

Policy: Informed Consent

ORGANIZATIONAL: Affects two or more departments.							
Folder	Organizational Choices: Nursing			Sub-Folder (If Applicable)	Documentation – Health History		
Original Effective Date	3/1/1989	Scope	<i>What departments does this policy apply to? State "All" as is may apply to the entire organization.</i> All				
Approved (Approver/Date)	Legal: 11/17 MDRC: 05/18 MEC: 5/18/18 Board of Directors: 5/31/18						
Last Reviewed/ Revised Date	9/24/2018	OSHA Category (If Applicable)	III	Standard (If Applicable)	CMS 428.51(b)(2) CMS482.13(b)(2) CMS482.24(c)(4)(v) TJC RI.01.03.01 19CSR 30-20.140	Number of pages	8

PURPOSE:

To define the process for obtaining informed consent from patients or authorized representatives for invasive procedures ensuring engagement, comprehension, and agreement.

SKILL LEVEL:

Clinical Staff

Licensed Independent Practitioner (“LIP”)

GUIDELINES:

The primary purpose of the informed consent process is to ensure that the patient, or the patient’s representative, is provided information necessary to enable him/her to evaluate a proposed procedure before agreeing to the procedure. All information, including examples or visual aids, should be provided in clear language, questions encouraged, and teach-back should be used to verify comprehension. The patients’ rights shall be considered throughout the informed consent process in accordance with the Patient’s Rights Policy.

Informed consent is a person’s agreement to allow something to happen, made with full knowledge of the risks involved and the alternatives. For a patient, this is a patient’s knowing choice about a medical treatment or procedure, made after a physician or other designated LIP discloses whatever information a reasonable provider in the medical community would give to a patient regarding the risks involved in the proposed treatment or procedure.

A complete informed consent process includes a discussion of the following elements:

- The nature of the proposed care, treatment, services, medications, interventions, or procedures;
- Potential benefits, risks, or side effects, including potential problems that might occur during recuperation;
- The likelihood of achieving goals;
- The range of treatment alternatives to surgery;

- The relevant risks, benefits, and side effects related to alternatives, including the possible results of not receiving care, treatment, and services;
- Questions from the patient or authorized representative;
- When indicated, any limitations on the confidentiality of information learned from or about the patient, including any possible filming or photography that may occur;
- Documentation of the items listed above must be included in the patient’s medical record prior to the performance of the procedure.

Informed consent must be obtained, and documentation of informed consent must be included in the patient’s medical record, prior to the performance of the procedure, except in the case of emergency surgery, legally mandated, or court-ordered treatment. The informed consent form may only be signed after the physician or designated LIP has had the informed consent discussion with the patient or the patient’s authorized representative, and prior to the administration of any preoperative medication or mind-altering drug.

PROCEDURE: *Include: Definitions, Equipment, Process, and Documentation*

When Informed Consent is Required

Informed consent is required for all invasive procedures. An invasive procedure is a procedure involving puncture or incision of the skin, or insertion of an instrument or foreign material into the body, including, but not limited to, percutaneous aspirations, biopsies, cardiac and vascular catheterizations, endoscopies, angioplasties, and implantations, but excluding venipuncture, arterial line placement, intravenous therapy, intramuscular or subcutaneous injections, urinary catheter insertion, laceration suturing, and naso-oro-gastric tubes other than those for nutritional purposes.

The following additional consent forms are required for the following procedures:

- Vaginal birth after cesarean (VBAC); the ‘VBAC consent’ form
- Peripherally inserted central catheter (PICC) procedures; the ‘CONS PICC LINE’ form
- All invasive procedures when anesthesia is participating in the procedure; the ‘Consent to Anesthesia/Sedation/Pain Management’ form
- Consent for Hemodialysis Therapy (new consent required for each admission).

Obtaining Informed Consent

The LIP responsible for carrying out the procedure is responsible for ensuring that informed consent is obtained and documented in the H&P or the declaration on the consent form prior to performance of the procedure. The responsible LIP may delegate the informed consent discussion to another designated LIP; however, the LIP performing the procedure remains responsible for documentation of informed consent and adequacy of the information conveyed in the informed consent discussion. Informed consent must be obtained from the patient, or the patient’s representative, and documented in the patient’s medical record prior to the performance of the procedure.

The 'Consent for Medical and/or Surgical/Treatment/Procedure/Blood' form is a general consent form that may be signed by the patient, or his or her representative, to document the patient's informed consent to the proposed procedure. See Appendix A. Southeast will accommodate the patient's or the patient's authorized representative's communication needs in accordance with the Language Assistance policy.

1. Fill in the first and last name of the responsible LIP who informed the patient and will be performing the procedure(s). (For example, Dr. John Smith)
2. Enter the date the procedure is to be performed (month, day, and year).
3. Fill in the name of the procedure to be performed in full terminology. Abbreviations must not be used.
4. Have the patient or person authorized to give consent for the patient sign the consent form.
5. If an authorized person other than the patient signs the consent form, enter the relationship of that person to the patient (for example, father, guardian, power of attorney).
6. The person or persons witnessing the signature must sign legibly in the witness area.
7. Enter the date that the consent form was signed (month, day, and year).
8. Enter the time the consent form was signed.
9. The responsible LIP fills in the date/time the declaration is signed.
10. The responsible LIP signs the physician's declaration after obtaining informed consent.

The 'Consent to Anesthesia/Sedation/Pain Management' form is required for all invasive procedures when anesthesia is participating in the procedure.

1. Check the box for the anesthetic planned on #2.
2. The anesthesia provider signs with their title and dates and times the form.
3. Have the patient or the authorized individual sign the consent form.
4. If an authorized person other than the patient signs the consent form, enter the relationship of that person to the patient (for example, father, guardian, power of attorney).
5. Enter the date that the consent form was signed (month, day, and year).
6. Enter the time the consent form was signed.
7. The person or persons witnessing the signature must sign legibly in the witness area.

Telephone Consent

Southeast may accept an informed consent decision via telephone consent for emergency, legally-mandated, court-ordered, or other treatment or procedures. If telephone consent is obtained, two (2) Southeast employees must monitor the conversation, document in the patient's medical record that consent was granted by telephone, and document their signatures as witnesses.

In addition, documentation must be obtained if informed consent is received from a patient's authorized representative documenting such authority. For example, if a patient is under a

guardianship, documentation must be received of the court-order establishing such guardianship and identification of the patient's guardian prior to the performance of the procedure.

Who May Give Informed Consent

For purposes of this section, Adult is defined as an individual eighteen (18) years of age or older. Minor is defined as an individual seventeen (17) years of age or younger.

The following individuals are authorized and allowed to provide informed consent to any surgical, medical, or other treatment procedures, including immunizations:

1. An adult may give informed consent for himself;
2. A parent may give informed consent for his minor child (so long as there is no documentation indicating the parent cannot give consent; for example, a termination of parental rights form previously provided indicating the parent's rights over his minor child have been terminated by a court order);
3. A minor who has been lawfully married may give informed consent for himself;
 - a. A minor parent of a child may give informed consent for the child;
4. A minor may give informed consent for himself for the treatment of:
 - a. Pregnancy (excluding abortions, which are not performed at Southeast);
 - b. Venereal disease; or
 - c. Drug or substance abuse
5. An adult who acts in the place of a parent for a minor in case of an emergency may give informed consent for the minor;
 - a. For example, a teacher during a field trip where a minor under their care is injured, or a college official when a college student is a minor and injured;
 - b. Emergency is defined as a situation where in competent medical judgment the proposed surgical or medical treatment or procedures are immediately or imminently necessary and any delay occasioned by an attempt to obtain a consent would reasonably jeopardize the life, health or limb of the person affected, or would reasonably result in disfigurement or impairment of faculties.
6. A guardian of a person may give informed consent for the person;
 - a. A guardian is someone who has the legal authority and duty to care for another person because of the other's incapacity or disability and has obtained a court order documenting this authority;
 - b. An attorney-in-fact or agent operating under a written Durable Power of Attorney for Health Care or Advanced Health Care Directive may give informed consent for an incapacitated person;
7. A relative caregiver of a minor child may give informed consent for the minor (a relative caregiver is an adult who is related to a minor by blood, marriage, or adoption, who is not the parent and who represents that the minor lives with the adult and that the adult is responsible for the care of the minor and has obtained a notarized affidavit documenting this authority);
8. A grandparent of a minor grandchild may give informed consent for his minor grandchild in the absence of a parent (absence shall mean absent at a time when further delay

occasioned by an attempt to obtain consent may jeopardize the life, health, or limb of the person affected or may result in disfigurement or impairment of faculties).

Any person acting in good faith and not having been put on notice to the contrary shall be justified in relying on the representations of any person purporting to give such consent including, but not limited to, his identity, his age, his marital status, and his relationship to any other person for whom the consent is purportedly given.

Individuals under guardianship are not allowed to give informed consent on their behalf. If a patient is under a guardianship, documentation must be received of the court-order establishing such guardianship and identification of the patient's guardian prior to the performance of the procedure. Incapacitated persons in need of a guardian may not sign an informed consent document and are required to have a court appointed guardian.

Capacity is the mental ability to understand the nature and effect of one's acts. Capacity is determined by the ability to make and communicate a choice and understand key information regarding the individual's condition, options for treatment, and the risks, benefits, and harm of treatment.

Content of Consent Documentation

Documentation of a patient's informed consent decision shall be included in the patient's medical record. This documentation may include the Consent for Medical and/or Surgical/Treatment/Procedure/Blood form or other documentation from the LIP detailing the patient's informed consent.

Questions related to informed consent should be referred to the Director/Manager/House Supervisor who will give direction or obtain administrative direction prior to treatment. An informed consent document will be valid for the length of the patient's stay except in the case of a change in the proposed procedure or change of LIP responsible for the procedure. A signed and dated informed consent document for an outpatient procedure is valid for ninety (90) days. If more than 90 days have elapsed since the consent document was signed, the consent and proposed procedure/treatment must be confirmed with the patient. The patient must initial and date the informed consent document, as well as the staff member confirming the proposed procedure/treatment. The patient's nurse must document that the proposed procedure/treatment was reconfirmed.

Witnessing Consents

If the Consent for Medical and/or Surgical/Treatment/Procedure/Blood form is utilized, the LIP responsible for performing the procedure must complete the "physician's declaration" and document the informed consent in the patient's medical record. The patient's consent must be witnessed, timed, and dated. Admitting clerks, registered nurses, nursing assistants or other of similar responsibility may serve as a witness, provided they are at least eighteen (18) years of age. The date, time, patient's signature, and the signature of the witnesses' must be in ink. If

someone other than the patient signs the consent form the relationship must be noted next to the signature.

- A patient's written signature requires documentation of one (1) witness.
- A patient's oral consent requires documentation of two (2) witnesses.
- A patient's consent signed by an 'X' requires documentation of two (2) witnesses.

Incorrect Consents

If a consent form is incorrect, a new informed consent document must be completed and re-signed. If the patient has received a mind-altering drug such as preoperative medication:

1. The LIP responsible for the procedure may make an assessment of the patient's mental capacity for understanding, document the results of that assessment in the patient's 'progress notes', and have the patient sign a new consent form.
2. An event report form must be completed under these circumstances.

Existing consent forms shall not be altered post-procedure. Any condition change requires a reassessment and evaluation of the patient and of the risk and mortality of the proposed procedure/treatment carries. A new form may be required with the patient's informed consent.

Questions, Concerns or Complaints

Everyone is responsible for following this informed consent policy. If you have questions or concerns, or to report that this policy is not being followed, please contact your immediate supervisor, call Quality Management at extension 5577, and enter an electronic event report.

Additional Consents

In addition to documentation of the patient's informed consent, the following additional forms are required, if applicable:

1. Elective Photography/Videotaping consent
2. State sterilization consent
3. Refusal of medical treatment
4. Forms related to the Examination, Treatment, Transfer for Emergency Medical Conditions and Women in Labor Act (EMTALA) policy
5. Research, investigation or clinical trials

External Consents

The Southeast 'Consent for Medical and/or Surgical/Treatment/Procedure/Blood' form is required to be completed prior to the performance of a procedure at Southeast hospital. The LIP responsible for the proposed procedure/treatment may submit an informed consent document that was obtained outside the hospital evidencing the patient's informed consent. For example, the responsible LIP may have obtained the patient's informed consent at an office visit prior to scheduling the proposed procedure/treatment. If informed consent was obtained prior to the performance of the proposed procedure/treatment outside the hospital, the informed consent document shall be submitted to Southeast when the proposed procedure/treatment is scheduled and shall be included as part of the patient's medical record.

Pre-Anesthesia Testing staff shall be responsible to ensure the informed consent document is included in the patient’s medical record prior to the proposed procedure/treatment.

Emergency

Consent is implied under the law if a life-threatening emergency exists. Informed consent to surgical or medical treatment or procedure shall be implied when an emergency exists if there has been no protest or refusal of consent by a person authorized and empowered to consent or if so, there has been a subsequent change in the condition of the person affected that is material and morbid, and there is no one immediately available who is authorized, empowered, willing and capacitated to consent.

Emergency is defined as a situation wherein, in competent medical judgment, the proposed surgical or medical treatment or procedures are immediately or imminently necessary and any delay occasioned by an attempt to obtain consent would reasonably jeopardize the life, health or limb of the person affected, or would reasonably result in disfigurement or impairment of faculties.

Periodic Review of Policy

This policy shall be reviewed and updated in accordance with the Development and Review and Policies and Procedures Policy by the Multidisciplinary Policy Review Committee.

REFERENCES:

- Black’s Law Dictionary (2014)
- DHSS Code of State Regulations 7/31/2014, 19 CSR 30-20.084, 19 CSR 30-20.140
- Medical Staff Rules and Regulations, Article 6.02
- Missouri Revised Statutes Sections 431 and 404 (August 28, 2016)
- State Operations Manual Appendix A Regulations and Interpretive Guidelines for Hospitals 11/20/2015, 42 CFR 482.13(b) (2), 42 CFR 482.51 (b) (2), 42 CFR 482.24 (c) (2) (v)
- TJC CAMH 2017 Guidelines: RI.01.03.01, RI.01.03.03, RI.01.03.05

Attachments: (Label as Appendix A, B, C, etc.)

Appendix A: ‘Consent for Medical and/or Surgical/Treatment/Procedure/Blood’ form

Name of Policy: Informed Consent

Document Metadata

Document Name:	Informed Consent.docx
Original Location:	/Southeast Health/Cape/Organization Wide/Clinical/Documentation-Health History
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Creator:	Ward, Myrna <i>Administrative Staff</i>
Committee / Policy Team:	General Policy Committee
Owner/SME:	Rigdon, Jan <i>Manager</i>

Summary of Changes/Updates:

Appendix A updated 9/24/2018