

Obtaining Valid Informed Consent and Refusal

I. The functions of valid informed consent

- The promotion of individual autonomy
- The protection of patients and research subjects
- The avoidance of fraud and duress
- The encouragement of self-scrutiny by medical professionals
- The promotion of rational decisions
- Promotion of good patient care-beneficence

II. Elements of valid informed consent *

Threshold elements (preconditions)

- Decision-making capacity (to understand and decide)
- Voluntariness (in deciding)

Information elements

- Disclosure (of material information)
- Recommendation (of a plan)
- Understanding (of 1 and 2)

Consent elements

- Decision (in favor of a plan)
- Authorization (of the chosen plan)

III. Disclosure

Information provided to a patient to enable him or her to make a decision whether or not to accept the recommended medical treatment or procedure

- Diagnosis
- Proposed procedure and benefits of procedure
- Physician or physicians performing the procedure
- Description of the procedure in layperson's terms
- Risks of procedure
- Alternative procedures
- Risks of alternative procedures
- Risks of no treatment
- Additional information requested by the patient in response to the query, "Any questions?"

The reasonable patient standard - The physician is to disclose "material" risks, i.e., risks which a reasonable person in the patient's position would consider significant in deciding whether or not to submit to a particular procedure or treatment. This includes substantial risks of minor untoward effects of procedure (e.g., 20% risk of an allergic reaction) and small risks of a substantial untoward effect of a procedure (e.g., 1% risk of blindness or death)

The subjective standard - Ethically speaking, the physician has an obligation to provide to the patient not only the information that a reasonable person would want but also that information that the particular patient needs or wants to know to make a decision.

IV. Comprehension

Information should be explained to a patient in such a way that the patient can understand the information. Pictures or diagrams are often helpful, and layperson's terms should be used. A physician should not use the excuse that the information is too complicated for the patient to understand.

V. Voluntariness

Coercion or other means of undue pressure or influence are unacceptable and invalidate the consent.

VI. Authorization

The patient's oral or written agreement to have the operation or procedure performed.

VII. Reasons for obtaining valid informed consent and refusal

Valid consent or refusal is required by law.

Proceeding without valid consent, except in certain circumstances, constitutes unconsented touching which equals assault and battery.

Valid consent is ethically required based on professional standards of respect for autonomy and beneficence.

VIII. Barriers to obtaining valid consent

Inadequate time allowed for discussion

Failure to check the patient's understanding and to improve knowledge as needed

Failure by the physician to acknowledge uncertainty

Framing of information in such a way that biases are present or the patient is pressured into a decision (e.g., "If you don't allow me to do this procedure, you will die.")

IX. Exceptions to the requirement to obtain valid consent

Emergency- Consent is presumed in an emergency when there is an immediate threat to the patient's life, sight, or limb unless the patient is previously known not to want the procedure or treatment.

Therapeutic privilege (rarely justified)- The withholding of information from the patient by the physician on the justification that to disclose information and obtain consent would be severely detrimental to the mental health of the patient. The exercise of this privilege should be limited since it prevents patient self-determination.

Waiver of consent- The patient waives his or her right to disclosure and authorizes the physician to proceed (e.g., "I trust you, Doc. Just go ahead and do it.")

Legal requirements, specifically police orders for alcohol levels.

*From Tom L. Beauchamp and James F. Childress. Principles of Biomedical Ethics. 8th ed., New York: Oxford University Press, Inc., 2019.