

SUBJECT: INFORMED CONSENT	REFERENCE #10003
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APPROVED BY:	EFFECTIVE:
	REVISED:

Note: See state law for any additional requirements.

POLICY:

- All inpatient and outpatient medical records must contain a properly executed and completed written informed consent form for all procedures and treatments specified by the hospital's medical staff, and state or federal laws/regulations.
 - See Addendum A for a list of specific care, treatments and services that require informed consent, as approved by the medical staff.
- _____ Hospital's informed consent process shall assure patients or their legal representatives are given the information and disclosures needed to make an informed decision about whether to consent to surgery/procedures/treatments.
- Informed consent must be obtained from the patient, or the patient's legal representative, by the anesthesiologist prior to the administration of anesthesia **and** by the performing practitioner prior to the performance of operative and/or invasive procedures, diagnostic or therapeutic procedures, or situations when it is deemed advisable to have formal documentation of the patient's consent for treatment.
- Written verification of the informed consent **must** be on the patient's medical record **prior** to initiation of anesthesia or any of the above stated procedures, **except** in the case of emergency surgery.
 - The hospital's medical staff shall determine which surgeries and circumstances are considered an emergency and may be undertaken without an informed consent.
- The following healthcare professionals may obtain a patient's informed consent (as allowed under state law):

_____	_____
_____	_____
_____	_____
_____	_____

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PROCEDURE:

- A properly executed informed consent form shall contain at least the following:
 - Name of the patient and, when appropriate, the patient’s legal representative
 - Name of the hospital where procedure/treatment shall take place
 - Name of the specific surgery/procedure/treatment and indications for that surgery/procedure
 - Type of anesthesia
 - Name of the practitioner(s) performing the surgery(ies)/procedure(s)
 - Name of the practitioner who shall be administering the anesthesia
 - Whether physicians other than the operating practitioner, including but not limited to residents, shall be performing important tasks related to the surgery, in accordance with this hospital’s policies.
 - Important surgical tasks include:
 - ◆ Opening and closing
 - ◆ Dissecting tissue
 - ◆ Removing tissue
 - ◆ Harvesting grafts
 - ◆ Transplanting tissue
 - ◆ Administering anesthesia
 - ◆ Implanting devices
 - ◆ Placing invasive lines

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- Residents:
 - Discussions shall be held with the patient or the patient’s representative regarding residents who may perform important parts of the patient’s surgery. The following shall be discussed as applicable:
 - ◆ That it is anticipated that physicians who are in approved post graduate residency training programs shall perform portions of the surgery, based on their availability and level of competence.
 - ◆ That it shall be decided at the time of the surgery which residents shall participate and their manner of participation, and that this shall depend on the availability of residents with the necessary competence; the knowledge the operating practitioner/teaching surgeon has of the resident’s skill set; and the patient’s condition, *and*
 - ◆ That residents performing surgical tasks shall be under the supervision of the operating practitioner/teaching surgeon.
 - ◆ Whether, based on the resident’s level of competence, the operating practitioner/teaching surgeon shall not be physically present in the same operating room for some or all of the surgical tasks performed by residents.

Note: A “moonlighting” resident or fellow is a postgraduate medical trainee who is practicing independently, outside the scope of his/her residency training program and would be treated as a physician within the scope of the privileges granted by the hospital.
 - Whether, as permitted by state law, qualified medical practitioners who are not physicians shall perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner shall carry out; and that such practitioners shall be performing only tasks within their scope of practice for which they have been granted privileges by the hospital

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- The risks, drawbacks, complications, side effects and expected benefits or effects (including the likelihood of each) of anesthesia and procedures, treatments and therapies were explained to the patient or patient's legal representative
- The likelihood of achieving goals
- Potential problems related to recuperation
- Alternative choices of and to anesthesia and/or procedures, treatments or therapies including risks, drawbacks, complications, side effects and expected benefits of alternative treatments/therapies
- The risks, drawbacks and complications, side effects and expected benefits or effects of receiving no procedure/treatment/therapies
- Circumstances in which information about a patient must be disclosed or reported (i.e., HIV, TB, viral meningitis)
- The anesthesiologist's/performing practitioner's statement that the procedure was explained to the patient and/or legal guardian
- The names of the anesthesiologist and/or performing practitioner who explained the procedure to the patient and/or legal representative
- Documentation of the patient's understanding and agreement for the care, treatment or services
- The following signatures shall be required as part of the informed consent:
 - Patient or representative/legal guardian (signature may be written or electronic)
 - ◆ If the patient is unable to provide a signature, document the verbal agreement by the patient or patient's legal representative.
 - Professional individual witnessing the patient or patient's legal representative signing the consent form, including the date and time
- Date and time consent shall be signed by the patient or the patient's legal representative

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- Obtaining Informed Consent:
 - It shall be the responsibility of the practitioner(s) responsible for the surgery/procedure to obtain the informed consent.
 - Hospital staff cannot be involved in providing information that is necessary for informed consent. Only the performing practitioner and/or anesthesiologist can provide the information.
 - The informed consent form shall be:
 - Completed and discussed with the patient and/or legal representative by the anesthesiologist and/or performing practitioner
 - Supplemented with verbal discussion, and/or
 - Supplemented through written additions that give further relevant information
 - Medical information set forth needs to be written in clear, simple and easily understood terms.
 - Documentation must clearly indicate that the patient or legal guardian has had the opportunity to ask any questions he/she may have about the proposed anesthesia and/or procedure.
 - Documentation by the performing practitioner in the medical record shall include:
 - That the discussion was held with the patient
 - That the informed consent was obtained
 - Any limitations in the confidentiality of patient information that is discovered from or about the patient
 - The original copy of the informed consent must be in the patient's medical record prior to surgery.

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- Any special circumstance(s) must be documented on the informed consent.
- The patient shall sign where indicated and receive a copy of the informed consent form.
- The healthcare professional witnessing the signature of the patient shall sign as a witness and document the date and time.
- If a translator is used in the process, the translator shall sign in the area designated for party other than the patient.
- Third party consent for an incompetent or minor patient shall be obtained following the same procedure. An informed consent for anesthesia and/or any procedure must be obtained from the third party.
- Role of the Hospital in the Informed Consent Process:
 - The role of the hospital shall be limited to obtaining verification that consent has been obtained by the anesthesiologist and/or performing practitioner before anesthesia is administered and before the start of the surgery/procedure.
 - Hospital staff may not answer patient's questions about the nature of the anesthesia and procedure, and its benefits, risks or alternatives.
 - Hospital staff shall refer all questions to the anesthesiologist or performing practitioner to enable him/her to provide informed consent.
 - Hospital staff shall verify that a witness was present during the time that the patient signed the informed consent.
 - Check for validity of the informed consent against the following criteria:
 - Information has been explained to the patient by the anesthesiologist and/or the performing practitioner.
 - The applicable blanks have been filled in with the necessary information.
 - All the signatures required have been obtained.

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- The hospital staff must assure that the patient has been informed and can:
 - State the name of the performing practitioner or other practitioner who has primary responsibility for the patient's care
 - Identify the professional status of individuals responsible for authorizing and performing treatments and procedures
- The hospital staff shall inform the patient:
 - About any professional relationship the responsible performing practitioner, healthcare practitioner, hospital staff or the hospital has to another healthcare provider or institution, that might suggest a conflict of interest, and
 - About any relationship to educational institutions involved in the case of the patient, or
 - About any business relationships between individuals treating the patient or between the organization and any other healthcare, service or educational institutions involved in the case of the patient.
- Duration of Informed Consent:
 - Has continuing force and effect until the patient revokes the consent, or
 - Circumstances have changed which would affect the nature of, the risks of the procedure and/or the alternatives to the procedure for which the patient gave the consent.

NOTE:

Ensure that the Informed Consent policy is also in compliance with any state law governing the content of the Informed Consent Form.

