

Informed Consent: Substance and Signature

For decades, consent documents protected physicians against any legal recourse a dissatisfied patient might pursue. Times have changed. Modern medicine requires a more complex and complete acknowledgment of both the patient's and the physician's rights and responsibilities to each other. According to the Physician Insurers Association of America data, almost 6 percent of claims arise from lack of consent.

True informed consent is a process of managing a patient's expectations; it is not just a signature on a document. Achieving an accurate diagnosis requires the patient to provide accurate information to the physician. The physician must then provide sufficient information to the patient so that a reasonable and informed decision regarding a treatment plan can be made. This physician responsibility cannot be delegated.

A successful exchange of information between the doctor and the patient accomplishes two things. First, when the physician explains diagnoses, treatments, expected outcomes, and potential risks to the patient, it demonstrates that the physician recognizes the patient's rights and will remain responsive to them. Second, it shifts the decision-making responsibility from the physician alone to a mutual responsibility of both physician and patient. Informed consent should protect and inform both the patient and the doctor.

Litigation often results from a discrepancy between the patient's expectations and the outcome of treatment. Informed consent cannot completely eliminate malpractice claims, but an established rapport between the patient and the physician based on solid exchanges of information can prevent patient disappointment from ripening into a claim. The informed consent process is not limited to surgical procedures; it is also appropriate for comprehensive medical treatment plans.

Physician-Patient Dialogue

When discussing diagnoses, treatment plans, risks, and expected outcomes with the patient, use medically correct wording and names, but avoid medical terminology. If there are alternative treatment options, discuss them in detail. Also, outline the recovery process and the expected short- and long-term effect on the patient.

Identify any uncertainty and risk involved with a specific treatment plan, including the probability factors, if possible. Discuss reasonable assumptions the patient may make about the treatment plan. Whenever possible, supply reading materials and the consent form document for the patient to take home and discuss with his or her family.

Encourage questions. Questions provide a better understanding of the patient's comprehension of the information and facilitate the dialogue between the patient and the physician. Where time permits, consider scheduling a second visit with the patient to review the consent form, clarify expectations, and ensure patient comprehension of the proposed treatment—especially with elective surgery procedures.

Documentation

Documentation is another key component of the informed consent process that cannot be fully delegated to a nurse or other member of the healthcare team. If the doctor-patient discussion proceeds successfully and the patient requests treatment, the doctor is required in some jurisdictions to write a note in the patient's record. Additionally, the consent document must include the patient's name, doctor's name, diagnosis, proposed treatment plan, alternatives, potential risks, complications, and benefits.

To some extent, physicians who use an informed consent document can protect themselves further by including a statement to the effect that the form only covers information that applies generally and that the physician has personally discussed specific factors with the patient. The consent document must be signed and dated by the

patient (or the patient's legal guardian or representative). Many consent forms also require a physician signature.

We offer more than 100 sample forms in our informed consent resource center at www.thedoctors.com/consent. The information in the consent forms is for reference purposes only. The sample documents provide a general guideline, not a statement of standard of care. The documents should be edited and amended to reflect the policy requirements of the physician's practice site(s) and the legal requirements of the individual state.

Each sample consent form includes statements to be signed by the patient and the physician. The patient attests that he or she understands the information in the treatment agreement. The physician attests that he or she has answered all questions fully and believes that the patient/legal representative fully understands the information. This statement helps avoid any claim that the patient did not understand the information.

Informed Consent in Special Situations

The informed consent process for same-day surgery patients may occur in the physician's office before scheduling the procedure. That will allow the patient time to think through the information, ask questions, and make an informed decision.

Hospitalized patients must be informed as far in advance of the procedure as practicable. If time permits in an emergency where the patient is unable to provide consent, the physician must contact a legally authorized representative to obtain an informed consent. If the nature of the emergency does not permit time to contact a legally authorized representative, consent is implied. Consent may be waived under emergent conditions that threaten life, limb, eyes, and the central nervous system. If the patient is incompetent or otherwise cannot consent, the physician is legally bound to obtain informed consent from the incompetent patient's authorized representative, except in an emergency. This type of consent should be thoroughly documented in the medical record.

Additional Tips and Suggestions

- Develop and use procedure-specific forms that are signed by the patient when the informed consent discussion takes place.
- Obtaining consent from the patient after a sedative or sleep-inducing medication is administered is not recommended. However, when there is a change in the patient's condition that requires a change in treatment, consent should be secured from the patient. The facts and conditions surrounding the need for the revised consent should be thoroughly documented in the medical record.
- Additions or corrections to the consent form must be dated, timed, and signed by the person making the additions or corrections.
- Any member of the healthcare team may sign as a witness to the patient's signature, although this serves only to verify that it was the patient who signed the form. The witness does not obtain consent or verify the patient's competency to give consent.
- A patient's questions or obvious lack of understanding about the procedure should be referred to the attending physician as soon as possible.
- Translate consent forms to the most common non-English language that you encounter in your practice, and verify that the form is translated correctly.

Patient Safety Measures

Every physician should develop his or her own style and system for the informed consent process, making it easier to avoid omissions and—more importantly—ensuring consistency of application.

Do not speed through the process. Give the patient and the family time to absorb and comprehend the information. Preprinted materials are extremely helpful for patient understanding and will serve as a trigger for other questions.

Assessing the patient's level of understanding is the step just before documenting the process. One way of doing this is to ask the patient to repeat back to you his or her understanding of the information you have communicated. This will increase the likelihood that you will be able to manage the patient's expectations effectively.

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The guidelines suggested here are not rules, do not constitute legal advice, and do not ensure a successful outcome. The ultimate decision regarding the appropriateness of any treatment must be made by each health care provider in light of all circumstances prevailing in the individual situation and in accordance with the laws of the jurisdiction in which the care is rendered.

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