



## CLINICAL POLICY

### Informed Consent, Clinical – Obtaining and Documenting

**A. EFFECTIVE DATE:**

April 18, 2023

**B. PURPOSE:**

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

**C. POLICY:**

1. Informed 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, care, treatment and services is discussed and an opportunity for questions is allowed. For the purposes of this policy, the provider is a physician, as defined by Centers for Medicare/Medicaid Services (CMS)(MD, DO, dentist, podiatrist). The provider may be an advanced practice registered nurse (APRN) or Physician Assistant (PA) only if he or she has been credentialed to perform the procedure, care, treatment and services and is authorized by the attending physician to do so, on the specific patient. The physician may be a Resident or Fellow only if the residency/fellowship program has granted approval for the resident or fellow to independently perform the specific procedure, and the resident or fellow has also been authorized by the attending to complete the informed consent interactive verbal process with the specific patient.
2. The provider must ensure that the discussion includes the risks, benefits of, and alternatives to the procedure(s), including consequences of non-treatment. The discussion between the provider and the patient may be deferred in an emergency and when it is in the best interest of the patient.
3. A completed form HCH127 (Authorization for Medical/Surgical Procedure) is the patient's acknowledgement that he or she had an informed consent discussion with the provider and gives permission to perform the procedure(s). HCH127 must be signed by the patient or legal representative acknowledging that the consent-process transpired.
4. Informed Consent shall be obtained and documented for all inpatient and outpatient operative and invasive procedures performed regardless of the location where said operative/invasive procedure is performed (e.g., surgical suite, bedside or outpatient clinical area). Invasive procedures include but are not limited to:
  - a. Procedures that involve penetration of the skin with the exception of drawing blood, establishing peripheral access, minor laceration repair, superficial wound care, staple or suture removal, superficial abscess incision and drainage, superficial foreign body removal, ear cerumen removal and splint/cast placement and removal.

- b. Endoscopic procedures;
  - c. Intraluminal procedures including transesophageal procedures, but excluding placement of transurethral bladder catheters, diagnostic cystoscopes, direct naso-laryngoscopy, and oro-/nasogastric tubes, and anal and esophageal manometry;
  - d. Procedures which are considered irreversible.
5. Informed consent form (HCH127) Authorization for Medical/Surgical Procedure, must be completed and placed in the patient's medical record prior to the surgery/procedure or treatment, except in the case of an emergency. Consent forms from other institutions are not acceptable with the exception of Connecticut Children's Medical Center transfusion consent form for NICU patients.
6. Informed consent for Transfusion of Blood Components shall be obtained and documented for any patient prior to starting transfusion therapy. This consent will be documented on HCH-127A or on another approved special consent form (eg, apheresis). The consent process will include:
  - Benefits and risks of transfusion
  - Alternatives to transfusion, if they exist
  - Right of the patient to refuse transfusion
  - Opportunity for the patient to ask questions about transfusion
7. Informed consent from patients with Limited English Proficiency will be obtained and documented with the participation of a qualified interpreter, regardless of waiver of interpreter services. (Please see UCH Clinical Policy: Interpreters/Language Access for Persons Who Are Limited English Proficient (LEP), Deaf Or Hard of Hearing <https://health.uconn.edu/policies/wp-content/uploads/sites/28/2021/12/Interpreters-Language-Access-Policy.pdf>)
8. Medical/surgical procedures which are performed over multiple encounters may utilize an approved special consent form which is based on HCH127 and is customized to fit a special need.
9. Separate consents will be obtained and documented by each provider when:
  - a. different providers are performing different aspects of the same operative procedure, each with different risks and requiring different skill sets;
  - b. multiple sequential procedures will be performed on the same date by different providers.
10. Pursuant to Connecticut [\*\*\*Public Act 22-33\*\*\*](#), ***An Act Requiring Express Written Consent To The Intimate Examination Of A Patient Who Is Under Deep Sedation Or Anesthesia Or Unconscious***, informed consent is required before performing an intimate examination (pelvic, prostate, or rectal exam) on a patient who will be unconscious or under deep sedation or general anesthesia. This consent is not needed if the examination is within the scope of the patient's planned procedure, surgical procedure, or diagnostic examination for which the patient has given general consent. However, a patient's **separate** written consent is required, and cannot be obtained simply as part of the general surgical consent, if a medical student, resident, or fellow performs an intimate examination **exclusively** for training purposes and not as part of the patient's clinical care or clinical care team.
11. 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 HCH127 must be approved by the Medical Records Form Subcommittee before use and placement in the medical record.
12. 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 (HCH127):
  - a. Who will perform the procedure, care, treatment and services (Item #1);

- b. Specific procedure, care, treatment and services to be performed and a general description stated in plain language or layman's terms. The location must be unambiguous if there are any questions of laterality (e.g., left / right), multiple structures (fingers / toes), or multiple levels (spinal) (Item #2);
  - c. Whether an intimate exam will be performed (Item #3)
  - d. Medically significant potential benefits of the procedure, care, treatment and services (Item 4);
  - e. Medically significant potential risks, side effects and complications of the procedure, care, treatment and services as well as the problems that may occur during recuperation (Item #5);
  - f. Discussion of patient's goals and the likelihood of the patient achieving these goals (Item #5)
  - g. Medically significant potential risks, benefits, side effects related to alternatives for treatment and the risks related to not receiving proposed care, treatment and services (Item #6);
  - h. Authorization for use of anesthesia / sedation for the procedure (Item #7);
  - i. Advanced directive for emergency measures during procedure/treatment and limitation to such directive, if any (Item #8);
  - j. Disclosure of involvement of residents, fellows, and other credentialed providers, as appropriate (Item #9);
  - k. Disclosure of involvement of qualified non-physician medical (mid-level) practitioners within their scope of practice, as appropriate (Item #10);
  - l. Disclosure of involvement of students and/or health care industry representatives, as appropriate (Item #11);
  - m. Authorization for disposition of tissue or body parts (Item #12);
13. All Authorization for Medical/Surgical Procedure forms, even if modified in accord in section 7 above or section 3 of the Procedure as outlined below, must contain at a minimum the items from the standard consent form (HCH127) covering areas a, b, c, d, e, f, g and l as outlined above.

**SIGNATURE ON CONSENT FORM:**

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 provider. All such signatures must be dated and timed.
  - a. A patient, parent, guardian, conservator or other appropriate patient representative, may sign with an "X" or any other mark which the individual intends to constitute his/her signature, when the individual has a debilitating illness or disability, i.e., a significant physical impairment and/or difficulty in executing a signature due to an underlying health condition (s), or is illiterate. When the signature is indicated by any 'mark', two adults shall witness the act of signing. By signing, the witnesses are attesting only to the fact that they observed the patient or appropriate representative and the practitioner sign the form.
2. Notwithstanding the foregoing requirements for the interactive informed consent process which must be separately documented in the electronic medical record, the physician may delegate to a fellow, resident, APRN or PA the execution of the written form HCH 127 by the patient or patient's legally authorized representative.
3. Consent via telephone requires the signature of the person obtaining the consent as well as a witness. All such signatures must be dated and timed. The requirement for a witness may be waived by the responsible provider during a Public Health Emergency as declared by either local, state, or federal authority.

4. A completed consent form will be valid until the procedure has been performed, unless other developments in the patient's condition or other material factors during this period warrant changes in the procedure consented to and require new or additional explanation to the patient by the provider. In the event that state law or other regulations cite specific parameters for validity of consent, duration of consent validity will comply with the relevant statute.
5. Unless there are developments in a patient's condition or a new risk is identified to the blood supply that affects consent, a completed transfusion consent form will be valid:
  - throughout an inpatient admission until discharge
  - prior to and during electively scheduled operative procedures
  - for 12 months during any outpatient treatments
6. The signed consent (Authorization for Medical/Surgical Procedure form HCH127) is a part of the patient's official medical record. HCH127 is the required form on which informed consent should be documented.
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. These procedures may be found at: <https://ovpr.uconn.edu/services/rics/irb/irb-forms-templates/>

**PARTIES LEGALLY ABLE TO GIVE CONSENT:**

See Policy #2012-05 Legal Representative for Health Care Decisions

**PATIENTS NOT CAPABLE OF GIVING INFORMED CONSENT:**

See UConn Health Policy #2012-05 Legal Representative for Health Care Decisions

**EMERGENCY SITUATIONS:**

1. Consent is generally implied when an emergency exists and all reasonable attempts to seek a qualified medical treatment 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.
  - b. The patient is incapable of consenting.
  - c. Any potential risks associated with the treatment are materially outweighed by the potential benefits associated with treatment.
3. If any one or more of the aforementioned elements are deficient, then no emergency may be deemed to exist and the physician or physician delegate must get informed consent as defined elsewhere in the policy.

**D. DEFINITION:**

Physician: A physician is a doctor of medicine or osteopathy, dental medicine, dental surgery, podiatric medicine, optometry or chiropractic medicine legally authorized to practice by the state in which he/she performs such function or action as define in 1861 (r) of the social security act.

**E. MATERIAL (S) NEEDED:**

None

**F. PROCEDURE:**

1. Informed consent will be obtained and documented prior to the patient undergoing premedication.
  - a. The Authorization for Medical/Surgical Procedure form (HCH127) will be used to document

informed consent:

- i. Standards outlined in the UConn Health Policy #2012-05 of this document will be adhered to when completing the form.
  - ii. At the discretion of the provider, the consent may be modified by hand or additional comments may be entered in the medical record to:
    - document any unusual circumstances surrounding the consent;
    - enhance documentation pertaining to any section of the form; and/or
    - document any pertinent information
  - iii. If any form other than HCH127 is used, the provider will ensure that the form has been approved by the Medical Record Form Subcommittee. The provider creating such a customized form must agree to continuing responsibility for updating the content of the form to include any changes made to the common sections from HCH 127 and ensure that only current forms are in use. If the provider is unavailable the service chief will identify an alternate provider to take those responsibilities. The Health Information Management Forms Subcommittee will inform providers with approved, customized forms of changes to the common sections of HCH127.
2. The patient may cross out any part of the authorization that he/she does not wish to authorize; the patient and provider should initial each section crossed out.
  3. 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 medical 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.

**G. ATTACHMENTS:**

[HCH127 Authorization for Medical/Surgical Procedure](#)

[HCH127A - Authorization for Transfusion of Blood or Blood Components](#)

**H. ENFORCEMENT:**

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

**I. STAKEHOLDER APPROVALS:**

On File

**J. COMMITTEE APPROVALS:**

Medical Board 4/11/2023

**K. FINAL APPROVAL:**

1. Bruce T. Liang, MD (Signed) 05/05/2023  
Bruce T. Liang, MD  
**Interim Chief Executive Officer & EVP for Health Affairs**  
**Dean, School of Medicine**  
Date
2. Anne Horbatuck (Signed) 04/25/2023  
Anne D. Horbatuck, RN, BSN, MBA  
**Clinical Policy Committee Co-Chair**  
Date
3. Scott Allen, MD (Signed) 04/27/2023  
Scott Allen, MD  
**Clinical Policy Committee Co-Chair**  
Date
4. Caryl Ryan (Signed) 04/26/2023  
Caryl Ryan, MS, BSN, RN  
**Chief Operating Officer, JDH**  
**VP Quality and Patient Services & Chief Nursing Officer**  
Date

**L. REVISION HISTORY:**

Previously HAM Policy #06-002: Date Issued: 9/1978  
Date Revised: 10/1985, 9/1991, 3/1994, 9/1995, 3/2000, 1/2003, 10/2003, 12/2005, 11/2008, 05/2009, 1/2011, 2/2011, 10/2011, 08/2012, 3/2013; Date Reviewed: 5/1997

New Policy Effective: 4/14/2015

Date Revised: 9/8/2015, 5/9/2017, 1/2021, 8/16/2022, 3/21/2023

Date Reviewed: 11/15/2018