What is informed consent?

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

What are the elements of full informed consent?

The most important goal of informed consent is that the patient has an opportunity to be an informed participant in his/her health care decisions. It is generally accepted that complete informed consent includes a discussion of the following elements:

- the nature of the decision/procedure
- reasonable alternatives to the proposed intervention
- the relevant risks, benefits, and uncertainties related to each alternative
- assessment of patient understanding
- the acceptance of the intervention by the patient

In order for the patient's consent to be valid, he/she must be considered competent to make the decision at hand and his/her consent must be voluntary. It is easy for coercive situations to arise in medicine. Patients often feel powerless and vulnerable. To encourage voluntariness, the physician can make clear to the patient that he/she is participating in a decision, not merely signing a form. With this understanding, the informed consent process should be seen as an invitation to him/her to participate in his/her health care decisions. The physician is also generally obligated to provide a recommendation and share his/her reasoning process with the patient. Comprehension on the part of the patient is equally as important as the information provided. Consequently, the discussion should be carried on in layperson's terms and the patient's understanding should be assessed along the way.

Basic consent entails letting the patient know what you would like to do and asking him/her if that will be all right. Basic consent is appropriate, for example, when drawing blood. Decisions that merit this sort of basic informed consent process require a low-level of patient involvement because there is a high-level of community consensus.

How much information is considered "adequate"?

How do you know when you have said enough about a certain decision? Most of the literature and law in this area suggest one of three approaches:

- **reasonable physician standard**: *what would a typical physician say about this intervention?* This standard allows the physician to determine what information is appropriate to disclose. However, it is probably not enough, since most research in this area shows that the typical physician tells the patient very little. This standard is also generally considered inconsistent with the goals of informed consent as the focus is on the physician rather than on what the patient needs to know.
• **reasonable patient standard**: what would the average patient need to know in order to be an informed participant in the decision? This standard focuses on considering what a patient would need to know in order to understand the decision at hand.

• **subjective standard**: what would this patient need to know and understand in order to make an informed decision? This standard is the most challenging to incorporate into practice, since it requires tailoring information to each patient.

Most states have legislation or legal cases that determine the required standard for informed consent. In the state of Michigan, we use the "reasonable physician standard."

**What sorts of interventions require informed consent?**

Most health care institutions have policies that state which health interventions require a signed consent form. For example, surgery, anesthesia, and other invasive procedures are usually in this category. These 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 instance, a man contemplating having a prostate-specific antigen screen for prostate cancer should know the relevant arguments for and against this screening test, discussed in layman's terms. (See also Research Ethics.)

**When is it appropriate to question a patient's ability to participate in decision making?**

In most cases, it is clear whether or not patients are competent to make their own decisions. Occasionally, it is not so clear. Patients are under an unusual amount of stress during illness and can experience anxiety, fear, and depression. The stress associated with illness should not necessarily preclude one from participating in one's own care. However, precautions should be taken to ensure the patient does have the capacity to make good decisions. There are several different standards of decision making capacity. Generally you should assess the patient's ability to:

- understand his or her situation,
- understand the risks associated with the decision at hand, and
- communicate a decision based on that understanding.

When this is unclear, a psychiatric consultation can be helpful. Of course, just because a patient refuses a treatment does not in itself mean the patient is incompetent. Competent patients have the right to refuse treatment, even those treatments that may be life-saving. Treatment refusal may, however, be a flag to pursue further the patient's beliefs and understanding about the decision, as well as your own.

**What about the patient whose decision making capacity varies from day to day?**

Patients can move in and out of a coherent state as their medications or underlying disease processes ebb and flow. You should do what you can to catch a patient in a lucid state - even lightening up on the medications if necessary - in order to include him/her in the decision-making process.
What should occur if the patient cannot give informed consent?

If the patient is determined to be incapacitated/incompetent to make health care decisions, a surrogate decision maker must speak for him/her. There is a specific hierarchy of appropriate decision makers defined by state law (also see the DNR topic page). If no appropriate surrogate decision maker is available, the physicians are expected to act in the best interest of the patient until a surrogate is found or appointed.

Is there such a thing as presumed/implied consent?

The patient's consent should only be "presumed", rather than obtained, in emergency situations when the patient is unconscious or incompetent and no surrogate decision maker is available. In general, the patient's presence in the hospital ward, ICU or clinic does not represent implied consent to all treatment and procedures. The patient's wishes and values may be quite different than the values of the physician. While the principle of respect for person obligates you to do your best to include the patient in the health care decisions that affect his/her life and body, the principle of beneficence may require you to act on the patient's behalf when his/her life is at stake.