SAINT JOSEPH
Regional Medical Center

Version # 12

Title: Informed Consent

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POLICY:

1. It is the policy of Saint Joseph Regional Medical Center that the patient ("Patient") or the patient's legally authorized representative ("Representative"), as appropriate (hereinafter collectively referred to as "Patient" unless otherwise stated) shall give voluntary and informed consent prior to receiving any proposed treatment, other care or services that is either invasive or otherwise involving Material Risk (hereinafter collectively referred to as "Proposed Treatment").
2. The purpose of obtaining Informed Consent is to provide information to the Patient regarding appropriate care, treatment and services options. This is a process of information exchange that allows the Patient to make a voluntary and informed choice.
3. In non-Emergent situations, the Patient shall receive a clear explanation of his or her condition, the Proposed Treatment and its expected benefits, risks and side effects, and the reasonable alternatives to the Proposed Treatment and their related benefits, risks and side effects, including those related to not receiving the Proposed Treatment.

PROCEDURE:

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   1) **Definitions**
      a) **Adult** - A Patient, 18 years or over, or alternatively, a Minor who is:
         (1) Legally emancipated; or
         (2) At least fourteen (14) years of age and (i) not dependent on any parent for support; and (ii) living apart from any parent or from an individual in "loco parentis" which

means a person who acts in the place of or instead of a parent or a person charged, fictitiously with a parent's rights, duties and responsibilities; and (iii) managing their own affairs; or

(3) Is or was married; or

(4) Is in the military service of the United States; or

(5) Is authorized to consent to health care by any other statute, including but not limited to those pertaining to Proposed Treatment for Sexually Transmitted Diseases which are set forth in Section 2(i) herein.

b) **Capacity** – Understanding the nature and consequences of one's actions.

(1) Components of capacity include the ability to:

(a) Comprehend the information intellectually;

(b) Process the information; and

(c) Understand the consequences of the decision at hand.

(2) Medications can impair capacity temporarily; it is the Treating Practitioner's responsibility to determine whether a patient who has received medication is capacitated for the purpose of giving consent in any given situation.

(3) Patients are presumed to have capacity unless determined otherwise.

c) **Consent Form** – A document showing consent given for Proposed Treatment, signed by an Adult Patient and a witness who is at least eighteen (18) years of age and who is solely responsible for witnessing the Patient's Capacity or signature on the Consent Form. **NOTE:** The witness is never responsible for witnessing the Informed Consent discussion or attesting to the Patient's Capacity or understanding of the discussion. A signed Consent Form implies knowledge of what one is signing, the Proposed Treatment and the related benefits, risks and side effects of both the Proposed Treatment and any reasonable alternatives to the Proposed Treatment.

d) **Emergency** – A situation wherein, according to the Treating Practitioner of competent medical judgment, the Proposed Treatment is immediately or imminently necessary and any delay occasioned by an attempt to obtain Informed Consent would reasonably be expected to jeopardize the life, health or safety of the Patient or would otherwise result in Patient's disfigurement or impaired faculties.

e) **Incapacitated Person** – A person unable to perceive all relevant facts related to one's condition and Proposed Treatment so as to make an intelligent decision. This incapacity may be either be temporary or have existed for an extended period of time, whether due to a natural state, age, shock, illness, injury, drugs, sedation or intoxication.

f) **Informed Consent** – Consent given by a Patient for a Proposed Treatment after receiving both verbal and written information from the Treating Practitioner. The Informed Consent process is intended to enable the Patient to understand 1) the general nature of the Patient's condition; (2) the Proposed Treatment and its expected benefits, risks and side effects; and (3) the reasonable alternatives to the Proposed Treatment and their expected benefits, risks and side effects, including the benefits, risks and side effects of not receiving the Proposed Treatment.

(1) In order to give Informed Consent, the Patient must be informed of:

(a) The nature of the Proposed Treatment;

(b) The potential benefits, risks, or side effects, including potential problems related to recuperation associated with the Proposed Treatment;

(c) The likelihood that the Proposed Treatment will achieve care, treatment, and service goals;

(d) Reasonable alternatives to the Proposed Treatment;

(e) The relevant risks, benefits, and side effects related to the reasonable alternatives to the Proposed Treatment, including those associated with not receiving the Proposed Treatment; and

(f) When indicated, any limitations on the confidentiality of information learned from or about the Patient.

g) **Material Risk** – A risk a reasonable person would find important in determining his or her course of action. Material risks could include risks that are highly likely to occur but that would not result in serious injury. It also includes those risks that are rare but have the potential for causing serious injury.

h) **Minor** – A person who is under eighteen (18) years of age who does not otherwise qualify as an Adult as defined herein. **Please see the Consent for Treatment of Pregnant and Postpartum Minors policy as needed.**

i) **Parent** – A birth parent, an adoptive parent or an individual "in loco parentis" who acts in the place of or instead of a parent or who is charged, factitiously, with a parent's rights, duties and responsibilities.

j) **Proposed Treatment** – Most procedures 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 or vascular catheterizations, endoscopies, angioplasties, and implantation of a device that required Informed Consent. See Appendix I: "Proposed Treatment Requiring Informed Consent."

k) **Representative**

(1) In the case of a Minor who does not otherwise qualify as an Adult, a Representative shall be either: (i) a guardian or other representative appointed by a probate court with competent jurisdiction; or (ii) a parent of the minor or an individual "in loco parentis" if there is no judicially appointed guardian, or the guardian is not reasonably available or declines to act, or the guardian's existence is not known; or (iii) an adult sibling of the minor if there is no judicially appointed guardian, or a parent or an individual "in loco parentis" is not reasonably available or declines to act, or the existence of the parent or individual "in loco parentis" is unknown. A copy of "Letters of Authority" issued by the probate court should be contained in the minor patient's medical record as evidence of the legal guardian's authority to give consent. The authority of the Representative ends when the Minor reaches eighteen (18) years of age or otherwise qualifies as an Adult under this policy.

(2) In the case of an Adult who qualifies as an Incapacitated Person, a Representative shall be either (i) a Health Care Representative who has been authorized by the Patient, in writing, and who has been recognized by the Hospital in accordance with applicable laws and regulations; or (ii) a guardian or other representative appointed by a probate court with competent jurisdiction, or (iii) a spouse, a parent, an adult child, or an adult sibling, unless otherwise disqualified, if no guardian or Health Care Representative has been appointed, or the guardian or Health Care Representatives is not reasonable available or declines to act, or if the existence of the guardian or

Health Care Representative is not known; or (iv) the Patient's religious superior, if the Patient is a member of a religious order, and there is no guardian or Health Care Representative, or the guardian or Health Care Representative is not reasonably available or refuses to act, or the existence of the guardian or Health Care Representative is not known.

(3) Absent an Emergency, if a Minor or Adult Patient does not have a Legally Authorized Representative available to give Informed Consent, Treating Practitioners should communicate with Hospital Risk Management to resolve the situation. As necessary, the Hospital may consult with legal counsel to seek court intervention, as necessary.

l) **Treating Practitioner** –Those licensed health professionals duly qualified to independently obtain the Informed Consent of Patients in the Hospital in accordance with applicable Indiana laws and the Hospital's Medical Staff Bylaws, Rules and Regulations, namely (i) physicians – MD and DO; (ii) dental surgeons -- DDS, (iii) podiatrists – D.P.M.; (iv) advanced practice nurses – nurse practitioners (NP), clinical nurse specialists (CNS), and certified nurse midwives (CNM). NOTE: Physician assistants may obtain the Informed Consent of a Patient under the direct supervision of the Treating Practitioner who must also qualify as the physician assistant's supervising physician under Hospital Medical Staff Bylaws, Rules and Regulations.

2) **Standards**

a) **Types of Consent:**

(1) **Proposed Treatment Requiring Informed Consent**

(2) Except in an Emergency, Informed Consent shall be obtained by the Treating Practitioner and medical documentation, including but not limited to the signed Consent Form shall be placed in the Patient's chart prior to the performance of any Proposed Treatment or any other medical treatment identified by the Hospital's Medical Staff in the Medical Staff Bylaws, Rules and Regulations or other adopted policy.

(3) **Non-Invasive Procedures Or Other Diagnostic or Therapeutic Treatment Requiring a Special Informed Consent.**

(a) Where a Treating Practitioner identifies a particular medical service that may involve a Material Risk to a particular Patient, but which is not included in the listing set forth in Appendix I, the Treating Practitioner shall be responsible for ensuring that the Patient has received Informed Consent and executed a Consent Form in accordance with this Policy.

(b) Additionally, an Informed Consent and signed Consent Form shall be obtained for any other diagnostic or therapeutic care, treatment, service or procedure, including but not limited to certain medications, that although common, may have rare but serious side effects, consequences or other Material Risks.

(4) **General Consents**

(a) Other medical or related services provided by the Hospital which require a signed General Consent Form, including, but are not limited to the following:

[1] Admission to the Hospital;

[2] Admission to the Hospital's Emergency Department;

[3] EMTALA transfer from Hospital to another health care facility;

[4] Patient leave of absence;

[5] Patient discharge against medical advice;

[6] Patient photography, video taping and other imaging;

[7] Patient consent to presence and role of health care industry vendor or representative in the operating room;

[8] Body disposition form.

(5) **Research Consent**

(a) Informed Consent shall be obtained prior to any Hospital or medical care, treatment and services or procedure that is part of a research study in accordance with an Institutional Review Board (IRB) approved protocol.

(b) The Treating Practitioner with specific knowledge of the research protocol shall properly inform the Patient regarding the experimental procedure(s) or care, treatment(s) and service(s) as required by Federal regulations and by the IRB approved protocol and consent form.

(6) **Anesthesia, Sedation and Other Pain Management (Applies to Plymouth Campus only)**

(a) In addition to the Informed Consent and signed Consent Form that is the subject of this Policy, a separate Informed Consent and written Consent Form is required for any Proposed Treatment that otherwise qualifies as anesthesia, sedation or other pain management services, which may be performed in conjunction with another Proposed Treatment and which are listed in **Appendix I.**

b) **Patient/Treating Practitioner Discussion**

(1) For all Proposed Treatment and any other services that may involve a Material Risk, it is the responsibility of the Treating Practitioner to provide the Patient with sufficient information that can be understood and which, in the Treating Practitioner's professional judgment, is necessary to formulate a reasoned decision regarding acceptance of the care, treatment and services.

(2) The discussion shall include the following points:

(a) Detailed explanation of the procedure, including:

[1] The nature of the proposed care, treatment, services, medications, interventions, or procedures

[2] Potential benefits, risks, or side effects, including potential problems related to recuperation

[3] The likelihood of achieving care, treatment, and service goals

[4] Reasonable alternatives to the proposed care, treatment, and service

[5] The relevant risks, benefits, and side effects related to alternatives, including the possible results of not receiving care, treatment, and services

[6] Whether practitioners other than the Treating Practitioner, including residents, may perform important surgical tasks, including opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines.

[7] Statement, if applicable, that other qualified medical practitioners, including but not limited to residents, may perform important surgical tasks, in accordance

with Hospital policy and based on their skill set and under the supervision of the surgeon.

[8] When indicated, whether the Patient or Representative wants Do Not Resuscitate Orders suspended during surgery.

(3) During the discussion the Patient is allowed to ask questions and once satisfied, the Patient makes a choice. The Informed Consent obtained following disclosure of the information set forth above shall be evidenced by signing and dating the Consent Form by the Patient in addition to a progress note authored by the Treating Practitioner in the Patient's medical record.

c) **Requirements For a Legally Valid Consent Form**

(1) If the Patient agrees to proceed with the Proposed Treatment, the Consent Form signed by the Patient shall be completed by the Treating Practitioner before any Proposed Treatment is initiated.

(2) A legally valid Consent Form must include each of the following:

(a) The Patient's legal name, and when appropriate, the legal name of the Patient's Representative and the nature of relationship between Patient and Representative.

(b) The name of the Hospital;

(c) A statement that the designated Treating Practitioner explained the Proposed Treatment to the Patient;

(d) The complete name of the Proposed Treatment to be performed which must also be identically recorded on the Hospital's Operating Room schedule and on the Physician's Order Sheet by the Treating Practitioner responsible for obtaining the Informed Consent, abbreviations shall be avoided;

(e) A complete listing of the benefits, Material Risks and side effects of the Proposed Treatment;

(f) A complete listing of the reasonable alternatives to the Proposed Treatment and their related benefits, Material Risks and side effects, including those associated with not receiving the Proposed Treatment at all;

(g) The name(s) of all Treating Practitioners who will be responsible for the performance of the Proposed Treatment;

(h) The signature of the Patient or Representative, as appropriate;

(i) The signature of the person responsible for witnessing the signature of the Patient or Representative as appropriate, and their printed name and title; and

(j) The date and time the Consent Form is signed by the Patient or Representative and the designated witness.

(3) Informed Consent may be obtained by the Treating Practitioner before the Patient is admitted to the Hospital in which case the fully executed Consent Form is to be faxed to the Hospital's operating room scheduler. Properly executed, legible faxed copies on the pre-approved Hospital Consent Form shall be accepted and are binding as the original.

(4) Any subsequent refusal to receive the Proposed Treatment, or alternatively, any revocation of the Consent Form, whether by the Patient or Representative, as appropriate, is to be promptly communicated to the Treating Practitioner who is to note same on the original signed Consent Form and in the Patient's medical record.

Patient refusal of recommended care, treatment and services or revocation of a valid consent may be documented on the consent form or in the medical record.

d) **Medical Record Documentation**

(1) Documentation of the Informed Consent process shall be included in any of the following:

(a) The Signed Consent Form, on file in the Patient's medical record;

(b) The Informed Consent discussion may be documented in the Patient's medical record as a narrative dictated or written note (inpatient or outpatient progress note or operative report as appropriate) by the Treating Practitioner;

(c) In the case of an Emergency that does not permit the usual Informed Consent process to be conducted, the Treating Practitioner shall document the following in the Patient's medical record, as a narrative, dictated or written progress note, as soon a reasonably possible:

[1] The specific Emergency that did not allow the usual Informed Consent process and signed Consent Form to be obtained and the need for the Proposed Treatment, including the risks to the patient if the Proposed Treatment was not performed or was delayed; and;

[2] The efforts made by the Treating Practitioner to obtain same.

(d) In the case of a Research Consent, three (3) copies of the IRB approved Consent Form shall be executed by the Patient following the Informed Consent discussion. One (1) form is placed in the Patient's medical record prior to the Proposed Treatment. The principal investigator responsible for the research shall keep one (1) copy of the complete set of written and signed Consent Forms. The patient shall be given one (1) copy of the Consent Form, all in accordance with Federal regulations.

e) **Frequency of Obtaining Consent**

(1) The Patient's Informed Consent shall be obtained prior to and for the specified duration of any Proposed Treatment so long as the Patient's condition and the risks associated with the Proposed Treatment remain unchanged, as determined by the Treating Practitioner.

(2) The need for obtaining a new informed consent shall be evaluated whenever the course of care, treatment and services or the patient's condition is substantially altered.

(3) If a Patient, Representative, Medical Staff or Hospital personnel have any questions or concerns regarding the currency and validity of a Patient's Informed Consent, for any reason, including but not limited to the fact that significant time has elapsed between the Informed Consent and the Proposed Treatment and/or the Patient's condition has changed, the Treating Practitioner shall review these concerns, as appropriate, and update the Informed Consent with the Patient as necessary.

(4) For continuing and repetitive courses of Proposed Treatment, the Treating Practitioner may use a single Consent Form to document the Informed Consent process for continuing care.

(5) The Informed Consent remains valid:

(a) Until the Informed Consent is revoked by the Patient or Representative but only prior to the initiation of the Proposed Treatment, in which case the facts and circumstances resulting in the revocation shall be documented in the Patient's medical record; or

(b) If the Proposed Treatment must be postponed due to reasons not related to a change in the Patient's medical status (e.g., Treating Practitioner unavailability); or

(c) Until the Patient is discharged from the Hospital, with the understanding that upon any readmission to the Hospital, any follow up Proposed Treatment will require a new and separate Informed Consent process that must be conducted by the Treating Practitioner with a new and separate Consent Form executed by the Patient; or

(d) In the case of Research Consents where the experimental protocol is substantially altered, as determined by the principal investigator responsible for the research, a new and separate Informed Consent and signed Consent Form shall be obtained as required by Federal regulation and by the IRB approved protocol.

f) **Incorrect or Incomplete Consent**

(1) Minor errors in the Consent Form (e.g., misspelled word) that do not materially change the content of the Consent Form need not be corrected.

(2) Major errors in the Consent Form (e.g., misspelled Patient name, wrong site surgery) that materially change the content of the Consent Form must be brought to the attention of and corrected by the Treating Practitioner and re-executed by the Patient and witness prior to initiating the Proposed Treatment.

(a) For example, if the Treating Practitioner determines that the Patient received a proper Informed Consent that is not properly described hereto a major error in the Consent Form, and that any delay in the Proposed Treatment may represent a Material Risk to the Patient, a corrected Consent Form shall be prepared and signed by the Representative and witness.

(b) Alternatively, if the Treating Practitioner determines that the Patient or Representative, as appropriate, did not receive a proper Informed Consent, then the Proposed Treatment must be postponed until the Treating Practitioner has conducted an updated and corrected Informed Consent process and a new Informed Consent form has been signed by the Patient or Representative, as appropriate.

g) **Unanticipated Condition During Surgery or Procedure**

(1) If during the performance of a Proposed Treatment, the Treating Practitioner encounters an unanticipated change in Patient condition that requires one (1) or more additional Proposed Treatments that were not otherwise identified as the original Consent Form, and if the Patient otherwise qualifies as an Incapacitated Person as a result of general anesthesia, drugs sedation or otherwise, then the Treating Practitioner may either:

(a) Treat the condition without obtaining the patient's additional informed consent if treating the unanticipated condition would not materially alter risk or expected consequences of the care, treatment and services; or

(b) If the unanticipated condition would materially alter risk or expected consequences of the care, treatment and services, wait to treat the unanticipated condition only after the patient is able to provide informed consent, unless waiting to obtain additional informed consent would endanger the patient's life.

h) **Treating Practitioner(s) Responsible For Obtaining Informed Consent**

(1) The Treating Practitioner who is to perform or who is responsible for supervising the performance of the Proposed Treatment is responsible for obtaining the Informed Consent from the Patient.

i) **Authorized Persons Who May Provide Consent**

(1) The Patient who qualifies as an Adult as defined herein but does not otherwise qualify as an Incapacitated Person as defined herein; or

(2) A Legally Authorized Representative as defined herein.

(3) Special Rules

(a) **Blood Donations**. Any individual who is at least 17 years of age may give Informed Consent to donate blood in a voluntary and non-paying program without requiring the Representative's Informed Consent.

(b) **Treatment of Sexually Transmitted Diseases**. Any Patient, regardless of age, may give Informed Consent to Proposed Treatment for sexually transmitted diseases without requiring the Representative's Informed Consent.

(c) **Law Enforcement.** If a police officer requests that a test be performed on a patient to determine the amount of alcohol or presence of a controlled substance, or both, in the patient's blood, the police officer is responsible for obtaining written consent of the patient or legal guardian or representative. A copy of the written consent is included in the patient's medical record. If the patient refuses to submit to the test, the hospital shall honor the patient's wishes and not proceed with the test unless there is a court order/search warrant. Assuming a court order/search warrant has been obtained, the hospital shall abide by the court order/search warrant. Staff may refer to Legal Department or Risk Management if a question arises.

j) **Witnessing of Consent Forms**

(1) The signing of forms documenting informed consent for invasive, non-invasive and special procedures shall be witnessed.

(a) Registered Nurses, Advance Practice Nurses, residents in training, or Physician Assistants may sign as the witness on the consent forms

(2) Witness's signature on the consent form only attests to the fact that the patient signed the form, not to the patient's, guardian or representative's understanding of the consent of the form.

k) **Special Circumstances Impacting Communication**

(1) Informed Consent given by a Patient who is physically handicapped or illiterate but who otherwise maintains Capacity is valid where documented special efforts are made to conduct the Informed Consent process despite the particular physical handicap or illiteracy.

(2) Informed Consent given by a Patient who is physically unable to sign his/her name in execution of the Consent Form is valid if:

(a) The Patient makes a mark on the Consent Form and the person witnessing the form writes on the Consent Form that he/she witnessed the Patient make the mark; or.

(b) If the Patient cannot make any mark on the Consent Form, the Patient should ask someone else to sign his/her name on the Consent Form and the person witnessing the form writes on the form that he/she witnessed the third party sign the Consent Form at the Patient's request of the Patient, in the presence of the witness.

(c) If the Patient, as appropriate, has difficulty understanding or speaking English, the Hospital shall arrange for an independent interpreter, to the exclusion of any Patient family member, to assist the Patient during the Informed Consent process. Only the Patient can sign the Consent Form, but the interpreter should also sign his/her name

on the Consent Form with a short note indicating that he/she translated the form and the explanation provided by the Treating Practitioner.

l) **Telephone and Verbal Consents**

(1) In the case of extenuating circumstances short of an emergency, the verbal/telephone consent of a person is authorized to consent for a patient may be given by telephone. The Treating Practitioner may conduct the Informed Consent process and conduct the discussion, documenting the explanation with a Representative by telephone. In all such cases, the Treating Practitioner must include at least one (1) witness, preferably a licensed Hospital personnel, on the telephone call to monitor the conversation and document same in the Patient's medical record. After receiving an explanation from the Treating Physician as to the risks, benefits and alternatives, verbal consent of a person authorized to consent for a person may be given by telephone or by fax.

m) **Informed Consent by Fax**

(1) Fax consent is acceptable in those cases where the individual authorized to consent is unable to come to the hospital and the patient is unable to give a valid consent. If feasible, the Treating Practitioner should arrange to fax a completed Consent Form to the Representative for review, signature and return to the Treating Practitioner, The Treating Practitioner should complete the Consent Form and document, in addition, the name and address of the Representative giving Informed Consent, the date and time, and the signature of the witness to the telephone consent**.**

n) **Refusal to Consent/Revocation of Consent**

(1) Any Patient authorized to give Informed Consent under this Policy has the legal right to decide not to submit to a particular Proposed Treatment, for any reason, and at any time; however, in the case of any Patient who requires a Proposed Treatment in order to preserve life that does not otherwise qualify as an Emergency, the Treating Practitioner should communicate with Hospital Risk Management to review the situation. As necessary, the Hospital may consult with legal counsel to seek court intervention, as necessary.

(2) Any subsequent refusal to receive the Proposed Treatment, or alternatively, any revocation of the Consent Form, whether by the Patient or Representative, as appropriate, is to be promptly communicated to the Treating Practitioner who is to note same on the original signed Consent Form and in the Patient's medical record. Patient refusal of recommended care, treatment and services or revocation of a valid consent may be documented on the consent form or in the medical record.

o) **Persons Authorized to Consent for Incapable Parties (IC 16-36-1-5)**

(1) Healthcare Consent Hierarchy: If an adult incapable of consenting has not appointed a health care representative/power of attorney for healthcare or the health care representative/POA is not available or declines to act, consent to health care may be given in the following order of priority:

(a) Court appointed guardian

(b) A spouse

(c) An adult child (or majority of adult children*)

(d) A parent

(e) An adult sibling (or majority of adult siblings*)

(f) A grandparent (or majority of grandparents*)

(g) An adult grandchild (or majority of adult grandchildren*)

(h) The nearest other adult relative in the next degree of kinship who is not listed above

(i) An adult friend who has maintained regular contact with the individual and is familiar with the individual's activities, health and religious or moral beliefs

(j) The individual's religious superior if the individual is a member of a religious order

*If there are multiple members at the same priority level, then the majority of available individuals controls.

(2) The following individuals may NOT provide health care consent:

(a) A spouse who is legally separated or has a petition for dissolution, legal separation or annulment of marriage that is pending in court

(b) An individual who is submitted to a protective order or other court order to avoid contact with he individual that is unable to make their own decisions

(c) An individual who is subject to a pending criminal charge in which the ill individual was the allege victim

(3) Healthcare providers shall make a reasonable inquiry as to the availability of individuals who are able to provide healthcare consent. Reasonable inquiry includes examining the medical records and personal effects. The healthcare provider shall attempt to contact individuals who are high in the priority level and able to provide consent by telephone or other means.

References/Standards:

- The Joint Commission, *The Comprehensive Accreditation Manual for Hospitals (CAMH)*
- Centers for Medicare and Medicaid Services, Medicare Conditions of Participation and Interpretive Guidelines.
- Trinity Health Informed Consent Template Policy, version 031709
- Ind. Code § 16-36-1-5• Persons Authorized to Consent for Incapable Parties
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- Policy 162

Appendix I Procedures requiring Informed Consent, but not limited to

All procedure performed in the operating room or procedure room
All procedures requiring the use of moderate (conscious) or deep sedation.
All Transfusion of blood and/or blood products.
All procedures requiring contrast.
Amniocentesis

Anesthesia (all types and procedures except local and topical)
Angiography, Angioplasty, Stenting, Coiling, or Embolization
Aspiration Procedures from Organs or Body Cavities or Joints
Autopsy
Bacille Calmette-Guérin (BCG) Intra-vesicle Instillation
Biopsy Procedures (all organs and tissues including skin biopsies)
Burn Care with Reconstruction (all sites)
Cardioversion (elective)
Catheterization: any location including Dilatation, Stenting, Puncture or Ablation excluding Intravenous and Standard Peripheral sites and Urinary Bladder
Central Line Insertion (elective)
Cervical Ripening and Induction of Labor
Chemotherapy (initial cycle)
Circumcision
Chest Tubes
Cosmetic Procedures: Injections, Implantation, Reduction, Surgery, Suction, Topical
Skin Resurfacing and Laser Use
Cystoscopy
Debridement Procedure
Dental Restorative Procedures and Treatments
Dialysis (initial session), Insertion of Catheter
Electro Physiologic Studies (EPS)
Endoscopies (all body organs or orifices)
Evacuation of Hematoma
Extracorporeal Shock Wave Lithotripsy (ESWL)
External Cephalic Version
Florescence Angiography (initial session)
Hyperbaric Oxygen Treatments
Intravenous Immunoglobulin (IgG) IV therapy (initial session)
Pacemaker / Defibrillator Insertion (permanent)
I & Ds (Incision and Drainage)
Imaging Guided Needle Placements
Intubations (elective) excluding Oral or Naso Gastric Intubations
Invasive Diagnostic: Lumbar Puncture, Thoracentesis, Paracentesis, Joint Aspiration
Invasive Monitoring: Swan Ganz, Arterial Lines, etc.
Invasive Therapeutic: Tube Thoracostomy, Paracentesis, Thoracentesis, Punctures, Plasty Procedures
Lumbar Punctures
Nuclear Medicine Procedures Tests
Ophthalmology Procedures under local/ topical Anesthesia
Organ Donation

Organ Transplant
Pericardiocentesis
PICC Lines
Pneumatic Retinopexy
Radiation Oncology Therapy
Radioiodine I-131 Therapy for Goiter or Thyroid Cancer
Reconstructive Procedures
Roacutane Treatment
Sharp Wound Debridement
Stress Cardiac Scans / Echo / Tests
Subdural Tap
Thrombolytic Therapy
Tracheostomy
Trans-Illuminated Powered Phlebectomy Surgery (TIPPS)
Transesophogeal Echocardiograms
Ultrasounds: Endoscopic or Rectal
VCUG with Anxiolysis
Ventriculostomy