Catholic Health
Mount St. Mary's Hospital

Memo

To: Mount St. Mary's Hospital Medical & Allied Health Staff

From: Thomas A. Cumbo, M.D. / Vice President Medical Affairs

Date: November 2, 2017

Re: Informed Consent

Please read and adhere to the attached Catholic Health Policy on Informed Consent for Treatment.

It is the provider's responsibility to obtain informed consent - The provider performing the proposed procedure bears the responsibility for informing the patient about the procedure, the options, the risks and the benefits of all options. In order to obtain informed consent, the provider must first engage in a discussion with the patient about the patient's diagnosis and the proposed treatment. An informed consent discussion between patient and provider must include a description of the nature and purpose of the proposed treatment, the reasons for it, a description of the reasonably foreseeable risks and benefits of the treatment and, based on a realistic understanding of the treatment's potential risks and benefits, the likelihood of the patient achieving his/her goals, and of the available alternatives to the proposed treatment, including no treatment.

Thank you!

Attachment: Informed Consent for Treatment Policy & Form

Catholic Health	POLICY AND PROCEDURE	
TITLE: Informed Consent for Treatment	**POLICY NUMBER:** CHS-LS-RSK-005	**PAGE #** 1 of 7
RESPONSIBLE DEPARTMENT: CHS Medical Directors CHS Risk Management	**POLICY LEVEL:** Acute Care	**EFFECTIVE DATE:** 10/6/17
PREPARED BY: Nancy Sheehan, System Director of Risk Management and Legal Services, CHS Matthew Batt, System Director of Risk Management, CHS	**APPROVED BY:** Brian D'Arcy, M.D. Senior Vice President of Medical Affairs, CHS CSC September 5, 2017	**MSMH:** 10/6/17

PURPOSE:

To assure that informed consent is obtained from a patient or patient's surrogate to perform specific medical or surgical procedures on the patient. Informed consent is a communication between the treating professional and the patient wherein the patient is advised of the information relevant to deciding whether or not to undergo the proposed treatment.

APPLIES TO:

Catholic Health System hospitals and medical staffs

POLICY:

A. Consent to Treatment: In all nonemergency situations, informed consent is a legal and ethical precondition for the provision of medical treatment to a patient. A patient may not be treated unless consent to treatment has been given. A patient's consent must be based on a full and adequate explanation of the proposed treatment including the risks and benefits of said treatment.

Physician's Responsibility to Obtain Informed Consent: The provider performing the proposed procedure bears the responsibility for informing the patient about the procedure, the options, the risks and the benefits of all options. In order to obtain informed consent, the provider must first engage in a discussion with the patient about the patient's diagnosis and the proposed treatment. An informed consent discussion between patient and provider must include a description of the nature and purpose of the proposed treatment, the reasons for it, a description of the reasonably foreseeable risks and benefits of the treatment and, based on a realistic understanding of the treatment's potential risks and benefits, the likelihood of the patient achieving his/her goals, and of the available alternatives to the proposed treatment, including no treatment.

The patient's provider should tell the patient all the information that a reasonable physician under similar circumstances would disclose in order to permit the patient to make a knowledgeable evaluation. The information given to the patient by the physician must be given in a manner and in language which the patient can reasonably be expected to understand.

B. Right to Refuse Treatment: An adult patient with capacity has the right to refuse treatment or to limit treatment even if the refusal may be imprudent or detrimental to his other health. When this occurs, the attending physician should discuss treatment alternatives and the consequences of refusal with the patient. Hospital staff should make an additional effort to discuss with the patient the type of treatment, the need for it, and the consequences of refusal. If an adult patient with capacity seeks to be discharged from the Hospital and the attending physician advises against it, such physician, or his/her designee, should discuss with the patient the reasons for not leaving and the consequences of such that leaving may cause.

C. Who May Consent: Any patient who is 18 years of age or older, or who is the parent of a child or has married, may give effective consent for medical, dental, health and hospital services for himself or herself. A person who is expecting, or has borne a child may give effective consent for his or her child During marriage, the consent of one parent is sufficient. In the case of legal separation or divorce, the consent of the custodial parent is preferred, but unless parental rights have been relinquished, either parent is eligible to consent. A minor (under age 18) who is pregnant may give effective consent for medical, dental, health and hospital services related to prenatal care.

- A minor may also give consent for testing and treatment of Sexually Transmitted Diseases.
- A minor who is 17 years old may consent to give blood.
- If a patient is a non-emancipated minor (that is under 18 years of age and living with his or her parent or parents and is not the parent of a child or married) the consent of his or her parent or legal guardian must be obtained. The consent of one biological or adoptive parent is sufficient; however, if providers/staff are aware of a disagreement between the parents, treatment should not be provided unless it is an emergency. Providers/staff aware of the parental disagreement should notify Administration and Risk Management once they become aware of a disagreement between parents. Risk Management can be contacted for consultation via the Catholic Health Operator or directly at 716-821-4462.

D. Length of Time Consent is Valid: Generally, consents will be considered valid during the duration of a single admission or a specific intervention. A patient's consent to a particular treatment is valid for the duration of his or her course of treatment. If a significant change in a patient's physical/mental status occurs that could impact the level of risk/consequences for a procedure/treatment or potentially present new alternatives, a new consent must be obtained. The physician should explain why a new consent was needed and how the changes in the patient's condition have impacted the potential risks/consequences and/or alternatives for the procedure/treatment.

A patient may also at any time revoke his or her consent. Patients who, for whatever reason are readmitted to the Hospital, must sign appropriate new consents.

E. Emergencies: In the event of an emergency, if in the physician's judgement a patient is in need of immediate medical attention and an attempt to secure consent would result in delay of treatment which would increase the risk to the patient's life or health, the physician should consider consent to necessary emergency care is implied.

Similarly, if the patient is unconscious or otherwise unable to consent and an emergency exists, the physician need not wait until a qualified surrogate has been contacted. The circumstances of the emergency, and of any attempts made to contact the patient's surrogate during the emergency, must be documented in the patient's medical record. If questions arise about informed consent procedures in medical emergencies, Administration andRisk Management should be consulted if time permits.

F. Capacity to Make Health Care Decisions: The law presumes that an adult is competent to consent to treatment in the absence of evidence to contrary. An adult patient may be capable of giving informed consent to treatment under most circumstances, but may be temporarily incapable of doing so under certain circumstances, (e.g., because the patient is heavily sedated, in severe pain or is mentally confused as a result of his or her disease process). The physician should carefully assess the capacity of a patient to make health care decisions. Capacity to make health care decisions means the patient's ability to understand and appreciate the nature and consequences of health care decisions, including the benefits, risks and alternatives to any health care, and to reach an informed decision.

G. Consent for Patients Who Lack Capacity: If an adult patient is determined by his or her attending physician to lack capacity to make health care decisions and the patient has appointed a Health Care Agent or Proxy, the consent to treatment should be discussed with and obtained from the designated health care agent. If the patient has not previously given consent for the surgery or procedure, is not capable of consenting, and has not appointed a health care agent, consent may be obtained from the patient's surrogate.

The following is a listing, in the order of preference of qualified surrogates who may give consent on behalf of a patient who lacks capacity and has not appointed a health care agent:

- Guardian authorized to decide about health care pursuant to Article 81 of Mental Hygiene Law
- Spouse, if not legally separated from patient or domestic partner
- Adult child
- Parent
- Adult sibling
- Close friend (person who has maintained regular contact so as to be familiar with patient's activities, health, and religious or moral beliefs and who presents a signed statement to that effect to the attending physician)
- Committee for an Incompetent (See Policy RSK-016)

The surrogate is to be one person from the list from the class highest in priority . That person may designate any other person on the list to be surrogate, provided no one in a class higher in priority objects. If a patient has more than one surrogate in a particular category, the consent of one is sufficient, provided that none of the others object to the proposed treatment. If there is a disagreement about the proposed treatment, Administration and Risk Management should be contacted. If an incapacitated patient has no one available to give consent on his or her behalf, Administration should be contacted and Risk Management should be consulted. Additionally, the attending physician shall make a recommendation in consultation with hospital staff directly responsible for the patient's care and at least one other physician designated by the hospital must independently determine that he/she concurs that the recommendation is appropriate.

H. **Authority and Duties of the Surrogate :** The Surrogate shall have the authority to make any and all health care decisions on the adult patient's behalf that the patient could make. Health Care Providers are not obligated to seek the consent of a surrogate if an adult patient has already made a decision about the proposed health care, expressed orally or in writing. If a surrogate is refusing medically indicated treatment or is requesting the patient leave the Hospital against medical advice, Administration should be contacted and Risk Management should be consulted because under certain circumstances it may be appropriate to obtain a court order.

I. **Limitations for Minors:** If a parent or legal guardian refuses medically indicated treatment for a minor, the attending physician and Care Management should evaluate the circumstances surrounding the refusal of treatment to determine whether it is in the best interest of the patient to obtain a court order and if a child neglect referral is necessary. Risk Management should also be contacted to assist in evaluating the circumstances surrounding refusal of treatment and, should it be necessary, to coordinate the appropriate steps for making application for a court order.

J. **Commissioner of Social Services:** The local Commissioner of Social Services or the Commissioner of Health must be contacted for consent for non-emergency treatment of children whom the Family Court has deemed to be victims of child abuse, neglect or mistreatment.

K. **Consent by Telephone:** When the patient lacks the capacity to consent to treatment and no appropriate family member is available to give consent in person, the physician may obtain consent from a surrogate by telephone. However, it is preferable to obtain the consent in person, in writing. In addition to the physician obtaining the consent, a third party should listen to the conversation. The physician shall immediately document in the patient's medical record the time and content of the conversation, and the note shall be countersigned by the witness.

L. **Lack of Mental Capacity:** If a patient is lacking the mental capacity as determined by a psychiatric evaluation to make an informed decision, the Hospital shall obtain consent of the legal guardian, if any, or surrogate. In the absence of these individuals, the Hospital shall seek court appointment of guardian ad litem, a conservator or a committee depending on the patient's needs.

M. **Foster Children:** Consent for treatment of foster children is the responsibility of the child's biological or adoptive parents or legal guardian. If no emergency exists and time is not critical, attempts shall be made to contact the biological or adoptive parents or legal guardian for consent to treatment. If the biological or

adoptive parent or legal guardian is not available, the County (in which the child resides) Department of Social Services must be contacted for consent

N. Wards of State: Any patient who is a "Ward of the State" is the responsibility of a state governmental agency. The appropriate governmental agency that is responsible for the patient must be contacted to give consent for non-emergency medical treatment.

O. Administrative Consent: **Administrative consent is valid in two situations:**

i. For an autopsy of a deceased person so long as notice of the death is first given to the next of kin, and the body is not claimed and no objection is made within 48 hours after death. An autopsy or dissection must never be performed upon a corpse prior to the 48-hour waiting period; unless written consent from someone legally authorized to give consent has been obtained.

ii. If the Administrator is court appointed as guardian, conservator or committee with authority to consent for patient

PROCEDURE:

A. Admission and Treatment Consent: At the time of admission to the Hospital, a general consent authorizing general hospital care shall be obtained from the patient and witnessed by the admission clerk. The "Patient Consent and Financial Agreement" form # HIPAA PRIV-01-F02 is utilized for this purpose."

Emergency Department: **Patients who come in for emergency care and treatment will sign the general Consent for Treatment and Payment Agreement when and if said patient is medically able to sign. If the patient is unable to sign or is a non-emancipated minor, the authorization for emergency treatment shall be obtained from the patient's surrogate, parent or guardian.**

B. Written Informed Consent:

1. The provider performing the proposed procedure or their designee is responsible for obtaining the patient's consent to treatment; however, it is not necessary to obtain a signed consent form for every procedure. The procedures for which written informed consent must be obtained from the patient are set forth in Paragraph 2 of this Section. The "Consent to Surgery and/or Procedure and Anesthesia" form is annexed as Appendix "A" and shall be used to document the patient's written informed consent, with the exception of blood transfusions. Copies of these forms shall be provided to all physicians on the active staff and other members of the medical staff who admit patients to the Hospital. Copies shall also be available in the Outpatient Department and on Nursing Units.

2. Written informed consent shall be required for the following procedures:
   - all cystoscopic procedures
   - all "special" procedures (i.e.: angiography)
   - all surgical operations
   - arthrograms
   - biopsies
   - blood transfusion
   - bone marrows
   - endoscopic procedures
   - fine needle aspiration
   - lumbar punctures
   - myelograms
   - paracentesis
   - radiation therapy
   - stress testing
   - spinal tap
   - thoracocentesis
   - all stroke procedures

- all other invasive procedures involving more than minimal risk

3. It is preferable that consent be obtained in the physician's office whenever possible. It is recommended that the consent form be signed in duplicate with one copy remaining in the physician's files and one copy mailed to the appropriate Hospital Admissions Department. If this is not feasible, the consent should be obtained as soon as possible after the patient's admission.

   The physician is responsible for verifying that the correct name of the procedure and the layman's description appears on the authorization form.

4. When the consent is obtained in the hospital setting, any available adult hospital personnel may witness that the patient has given informed consent. There must be *at least* one witness, preferably a nurse.

   Physicians identities, excluding residents in certified training programs, but including anesthesiologists, podiatrists and dentists, must be disclosed to the patient if this physician will be performing an important task related to the procedure.

5. The anesthesiologists will be identified to the patient when the anesthesiologist talks to the patient and completes the pre-anesthesia evaluation form.

6. A non-emergent patient will *not* be given pre-op sedation or transferred from his/her room to surgery unless a documentation of a valid consent is in the medical record.

7. Except in an emergency situation, as declared by a physician, no patient will be transferred to or admitted to surgery and no surgical procedure shall be performed without a signed written informed consent in the patient chart. If the physician declares the procedure to be an emergency, he or she shall, at his or her earliest opportunity, so document in the patient's medical chart.

8. When physicians practice in partnerships, where possible, the physician who will perform the procedure or treatment should be the one designated on the form. If <u>either</u> partner may actually perform it, then the consent shall read "Dr. Smith <u>OR</u> Dr. Doe". The term "and" should only be used if they will operate together. Corporate titles and/or the practice group name shall not be used.

9. Consent Documentation must include:

   a) First and last name, date of birth of patient and medical record number of the patient

   b) Name and description of surgery or procedure in terms that are understandable to the patient (correct site/side, level and digit with side spelled out as "left, 'right" or "bilateral")

   c) No acronyms or abbreviations (except spinal levels C-Cervical, T- thoracic, L- Lumbar, S- Sacral)

   d) Specific implant/implant system to be placed or device to be removed

   e) Patient/family/ guardian/ health care agent signature and date

   f) Witness signature and date

   g) Physician signature and date

10. If the consent is altered or illegible, it must be re-done and re-signed by all parties.

C. <u>Do Not Resuscitate (DNR) Orders</u>

The administration of anesthesia necessarily involves some practices and procedures that might be viewed as resuscitation in other settings. Prior to any inpatient or outpatient undergoing an invasive procedure for

which Catholic Health requires informed consent, any existing DNR order will, when possible, be reviewed with the patient or the patient's surrogate decision maker. Health care providers should have a discussion with the patient or patient's surrogate about the risks, benefits, implications, and potential outcomes of anesthesia and surgery in relation to existing DNR orders before initiating anesthesia, surgery or other invasive procedures that require informed consent. The following strategy should be followed when discussing the suspension of DNR orders:

1. The provider(s) performing the proposed procedure should identify patients with existing Do Not Resuscitate (DNR) orders. Patients must be informed if the provider requires that existing DNR orders be suspended and/or not honored during operation(s)/procedure(s). Patients with DNR orders must also be advised that it is their right to direct that a DNR order be honored. As a result of this review, the status of the DNR order during the perioperative period should be affirmed, clarified, or modified based on the preferences of the patient or surrogate.

2. The provider(s) reviewing an existing DNR order with a patient/surrogate must (1) inform the patient/surrogate of the possibility of a procedure-induced, reversible cardiac or respiratory arrest during the procedure; and (2) determine if the patient/surrogate wishes the existing DNR order to be suspended during the duration of the procedure. This review ensures that the patient/surrogate and the providers responsible for the patient's care discuss the new intraoperative and perioperative risks associated with the procedure, the patient's treatment goals, and an approach for potentially life-threatening problems consistent with the patient's values and preferences.

3. The existing DNR order shall be suspended when a patient goes to surgery or other invasive procedures requiring informed consent <u>unless</u> (1) the patient/surrogate expressly directs that the DNR order be honored during the procedure; or (2) the patient/surrogate requests the existing DNR order be clarified or modified.

4. Any clarifications or modifications, along with any discussions regarding suspension of an existing DNR order, should be documented in the medical chart along with notation indicating if or when the original DNR order should be reinstated. *See DNR Orders section on page 2 of the Consent to Surgery and/or Procedure and Anesthesia.* Concurrence on these issues by the surgeon and anesthesia provider is critical.

5. The provider(s) can discuss existing DNR orders with a patient's designated surrogate if the situation is urgent and the patient lacks decision-making capacity. In emergency situations, it may be impossible or impractical for the provider(s) to speak with the patient/surrogate; in such situations, the provider must use his/her best judgment in determining how to honor the patient's wishes.

6. In the event that a patient's DNR order is suspended for an invasive procedure, it is reinstated when the patient is conscious, stable, without an artificial airway, and free of complications, unless otherwise stated. For the majority of patients this will occur in the Post Anesthesia Care Unit (PACU) and usually within 90 minutes post-operatively. For patients with co-morbidities this period of time may be extended at the discretion of the patient/surrogate with concurrence from the surgeon and anesthesia provider.

D. Emergency treatment may be provided in accordance with the Policy herein without express written informed consent. The existence of an emergency must be clearly documented in the patient's medical record by the physician.

ORIGINATION DATE:								
REPLACES (If applicable): N/A								
	Date/ Initials	Date/ Initials	Date/ Initials	Date/ Initials	Date/ Initials	Date/ Initials	Date/ Initials	Date/ Initials
REVIEWED:			2/05 CW	9/07 CPA				
REVISED:	3/10/04 NS	10/1/04 NS		3/09 CPA	11/10 CPA	3/13 CPA	8/17 MJB	

REFERENCES: NYS LAW: New York State Blood Resources Program, *NYS Education Law§6530, Article 131-A
NYS DOH New York State Surgical and Invasive Procedure Protocol, September, 2006
NYS Public Health Law, Article 29-CC Family Health Care Decision Act

JC STANDARD: RI 1.2.1 Informed Consent; RI.01.03.01

Catholic Health System

CONSENT TO SURGERY AND/OR PROCEDURE AND ANESTHESIA

Patient Identification Information

1. I,_____, hereby authorize Dr._____and/or whomever he/she designates to assist him/her to perform upon the above named person or me the following surgical operations and/or procedures:

   (Describe in medical terms):_____

   _____

   _____

   (Describe in lay terms):_____

   _____

   _____

2. The above named physician has fully explained to me the nature and purposes of the operation/procedure, has informed me whether any physician, other than him/herself, will be performing important tasks related to this operation/procedure, and has also informed me of expected benefits, the likelihood of achieving goal, possible complications, discomforts and risks that may arise, as well as alternatives to the proposed treatment and the risks and consequences of no treatment. I have been given an opportunity to ask questions, and all my questions have been answered to my satisfaction.

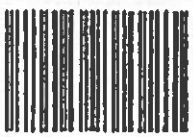
3. I understand that during the course of the operation or procedure unforeseen conditions may arise which require operations or procedures different from those described. I consent to the performance of those additional operations or procedures. I acknowledge that no guarantees or assurances have been made to me concerning the results intended from the operation or procedure.

4. I understand that any tissue or parts surgically removed shall be disposed of by the hospital in accordance with its customary practice.

5. If I am to receive the implantation of an equipment/device, I consent to the disclosure of my Social Security number to the manufacturer for the purposes of tracking the equipment/device in accordance with the Safe Medical Device act regulation.

6. For the purpose of advancing medical knowledge, I consent to the admittance of medical students, technical specialists or observers in accordance with the ordinary practice of the above noted Hospital, Catholic Health System. I consent to the use of closed-circuit television, taking of photographs (including videos), and the preparation of drawings and similar illustrative graphic material for scientific purposes providing my identity is not revealed.

7. At the discretion of my surgeon, I consent to the presence of a manufacturer's representative to observe during the procedure, but that such representatives will not be involved directly or indirectly in the operation/procedure.



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Catholic Health System

CONSENT TO SURGERY AND/OR PROCEDURE AND ANESTHESIA

Patient Identification Information

8. ANESTHESIA

I consent to the administration of such anesthetics as may be considered necessary or advisable by the physician responsible for anesthesia. The anesthesia team may consist of Anesthesiologists, Residents and Nurse Anesthetists. Advanced Emergency Medical Technicians may also participate in my care under the supervision of the Anesthesiologist.

I realize that there is the possibility of unavoidable damage to teeth during surgery and anesthesia, particularly if teeth are weak, loose, decayed, baby teeth, or artificial.

9. DNR ORDERS

☐ Not applicable

I have been advised and understand it is the Facility's policy that Do Not Resuscitate (DNR) orders shall be suspended and not honored during this operation(s)/procedure(s). However, I have been further advised that it is my right to direct that a DNR Order be honored during this operations)/procedure(s). Check appropriate box below, if applicable:

☐ I want the DNR Order to be honored throughout the operation(s)/procedure(s)

☐ I want the DNR Order suspended and *not* honored during the operation(s)/procedure(s)

10. BLOOD TRANSFUSION

☐ Not applicable

Blood is essential for the body to function. Care is taken to limit a patient's loss of blood and thus reduce the need for a transfusion. However, if the blood count falls too low, the patient may go into shock or coma and/or suffer serious harm or even death. If a low blood count poses a threat to you in your course of treatment, there may be no effective alternative to transfusion. I have been fully informed that no transfusion is 100% safe, however, present testing methods make the risks very small. Risks do include, HIV infection, Hepatitis B, Hepatitis C, other infection as well as fever, itching, or transfusion of incorrect blood type which is highly unlikely but can be fatal.

I have discussed possible alternatives with my care provider, including no transfusion, autologous transfusion (donation of my own blood), and designated/directed donor transfusion (collection of blood from donors selected by me). I understand that all these alternatives may not be available due to timing or health reasons, and that the above risks may still apply.

☐ I consent to the transfusion of blood or blood components that may be necessary relative to the procedure whether before, during, or after the procedure.

☐ I refuse the transfusion of blood or blood components

My signature confirms that the procedure _____

_____

with its associated risks and benefits has been explained to me, understood and accepted.

PATIENT/RELATIVE/ HEALTH CARE PROXY OR GUARDIAN:

_____ _____ _____

(Signature) (Date) (Time)

_____

(Relationship, if not patient)

WITNESS:

_____ _____ _____

(Signature) (Date) (Time)

Physician's Certification: I certify that either a designated physician or I have explained the procedure to the patient/ patient's representative named above in manner to permit the patient to make a knowledgeable decision of the reasonable risks and benefits involved in this procedure.

_____ _____ _____

(Physician's Signature) (Date) (Time)

CONSEN