St.JosephHealth
Santa Rosa Memorial

TITLE: VERIFICATION OF INFORMED CONSENT

POLICY# B1-14

MANUAL: ADMINISTRATIVE POLICY/PROCEDURE MANUAL

Effective Date: 4/87 Approval /s/
Reviewed/: 1/93; 6/95; 11/95; 6/96; 4/98; 2/99; 1/00; 7/00; 10/00; 12/03, 09/04, 11/06; 9/10, 6/14, 9/14, 1/15, 1/10/17

VALUES

Guided by our four core values, our Mission and Vision calls us to be in support of the human spirit and asks for the commitment and participation of others to achieve them.

PURPOSE:

A. To ensure the quality of care for patients and to facilitate compliance with Santa Rosa Memorial Hospital ("Hospital") policies, as well as state and federal laws concerning informed consent for surgeries and other procedures. .

B. To provide medical and hospital staff with clear a process for ensuring that patients, and/or surrogates, patient representatives:

1. receive an explanation of the patient's condition and proposed procedure(s) in language they can understand, so the patient/surrogate can

2. decide whether or not to accept the proposed procedure(s), and

3. sign an appropriate verification form acknowledging their informed decision to proceed with (or decline) the proposed treatment or procedure(s).

POLICY:

A. It is the performing physician's responsibility to provide information needed by the patient (or surrogate) to make an informed decision.

1. Informational elements required for informed decision-making to be provided to the patient, and/or surrogate must include:

a. The procedure(s) listed on the consent form;

b. The risks and benefits of the procedure(s), and the possible use of blood or blood products (Paul Gann pamphlet to be delivered to the patient);

c. Any adverse reactions that may reasonably be expected to occur;

d. Any alternative efficacious methods of treatment which may be medically viable;

e. The likelihood of achieving treatment goals;

f. Any potential conflicting interests such as research or financial interests;

g. All patient questions answered; and

h. The identity and professional status of individual(s) responsible for performing procedure(s).

B. Exception to informed consent that always apply:

1. Treatment of a medical emergency if provider believes that a medical procedure should be undertaken immediately, and there is insufficient time to obtain consent of the patient, there is risk of loss of life and/or function or serious disability from a delay and there is no evidence the patient would refuse the treatment.

Additionally, informed consent is not necessary for elements of care that are routine, which require only simple consent and are covered by the "Consent for Treatment" form obtained during the admission process.

PROCEDURE TO OBTAIN INFORMED CONSENT:

DEFINITIONS:

A. Personal Representative – a person who has the authority, under California law, to make health care decisions on behalf of the patient. The following persons may act as a Personal Representative.

B. Surrogate – a person who is 18 years or older and appointed by the patient to make health care decisions on behalf of the patient. This could include family and/or close friends.

C. Healthcare Durable Power of Attorney (DPOA - A legal document that allows an individual to empower another with decisions regarding his or her **healthcare** and medical treatment. **Healthcare Durable Power of Attorney** becomes active when a person is unable to make decisions and/or cannot consciously communicate his/her intentions regarding medical treatment.

D. Conservator – an individual appointed through court-issued documents to represent the patient.

A. Role of the Physician:

1. The treating physician is responsible for discussing information required by the patient to understand the treatment/procedure to be performed, as well as obtaining the patient's informed consent for said treatment/procedure.

2. Physician Documentation Requirements: The physician documents in the Hospital medical record those discussions with the patient regarding informed consent and that informed consent was obtained.

B. When the patient is unable to Consent to Medical Care

1. Generally, a patient presenting himself/herself for treatment is assumed to have the capacity to make health care decisions.

    a. The determination that the patient does or does not have the capacity to consent to medical care is made by the patient's primary physician. If that physician is not reasonably available, the determination may be made by any physician who undertakes the responsibility.

    b. A physician who determines that a patient lacks (or has recovered) capacity must promptly record that determination in the patient's medical record. The physician must communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

2. "Implied Consent" exists for medical care, when:

    a. The patient is unable to consent, and;
    b. No surrogate decision maker is readily available, including by phone, and;
    c. No compelling evidence exists that the patient would not want the planned treatment, and
    d. Patient safety and well-being is at risk;
    e. Immediate services are;
        i. required for the alleviation of severe pain, or
        ii. required for diagnosis and treatment of unforeseeable medical conditions if such conditions would lead to serious disability or death if not immediately diagnosed and treated.
    f. The medical findings upon which the patient's incapacity to consent is based, along with the nature of an emergency medical condition must be documented in the medical record by the treating physician. If possible, a second physician should concur with the findings.

3. When a patient is unable to consent, and the medical need is not emergent, all reasonable efforts to identify and contact an appropriate Personal Representative should be made and documented.

    a. If the patient's incapacity fluctuates or is expected to deteriorate,

arrangements should be made for the Personal Representative with the patient's assistance, if possible.

b. If the patient has not appointed a Surrogate or a DPOA, through a valid written or oral directive and if there is no court appointed conservator for health care decision-making; or if the designated Surrogate, or Conservator is not reasonably available, the primary physician may identify an individual to make health care decisions on behalf of the patient. This Surrogate shall be the individual who appears, after a good faith inquiry, to be best able to function in this capacity. In identifying a surrogate, input from any or all of the following may be used as appropriate: family and friends of the patient, other health care professionals, institutional committees, social workers and chaplains.

c. A physician may not act as a decision maker for the patient in a non-emergent situation.

4. If the patient is medically stable and no Patient Representative is available and willing and able to participate in healthcare decision making, or there is continuing uncertainty about Patient Representative, a physician or another member of the healthcare team will request assistance from the Ethics Committee and/or Risk Management.

5. Exceptional Circumstances — Legal counsel may be consulted along with the Ethics Committee if a decision to withdraw or withhold treatment is likely to result in the death of the patient, and/or a situation arises in any of the following circumstances:

   a. The patient's condition is the result of an injury that appears to have been inflicted by a criminal act;
   b. The patient's condition was created or aggravated by a medical accident;
   c. The patient is pregnant; and/or
   d. The patient is a parent with sole custody or responsibility for support of a minor child.

C. Signatures on Consent Forms

1. Adult patients (18 years or older; see below for consent for minor's care) with decision-making capacity must sign the consent form personally.

2. If patient has a court appointed conservator for medical treatment, the conservator provides consent.

3. If an emergency exists in which action must be taken to preserve the patient's life or to prevent a possible permanent impairment of the patient's health and the patient is momentarily incapacitated to sign his/her own consent, the Patient Representative may sign. If the Patient Representative is not immediately available and time does not

permit waiting, the physician may proceed. Documentation of the emergency situation shall be made in the medical record.

4. Consents by the Patient Representative are only utilized for patients who are incapacitated to give informed consent.

5. Consent may be obtained by telephone:

   a. Telephone consents without concurrent signing of a consent form require:

      i. the signatures of two witnesses to the verbal Verification of Informed Consent recorded on the Hospital consent form;

      ii. the name of the Patient Representative should be recorded on the line for the patient's signature, and clearly identified as Patient Representative via telephone;

      iii. the elements of informed consent should be read to the Patient Representative; and

      iv. the Patient Representative must state that the physician talked with them about benefits and risks of the proposed procedure(s) and of alternatives to the proposed procedure(s) and they have had their questions adequately answered by the physician.

   b. An email message of consent can also be accepted; however, staff should seek to verify that the Patient Representative is, in fact, the individual providing such consent.

6. If a patient with capacity for decision-making is unable to sign a consent form, an "X" in place of a signature may be obtained.

   a. The patient's name should be entered alongside the "X" or in the place of the patient's signature, clearly identified as a patient who is verifying informed consent but unable to sign the form.

   b. Two staff witnesses to the patient's "X" or otherwise communicated consent must sign the form on the witness's line.

5. For non-English speaking patients, the services of an interpreter are obtained.

D. Minors' Informed Consent:

1. Minor patients *(under 18 years of age, except as noted under Section 2) must have the consent form signed by their parent or legal guardian. Minors should be included in the informed consent process as appropriate for their age and ability, and if possible, can assent vs. consent. Assent means a child’s affirmative

agreement to the medical procedure or treatment.

2. Under the following circumstances, some minors have the right to consent independently to medical treatments:

   a. Minors (15 years of age or older) living away from home (emancipated minor)
   b. Minors on active duty with the U.S. armed forces
   c. Minors receiving pregnancy care (includes treatment and post-partum care prevention of future pregnancies, excluding sterilizations or necessary abortions)
   d. Minors receiving care for reportable infectious, contagious or communicable/sexually transmitted diseases
   e. Minors seeking outpatient mental health treatment or counseling
   f. Minors (12 years of age or older) seeking treatment as victims of sexual assault
   g. Minors (12 years of age or older) seeking treatment related to alleged rape
   h. Minors (12 years of age or older) seeking treatment for drug or alcohol related problems

3. Parents who are minors may give consent for their children.

SPECIAL CIRCUMSTANCES REQUIRING ADDITIONAL INFORMATION OR CONSENT PROCEDURES TO OBTAIN INFORMED CONSENT:

A. **Consent for Blood Transfusion**s

Blood transfusion is viewed as a "complex" procedure requiring informed consent. When blood or blood products are administered under any circumstances other than in an emergent situation, the physician informs the patient of the benefits, risks and purpose of transfusion, transfusion alternative together with the benefits, risks and side effects of alternative treatments, the possible results of declining or not receiving treatment, and documents informed consent.

The Paul Gann Blood Safety Act imposes specific obligations upon physicians to provide information concerning transfusions. According to the Health and Safety Code, section 1645, the physician must use the standardized written summary developed by the California State Department of Health Services. "If You Need Blood A Patient's Guide to Blood Transfusion". The physician must use this summary; no other information or pamphlet will satisfy the physician's obligation under this law.

REFERENCES:

- California Association of Hospitals and Health Systems Consent Manual 2016
- Comprehensive Accreditation Manual for Hospitals, JCAHO 2016
- Health & Safety Code, section 1645

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Medical Executive Committee and other Quality Review Committees of the Medical Staff

ATTACHMENT A

Complex Procedure(s) performed outside of Surgical Services, Labor and Delivery, Angiocardiology or Imaging Requiring Informed Consent Require Verification of Informed Consent completion;

Including but not limited to:

Bronchoscopy
Cardioversion
Central Lines (not including PICC lines or umbilical lines)
Chest tube placement
Closed Reductions
Deep Sedation
Epidural for Pain Management
Hemodialysis access
ICP monitor insertion
IABP (Intraaortic Balloon Pump Insertion)
Lumbar Puncture
Moderate Sedation
Peracardiocentesis
Paracentesis
Swan Ganz catheter insertion
TEE (transesophageal echocardiogram)
Thoracentesis
Thrombolytic therapy (intracoronary, intravenous, intra-arterial)
Tracheostomy