

THE UNIVERSITY OF CONNECTICUT HEALTH CENTER
JOHN DEMPSEY HOSPITAL
ADMINISTRATIVE MANUAL

SECTION: MEDICAL/DENTAL STAFF

NUMBER: 06-002

SUBJECT: DOCUMENTATION OF INFORMED CONSENT

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PURPOSE:

To clarify the process to be used in obtaining informed consent to assure and document the understanding and authorization of the patient in advance of all medical/surgical interventions.

POLICY:

1. An informed consent form, *Consent for Surgical and Medical Procedures*, must be obtained and placed in the patient's medical record prior to the surgery/procedure or treatment, except in the case of an emergency.

2. Informed Consent shall be obtained and documented for:

All inpatient and outpatient operative and invasive procedures performed regardless of the location where it is performed (e.g., surgical suite, bedside or outpatient clinical area. Invasive areas include, but are not limited to:

- A. Procedures that involve penetration of the skin with the exception of drawing blood or establishing peripheral access
- B. Endoscopic procedures
- C. Intraluminal procedures including transesophageal procedures, but excluding placement of transurethral bladder catheters, diagnostic cystoscopes, and nasogastric tubes
- D. Procedures which are considered irreversible

2. A consent is an interaction between a patient or legal representative and a provider in which the nature of the illness and purpose of the procedure is discussed, and an opportunity for questions is provided. The provider must ensure that the discussion includes the risks, benefits of, and alternatives to the procedure, including consequences of non-treatment. The discussion must be documented in the medical record by the attending or by note on form HCH #127. HCH #127 must be signed by the patient or legal representative acknowledging that the consent occurred. If the attending has made a note in the medical record about the informed consent, then form HCH #127 may be executed by a practitioner designated by the attending. The discussion between the attending and the patient may be deferred in an emergency and when it is in the best interest of the patient.

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3. In the case of patients with Limited English Proficiency, all informed consents require the presence of a qualified interpreter, regardless of the patient's wishes to the contrary. Following the interpretation and patient's signature, alternative communication resources may be utilized if the patient desire, and if an Interpreter Services Waiver Form (HCH #1874) has been previously signed by the patient. A qualified interpreter may be a bilingual employee whose skills have been assessed and documentation maintained through the Interpreter Services office (x2289). Or Language Line telephonic interpretation may be utilized for this purpose; when relying on this service, the ID# of the interpreter must be documented within the provider's notes.
4. Medical/surgical procedures which are performed over multiple hospital stays or outpatient visits or include planned return to the Operating Room may utilize an approved special consent form which is based on HCH #127 and is customized to fit a special need. In no event shall this consent extend beyond the period of six (6) months.
5. The guidelines outlined in this policy for completing the form will be adhered to unless a customized form is approved. All customized consent forms and any revisions to HCH #127 **must be approved by the Medical Records Form Subcommittee** before use and placement in the medical record.
6. The following standards are required for an informed consent. Each disclosure must be made in such a way that the patient understands it. The patient must be given a chance to ask questions. Please refer to the corresponding item number of the Authorization for Medical/Surgical Procedure form (HCH #127):
 - A. Who will perform the procedure/treatment (Item #1);
 - B. Specific procedure/treatment to be performed and a general description stated in plain language or layman's terms. The location must be unambiguous if there is any questions of laterality (left / right), multiple structures (fingers / toes), or multiple levels (spinal) (Item #2);
 - C. Medically significant benefits of the procedure (Item #3);
 - D. Medically significant risks and complications of the procedure (Item #4);

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- E. Medically significant alternatives for treatment and the consequences associated with no treatment (Item #5);
- F. Authorization for use of anesthesia / sedation for the procedure (Item #6);
- G. Advanced directive for emergency measures during procedure/treatment and limitation to this, if any (Item #7)
- H. Disclosure of involvement of residents, fellows, and other credentialed physicians, as appropriate (Item #8);
- I. Disclosure of involvement of qualified non-physician medical (mid-level) practitioners within their scope of practice, as appropriate (Item #9);
- J. Disclosure of involvement of students and / or health care industry representatives, as appropriate (Item #10);
- K. Authorization for disposition of tissue or body parts (Item #11);
- L. Exposure to x-rays must be disclosed and the area of skin most likely to be affected must be identified if the location will be anywhere other than the vicinity of the operative site.
- M. Voluntary nature of the consent (Section #10)

SIGNATURE

1. The Authorization for Medical/Surgical Procedure form will be signed by the Patient, Parent, Guardian, Conservator or other appropriate patient representative after full explanation from the involved physician, dentist, podiatrist, or physician delegate.
2. All signatures must be dated and timed, including those of the physician, dentist, podiatrist, or physician delegate, and the patient or party providing consent.

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3. Consent via telephone requires the signature of two people, the person obtaining consent and a witness.
4. The responsible physician, dentist, podiatrist, or physician delegate must sign the consent form, including consents obtained via telephone. A physician delegate may be an advanced practice registered nurse or a physician assistant, credentialed by the Medical Staff Services Office.
5. A signed consent form will be valid for up to 30 days, unless other developments in the patient's condition during this period warrant changes in the procedure consented to and require new or additional explanation to the patient by the physician, dentist, podiatrist, or physician delegate. Any consent older than 30 days may be updated by having newly dated and time signature entries by both the patient and the physician, dentist, podiatrist, or physician delegate completing the consent form.
6. The signed consent (Authorization for Medical/Surgical Procedure form HCH#127) is a part of the patient's official medical record.
7. Informed consent must be documented for any and all procedures involving research. A separate Institutional Review Board approved consent form is required for such procedures.

PARTIES LEGALLY ABLE TO GIVE CONSENT

1. In general, a patient under the age of 18 years, unless deemed an emancipated minor by court order, must have the written consent of legal guardian or parent (not a step-parent).
2. Informed consent may be given for abortion by a Mature Minor (minors who know the nature, quality and consequences of their actions) if the physician, dentist, or podiatrist determines that the minor is capable of making an independent decision to undergo such a procedure.
3. A court appointed conservator or legal guardian may sign the consent if the patient is unable.

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4. Telegram permission is acceptable where the appropriate patient representative cannot be present.
5. Telephone permission is acceptable as noted under Signature section above.

PATIENTS NOT CAPABLE OF GIVING INFORMED CONSENT

1. For all non-emergent procedures/treatments, the determination of who is to give consent if the patient is unable for any reason, should be done in advance and all necessary paperwork placed in the medical record.
2. The physician, dentist, or podiatrist is ultimately responsible for determining if informed consent has been legally obtained by the patient or by an appropriate representative.
3. Patients who are not capable of giving informed consent, written or verbal shall be handled as follows:
 - A. Mentally Retarded Adults:
 - 1) Mentally retarded adults who have been declared incompetent must have a legal guardian appointed. The guardian assumes all responsibility and gives informed consent. The natural parents of such adults are not authorized to give permission unless they have been appointed legal guardian.
 - 2) If a mentally retarded adult has not been declared incompetent, the physician, dentist, or podiatrist must decide if the patient is capable of understanding the elements of informed consent as defined in this policy and thereby capable of giving informed consent.
 - a. If the physician, dentist, or podiatrist believes the patient is competent, the patient should sign the consent and a family member or other appropriate patient representative should be asked to co-sign.
 - b. If the physician, dentist, or podiatrist decides the patient is not competent, a legal guardian must be appointed and must give informed consent before a procedure can be performed.

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3) In an emergent situation, the following individuals may give informed consent for mentally retarded adults:

- a. Parents of retarded adults
- b. Relations of retarded adults
- c. Directors of Regional Centers
- d. Directors of Training Schools

B. Incompetent Adults (Other than Mentally Retarded)

1) If an adult is unable to give informed consent due to unconsciousness, traumatic brain injury, dementia, etc., permission is obtained from another individual as follows:

- a. If a legal guardian has been appointed, informed consent is obtained from the named individual.
- b. If power of attorney (which specifically includes medical treatment) has been given, informed consent is obtained from the named individual.
- c. In all other cases informed consent is obtained from the nearest relative in the following order:

- 1] spouse or "civil union partner"
- 2] adult child
- 3] parent
- 4] adult sibling
- 5] court order

EMERGENT SITUATIONS

1. Consent is generally implied when an emergency exists and all reasonable attempts to seek a qualified decision-maker have been made within an appropriate amount of time.

2. An emergency must meet all of the following criteria:

A. The patient's life or health must be in immediate and substantial danger.

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- B. The patient is incapable of consenting (i.e., unconscious).
 - C. Any risks associated with the treatment are outweighed by the benefits associated with treatment.
3. If any one or more of the elements are missing, then no emergency exists and the physician or physician delegate must get informed consent as defined in the policy.

PROCEDURE:

1. Informed consent will be obtained from the patient by the physician, dentist, podiatrist, or physician delegate prior to the patient undergoing premedication for a medical/surgical procedure and will include documented evidence of discussion of possible complications and reasonable risks.
 - A. The Authorization for Medical/Surgical Procedure form (HCH #127) will be used to document informed consent:
 - 1) Standards outlined in the policy section of this document will be adhered to when completing the form.
 - 2) At the discretion of the physician, dentist, podiatrist, or physician delegate, the consent may be modified by hand or additional comments may be entered in the medical record to:
 - a. document any unusual circumstances surrounding the consent
 - b. enhance documentation pertaining to any section of the form
 - c. document any pertinent information
 - 3) If any form other than HCH #127 is used, the physician or physician delegate will make sure that the form has been approved by the Medical Record Form Subcommittee.

2. Informed consent will be obtained by the physician of record, dentist, or physician delegate at the time of discussion of the procedure with the patient. It is encouraged that a note be entered into the medical record documenting such discussion and any unusual circumstances.
3. The patient may cross out any part of the authorization that he/she does not wish to authorize. The patient must initial each section crossed out.
4. In the case of an emergency situation as described above, documentation must include that an emergency situation exists, the patient is incapable of consenting, reasonable attempts to seek a qualified decision-maker have been made, the patient's life or health is in immediate or substantial danger due to lack of treatment, and that any risks associated with the treatment are outweighed by the benefits associated with treatment.

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--Attachment can be found in the Hospital Administrative Manual--