

ADMINISTRATION

POLICY MEMORANDUM

POLICY TITLE:	Disclosure and Consent For Medical and Surgical Procedures, and Radiation Therapy
POLICY NUMBER:	MCH-2004
FUNCTION AREA:	Ethics, Rights, and Responsibilities
POLICY APPLICABLE TO:	Organization-wide. Applies to all services and care settings where procedures or treatments requiring informed consent are performed
POLICY EFFECTIVE DATE:	5/4/1995
POLICY REVISED:	03/2021

POLICY STATEMENT:

To provide to patients or persons authorized to consent for patients the disclosure of benefits, risks and hazards involved in medical care or surgical procedures rendered by physicians or health care providers.

PROCEDURE:

Each patient or person authorized to consent for a patient shall have the right to be informed about the patient's condition and the recommended surgical, medical or diagnostic procedures to be used so that the patient or person authorized to consent may make the decision whether or not to undergo the procedures after knowing the risks and hazards involved.

To that end, it shall be the duty of each physician, anesthesia care provider, dentist, oral surgeon or podiatrist (hereafter referred to as "Physician") who will perform a surgical, medical, diagnostic or anesthesia procedure to obtain informed consent, as required by this Policy, utilizing the appropriate Disclosure and Consent Forms.

The "Disclosure and Consent for Medical and Surgical Procedures" form is hereafter referred to as the "Consent Form." Copies of appropriate consent forms are attached. Limited English-proficient patients will be provided with applicable language-specific forms and/or translation services will be provided and documented in the health record.

WHEN TO OBTAIN:

The Texas Medical Disclosure Panel has determined which risks and hazards related to medical care and surgical procedures must be disclosed to patients or persons authorized to consent for patients.

- 1) Texas Administrative Code, Chapter 601, Rule 601.2, List "A" enumerates the treatments and procedures which require full disclosure. A Consent Form shall be obtained and used for such treatments and procedures, setting out, as a minimum, the required disclosures.
- 2) Texas Administrative Code, Chapter 601, Rule 601.3, List "B" enumerates the treatments and procedures which require no disclosure. Although no disclosure is required, a Consent Form shall be obtained and used for such treatments and procedures.
- 3) Treatments and procedures may not be included on List "A" or List "B". In such event, a Consent Form with adequate disclosures of risks and hazards will be obtained and used for any treatment or procedure carrying an inherent risk which is material in that it could influence the decision of a reasonable person to consent to such treatment or procedure.

THE CONSENT FORM:

- 1) An appropriate Consent Form will be available from Medical Center Hospital. Such Consent Form must be used by the Physician. Medical Center Hospital will assist any physician in reproducing its consent form on the physician's letterhead. In addition, but not in lieu thereof, a Physician may utilize his or her own form, provided it is pre-approved by the Director of Performance Improvement or the Director's designee.
- 2) More than one procedure may be documented on the same Consent Form, if performed by the same physician. Otherwise, a separate Consent Form shall be completed for each medical, surgical, or diagnostic procedure.
- 3) Documentation on the Consent Form should include the condition which the patient has, the procedures planned, alternative forms of treatment/anesthesia, risks of non-treatment, and the risks and hazards which may occur. The Physician may also write on the Form any pertinent information concerning his or her conversation with the patient and/or the person authorized to consent for the patient. The Consent Form may be signed by the patient or person authorized to consent only after the Form has been completed. The Physician will sign, date and time the Consent Form and document involvement in the informed consent process in the patient health record.
- 4) The Consent Form may only be signed by the patient (or if applicable by the Surrogate Decision Maker) prior to the administration of any preoperative medication and mind-altering drug.
- 5) The Consent Form must include the first name, middle initial (if one) and the last name of the Physician in the appropriate space.
- 6) The full terminology of the procedure(s) must be written in the appropriate space on the Form without the use of abbreviations.
- 7) When care of the patient requires a series of treatment within the same admission, (e.g., surgical debridement) one Form may be used for all procedures. Documentation on the Consent Form should include a notation that a series of

treatments are planned. The Physician must explain the treatment plan to the patient or person authorized to consent.

- 8) Witnesses, in the number hereafter indicated, must always sign in the space provided on the Form. Witnesses are to realize they are witnessing the signature only, not contents of the Consent Form.
- 9) The date, time, patient's signature and the witnesses' signature must be in blue or black ink. If someone other than the patient signs, the relationship is to be noted next to the signature.
- 10) Patients may sign the Consent Form in the Physician's office. The original signed and witnessed form, or an electronic equivalent, must be present in the patient's health record prior to the procedure being performed.
- 11) The signed and witnessed Consent Form is effective until the actual procedure is performed not to exceed a period of 90 days, unless revoked or cancelled by the patient beforehand.
- 12) All consent forms will be completed and signed before the patient is taken to the procedure room.

SURROGATE DECISION MARKER

- 1) As long as a patient is legally competent, he or she is the only person who can consent to medical or surgical procedures or treatment.
- 2) If an adult patient is comatose, incapacitated, or otherwise mentally or physically incapable of communication, and there is no directive to physicians, no agent under a medical power of attorney, and no legal guardian, then the following persons, in the priority shown may consent to the planned medical or surgical care or treatment and sign the Consent Form:
 - a) the patient's spouse;
 - b) an adult child of the patient who has the waiver and consent of all other qualified adult children of patient to act as the sole decision-maker.
 - c) a majority of the patient's reasonably available adult children;
 - d) the patient's parents;
 - e) the individual clearly identified to act for the patient by the patient before the patient became incapacitated, the patient's nearest living relative or a member of the clergy.

Any such consent must be based on knowledge of what the patient would desire, if known.

- 3) The attending physician shall describe the patient's comatose state, incapacity, or other mental or physical inability to communicate in the patient's health record and the proposed medical treatment. The attending physician shall also make reasonable, diligent effort to contact or cause to be contacted the person eligible to serve as surrogate decision maker. Efforts to contact those persons shall be recorded in detail in the patient's health record. If a surrogate decision maker consents to medical treatment on behalf of the patient, the attending physician shall record the date and time of the consent and sign the patient's health record.
- 4) A surrogate may not consent to the following:
 - a) A decision to withhold or withdraw life sustaining treatment;
 - b) Medical treatment of minors;

- c) Voluntary inpatient mental health services;
- d) The appointment of another decision maker.

CARE/PROCEDURES PERFORMED WITHOUT INFORMED CONSENT:

- 1) A “medical emergency” is the sudden onset of a medical or traumatic condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in:
 - a) placing the patient’s health in serious jeopardy;
 - b) serious impairment to bodily functions; or
 - c) serious dysfunction of any bodily organ or part.
- 2) An effort should be made at the time of a medical emergency to obtain execution of the Consent Form. However, if the patient is comatose, incapacitated, or otherwise mentally or physically incapable of communication, and no authorized surrogate decision maker is readily available, appropriate medical and surgical care and treatment may be rendered without a Consent Form. If available, two physicians, otherwise one physician, must describe the following in the patient’s records:
 - a) The patient’s comatose state, incapacity, or other mental or physical inability to communicate;
 - b) The proposed medical treatment;
 - c) The medical emergency;
 - d) The efforts made by the physician (or others to the physician’s knowledge) to contact persons eligible to serve as surrogate decision makers.
- 3) In a medical emergency, telephone consent is acceptable. Such consent requires two witnesses on the telephone connection at the same time. Any surrogate decision-maker’s consent to medical or surgical treatment which is made by telephone shall be reduced to writing in the patient’s health record, along with the date and time of such consent, and signed by the two witnesses receiving the consent. The consenter’s name and relationship to the patient and “by telephone consent” should be documented on the consent form. As soon as is reasonably possible, health records shall be countersigned in an appropriate place or the consent form shall be executed by the surrogate decision-maker.

MINORS AND CHILDREN:

- 1) DEFINITION: A minor or child is anyone under the age of 18 years who is not and has not been married or who has not had the disabilities of minority removed for general purposes.
- 2) The following may consent to medical and surgical treatment or care for a minor child:
 - a) A child’s parent who is not divorced or who is the only surviving parent;
 - b) A sole managing conservator of a child;
 - c) A joint managing conservator, if such conservator has been allocated such consent rights or duties;

- d) A possessory conservator who has possession of a child, but such conservator may not consent to medical care involving an invasive procedure;
 - e) Any parent appointed as a conservator during an emergency involving an immediate danger to the health and safety of the child;
 - f) A guardian of the person of a child.
- 3) Copies of conservatorship and guardianship documents and court orders must be filed with the health record prior to execution of the Consent Form by the conservator or guardian.
- 4) The Consent Form must include the following:
- a) The name of the patient;
 - b) The name of one or both parents, if known, and the name of any managing conservator or guardian of the child;
 - c) The name of the person giving consent and the person's relationship to the child;
 - d) A statement of the nature of the medical treatment to be given; and
 - e) The date the treatment is to begin.
- 5) The following persons may consent to medical and surgical treatment or care for a child when the person having the right to consent, listed in paragraph 2 above, cannot be contacted and that person has not given actual notice to the contrary:
- a) a grandparent of the child;
 - b) an adult brother or sister of the child;
 - c) an adult aunt or uncle of the child;
 - d) an educational institution in which the child is enrolled that has received written authorization to consent from a person having the right to consent;
 - e) an adult who has actual care, control, and possession of the child and has written authorization to consent from a person having the right to consent;
 - f) a peace officer who has lawfully taken custody of a minor, if the peace officer has reasonable grounds to believe the minor is in need of immediate medical treatment.
- 6) A child may consent to his or her medical and surgical treatment or care if the child:
- a) is on active duty with the armed services of the United States of America; or
 - b) is 16 years of age or older and resides separate and apart from the child's parents, managing conservator or guardian, with or without the consent of the parent, managing conservator, or guardian and regardless of the duration of the residence; and managing the child's own financial affairs, regardless of the source of income; or
 - c) consents to the diagnosis and treatment of an infectious, contagious, or communicable disease that is required by law or a rule to be reported by the Physician to a local health officer or the Texas Department of Health, including all diseases within the scope of Section 81.041, Health and Safety Code; or
 - d) is unmarried and pregnant and consents to hospital, medical, or surgical treatment, other than abortion, related to the pregnancy; or

- e) consents to examination and treatment for drug or chemical addiction, drug or chemical dependency, or any other condition directly related to drug or chemical use; or
 - f) is unmarried and has actual custody of the child's biological child and consents to medical, dental, psychological, or surgical treatment for the child.
 - g) consent of the parents, managing conservator or guardian of a child is not necessary in order to authorize medical and surgical treatment or care under this section 6.
 - h) a physician may, with or without the consent of a child who is a patient, advise the parents, managing conservator, or guardian of the child of the treatment given to or needed by the child.
- 7) Minors abandoned by parents:
- a) a social worker shall be contacted to determine if the child has been abandoned.
 - b) Child Protective Services shall be contacted.
 - c) If treatment is urgent for the health or life of the child, medical treatment shall be provided while guardianship is being determined
- 8) Minors in foster care:
- a) The foster parents shall provide legal supporting documentation of the guardianship of the child.

WITNESSING:

- 1) The patient's consent, written or oral, must be witnessed by a competent adult.
- 2) A patient's written signature will require documentation of one (1) witness.
- 3) A patient's oral authorization will require documentation of two (2) witnesses.
- 4) A patient's authorization signed by an "X" will require documentation of two (2) witnesses.
- 5) Consent Form authorization acquired over the telephone requires two (2) witnesses on the telephone connection at the same time.

ADDITIONAL CONSENTS:

- 1) In addition to the Consent Form, the following forms are required, if applicable:
 - a) Organ/Tissue Donation (refer to Nursing Policy #6030-100-0011 Organ and Tissue Donation)
 - b) Consent to Photograph/Interview/Videotape – Photographs, interviews, and/or videotapes of patients obtained for non-medical care and treatment reasons require patient permission by use of the Consent to Photograph/Interview/Videotape. Any unauthorized photographs, interviews, or videotapes are a violation of the patient's rights to privacy under the Federal HIPAA Rules.
 - c) State Sterilization Consent
 - d) Blood Transfusion Consent (refer to Nursing Policy NADM-0019 Blood and Blood Product Administration)
 - e) Cytotec Administration Consent Form

- 2) Such forms will be available from Medical Center Hospital.
- 3) Medical Center Hospital shall be responsible for obtaining execution of the basic "Consent for Treatment" form at the time of admission if possible.

INCORRECT CONSENTS:

- 1) If the Consent Form is incorrect, a new form must be completed and signed.
- 2) If the patient has received a mind-altering drug, such as the preoperative medication:
 - a) The procedure will be delayed for a minimum of four (4) hours; or
 - b) A second Physician may make an assessment of the patient's mental orientation and capacity for understanding the nature and consequences of a treatment decision including the benefits, risks and hazards, document the results of that assessment in the "Progress Notes" and have the patient sign a new form.
- 3) If the patient has received a mind-altering drug within four hours of the procedure and the Consent Form is incorrect, an "ORTS" Report (Occurrence Report Trending System) must be completed.
- 4) NEVER ALTER any existing signed Consent Form. A new form must be completed as required by this Policy.

RADIATION THERAPY (Texas Administrative Code § 601.5):

- 1) The Texas Medical Disclosure Panel has adopted a form to be used by the physician to inform the patient or person authorized to consent for the patient of the possible risks and hazards involved in radiation therapy. This form is to be used in lieu of the general Consent Form for disclosure and consent relating only to radiation therapy procedures. The completion and execution of this form shall follow and be subject to the procedures set out above for the Consent Form.
- 2) If, in addition to radiation therapy, a surgical, medical, anesthetic, or diagnostic procedure is also recommended or proposed which would require a Consent Form, then a separate Consent Form shall be obtained as well as the Radiation Therapy Consent Form.
- 3) An appropriate Radiation Therapy Consent Form will be made available by Medical Center Hospital. Such Radiation Therapy Consent Form must be used by the Physician.

HYSTERECTOMY (Texas Administrative Code § 601.8):

The Texas Medical Disclosure Panel has adopted a separate "Hysterectomy Disclosure and Consent Form" which shall be used to provide informed consent to a patient or person authorized to consent for the patient of the possible risks and hazards involved in the hysterectomy surgical procedure named in the form. This form is to be used in lieu of the general disclosure and consent form.

TERMINATION OF PREGNANCY:

Termination of pregnancy is performed at MCH under exceptional circumstances on a case by case basis or when medically necessary.

Medical Center Hospital defines medically necessary as:

- a) According to the physician's best medical judgment, the termination is necessary to prevent the death or risk of physical injury, impairment and/or harm to the health of the mother.
- b) The fetus has severe and irreversible abnormalities not conducive to life, identified by documented diagnostic procedures.
- c) In situations where the life of the pre-viable fetus is in jeopardy; the fetus is

unlikely to reach viability without serious, life threatening consequences; and the patient has been given the choice of conservative management or the termination of the pregnancy; and the patient has consented to the termination of pregnancy.

In addition to the standard Consent Form delineating specific medical risks associated with termination of pregnancy, written certification of the receipt of information as delineated in the Woman's Right to Know Act (Ch. 171 Texas Health and Safety Code) must be included in the health record prior to the start of the procedure. Such certification form is available from MCH for use by the physician in compliance with legal requirements.

ANESTHESIA AND/OR PERIOPERATIVE PAIN MANAGEMENT (Texas Administrative Code § 601.9):

The Texas Medical Disclosure Panel has adopted a separate form which shall be used to provide informed consent to a patient or person authorized to consent for the patient of the possible risks and hazards involved in anesthesia and/or perioperative pain management (analgesia).

DEFINITIONS:

- **Legally competent:** an adult who has the ability, based on reasonable medical judgment, to understand and appreciate the nature and consequences of a treatment decision, including the significant benefits and harms of and reasonable alternatives to, any proposed treatment decision.
- **Incompetent:** lacking the ability, based on reasonable medical judgment, to understand and appreciate the nature and consequences of a treatment decision, including the significant benefits and harms of, and reasonable alternatives to, any proposed treatment decision.
- **Adult:** "Adult" means a person 18 years of age or older or a person under 18 years of age who has had the disabilities of minority removed.
- **Legal guardian:** a person who is appointed guardian of the person of an incapacitated individual under the terms and provisions of the Texas Probate Code.
- **Qualified adult child:** a child by birth or adoption who is an adult and who has the ability to understand and appreciate the nature and consequences of a decision regarding medical treatment and the ability to reach an informed decision in the matter.
- **Disabilities of minority:** the legal inability or lack of capacity of a minor to make certain decisions or undertake certain acts such as consent to medical care and treatment, enter into contracts, select his or her domicile, and sell or convey real property.
- **Sole managing conservator:** a parent, competent adult, an authorized agency or a licensed child-placing agency who by law and court order has certain rights and duties with respect to a child to be exercised independently of any other person, including primary custody of the child and (unless limited by court order) the right to consent for the child to medical, dental, and surgical treatment involving invasive procedures, and to consent to psychiatric and psychological treatment.
- **Joint managing conservator:** a parent who, by court order, has certain specified rights and duties with respect to a child's physical care, support, and education to be exercised independently or jointly with another, usually the other parent, including the right (whether or not specified in a court order)

to consent for the child to medical and dental care not involving an invasive procedure during the time such conservator has possession of the child and to consent for the child to medical, dental, and surgical treatment during an emergency involving an immediate danger to the health and safety of the child.

- Possessory conservator:** a parent who is not appointed as a sole or joint managing conservator of a child and who, by court order, typically has express visitation and/or custody rights and other express rights and duties with respect to a child including (unless limited by court order) the right to consent for the child to medical and dental care not involving an invasive procedure during the period such conservator has possession of the child and the right to consent for the child to medical, dental, and surgical treatment during an emergency involving immediate danger to the health and safety of the child.

References:

CMS Medicare Conditions of Participation: §482.13, §482.51,
 §482.24 Texas Administrative Code Chapter 601

AUTHOR'S SIGNATURE	
This will be authorized electronically	Director of Performance Improvement
AUTHORIZING SIGNATURE(S)	
This will be authorized electronically	ACNO, Surgical Services Division
	Chief Compliance Officer
	Vice President/Chief Legal Counsel
	Chief Nursing Officer
	Chief Medical Officer
	President/Chief Executive Officer
END OF POLICY	