Institutional Handbook of Operating Procedures Policy 09.03.17	
Section: Clinical	Responsible Vice President: Senior VP & Chief Legal Officer
Subject: Patient Rights	Responsible Entity: Department of Legal Affairs

I. Title

Consent – Overview and Basic Requirements

II. Policy

In accordance with state and federal law, prior to providing care, treatment, or services, informed consent must be obtained from the patient or the person with the right to provide consent on behalf of the patient (e.g., parent in the case of a minor patient or surrogate decision maker for an incapacitated patient), in that person's preferred language. The informed consent process includes a discussion about the potential benefits, risks, and side effects of the patient's proposed care, treatment, and services, as well as any reasonable alternatives (including not receiving the proposed care); the likelihood of the patient achieving his or her goals; and any potential complications that might occur during recuperation.

UTMB respects the diverse cultural needs, preferences, and expectations of the patients and families it serves to the extent reasonably possible while appropriately managing available resources and without compromising the quality of health care delivered.

This policy is intended to provide a general overview. Specific issues are detailed further in the following policies:

1. Consent for **treatment of a minor** is addressed in IHOP 09.03.18;
2. **Withdrawal or refusal of consent** is addressed in IHOP 09.03.16;
3. **End of life issues**, including advance directives and treatment decisions involving withholding or withdrawing life sustaining treatment, are addressed in the policies of IHOP Section 09.15.05;
4. Consent for **HIV antibody testing and for disclosure of results** is addressed in IHOP 09.03.10;
5. Consent for **universal childhood and adolescent immunizations** is addressed in IHOP 09.03.20;
6. Consent for **sterilization** is addressed in IHOP 09.03.21; and
7. Consent for **participation in clinical research or clinical trials** is addressed in the policies and procedures manual of the Institutional Review Board (IRB), available on the IRB webpage.
8. Patient-centered Communication is addressed in IHOP 09.03.35.

III. Procedure

A. General Consent

1. When is Informed Consent Required and Implied Consent is not enough?

a. Physicians are required to obtain written consent for procedures or treatments indicated by the Texas Medical Disclosure Panel (TMDP).
b. Informed consent must be obtained for all procedures listed in The Texas Medical Disclosure Panel List A (Procedures Requiring Full Disclosure of Specific Risks and Hazards).
c. Procedures not requiring disclosure of specific risks and hazards are contained in List B (Procedures Requiring No Disclosure of Specific Risks and Hazards).
d. A written consent form for sensitive examinations (breast, pelvic, prostate, and rectal examinations) for educational and training purposes is required for patients undergoing anesthesia. Verbal consent is sufficient for these examinations when the patient is not undergoing procedures.

2. If a patient's medical condition changes after a consent form for a specific medical or surgical procedure has been signed, and the change in the patient's medical status results in an increased or additional risk associated with the planned procedure or treatment, a new informed consent discussion and consent form must be completed before the specific medical or surgical procedure may be performed unless the treatment or care is being provided emergently.

B. Discussion and Education

Adult patients (or, when appropriate, their surrogate decision-makers) must receive from their attending physician information regarding the risks and benefits of a proposed treatment and/or procedure. The attending physician may authorize an Advanced Practice Nurse or a Physician's Assistant to obtain informed consent from the patient if, in the physician's clinical judgment, the Advanced Practice Nurse or Physician's Assistant has the requisite skills and training to do so. In all such situations, the attending physician must be available to answer any questions the patient may have that the Advanced Practice Nurse or Physician's Assistant is unable to answer. The attending physician is ultimately responsible for ensuring that the patient understands the nature of their condition and the proposed treatment regimen or procedure to be performed. Obtaining informed consent also allows the patient to fully participate in their care. In the case of a patient or surrogate decision-maker who is Limited English Proficient, discussion and consent should occur in their preferred language. Except in emergencies, this information may include, but is not limited to:

1. The patient's diagnosis, if known;
2. The general nature and purpose of the procedure or treatment, including its risks and benefits and whether it is experimental;
3. The name(s) of the person(s) performing the procedure or administering the treatment;
4. The benefits, risks, discomforts, side effects, complications, and potential problems related to recuperation associated with the procedure or treatment;
5. The likelihood of success;
6. The patient's prognosis and risks and benefits of not receiving or undergoing a treatment or procedure; and
7. Reasonable alternatives (regardless of their cost or the extent to which treatment options are covered by health insurance).

C. Written Consent

1. A Disclosure and Consent for Medical and Surgical Procedures form must be used to document consent if:
   a. The procedure or treatment is included in List A;
   b. The procedure requires the administration of general, spinal, epidural, or regional anesthesia, other than local infiltration;

c. The procedure (invasive or non-invasive) involves more than a slight risk of harm to the patient's body structure (i.e., a risk is more than slight if its disclosure would be material to a reasonable patient's decision whether to accept or reject a treatment option); or
d. The procedure is experimental.

2. Consent forms must be signed by the patient (or person providing consent on behalf of the patient) and a competent witness.

D. Clinics

General consent will be obtained annually before a UTMB provider examines an individual. This general consent extends to all UTMB providers, regardless of which clinic obtains consent, and is valid for a period of one year.

1. Patients will provide general consent to diagnosis and treatment by UTMB providers by signing an electronic or paper Consent for Diagnosis and Treatment (General Consent) form.

2. If consent is not given in person, the consent should be reduced to writing in the patient's medical record and signed by the staff member receiving the consent. The person providing consent on behalf of the patient, if possible, should also sign an informed consent form, and the form then scanned into the patient's medical record thereafter. Additional information regarding this process is available in IHOP 09.03.03, Telephone Consent for Treatment or Procedures.

E. Hospital

General written consent for diagnosis and routine hospital services must be obtained upon each patient's admission to a UTMB (i.e., upon admission to the Emergency Department for 3 hours or longer; to Day Surgery for 1 day; or as an inpatient for an indefinite stay).

F. Revocation of Consent

Unless revoked orally or in writing, written general consent is effective for the duration of the patient's hospitalization, and written informed consent is effective until the listed procedure(s) have been performed, unless the patient's condition has changed such that the risks and/or benefits of the treatment or procedure have changed.

G. Incapacitated Patients

1. Adults and emancipated minors are presumed to be competent to make their own medical decisions as patients. However, if a patient becomes comatose, incapacitated, or otherwise mentally or physically incapable of communication, an adult surrogate decision-maker may consent to medical treatment on the patient's behalf.

2. If a patient has not designated an individual to act as their surrogate decision-maker (for example by medical power of attorney or written declaration), an adult from the following list, in descending order of priority, who has decision-making capacity, is available after a reasonably diligent inquiry, and is willing to consent to medical treatment on behalf of the patient, may act as the patient's surrogate decision-maker:

a. Patient's spouse;
b. Patient's adult children, Patient's parent (s); or

c. Patient's nearest living relative.

3. If the patient does not have a legal guardian, an agent under a medical power of attorney, or a person listed above who is reasonable available after a reasonably diligent inquiry, another physician who is not involved in the medical treatment of the patient may concur with the treatment.

4. Any dispute as to the right of an individual to act as a surrogate decision-maker may only be resolved by a court having jurisdiction.

5. Any decision by a surrogate decision-maker must be based on knowledge of what the patient would desire, if known.

6. A surrogate decision-maker may not, under any circumstance, consent to voluntary inpatient mental health services, electro-convulsive therapy (ECT), or the appointment of another surrogate decision-maker.

7. A surrogate decision-maker's consent to medical treatment that is not made in person shall be reduced to writing in the patient's medical record, signed by the attending physician receiving the consent, and countersigned in the patient's medical record or on an informed consent form by the surrogate decision-maker as soon as possible.

H. Emergency Situations

If a patient's condition precludes obtaining consent, express consent for emergency care of an individual is not required if:

1. The individual is:
   a. Unconscious or unable to communicate because of an injury, accident, or illness; and
   b. Suffering from what reasonably appears to be a life-threatening injury or illness.

2. A court of record orders the treatment of an individual who is in an imminent emergency to prevent the individual's serious bodily injury or loss of life; or

3. The individual is a minor who is suffering from what reasonably appears to be a life-threatening injury or illness and whose parents, managing or possessory conservator, or guardian is not present. (For more information on minors, see IHOP 09.03.18 Consent Treatment of a Minor.)

4. In the event that an incapacitated adult or minor patient's status deteriorates to the point that death or irreparable harm will result unless the urgent/emergent medical care is instituted immediately, two physicians can determine the need for emergency care. Prior to commencing such care, the physician should inform the patient's reasonably available family that the care will be provided despite their objections, if any.

I. Emergency Status Operation – Public Health Emergency

During a public health emergency general consent to treat may be taken verbally in the effort to reduce exposure and promote efficiency. The patient's medical record will be documented to reflect the patient's consent to treat.

J. Documentation of Informed Consent in Chart

1. The consent forms will become part of the patient's permanent medical record.

2. In addition to the signed consent form, the attending physician should document the informed consent process in the medical record.

K. Additional Documentation for Incapacitated Patients

1. If the patient is incapacitated, the attending physician must document in the patient's medical record:

   a. The patient's comatose state, incapacity, or other mental or physical inability to communicate;
   b. The proposed medical treatment;
   c. The efforts made to contact persons eligible to serve as the patient's surrogate decision-maker;
   d. The date and time consent was given, if a surrogate decision-maker consents to medical treatment on behalf of the patient; and
   e. The attending physician's signature.

IV. Relevant Federal and State Statutes

Texas Health and Safety Code Chapter 313 (Consent to Medical Treatment Act)
Texas Health and Safety Code Chapter 773 (Emergency Health Care Act)
Texas Family Code Chapter 32 (Consent to Treatment of Child by Non-Parent)
Texas Administrative Code Title 25, Part 7, Chapter 601 (Informed Consent)
Texas Civil Practice and Remedies Code Chapter 74

V. Related UTMB Policies and Procedures

IHOP - 06.02.16 - Permitted Uses and Disclosure of PHI in Special Situations
IHOP - 09.01.21 - Examination and Treatment of Emergency Medical Conditions and Women in Labor
IHOP - 09.03.03 - Telephone Consent for Treatment Procedures
IHOP - 09.03.10 - Consent for HIV Antibody Testing & for Disclosure of Results
IHOP - 09.03.16 - Refusal of Consent/Treatment
IHOP - 09.03.18 - Consent - Treatment of a Minor
IHOP - 09.03.20 - Universal Childhood and Adolescent Immunizations
IHOP - 09.03.21 - Consent for Sterilization
IHOP 09.03.35 – Patient Centered Communication

VI. Dates Approved or Amended

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VII. Contact Information

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