

## LEE HEALTH POLICY & PROCEDURES

<b>INFORMED CONSENT</b>		<b>LOCATOR NUMBER</b>																					
<b>T Y P E</b>	<input checked="" type="checkbox"/> <b>System-wide</b> - A formal statement of values, intents (policy), and expectations (procedure) that applies to every employee throughout the System. <input type="checkbox"/> <b>Multidisciplinary/Interdisciplinary</b> - A formal statement of values, intents (policy), and expectations (procedure) that applies to more than one discipline and is usually of a clinical nature. <b>Check below all areas to which this applies.</b> <input type="checkbox"/> <b>Departmental</b> - A formal statement of values, intents (policy), and expectations (procedure) exclusive to a particular department or group of people within a department at one or multiple locations that does not impact any other area.	<b>CHAPTER: S03</b>  <b>TAB: 05</b>  <b>POLICY #: 422</b>																					
<b>Disciplines / locations to which this interdisciplinary policy applies:</b>																							
<table style="width: 100%; border: none;"> <tr> <td style="width: 33%;"><input type="checkbox"/> Health Information Management</td> <td style="width: 33%;"><input type="checkbox"/> Pharmacy</td> <td style="width: 33%;"><input type="checkbox"/> Acute Care Hospital Nursing</td> </tr> <tr> <td><input type="checkbox"/> Environmental Services</td> <td><input type="checkbox"/> Plant Operations</td> <td><input type="checkbox"/> Outpatient Services</td> </tr> <tr> <td><input type="checkbox"/> Information Systems</td> <td><input type="checkbox"/> Radiology</td> <td><input type="checkbox"/> Home Health</td> </tr> <tr> <td><input type="checkbox"/> Laboratory</td> <td><input type="checkbox"/> Rehabilitation Services</td> <td><input type="checkbox"/> Skilled Nursing Services</td> </tr> <tr> <td><input type="checkbox"/> Legal Services</td> <td><input type="checkbox"/> Respiratory</td> <td><input type="checkbox"/> Physician Offices</td> </tr> <tr> <td><input type="checkbox"/> Nutrition</td> <td><input type="checkbox"/> Public Safety</td> <td><input type="checkbox"/> Rehab Hospital</td> </tr> <tr> <td><input type="checkbox"/> Other _____</td> <td></td> <td></td> </tr> </table>			<input type="checkbox"/> Health Information Management	<input type="checkbox"/> Pharmacy	<input type="checkbox"/> Acute Care Hospital Nursing	<input type="checkbox"/> Environmental Services	<input type="checkbox"/> Plant Operations	<input type="checkbox"/> Outpatient Services	<input type="checkbox"/> Information Systems	<input type="checkbox"/> Radiology	<input type="checkbox"/> Home Health	<input type="checkbox"/> Laboratory	<input type="checkbox"/> Rehabilitation Services	<input type="checkbox"/> Skilled Nursing Services	<input type="checkbox"/> Legal Services	<input type="checkbox"/> Respiratory	<input type="checkbox"/> Physician Offices	<input type="checkbox"/> Nutrition	<input type="checkbox"/> Public Safety	<input type="checkbox"/> Rehab Hospital	<input type="checkbox"/> Other _____		
<input type="checkbox"/> Health Information Management	<input type="checkbox"/> Pharmacy	<input type="checkbox"/> Acute Care Hospital Nursing																					
<input type="checkbox"/> Environmental Services	<input type="checkbox"/> Plant Operations	<input type="checkbox"/> Outpatient Services																					
<input type="checkbox"/> Information Systems	<input type="checkbox"/> Radiology	<input type="checkbox"/> Home Health																					
<input type="checkbox"/> Laboratory	<input type="checkbox"/> Rehabilitation Services	<input type="checkbox"/> Skilled Nursing Services																					
<input type="checkbox"/> Legal Services	<input type="checkbox"/> Respiratory	<input type="checkbox"/> Physician Offices																					
<input type="checkbox"/> Nutrition	<input type="checkbox"/> Public Safety	<input type="checkbox"/> Rehab Hospital																					
<input type="checkbox"/> Other _____																							
Date Originated: 8/91	Reviewed/No Revision: 9/12, 12/15	Dates Revised: 2/95, 4/98, 1/00, 2/02, 3/04, 9/06, 8/08, 2/10, 9/10, 10/13, 11/16, 9/17, 10/17, 10/19																					
Next Review Date: 10/21																							
Author(s): Mary Lorah, RN, BA, LHRM																							
Reviewed by: <table style="width: 100%; border: none;"> <tr> <td style="width: 70%;">Clinical Practice Council:</td> <td style="width: 30%;">Date:</td> </tr> <tr> <td style="border-top: 1px solid black;"></td> <td style="border-top: 1px solid black;"></td> </tr> <tr> <td style="width: 60%;">Clinical Education Council</td> <td style="width: 10%;">Yes</td> <td style="width: 10%;">No:</td> <td style="width: 20%;">Education Completed:</td> <td style="width: 10%;">Date:</td> </tr> <tr> <td style="border-top: 1px solid black;">Education Plan Required:</td> <td style="border-top: 1px solid black;"><input type="checkbox"/></td> <td style="border-top: 1px solid black;"><input type="checkbox"/></td> <td style="border-top: 1px solid black;"></td> <td style="border-top: 1px solid black;"></td> </tr> </table>			Clinical Practice Council:	Date:			Clinical Education Council	Yes	No:	Education Completed:	Date:	Education Plan Required:	<input type="checkbox"/>	<input type="checkbox"/>									
Clinical Practice Council:	Date:																						
Clinical Education Council	Yes	No:	Education Completed:	Date:																			
Education Plan Required:	<input type="checkbox"/>	<input type="checkbox"/>																					
Approved by: <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">Policy Administrator:</td> <td style="width: 30%;">Date:</td> </tr> <tr> <td style="border-top: 1px solid black;">Lisa Sgarlata, DNP, MSN, MS, FACHE</td> <td style="border-top: 1px solid black;">9/26/19</td> </tr> </table>			Policy Administrator:	Date:	Lisa Sgarlata, DNP, MSN, MS, FACHE	9/26/19																	
Policy Administrator:	Date:																						
Lisa Sgarlata, DNP, MSN, MS, FACHE	9/26/19																						
As Needed: <table style="width: 100%; border: none;"> <tr> <td style="width: 70%;">Medical Director:</td> <td style="width: 30%;">Date:</td> </tr> <tr> <td style="border-top: 1px solid black;"></td> <td style="border-top: 1px solid black;"></td> </tr> </table>			Medical Director:	Date:																			
Medical Director:	Date:																						

### PURPOSE:

To delineate the relative rights and responsibilities of hospital employees and physician members of the medical staff with regard to obtaining and documenting informed consent, as required by the Florida Statutes, CMS Conditions of Participation and NIAHO Accreditation guidelines (DNV-GL).

## DEFINITION OF TERMS:

**Capacity** - patient is physically and mentally able to communicate a willful and knowing health care decision. The patient is alert and oriented and is capable of understanding the information that is being provided to he/she and then gives consent or refuses to have the procedure /surgery performed.

**Advanced Practice Registered Nurse (APRN)** – an individual licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice, including certified registered nurse anesthetists, certified nurse midwives, and nurse practitioners.

The APRN may also perform acts of medical diagnosis and treatment, prescription, and operation which are identified by a joint committee composed of three members appointed by the Board of Nursing, Florida Statute 464.00.

**Informed Consent** – consent voluntarily given by a person after a sufficient explanation and disclosure of the subject matter involved to enable that person to have a general understanding of the treatment or procedure and the medically acceptable alternatives, including the substantial risks and hazards inherent in the proposed treatment or procedures, and to make a knowing health care decision without coercion or undue influence.

**Licensed Personnel** – Lee Health staff or contract staff who are licensed and regulated by the Florida Department of Health to practice medicine, nursing, respiratory therapy and/or radiology technology.

**Medical Staff** – physicians licensed under Florida Statute chapter 458 or chapter 459 with privileges in a licensed facility, as well as other licensed health care practitioners with clinical privileges as approved by a licensed facility's governing board.

**Minor or Pediatric Patient** – a patient under the age of 18, generally considered to lack the legal capacity to provide informed consent.

**Personal Representative** – if a patient is incapacitated or is unable to communicate his or her wishes, and there is no advance directive or health care surrogate designation on file or presented, a Personal Representative may be a patient's spouse, domestic partner (including a same sex partner), adult child, adult sibling, parent (or someone who has permission from the parents to make health care decisions for the minor child) or other family representative.

**Surrogate** – any competent adult expressly designated by a principal to make health care decisions and to receive health information. The principal may stipulate whether the authority of the surrogate to make health care decisions or to receive health information is exercisable immediately without the necessity for a determination of incapacity or only upon the principal's incapacity as provided in Florida Statute S.765.204.

## POLICY:

- A. It is the policy of Lee Health to provide mechanisms that enable the patient, their Legal representative and/or the minor patient's parents or legal guardians, to be informed and involved in making decisions about his/her health care.

- B. In accordance with Florida law, it is the physician's responsibility to obtain the expressed, informed consent of patients or their representatives when the procedure to be performed is surgical, or is invasive and involves a significant risk of adverse or injurious outcome to the patient, or when required by the prevailing professional standard of care (refer to Patient's Rights and Organization Ethics Policy, S01 01 709). Advanced Registered Nurse Practitioners may obtain informed consent for procedures that they have been approved to perform independently, and have been confirmed on e-priv. Informed consent will be obtained for all surgical, invasive diagnostic procedures posing significant risk and all procedures involving conscious sedation, general or regional anesthesia (refer to Attachment A – list of procedures requiring consent). Obtaining informed consent is the sole responsibility of the procedural provider, and cannot be delegated to associate physicians, midlevel providers or other licensed hospital personnel. The informed consent process includes discussions of the following elements between physicians and patients or their representatives or the parents/guardian of a minor, as well as their families when appropriate. Midlevel providers are permitted to answer questions as appropriate.
1. A clear, concise explanation of the patient's current condition.
  2. The nature of and reasons for the proposed treatment(s) or procedure(s).
  3. The potential benefits, risks, or side effects of the proposed treatment(s) or procedure(s), and may include discussion of specific needs during recuperation.
  4. The likelihood of achieving care and treatment goals.
  5. Reasonable alternatives to the proposed treatment(s) or procedure(s).
  6. The substantial risks and hazards inherent in the proposed treatment(s) or procedure(s).
  7. The reasonable alternatives and relevant risks, benefits, and side effects related to reasonable alternatives, including the possible results of not receiving the proposed treatment(s) or procedure(s).
  8. Information related to outcomes of care, including unanticipated outcomes.
  9. Adequate information about the person(s) responsible for the delivery of their care and treatment, including confirmation of who will actually perform planned procedures or surgical interventions.
- C. When unforeseen circumstances result in an alternative physician assuming the responsibility for performing a procedure, an informed consent discussion between the alternative physician and the patient, parent or representative must take place. In this unique situation, the identity and professional status of individuals responsible for authorizing and performing procedures or treatments, including the existence of any professional relationship among individuals treating the patient, as well as the relationship to any other health care or educational institutions involved in the patient's care shall be discussed. A new consent document must be completed, including the name of the physician, as well as the signature of the patient, parent or representative.

D. There should be documented evidence in the medical record that the patient, parent or representative has been given information necessary to make treatment decisions that reflect his/her wishes in accordance with the above.

1. Discussion of explanation of condition, proposed treatment(s) or procedure(s), the potential benefit(s) and risk(s) of proposed treatment(s) or procedure(s), potential needs (i.e. physical therapy, occupational rehab) related to recuperation and the likelihood of success can be recorded in the History and Physical, the Progress Notes, and/or under consultations, to cover information not addressed by the Surgery/Procedure Consent, or other applicable consent forms.

Consent forms were developed to assist physicians in documenting informed consent. However, since other methods of approved documentation exist, a physician signature on the consent form is optional when evidence of the informed consent discussion is documented in the medical record. This documentation will reference the discussion of risks, benefits, and alternatives to the consented procedure.

2. As defined in the patient rights policy, the explanation to patients, parents, or representatives should be communicated in terms the patient can reasonably be expected to understand. Pursuant to policy S03 00 200 Language Services, qualified interpretation services are available to physicians and staff when communicating with any individual who needs interpretive services, including foreign language speaking, blind, visually impaired, deaf or hearing impaired.

A properly executed informed consent form will contain the following:

1. Patient's name and date of birth, and the name of the parent or legal representative, if applicable
2. Name of hospital
3. Legible documentation of the procedure or medical treatment, with specification of site and/or side, if applicable, and without abbreviations
4. Full first and last name of the responsible practitioner who is performing the procedure(s) or administering the medical treatment
5. Signature of the patient, parent and/or legal representative
6. Date and time the consent form is signed by the patient, parent and/or legal representative
7. Statement that the procedure/treatment, including unanticipated events, material risks, and alternative therapies, was explained to the patient, parent and/or legal representative

E. In the event of an emergency medical condition which endangers the life or health of the patient, and it is impractical or impossible to obtain consent from the patient, parent or legal representative for treatment(s) or procedure(s), the physician may proceed in accordance with acceptable standards of medical practice. Physician should document need for emergent intervention.

- F. A physician's order for the consented procedure is required. The physician's order for the consented procedure is used to fill out the procedure on the informed consent form. If the patient does not have an informed consent form initiated, an additional order to do so is not necessary if there is an order for the procedure.

**G. Adult Patients**

Every competent adult has the fundamental right to make knowing and willful health care decisions. An adult is considered to have capacity to make health care decisions when they are physically and mentally able to communicate their knowing and willful health care decisions. If an adult patient lacks the capacity (i.e., not capable of comprehension or is unable to communicate), informed consent may be obtained as follows:

1. If the incompetent adult has a designated health care surrogate, then the surrogate may consent to the procedure.
2. If the surrogate is not available or if the patient has not designated a health care surrogate, consent may be signed by anyone of the following individuals in the following order of priority:
  - a) The judicially appointed guardian of the patient, who has been authorized to consent to medical treatment if such guardian has been appointed.
  - b) The patient's spouse.
  - c) An adult child of the patient, or if the patient has more than one child, a majority of the adult children who are reasonably available for consultation.
  - d) The adult sibling of the patient or, if the patient has more than one sibling, a majority of the adult siblings who are reasonably available for consultation.
  - e) An adult relative of the patient who exhibited special care and concern for the patient and who has maintained regular contact with the patient and who is familiar with the patient's activities, health, and religious or moral beliefs.
  - f) A close friend of the patient.

**H. Pediatric / Minor Patients**

As a general rule, a minor lacks the legal capacity to consent to medical services or treatment, however they should be engaged in the process whenever developmentally appropriate and/or desired by the minor's parent or legal representative. Unless an exception applies, the parent has the legal authority to consent to medical care and treatment. Florida law does permit a minor, under certain circumstances, to consent to medical care and treatment. If one of the following exceptions applies, the minor has legal authority to consent to care and treatment:

1. A minor who is, or has been, married.
2. An unwed pregnant minor consenting to the performance of medical or surgical care or services related to her pregnancy. However, an unwed pregnant minor must have

- consent obtained from a parent or legal guardian for medical or surgical care not related to her pregnancy.
3. An unwed minor mother consenting to the medical or surgical services of her child.
  4. A minor seeking voluntary substance abuse impairment services.
  5. A minor with a court order removing the disability of nonage.
  6. A minor consenting to the examination and treatment of sexually transmitted disease.
  7. A minor receiving contraceptive information or services.

## **PROCEDURES:**

After confirmation that expressed informed consent has been obtained, licensed hospital personnel may assist members of the medical staff in completing forms and obtaining patient, parent or legal representative signatures pertinent to documenting informed consent. Licensed hospital personnel shall have no affirmative responsibility to inform the patient, parent or representative about those aspects of the treatment or procedure that only the physician is professionally qualified to discuss. Licensed hospital personnel may, if questioned by a patient, parent or legal representative, provide information concerning a procedure relative to:

- When the treatment or procedure will be performed
- Who will perform the treatment or procedure
- Where the post procedure recovery will take place
- Rules for visitation
- Any other information which, in accordance with the prevailing nursing standard of care, nurses customarily provide to patients, parents and representatives
- Information nurses or other licensed hospital personnel are expected to communicate with patients, parents or representatives pursuant to hospital policy and procedure

## **Guidelines for Completing Consent Forms:**

- A. Licensed hospital personnel should verify that the consent form is complete, including the patient name and date of birth, signature of the patient, parent and/or legal representative, clear documentation of the procedure or treatment to be performed, and clear documentation identifying the name of the provider who obtained informed consent from the patient, parent or legal representative. The completed and verified informed consent document shall be present on the chart before the patient is transported to the pre-procedure area or the Operating Room.
- B. It is generally recommended that the consent form be completed and signed prior to the administration of any medication (i.e., narcotics, sedation, tranquilizer, or hypnotic) that may interfere with the patient's capacity. However, there may be times when patients have received these medications prior to signing the consent form, but they have not lost their

capacity to make a knowing and willful health care decision. In this situation, if a patient still has capacity, they may be asked to sign the consent form.

- C. The procedure written (printed) on the consent form should be legible and written in ink. Please note that the consent forms may include a provision in which the patient, parent or legal representative expands the scope of the procedure for which the consent is being provided. For example, the LMHS Consent to Operation, Anesthesia and Other Medical Services form indicates: "I consent to the performance of operations and procedures in addition to or different from those now contemplated, whether or not arising from presently unforeseen conditions which the above named doctor or his/her associates or assistants may consider necessary or advisable in the course of the operation."
- D. If the patient, parent or legal representative indicates a lack of understanding about the procedure, and the procedure is elective, inform the physician and ask him/her to explain the procedure to the patient. If the physician is not available or refuses, the procedure shall be postponed to allow time for the physician to provide information to the patient, parent or legal representative to answer their questions.
- E. Procedure shall correspond with the physician's order, indicating the specific procedure and site or side as applicable.
- F. Telephone or verbal communication of orders are discouraged and are to be limited to situations where immediate computer order entry by the prescriber is not feasible. To avoid errors in transcription, verbal procedure orders shall be read back to the responsible physician, and co-signed by the responsible physician as soon as possible. Orders that have not been co-signed by the responsible physician will not be considered as source documents. Orders written as "consent as scheduled" or "obtain informed consent" are not acceptable. The use of abbreviations is discouraged, but if the order is written as an abbreviation from the approved list or is defined in Stedman's Medical Abbreviations (see Stedman's Online: <http://intranet1/lmhsredir.html?http://stedmansonline.com>) the nurse may transcribe that abbreviation and insert the words contained on the approved list or Stedman's Medical Abbreviations that describes the abbreviation.
- G. Verification that the informed consent has been obtained shall include the confirmation of documentation in the medical record. Acceptable forms of documentation include medical record entries that describe the consent discussion, including risks, benefits, and alternatives. The physician signature on an informed consent document may be substituted by any one of the following electronic medical record entries: progress notes, consult notes, and/or history and physical examinations that have been authenticated with an electronic signature by the physician responsible for performing the procedure.
- H. Time and date shall indicate time patient, parent or legal representative signed the consent form. The name of the physician performing the procedure shall be identified.
- I. If the consent form is executed by the patient's legal representative, the nature of the relationship should be indicated. For example, this includes designated health care surrogate, guardian, spouse, parent or other decision maker listed in G and H of the Policy section of this document.

- J. If the patient, parent or legal representative has spoken with an anesthesiologist, the anesthesia consent form should also be signed by the patient, parent or legal representative at the time the surgical consent is being signed. Any questions that the patient, parent or legal representative has regarding anesthesia should be referred to an anesthesiologist.
  - 1. If a patient is intubated or incapacitated and lacks the ability to provide informed consent, the consent for anesthesia may also be obtained from the representative, the parent or judicially appointed guardian of the patient at the same time procedural consent is obtained.
- K. Signature(s) of witness(es): Anyone employed by the hospital and directly or indirectly associated with the care of the patient may witness the signature of the patient, parent or legal representative. In order to witness the signature, the witness must be present and observe the patient's, parent's or legal representative's signature. The witness is not responsible for providing information to the patient, parent or legal representative, but as indicated should advise the physician if questions arise about the procedure. If the consent form has been executed in the Physician's office and the Patient and the physician have signed the consent form it will not be necessary for staff to sign as a witness. Staff will verify signature with patient.
- L. In order to ensure patient safety, validation that the planned procedure corresponds with the patient's and/or health care surrogate's verbal confirmation, the physician's order, and the history and physical shall be documented in the medical record prior to moving the patient into the procedure areas. If there are any discrepancies, clarification from the physician must be reconciled and documented prior to transporting the patient to the Operating Room (see policy M03 05 732 Pre-Procedure Surgical Checklist and Assessment - Adult).
- M. Separate consents are required when more than one procedure is planned at the same time on the same patient by different physicians.

### **Telephone Consent**

The informed consent process and form may be obtained via the telephone when the individual lacks capacity, including minor patients and the legal representative is only available by telephone. The following procedure should be applied:

- A. The physician should explain the circumstances giving rise to the necessity for the procedure or treatment, providing the person with the information needed for the informed consent.
- B. Two nurses or one nurse and other clinical staff member shall witness the telephone consent, alerting the individual of the existence of two parties on the line.
- C. Two nurses shall complete and sign the written consent form, noting clearly that the consent was obtained via telephone.
- D. The nurses should include on the consent form the name of the person giving consent and the relationship to the patient. As stated previously, examples of legal relationships include a designated health care surrogate, guardian, spouse or parent (see page 5, G. #2).
- E. Both witnesses should sign the consent form as witnesses.

## Consent Corrections

- A. Generally consent forms that are signed by a patient or their representative should not be altered. If the information contained on the consent form needs to be revised, a line should be drawn through the original planned procedure with a notation of the change and initialed by the physician and patient. If a new consent is completed, the original consent should be labeled "*Not Valid; See Revised Consent Form*" on the original form, along with signature of the person making the change and the date noted. The original consent form remains a part of the medical record.

## How Long a Consent is Valid

- A. A signed consent is valid as long as the patient, parent or legal representative gives his or her consent for the described treatment or procedure.
- B. In some cases, such as consents for dialysis and blood transfusions, it is recommended to get a new consent for each inpatient admission.

## Withdrawing Consent

If at any time the patient or person empowered to give consent wishes to withdraw consent or change the nature of the treatment or procedure listed on the consent, the staff member receiving this information must follow these described steps:

- A. Notify the physician who ordered the procedure/treatment.
- B. Notify the department where the procedure is scheduled to be performed.
- C. Clearly indicate on the form that the patient has withdrawn consent, and date, time and sign this note.
- D. Mark an "X" through the procedure/treatment and place in the patient's medical record.
- E. Document patient's withdrawal of consent in the patient's medical record and note who was notified of the withdrawal.

## Minor or Pediatric Patients – Special Provisions

- A. If the parent(s) or legal representative of a minor consents to a treatment or procedure, but the minor patient objects, the case should be referred to Risk Management and the treatment or procedure should not be performed until the conflict is resolved if possible and medically prudent.
- B. In the event that two divorced parents have joint custody of a minor patient, and if they disagree about providing consent for a treatment or procedure, Risk Management should be called.
- C. The absence of parental or legal guardian consent notwithstanding, a physician may render emergency medical care or treatment to any minor patient who has been injured in an

accident or who is suffering from acute illness, disease or condition if, within a reasonable degree of medical certainty, delay initiation or provision of emergency medical care or treatment would endanger the health or physical well-being of the minor, and provided such emergency medical care or treatment is administered in a hospital.

- D. Section C applies only when parental or legal guardian consent cannot be obtained immediately for one of the following reasons:
1. The minor patient's condition has rendered him or her unable to reveal the identity of his or her parent(s), guardian(s) or legal custodian(s), and such information is unknown to any person who accompanied the minor patient to the hospital.
  2. The parent(s), guardian(s) or legal custodian(s) cannot be immediately located by telephone.
- E. Notification shall be accomplished as soon as possible after the emergency care or treatment is administered. The medical record shall reflect the reason such consent was not initially obtained and shall contain a statement by the attending physician that immediate emergency care or treatment was necessary for the patient's health or physical well-being. The medical record shall be open for inspection by the person legally responsible for the minor patient.

### **Other Considerations**

- A. Hospital personnel shall have a responsibility to institute appropriate measures to delay any invasive procedure and maintain the patient's status quo if, through conversation with the patient, parent or patient's representative, or otherwise, if it becomes apparent that there is a serious discrepancy between the treatment or procedure planned or scheduled and that to which the patient, parent or patient's representative believe they have consented.
- B. In any situation in which there is doubt or a question about the issue of informed consent to treatment, contact the Legal Services Department at 239-343-2382 between 7:00 a.m. and 5:00 p.m. weekdays, or call the hospital operator and ask for the attorney or risk manager on call to be paged.

### **RELATED POLICIES:**

M01 01 010 Advance Directives

S01 01 709 Patient Rights and Organization Ethics

S01 01 711 Patient Rights and Responsibilities

S03 00 200 Language Services

M03 03 922 Verbal Orders

M03 05 376 HIV Consent for Patient Testing

M03 05 732 Pre-Procedure Surgical Checklist and Assessment – Adult

- M03 05 811 Sedation for Procedure by Non-Anesthesia Personnel Moderate and Deep – Adult / Pediatric
- M03 07 080 Blood Transfusion Consent
- M03 08 734 Pre-Procedure Surgical Checklist and Assessment – Pediatric and Neonatal
- M03 10 711 Peripherally Inserted Central Catheter (PICC) / Midline Catheter Ultrasound Guided Placement of – Adult
- S10 02 741 Proper Use of Abbreviations in Medical Record (Unsafe Abbreviation List)
- S25 00 705 Patient Identification / Red Rule

## **REFERENCES:**

Emergency Medical Care or Treatment of Minors without Parental Consent; Section 743.064 FL Statute

Florida Case Law

Florida Medical Consent Law, section 766.103, FL Statute

Florida Patient's Bill of Rights and Responsibilities; Section 381.026

AHIMA Electronic Signature, Attestation and Authorship; Appendix D: Glossary of Terms

NIAHO Accreditation Requirements, PR.4, SS.4, SR.3 Version 11, 7/2014

Centers for Medicare & Medicaid Services (CMS) State Operations Manual: Patients' Rights. Condition of Participation (CoP) 42 CFR 482.13 Surgical Services CoP 42 CFR 482.51 and Medical Records CoP 42 CFR 482.24

## Attachment A

Informed consent is required for all surgical procedures, invasive diagnostic procedures posing significant risk, and all procedures involving moderate sedation, general or regional anesthesia.

An informed consent is obtained for, and includes, but is not limited to:

- a. Surgery/Operative Procedures
- b. Invasive Procedures:
  - Swan-Ganz Catheter
  - Chest Tube
  - Spinal Tap/Lumbar Puncture (LP)
  - Biopsies
  - Circumcision
  - Chemotherapy
  - Elective Intubation
  - Dialysis (any form) & Placement of Dialysis Catheter
  - Intracranial Pressure Catheter
  - Bronchoscopy
  - Thoracentesis
  - Paracentesis
  - Amniocentesis
  - Central Line Catheters
  - Laser Therapy
  - Arthrocentesis
  - Cardiac Procedure (PTCA, Cardioversion)
  - Endoscopy Procedure
- c. Procedures or tests in which anesthetic agents that have the potential to inhibit the patient's protective reflexive responses are used, including procedures requiring the administration of moderate and deep sedation.
- d. Blood or blood component(s) transfusion therapy and the use of IV contrast require a specialized consent ([FM #1041](#)). Please refer to individual corresponding policies.
- e. Written consent for HIV testing ([FM #0513](#)) is only required if the patient is a minor or the patient lacks capacity. Refer to policy M03 05 376 HIV Consent for Patient Testing.
- f. Invasive Radiologic Procedures:
  - Angiogram
  - Needle biopsy under fluoroscopy, CT scan or ultrasound
  - Myelogram
  - Epidural Block
  - Arthrography
  - Abscess Drainage
  - Biopsy

- Therapeutic Radiopharmaceutical Procedures
  - All Diagnostic Arteriography Procedures
  - Inferior and Superior Cavagrams
  - Portogram
  - Percutaneous Nephrostomy
  - Antegrade Ureteral Stent
  - Drainage Procedures
  - Cyst Aspiration
  - Percutaneous Transhepatic Cholangiogram
  - Stone Extraction: Biliary and Renal
  - Lymphangiogram
  - Percutaneous Transluminal Angioplasty
  - Vascular Stent Placement
  - Thrombolysis
  - Transcatheter Embolization
  - Vena Cava Umbrella Placement
  - Percutaneous Biliary Endoprosthesis
  - Transjugular Intrahepatic Portosystemic Shunt
  - Retrieval of Foreign Body
  - Renal Vein Renin
- g. Investigational devices, pharmaceutical agents, or procedures referred to the Institutional Review Board (IRB), policy S03 03 428 Institutional Review Committee.

# INFORMED CONSENT PROCESS - HIGHLIGHTS

