

**PURPOSE:** Provide guidelines for obtaining informed consent.

**SCOPE:**

Applies to all elective non-surgical invasive diagnostic and/or therapeutic procedures; major or minor surgery that involves entry into the body, either through an incision or natural body opening; and procedures in which anesthesia is used. (See appendix A for a list of procedures, which require informed consent.)

**POLICY:**

1. Physician/Allied Medical Provider Responsibilities:
  - a. The physician or allied medical provider, who will be performing the diagnostic, surgical and/or therapeutic procedure, including blood and blood products administration, is responsible for educating and obtaining informed consent from the patient or the patient's legal representative. The informed consent process and the signature of the patient/legal representative must be obtained prior to the performance of the planned procedure. Physicians may use their specialty specific consent form, provided that such form and its content are satisfactory to the Medical Staff OR Committee, or the physicians may use the FMDH informed consent form. (See appendix B for copy of FMDH Informed Consent Form.)
  - b. Information provided to the patient will be in layman's terms and include:
    1. The patient's diagnosis;
    2. Who will be performing the procedure;
    3. Nature and purpose of the procedure;
    4. Benefits, risks, and consequences of having the procedure and risks and consequences of not having the procedure;
    5. The likelihood that the procedure will accomplish the desired results;
    6. Alternatives to the procedure
      - a. risks and consequences of the alternative procedure(s),
      - b. potential effectiveness of the alternative procedure(s) and
      - c. prognosis if no treatment or alternative procedure(s) are provided.
        - i. Informed consent obtained for a procedure by telephone, fax or other electronic media is acceptable. If a telephone consent is necessary, a second person will also listen and sign as a witness.

- c. The requirement for obtaining informed consent from the patient will be waived when the following conditions are met:
  - i. Emergency Situation: Documentation in the medical record supports that an emergency condition exists. A thorough explanation of the surgery will be given to the patient after the emergency procedure.
  - ii. Mentally Incompetent Patient: Patient's legal guardian or responsible party will be required to sign for the patient.
- d. Certified Registered Nurse Anesthetist (CRNA)
  - i. Certified Registered Nurse Anesthetist (CRNA) is responsible for informing the patient about anesthesia options available to the patient, the risks and benefits of each option, and who will be administering the anesthesia to the patient. CRNA will sign and enter date and time that the informed consent is obtained on the Informed Consent Form.
    - 1. Hospital Staff Responsibilities:
      - a. Registered/Licensed Practical Nurse will:
        - 2. Prior to a procedure, RN/LPN will have patient review consent form to verify that procedure listed is correct,
        - 3. Ascertain if patient has any questions regarding the proposed procedure,
        - 4. If patient has questions about procedure contact physician to talk with patient,
        - 5. If a patient has questions about anesthesia contact CRNA to talk with patient.
      - 6. Registered Nurse is responsible for informing the patient about the procedure that the RN will perform. An explanation of risks and benefits will be given by the Nurse.
        - a. Chemotherapy
        - b. Wound debridement
  - e. Radiology is responsible for informing the patient about the procedure that the Radiology Tech will perform. An explanation of risks and benefits will be given by the Radiologist or Radiology Technologist.

## Informed Consent Appendix A

### Procedures requiring an informed consent:

1. Major or minor surgery that involves entry into the body, whether through an incision or through a natural body opening.
2. All procedures in which anesthesia is used, regardless of whether an entry into the body is involved (e.g., regional or general anesthesia, labor pain management, epidural steroid injection).
3. The administration of medicines that may cause a change in the patient's body structure (e.g., chemotherapy, experimental medications).
4. Non-surgical invasive diagnostic and/or therapeutic procedures (e.g., cardio version, thoracentesis, chest tubes, paracentesis, lumbar punctures, colonoscopy, gastroscopy, bronchoscopy, myelograms, arteriogram).
5. IV injection of contrast material (Radiology Informed Consent Form)
6. Abscess drainage (Radiology Informed Consent Form)
7. Ultrasound biopsies (Radiology Informed Consent Form)
8. Transfusion of blood and blood products
9. Drawing of autologous blood
10. Insertion of peripherally inserted central lines, arterial catheters, central lines, Groshong catheter.