and Physical or the first Progress Note. We discourage this documentation on the Operative Report, as it may be misleading as to when the discussion took place and whether or not the patient was in a state of mind to make an informed decision. For outpatient surgery procedures, you may not write progress notes, so it may be appropriate to include the documentation of your discussion with the patient in the Operative Report. In these circumstances, we suggest that this be documented under a separate heading of “indications/discussions” or something similar, rather than “Procedure in Detail”.