Name of Policy:	**Consent to Treat and Informed Consent**	THE UNIVERSITY OF TOLEDO MEDICAL CENTER
Policy Number:	3364-100-10-01	
Department:	Hospital Administration	
Approving Officer:	Chief Executive Officer - UTMC Chief of Staff	
Responsible Agent:	Chief Medical Officer	
Scope:	The University of Toledo Medical Center and its Medical Staff	**Effective Date**: 9/1/2023 Initial Effective Date: 7/6/1977

_____	New policy proposal	_____	Minor/technical revision of existing policy
_____	Major revision of existing policy	X	Reaffirmation of existing policy

(A) Policy statement

Appropriate information **must be** provided and consent must be obtained from patients before providing care in non-emergency situations at the University of Toledo Medical Center inpatient units, clinics, outpatient departments or other facilities or locations (collectively referred to as "UTMC").

(B) Purpose of policy

To obtain the general and informed consent of patients to treat by providing an explanation of the nature and purposes of the care, along with alternatives and their benefits, and reasonably known risks. This policy will also outline the process for obtaining an informed consent, how the informed consent is to be documented, where it must be stored and accessibility.

(C) Scope

This policy applies to all procedures and treatments requiring informed consent performed at UTMC.

(D) Definitions

(1) Legally Authorized Representative is:

(a) An attorney-in-fact through a durable power of attorney for healthcare decisions, or

(b) The legal guardian if patient is a minor or has been adjudged incompetent; or

(c) A family member who, in good faith, can make a decision consistent with either the patient's expressed wishes or with what the patient would have wanted (e.g. determined in descending order of priority as follows);

(i) The patient's spouse;

(ii) An adult child of the patient, or if there is more than one adult, a majority of the patient's adult children who are available within a reasonable period of time for consultation with the patient's attending physician;

(iii) The patient's parents;

(iv) An adult sibling of the patient, or if there is more than one adult sibling, a majority of the patient's adult siblings who are available within a reasonable period of time for such consultation;

(v) The nearest adult who is not described in this section who is related to the patient by blood or adoption, and who is available within a reasonable period of time for such consultation.

(E) General Consent for Treatment

Upon first contact with UTMC and no less than yearly thereafter, every UTMC inpatient and outpatient, or Legally Authorized Representative for the patient, will be asked to sign the UToledo General Consent for Treatment form – Form AF001. The General Consent for Treatment form includes a general consent to treat, agreement for payment, the consent to photograph or taking of pictures for clinical documentation and medical education, the understanding of the patient with regard to blood transfusions and blood products that may be administered.

(F) Informed Consent

(1) *General Procedure.*

(a) Providing Information to the Patient for Purposes of Informed Consent. The physician, dentist or other health care provider who is privileged to provide or perform the treatment or procedure shall explain to the Patient, or the Patient's Legally Authorized Person, the following and will confirm that all questions have been answered:

(i) The nature and purpose of the proposed procedure or treatment;

(ii) What the procedure or treatment is expected to accomplish and the likelihood of achieving those goals;

(iii) The alternatives to the procedure or treatment, including the attendant material risks and benefits;

(iv) The probable consequences of declining recommended procedure or treatment or alternative therapies;

(v) The reasonably known risks and benefits of the procedure or treatment;

(vi) The effects of no treatment at all, including the effect on prognosis and the reasonable risk associated with no treatment;

(vii) Attendant treatment modalities associated with the proposed procedures including but not limited to anesthesia and blood transfusion; and

(viii) A discussion about any circumstances under which information about the patient must be disclosed or reported. Note: Such circumstances may include requirements for disclosure of information regarding cases of HIV, tuberculosis, viral meningitis and other diseases that are reported to organizations such as health departments or the Centers for Disease Control and Prevention.

(b) Teach Back. If possible, ask each patient or Legally Authorized Person to "teach back" in his or her own words, key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent.

(c) Informed Consent Form. The form to use to document informed consent is the informed consent acknowledgement form #HM007, attached to this policy ("UT Informed Consent"). See also special consents required for anatomical gifts and HIV testing in policies 3364-100-45-03 and 3364-100-10-9. Blood or blood product administration does not require completion of the UT Informed Consent, but the patient or Legally Authorized Person must be provided the Blood Transfusion Consent or Refusal form (LG002) with Blood Information Sheet approved by the Blood Utilization Review Committee which should be signed by the patient and placed in the medical record.

(d) Indicating who will Provide the Services or Administer Anesthesia. The primary practitioner may require assistants to safely and effectively complete the procedure. These may be technicians, licensed assistants or trainees. The practitioner primarily responsible for performing the procedure and any other practitioners who will be involved in important tasks for the patient's care must be identified in the Informed Consent. Assistants may be referred to by category if not specifically known or if the schedule is varied or frequently amended. The assistants may be assigned important tasks related to surgery and "important tasks" may include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines.

(i) For surgeries in which residents will participate in important parts of the surgery, discussion *is encouraged* with the patient to include the following:

(a) That it is anticipated that physicians who are in approved post graduate residency training programs, or hospital staff, will participate in the surgery based on their availability and level of competence;

(b) If applicable, that it will be decided at the time of surgery which residents will participate and their manner of participation, and that this will depend on the availability of residents with the necessary competence, the knowledge the operating practitioner has of the resident's skill set and the patient's condition; and

(c) That residents performing surgical tasks will at all times be under the supervision of the operating practitioner and the practitioner will be present to the level necessary for the resident's competence.

(ii) For surgeries in which qualified medical practitioners who are not physicians will perform important parts of the surgery or administer anesthesia, discussion should be had indicating the types of tasks each practitioner (e.g., students, nursing assistants, nurse anesthetists) will conduct and that such practitioners will only be performing tasks within the scope of practice for which they have been granted privileges by UTMC.

(e) Completion of the Documentation for Informed Consent. After the informed consent discussion, a health care provider, which *may* include a person who participated in the discussion, is to fill out the UT Informed Consent that acknowledges the discussion. The physician or practitioner who provides the information to the patient or Legally Authorized Representative for informed consent should document the conversation in the ambulatory or inpatient electronic medical record ("EMR"), if the physician or practitioner is not a signer to the informed consent document. The information documented in the UT Informed Consent is to be as specific as possible with regard to the discussion held with the patient. The person obtaining the consent documentation must:

(i) Complete the UT Informed Consent and attach other documentation if presented to the Patient or Legally Authorized Representative;

(ii) Confirm with the Patient or Legally Authorized Representative that such information has been disclosed and that all questions about the procedure or procedures have been answered;

(iii) Obtain the signature of the Patient or Legally Authorized Representative;

(iv) Have one witness to the signature sign the form;

Note: If consent is provided over the phone, an additional witness must be present, who should also sign the UT Informed Consent (with the witness attesting to the conversation, not the adequacy or accuracy of the form or the understanding of the individual receiving the information);

(v) Make sure that the Patient or Legally Authorized Representative has checked the box on the Informed Consent Form indicating that this person is able to communicate effectively in English or any other language in which the UT Informed Consent is written;

(vi) Time and date the UT Informed Consent; and

(vii) The UT Informed Consent must be placed in the patient's EMR or, in the alternative, the preoperative/pre-procedural progress note must state that the informed consent discussion has occurred. If an informed consent is obtained in an outpatient clinic setting for a scheduled procedure, clinic staff will forward the informed consent document to the procedure area and take all necessary steps to see that the consent is placed into the patient's EMR prior to the procedure.

(2) *What the single UT Informed Consent Covers and Timing of Consent.*

(a) Multiple or additional procedures to be performed at the same time may be covered in a single UT Informed Consent, including in this same form the potential administration of blood products.

(b) A single course of treatment with a series of nearly identical procedures may be contained within a single UT Informed Consent.

(c) If a procedure is rescheduled from its original date, the UT Informed Consent remains valid if the course of treatment or the patient's condition is not substantially altered.

(d) A separate informed consent process and a new UT Informed Consent must be obtained whenever:

(i) The course of treatment or the patient's condition is substantially altered;

(ii) The physician named to perform the procedure has changed;

(iii) If additional surgical or medical procedures are going to be provided that were not initially discussed with the Patient and set forth in an informed consent form; *or*

(iv) When the interval between the initial informed consent and the procedure or course of treatment exceeds six months.

(e) A patient will not be pre-medicated, including analgesics and even moderate sedation, if the UT Informed Consent documentation is not completed.

(f) If a patient has been administered pre-anesthesia medication, including analgesics and moderate sedation, before informed consent has been obtained and a UT Informed Consent form has not been signed, the case will be delayed until the responsible physician or dentist obtains the UT Informed Consent or otherwise can document in the progress notes that consent was given.

(g) Hospital Staff will check for a completed UT Informed Consent or a progress note documenting informed consent. Responsibility for providing informed consent rests with the practitioner providing the care and all staff should assist in obtaining the proper documentation of said informed consent.

(3) *The procedures that require informed consent include but are not limited to the following:*

(a) Major or minor surgery which involves an entry into the body, either through an incision or one of the natural body openings;

(b) All procedures (including conscious sedation) in which anesthesia is used excluding local, topical, intradermal or superficial administration;

(c) Any major invasive procedure (e.g., intracranial pressure monitoring, tube thoracostomy, cardiac catheterization, PTCA, central line insertion);

(d) Non-surgical procedures involving more than a slight risk of harm or the risk of a change in the patient's body structure (e.g., myelogram, arteriogram);

(e) Procedures involving the use of x-ray therapy;

(f) Experimental procedures or off-label drug therapy; and

(g) Any other procedures with a substantial risk, including procedures listed on Addendum 1 of the UTMC Universal Protocol Policy – Procedural Verification/Time Out (Policy No 3364-100-53-05).

(G) Situations When Unable to Provide Informed Consent and Obtain Documentation

(1) Decision Making Capacity

(a) Generally, a person is considered competent if the person can understand the nature and consequences of his or her actions and can care for himself or herself and property. Adults are presumed to be competent. Mental retardation and mental illness do not necessarily result in a finding of incompetence. Only a judge can definitively determine that an adult is incompetent.

(2) *Consent for Patients with Impaired Decision Making Capacity.*

(a) When patients are experiencing impaired decision making capacity or are determined to be incompetent to give consent, the physician must be certain that the informed consent is received and acknowledged by a Legally Authorized Representative prior to any elective procedures.

(b) Certain medications, injuries and illnesses can impair a person sufficiently to render the person incompetent, at least temporarily. In these cases, it is the physician's responsibility to determine whether a patient is capable of giving consent

(3) *Consent for Patients with Impaired Decision Making Capacity (in a non-emergency situation).*

If a patient has impaired decision making capacity and therefore is unable to provide informed consent, the caregiver and staff must attempt to obtain consent from a Legally Authorized Person to receive the informed consent and provide acknowledgement of the consent. In situations where a Legally Authorized Person is not physically present in the hospital to give consent, the effort should be directed toward obtaining telephone consent witnessed by two staff members. This will be recorded in the medical record, including date, time, location of consenting party, telephone number and the names of the two witness.

(4) *Consent in Emergency Situations.*

When it is impossible to obtain the consent of the patient or legal representative, emergency consent situations are deemed valid for a physician to proceed when the following factors exist:

(a) It is the attending physician's determination that treatment is required immediately to preserve the life or health of the patient or a sudden, unexpected happening resulting in harm to a person which, if left untreated, represents an imminent threat of (i) loss of life, (ii) loss of limb or body function, (iii) major disfigurement, or (iv) major, irreversible psychiatric damage, and such determination is documented in the progress notes;

(b) Reasonable attempts are made to contact a Legally Authorized Person;

(c) The care rendered is consistent with recognized professional standards and its scope does not extend beyond what is required to deal with the emergency; and

(d) There is no evidence that the patient does not wish to receive the recommended medical care to save his or her life or prevent other serious consequences.

(5) *Telephone Consent.*

When in-person consent cannot be timely obtained, telephone consent may be used. Consent by telephone must be witnessed by two individuals other than the attending physician and documented in the medical record indicating the exact time, nature of the consent given and from whom consent was received.

(6) *Consent for Unaccompanied, Un-emancipated Minor.*

(a) Determining Who is an Unaccompanied, Un-emancipated Minor. A "Minor" is any person who has not yet attained the age of 18 years. Initially, it must be determined if the individual is an emancipated Minor, which in Ohio, is a Minor with sufficient evidence of emancipation from parents or guardians indicated through marriage, fiscal and residential independence, has other minor children or is on active duty with the armed services.

(b) Obtaining Consent for an Unaccompanied, Un-emancipated Minor.

(i) Where it is determined that the Minor is not emancipated, parental or legal guardian consent must be obtained.

(ii) Treatment of Minors presenting to UTMC should not be initiated without proper authorization, unless otherwise permitted by law.

(iii) Concerted efforts must be made to locate parents or the proper legal guardian to provide consent for unaccompanied Minors requesting or requiring medical treatment. Those with authority to consent may include the following:

(a) The natural parents of a Minor or a parent with legal custody;

(b) If the parents are unmarried, the parent of the Minor with legal custody as indicated through court order;

(c) Legally appointed guardian.

(c) When Unable to Obtain Consent for a Minor.

(i) The Minor's assent should be obtained in addition to the parent or legal guardian's consent where the Minor is of sufficient maturity to understand the nature and the risks of the proposed treatment.

(ii) For situations involving emergencies, (See Paragraph (G)(4) above) treatment may be given without consent.

(iii) If it has not been possible to obtain the consent of the parent or legal guardian after every reasonable effort has been made, in an urgent but non-emergency situation, hospital personnel should contact Outcomes Management or Risk Management to assist in determining whether a court order is necessary to clarify legal authority.

(iv) Should parents or legal guardians withhold consent when in the professional judgment of the physician and it is contrary to best interests of a Minor, court proceeding should be considered.

(v) In situations where the Minor has an accompanying Emergency Medical Authorization Form, treatment may be provided to the extent permitted per the authority granted in the form.

(d) Certain federal laws, including Medicaid, provide for confidential family planning services (contraception and pregnancy) regardless of age.

(i) The Informed Consent processes set forth above should be followed with the Minor as if they were a fully competent adult patient.

(ii) Notice to parents or legal guardians should be provided for victims of sexual offenses as required by law and victim should be informed of treatment for sexually transmitted diseases, pregnancy and medical and psychiatric services.

(iii) Hospital staff should understand that the parent or legal guardian may be responsible for all costs of care rendered.

(iv) In regard to treatment of pregnancy, other than abortion, the physician will assess the Minor's ability to understand the nature and consequences of the planned procedure, and document his assessment of the Minor's level of decision making capacity.

(v) The Minor patient should be notified that if a parent consents for certain medical services, the parent or legal guardian may be responsible for costs of care rendered.

(7) Ohio law provides that a Minor may consent to the following medical services, without the requirement of parental consent:[1]

(a) Physical examination of a Minor who is a victim of a sexual offense with written notification to the parent/guardian (ORC § 2907.29);

(b) HIV testing (ORC § 3701.242);

(c) Diagnosis/treatment of any venereal disease (ORC § 3709.241);

(d) Outpatient mental health services of a minor 14 years of age or older (ORC § 5122.04); and

(e) Diagnosis/treatment for substance abuse of any condition which is reasonable to believe is caused by a drug of abuse, beer or intoxicating liquor (ORC § 3719.012).

[1] The parent or legal guardian is not responsible for costs of care rendered without their consent.

(8) Research.

For treatment or procedures performed as part of a research study, informed consent must be obtained from the patients as directed by the UT Institutional Review Board (IRB). If the IRB requires written consent in connection with a clinical trial, the consent document must include the information specified by the IRB. The research consent should also conform with this policy.

Approved by:

_____ _____
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/s/ _____
Richard P. Swaine
Chief Executive Officer – UTMC

Date

/s/ _____
Puneet Sindhwani, MD
Chief of Staff

Date

Review/Revision Completed By:
HAS
Chief of Staff
Office of Legal Affairs – HSC

Review/Revision Date:

10/1/1981	1/30/1995	9/1/2023
4/4/1984	3/10/1999	
4/12/1985	6/7/2002	
10/27/1986	6/8/2005	
10/1/1987	8/1/2008	
10/20/1988	12/1/2009	
2/17/1989	11/15/2010	
5/25/1990	8/27/13	
10/1/1991	7/1/2017	
5/7/1993	3/20/2020	
10/20/1993	9/1/2020	

Next Review Date: 9/1/2026

Policies Superseded by This Policy: 3364-87-28

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Informed Consent to Medical or Surgical Procedure

Patient Label

Please Read Carefully Before Signing

PATIENT_____Age_____

1. As discussed with me by Dr._____that this Physician and his/her resident physicians,/physician associates(s)/assistant(s) (list if known): _____) are authorized by me to perform the surgical or medical procedure known as (name or describe):

_____

_____

2. As explained to me, I understand that this medical or surgical procedure is for the purpose of (describe fully):

_____

_____

and although no specific result has been guaranteed, it is expected to accomplish the following (list benefits and include likelihood of achieving) :

_____

_____

3. (Please select A, B or C)

A. ☐ I consent to the use of anesthesia under the direction and supervision of the UTMC Department of Anesthesiology (I understand that I can request to see a list of the Anesthesiology faculty, and such list will be provided upon my request). All of my questions have been answered about the use of this anesthesia. I understand that the attending anesthesiologist may be assisted by resident physicians, certified registered nurse anesthetists or anesthesiology assistants. I consent to the use of the anesthetics that the anesthesiologist has advised, with the exception of (none or a particular one):_____

B. ☐ I consent to the use of sedation (to relax me) and/or analgesia (to prevent and relieve my pain), to be administered by or under the direction and supervision of Dr.(s) _____ All of my questions have been answered about the use of sedation and/or analgesia. I consent to the use of such drugs as determined by the anesthesiologist, with the exception of (none or a particular one):_____

C. ☐ *I DO NOT authorize sedation and have been advised of the potential risks of no sedation.*

4. (Please select A or B):

A. ☐ I authorize the use of blood and blood products determined to be necessary by my physician(s). I understand that this involves risk of hepatitis, Human Immunodeficiency Virus (HIV) or other adverse reactions. There can be no assurance against these risks. I have been informed about alternative means of therapy.

B. ☐ *I refuse to authorize the use of blood or blood products. My physician has explained alternative means of therapy and the expected or potential consequences of this refusal.*

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Informed Consent to Medical or Surgical Procedure

Patient Label

5. As explained to me, I understand that any surgery or medical procedure(s), involve elements of risk. As also explained to me, I understand that there may be risks which are unexpected or not reasonably known. I further understand that in my case, the reasonably known material risks include those listed here:

6. I recognize that, during the course of the surgery or medical procedure unforeseen conditions may necessitate additional or different procedures from those listed above. In emergency situations, my physician is permitted to proceed with necessary additional or different procedures that are in my best interest.

7. I acknowledge that the physician(s) has(have) explained to me the nature and purpose of the procedure(s) and what the procedure(s) is (are) expected to accomplish together with the reasonably known risks. I understand that I have a right to refuse the recommended procedure. I have been informed of alternative methods of treatment. I have also been informed of the likely results if I remain untreated. I have had an opportunity to ask questions and all of my questions have been answered in a satisfactory manner.

I hereby state that I have read and understand this form.

Signature of Patient (If necessary Legal Representative)_____Relationship_____

Witness_____ Date: _____ Time: _____ (☐ A.M ☐ P.M.)
(Witness is the person who observes the signature of the patient [or the patient's legal representative]. The witness may be the Physician/Resident, assistant, or any hospital staff member. The witness may be the same person below, assisting in completion of the form.) The witness signature line must always be completed (even if the witness and the person assisting in the completion of the form are the same).

Printed Name & Position of Person assisting in completion of Form:_____
(This person may be the Physician/Resident providing the informed consent discussion or may be an assistant to the Physician/Resident familiar with the informed consent. If an assistant completes the form, the Physician/Resident must document the informed consent process in the medical record.)

Signature of Person assisting in completion of Form:_____

Time: _____ Date: _____

IF PATIENT SPEAKS A LANGUAGE OTHER THAN ENGLISH OR IS COMMUNICATIVELY DISABLED:
I have translated the information and advice presented orally to this patient by the person obtaining this consent, and I have also read this consent form in_____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this translation.

_____	_____	_____	_____
Interpreter	Date	Time	Phone #

Specifications

Form Description Informed Consent New version 12/09 **Current Form Number** HM007

Print

Stock

- ☒ 20# White
- ☐ 60# Pastel _____
- ☐ 2 pt carbonless
- ☐ 3 pt carbonless
- ☐ 4 pt carbonless
- ☐ 5 pt carbonless
- ☐ other carbonless
- ☐ Other Stock_____
- ☐ Special Instructions (see below)

Size

- ☒ 8 ½ x 11
- ☐ 8 ½ x 14
- ☐ 11 x 17
- ☐ Special Instructions (see below)

Sides

- ☐ Front
- ☒ Front & Back

Finishing

Padding

- ☒ Top
- ☐ Left

_50_ sheets / pad

_____ sheets / pack

Unit Size

- ☐ 25 to a pack
- ☐ 50 to a pack
- ☐ 100 to a pack
- ☐ Special Instructions (see below)

Folding

- ☐ **Letter Fold**
- ☐ Z Fold
- ☐ Special Instructions (see below)

Drilling

- ☒ Long edge std 3 holes
- ☐ Long edge 2 holes
- ☐ Long edge 5 holes
- ☐ Long edge 7 holes
- ☐ Long edge 9 holes
- ☐ Short edge 2 holes
- ☐ Staple, Where _____
- ☐ Special Instructions (see below)

Packaging ☐ **Yes** ☐ **No**

_____units / wrap

Special Instructions: