LOMA LINDA UNIVERSITY
MEDICAL CENTER

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OPERATING POLICY

CATEGORY:	PATIENT'S RIGHTS	**CODE:**	P-2
		EFFECTIVE:	08/2017
SUBJECT:	PATIENT CONSENT	**REPLACES:**	08/2015
		PAGE:	1 of 9

DEFINITION:

Surrogate: A surrogate is a person designated by the adult patient as a health care agent by personally informing the supervising health care provider orally or in writing.

Related Policies:
Sterilization Consent Requirements (M-18)
Authorization for Treatment of Minors who Lack Capacity to Consent (M-100)
Emergency Treatment When Consent is Unobtainable (P-8)
Healthcare Decisions for Unrepresented Patients (P-23)

A. GENERAL PRINCIPLE

1. Loma Linda University Medical Center shall not render medical treatment unless the patient, or a person legally authorized to act on the patient's behalf, has consented to the treatment.

B. EXCEPTIONS

1. Limited instances when the patient's personal consent is not required shall include:

1.1 Medical treatment of a minor: Consent shall be given by the parent(s)/guardian unless a specific law requires an exception, e.g., an emergency exists or the minor meets certain requirements that allow him/her to consent to medical treatment (reference CHA Consent Manual, Chapter 2).

1.2 Emergency medical treatment when necessary to preserve the life or health of the patient (reference Policy Emergency Treatment When Consent is Unobtainable (P-8)).

1.3 When the patient lacks capacity to give his or her consent, in which case the process described in section C must be followed.

C. CAPACITY TO GIVE CONSENT

1. The physician shall determine whether the patient has the legal capacity to consent to medical treatment, procedure, or operation, unless that determination has already been made by the court.

   NOTE: Adults are presumed to be competent to consent to medical treatment even if developmentally disabled, and even if a conservator has been appointed. The fact that a patient has a conservator does not necessarily preclude the patient from giving valid consent to medical treatment. The opposite is also true.

2. The patient's conservator may consent to health care for a patient having capacity to consent if one of the following situations exists:

   2.1 The patient has not expressed an objection to the consent

   2.2 The patient expresses an objection to consent, but the conservator then obtains a court order specifically authorizing treatment

   2.3 The conservator determines in good faith on the basis of medical advice that:

   a. An emergency exists and treatment is required for alleviation of severe pain or
   b. The patient has medical condition which, if not immediately diagnosed and treated, will lead to serious disability or death.

D. "INCOMPETENT" ADULT

1. If the patient does not have a conservator with power to make health care decisions, and there is no designation of a person with that power in an advance health care directive, the primary care physician shall make determinations for the following:

   1.1 That the patient lacks, or has recovered, capacity to make health care decisions.

   1.2 That another condition exists (e.g., effects of medication) which affects a health care directive (verbal or written) given by the patient to the staff.

   1.3 That another condition exists which affects the authority of an agent or surrogate (e.g., information which may indicate that the surrogate or agent is not acting in the patient's best interest).

2. In the event the adult is found to be incompetent, i.e., lacks capacity to make an informed health care decision, one of the following shall give consent:

2.1 An agent known to the health care provider under a Power of Attorney for Health Care, who is known to be reasonably available and willing to make health care decisions.

NOTE: If the patient objects, the agent has no authority to act, whether the patient has capacity or not. If the patient objects, the matter will be governed by the law that would apply if there were no power of attorney for health care.

2.2 An adult surrogate designated orally or in writing by the patient to the health care provider.

a. Oral designation of an adult surrogate to make health care decisions shall be effective only during the course of treatment or illness, or during the stay in the Medical Center when the designation was made.

b. A health care surrogate shall not have priority over a conservator in making health care decisions.

2.3 A conservator, if patient has been legally judged to lack capacity to make health care decisions, and no agent has been designated under an advance health care directive.

a. In this case, the conservator may require the patient to receive treatment, even if the patient objects.

b. The conservator may obtain a court order if the patient has an existing or continuing medical condition not otherwise authorized for treatment.

2.4 A court-authorized person, if the adult patient is unable to give consent and does not have an agent under an advance health care directive, designated health care surrogate, or conservator of person, if treatment is for an existing or continuing medical condition.

2.5 The closest available relative, if none of the agents described in pars. 2.1-2.4 is designated, and none of the following circumstances are present:

a. The closest available relative's capacity to make health care decisions or motives are questionable.

b. There is a substantial question as to whether the patient, if he or she had the capacity to make health care decisions, would consent to the procedure.

c. Another close relative objects to the medical procedure.

NOTE: In any of these situations, or any others in which there is doubt as to the suitability of an individual providing consent, contact the Office of General Counsel before obtaining consent.

NOTE: In an emergency situation, the principles of emergency consent supersede the statements in Section D (reference Policy Emergency Treatment When Consent is Unobtainable (P-8)).

E. CONSENT PROCEDURE (Not applicable to emergency medical treatment)

1. Consent shall be obtained by the free will of the patient or person legally authorized to act on the patient's behalf.

2. Express written or electronic consent shall be obtained after the licensed physician or provider, who is authorized/privileged to perform the procedure, has given the patient or legally authorized representative a comprehensive disclosure of the nature of the treatment, inherent risks, and potential consequences and complications of the proposed treatment and available alternative methods of treatment (informed consent).

   2.1 It shall be obtained before the treatment or procedure.

   2.2 Hospital employees shall verify that the provider has obtained the patient's informed consent. (Reference "Informed Consent" in Section F.)

3. Telephone, facsimile, or other technology (e.g., e-mail), shall be used only if the person(s) having legal capacity to consent for the patient is not otherwise available. If a telephone, facsimile or other technology is used, the responsible provider shall, when possible, provide the patient's legal representative with the information the provider would disclose if the person were present. See below for witness requirements.

   3.1 When consent is obtained by telephone, confirmation of the consent should be obtained by facsimile or other technology.

   3.2 Consent documents received by facsimile or other technology shall be placed in the medical record along with any transmittal cover sheets. The sender shall be requested to send the original of signed document(s) to the hospital when possible.

4. A refusal of treatment may be executed by the patient at any time before treatment, including during his or her stay in the hospital.

5. LLUMC shall arrange for an interpreter where the patient or the patient's legal representative cannot communicate with the provider because of language or communication barriers (reference Policy Communication with Patients who have Limited English Proficiency and/or Are Hearing, Speech, or Vision Impaired (M-113)). Minors shall not serve as interpreters.

6. The hospital shall make every effort to obtain certified copies of court orders, power of attorney, advance directives, letters of conservatorship, revocation of advance directives or power of attorney, and place them in the patient's medical record.

7. Consent shall include:

   7.1 Use of the designated paper or electronic consent form (meeting the CHA Consent Manual criteria), with the following information recorded:

   a. Intended treatment, procedure or operation;

   b. Names of individuals performing procedure or treatment; and

   c. Required signatures, including date and time of signature of:

   1) The patient or representative, and

   NOTE: The person consenting to the treatment, procedure or operation should sign the form. If a person legally entitled to represent the patient signs the form, the relationship should be indicated below the signature. If the person required to sign is physically unable to write his or her name, the hospital representative should write the person's full name on the form and allow the patient to place an X beneath it. If the form is electronic, the hospital representative should allow the patient to place an X in the signature box. Two people must witness the signer place his or her mark on the consent form and then must sign the consent form as witnesses.

   2) A witness on behalf of LLUMC or LLUH if:
   a) The signer used an X to indicate consent (two witnesses)
   b) The consent was obtained over the phone (two witnesses)
   c) Other as required by specific process or regulation.

   NOTE: When a witness is required to sign the patient's consent form, such witness(es) should be eighteen (18) years of age or over and present when the form is signed by the patient or the patient's legal representative. Unless otherwise indicated, admitting clerks, registered nurses,

licensed vocational nurses, or other hospital employees of similar responsibility may act as witnesses to signatures on hospital forms. Witness signature indicates only that the employee observed the patient or representative sign the consent document with an X or verified the consent process on the phone.

3) Providers (with documentation of informed consent – see below) .

NOTE: The standard patient authorization and consent form/electronic consent is used for all procedures requiring consent (including those procedures for which a special consent form is necessary). A copy of the completed consent document shall be made available to the patient or representative; the other is retained for the medical record.

F. INFORMED CONSENT

1. Informed consent shall be required for complex medical treatments and procedures and all operations.

2. Informed consent also shall be obtained and documented for the following, to include, but not be limited to:

2.1 Operating room procedures.

2.2 Procedures done in areas designated as special procedure areas.

2.3 Procedures for which moderate or greater sedation is used.

2.4 Administration of blood or blood products

2.5 Procedures for which a provider's note is required.

2.6 The use of any experimental device, drug, or research.

2.7 Breast cancer or prostate cancer treatment/surgery.

2.8 Others as required by department.

NOTE: The various treatments, procedures or operations listed above may have more specific consent requirements, as well as shorter periods of validity for consent. Also, special consent forms may be required.

3. Exceptions to informed consent shall be documented in the patient's medical record, and include:

    3.1 Requests by the patient that he or she not be so informed.

    3.2 Situations where such disclosure would seriously harm, rather than benefit, the patient.

        NOTE: Disclosure need not be made beyond that required within the local medical community when a provider can prove by the preponderance of the evidence that he or she relied upon facts which would demonstrate to a reasonable person (not a reasonable physician) that the disclosure would have so seriously upset the patient that the patient would not have been able to dispassionately weigh the risks of refusing to undergo the recommended treatments.

4. Informed consent shall include:

    4.1 Documentation by the provider in the patient's medical record that a discussion was held with the patient and that informed consent was obtained.

    4.2 Explanation of the following in terms and language that are clear and easily understood:

        a. The intended treatment.

        b. The risks and possible complications of treatment.

        c. The expected benefits or effects of the treatment.

        d. The likelihood of achieving treatment goals

        e. Any alternatives to the treatment with their risks and benefits.

        f. The risks of not receiving the intended treatment.

5. Informed consent, as described above, shall:

    5.1 Be obtained by one of the following:

        a. The attending physician who is treating the illness/condition related to the proposed surgery/procedure/treatment

        b. A licensed physician or provider who is:

1) Part of the treatment team
2) Familiar with the patient's history and condition
3) Authorized/privileged to perform the proposed surgery/procedure, or is familiar with the risks and benefits of the procedure (e.g., line placement).

c. Other licensed healthcare provider, for procedures he or she will perform within the scope of his/her practice.

5.2 Be obtained before administration of preoperative or pre-diagnostic medication (or any narcotic or sedative that may affect mental clarity).

NOTE: Written materials used by the physician to explain the treatment, procedure, or operation should be designated as the physician's information as opposed to LLUMC's information.

6. Informed consent shall remain in effect unless or until a change in circumstances occurs, e.g.:

6.1 Risks/benefits

6.2 Treatment alternatives

6.3 Patient condition

6.4 Procedure

6.5 An inpatient is discharged and readmitted

6.6 A series of treatments has ended and then resumed

6.7 Patient revokes his or her consent.

7. An individual on behalf of LLUMC shall:

7.1 Unless acting as a translator, not be involved in describing the procedure or responding to patient questions concerning the nature of the intended procedure(s) before consent signature is obtained. Exception: Nurse Practitioner or other healthcare provider who will perform the procedure.

NOTE: If it appears that the patient has significant questions about the treatment, procedure or operation, the patient's provider should be contacted to ensure informed consent is given.

7.2 Verify that all required elements of the electronic or paper consent have been completed before pre-procedure medication is administered and/or procedures are performed (reference Policy Universal Protocol for Patient, Procedure, and Site Verification (M-123)).

8. The person responsible for administering anesthesia, or the surgeon/practitioner if a general anesthetic will not be administered, shall ascertain that a written or electronic informed consent form for the contemplated surgical procedure is in the medical record prior to non-emergency surgery.

Reference CHA charts "Consent for Medical Treatment of Adults" and "Consent for Medical Treatment of Minors"

APPROVED: Hospital Executive Leadership, LLUMC Chief Executive Officer, LLUMC Chief Nursing Officer, LLUMC Medical Staff President