LAC+USC MEDICAL CENTER POLICY

Subject:	Original Issue Date:	Policy #
CONSENT FOR CARE	7/11/79	**205**
	Supersedes: 11/18/19	Effective Date: 12/7/22

Departments Consulted:	Reviewed & Approved by:	Approved by:
Office of Risk Management Office of Human Resources Health Information Management Ethics Resource Committee	Attending Staff Association Executive Committee Senior Executive Council	(Signature on File) Chief Medical Officer (Signature on File) Chief Executive Officer

PURPOSE

To ensure that patients receiving medical care are provided with the information necessary to give permission and sign a consent prior to treatment (with the exception of immediate/emergency situations, as delineated in the policy), and to assure compliance with federal and state statutes and regulations regarding informed consent.

POLICY

Informed consent must be obtained prior to provision of care for all patients at the Medical Center, unless patients have conditions that meet California "immediate exception" criteria and lack surrogates. Informed consent is the result of an interactive dialogue between the Practitioner and patient/decision-maker, which allows for sufficient time for the patient to consider his/her decision. The informed consent must be free of coercion, duress, or fraud, any relevant conflicts of interest must be disclosed, and the process must enable the patient/decision-maker to ask questions for clarification as needed such that the patient/decision-maker understands the care/procedure being offered, its risks, benefits, and alternatives. Informed consent must be obtained by a Practitioner who is a member of the team that performs the procedure or treatment for which informed consent is required. The patient/decision maker who gives informed consent must have decision-making capacity; the information provided to the patient/decision maker must be complete and in a language the patient understands. After informed consent is obtained, the written, signed confirmation of informed consent takes one of several forms depending on the clinical circumstances, as elaborated below:

A. Conditions of Admission/Clinic Visit or Emergency Medical Treatments Consent (aka *General Consent*)

All patients receiving care at the Medical Center must have a Conditions of Admission/Clinic Visit or an Emergency Medical Treatments Consent (aka *General Consent*) prior to receipt of treatment at the point of service. An exception is granted for patients who are documented in the medical record to meet California state law criteria for "immediate exception", as described in section D below, and who lack surrogates. For such patients, an Immediate Exception is granted based on medical documentation, and lasts for the duration of hospitalization, or until such time as a patient regains consciousness and capacity and indicates that they refuse consent for further care. Informed consent for newborns delivered at the Medical Center is covered under the same General Consent for the mother who delivered the child.

The General Consent should be renewed at least annually for outpatients and remains in effect throughout the duration of ED stay or hospitalization for inpatients.

The General Consent covers routine elements of care, including but not limited to venipuncture and routine diagnostic tests, peripheral intravenous (iv) catheter placement, placement of a urinary catheter in the bladder, placement of a nasogastric tube, dressing changes, general medication prescription and administration, splinting/casting, and routine radiographic testing including X rays, CT scans, MRI scans, and ultrasounds. Higher risk, invasive procedures are not covered under the General Consent and require their own separate written consents (see B below). In accord with California state law, HIV testing no longer requires a separate informed consent, however it falls under opt-out testing, meaning that the patient must be verbally informed the test is being ordered and has an opportunity to refuse. If the patient refuses, this will be documented in the medical record.

B. Consent for Complex (Invasive) Procedures

Specific complex procedures conducted for diagnostic or therapeutic purposes require separate, written informed consent for the procedures. In general, procedures are considered complex, requiring specific written consent when percutaneously placing foreign materials in the body (excepting peripheral iv placement), or when scopes are placed within the body. A non-exclusive list of procedures that requires specific, written informed consent is included in Appendix A.

The consent for a specific procedure may be considered to have continuing force and effect unless the patient revokes the consent verbally or in writing or until circumstances change so as to materially affect the nature or the risks of the procedure and/or the alternatives to the procedure to which the patient consented, not to exceed one (1) year.

Content required for a valid written informed consent for invasive procedures includes:

a. The name/type of specific treatment/procedure
b. The purpose of the procedure
c. The name of the supervising physician performing the procedure
d. The specific site, including laterality if appropriate
e. The risks and possible complications of the procedure in the particular patient (taking into consideration comorbidities)
f. Expected benefits of the treatment
g. Reasonable alternatives, and their risks and benefits
h. A valid signature from the patient or surrogate decision maker
i. Date and time the form is signed

If the patient is unable to sign the consent form due to physical disability, they can make a mark on the consent form, even by holding the pen with the mouth, if necessary, to acknowledge the consent.

If physical signature or mark cannot be obtained from the patient or a surrogate, verbal consents may be obtained, and/or consent may be obtained from an off-site surrogate via telephone, fax, or e-mail. In all such cases, all of the normally required elements of informed consent must be documented in the medical record, and the note documenting the consent must be signed by the Practitioner.

C. Bundled ICU Consents

Given the complexity of care in critically ill patients in the ICU, a single bundled consent may be used to obtained informed consent for common invasive procedures required in critical care,

including:

a. Central line insertion
b. Arterial line insertion
c. Pulmonary artery catheter insertion
d. Lumbar puncture
e. Thoracentesis
f. Chest tube placement
g. Mechanical ventilation
h. Bronchoscopy

The bundled consent is valid only for the duration of the current ICU stay.
All ICU bundled informed consent templates/forms, and the procedure by which they will be used, must be approved by the Medical Executive Committee and hospital administration prior to implementation of their use.

D. Immediate Exception to Informed Consent

Per California code, treatments may be administered without consent to patients who lack decision-making capacity and who lack a surrogate decision maker, when a licensed Practitioner reasonably believes that there is an "immediate" need to alleviate:

1. Sever pain; or
2. Risk of serious disability; or
3. Risk of death

Only the immediate risk condition can be treated in such circumstances. The provision of medical services for conditions that do not meet this definition require the permission of the patient or the surrogate even if the conditions occur concurrently with the immediate condition. Since the immediate exception is based on the theory of implied consent, it is not applicable when a patient has validly refused medical treatment, and the immediate condition arises from the fact that treatment was not given.

Provision of care using an immediate exception to informed consent requires documentation in the medical record to include:

1. The nature of the condition causing immediate severe pain or risk of disability or death
2. The lack of availability of the patient or a surrogate decision maker to consent, *and*
3. Reasonable efforts by the hospital to contact the patient's representative
4. Why a delay in provision of care to contact a surrogate decision maker creates a risk of unacceptable prolongation of severe pain or disability or death

Such documentation must include the name of the licensed Practitioner who has made the assessment that an immediate condition exists precluding the ability to obtain consent.
Specific to use of blood/blood components, providers should also sign "Provider Attestation" on the Blood consent form to the necessity of the transfusion and reason for lack of informed consent.

For minors (< 18 years old), the Los Angeles County Department of Children and Family Services (DCFS) is responsible for authorizing care if no legally responsible individual is immediately available to give consent. However, the provision of emergency care must not be delayed while obtaining authorization from DCFS. DCFS can be reached by calling (800) 540-4000. For minors in custody/or sent from Juvenile Court Health Services, a copy of a signed informed consent for treatment obtained within the last year may be used in lieu of the Medical Center's standard General Consent forms.

E. Non-Emergent Treatments in Patients without Capacity and without a Surrogate
According to California Probate Code Section 4650(c), "In the absence of controversy, a court is normally not the proper forum in which to make health care decisions, including decisions regarding life-sustaining treatment." Thus, in accord with this statutory declarative, and as recommended by the California Hospital Association Manual of Consent (Appendix 2D), LAC+USC Medical Center will use a multi-disciplinary approach to serve as a surrogate decision maker for certain medical decisions for patients who lack capacity and have no surrogate decision maker available.

The multi-disciplinary committee may be requested by the primary team attending to convene. The request should be made to the Medical Officer of the Day, who will determine if the request being made is appropriate for adjudication by the multi-disciplinary committee (i.e., a patient without capacity and with no surrogate decision making requires a non-emergent healthcare decision to be made).

The multi-disciplinary committee may only make decisions if extensive efforts have been made over time to identify a surrogate decision maker, without success. Such efforts must be documented in the medical record. If the MOD agrees that the medical decision is appropriate for consideration by the multi-disciplinary committee, the MOD will inform the provider to contact the Ethics Committee member who is on call to initiate the process.

The voting members of the committee will be comprised of:

1. The patient's primary attending physician—the attending must be present, and residents/fellows cannot serve/vote in place of the attending, although they may be present to provide background information
2. A nurse from the patient's care team, who should be identified by name by the primary team
3. The on-call member of the Ethics Committee, or for pregnant patients a member of both the Ethics Committee and the Fetus/Infant/Child (FIC) committee, or for a pediatric case, only a member of the FIC Committee.
4. Any consulting attending physicians who have made recommendations relevant to the decision at hand, who should be identified by name by the primary team
5. A social worker who is familiar with the patient and has participated in the care team
6. A non-medical community member of the Ethics Committee (strongly preferred) or a representative from the patient advocacy/relations office.

The Ethics Committee on call member will provide the names of the participants to the Attending

Staff Office which will provide administrative support to set up the meeting.

The multi-disciplinary team will review the patient's diagnoses and prognosis and determine goal of care by considering:

1. Any known prior patient wishes
2. Prioritizing relief of suffering or pain
3. Preservation or improvement of function
4. Quality of life
5. Degree of intrusiveness/invasiveness and discomfort of the procedure and future care needs.
6. Decisions regarding end-of-life will be limited to patients who are comatose or in a persistent vegetative state, or who are terminally ill with a life expectancy of less than 6 months.

Decisions made by the committee without clear knowledge of an unrepresented patient's specific treatment preferences must be made in the patient's best interest, taking into consideration the patient's personal history, values and beliefs to the extent that these are known. Decisions about treatment should be based on sound medical advice and should be made without the influence of material conflicts of interest. These decisions must be made with a focus on the patient's interests, and not the interests of providers, the institutions, or other affected parties. In this regard, appropriate health care decisions include both the provision of needed medical treatment and the avoidance of non-beneficial or excessively burdensome treatment, or treatment that is medically ineffective or contrary to generally-accepted health care standards.

All treatment decisions by the committee must be unanimous to take effect. If there is disagreement, effort should be made to resolve the disagreement through dialogue or further-fact finding. If unanimous agreement cannot be reached, the action requested should not be undertaken.

Except to the extent that such a factor is medically relevant, any medical treatment decision made pursuant to this policy shall not be biased based on the patient's age, sex, race, color, religion, ancestry, national origin, disability, marital status, sexual orientation, gender identity (or any other category prohibited by law), the ability to pay for health care services, or avoidance of burden to family/others or to society. The multi-disciplinary team must assure itself that the medical decision is made based on sound medical advice, is in the patient's best interest and takes into account the patient's values, to the extent known. In determining the best interest of the patient, it is not required that life support be continued in all circumstances, where treatment is otherwise nonbeneficial or is medically ineffective or contrary to generally-accepted health care standards, when the patient is terminally ill and suffering, or where there is no reasonable expectation of the recovery of cognitive functions.

The outcome of the multi-disciplinary committee should be documented in the medical record, including the team members and roles of the people who met, and unanimity or not of the decision. Also, this process generally should not be used to make decisions regarding administration of anti-psychotic drugs. Finally, this policy shall not apply to decisions pertaining to disposition of remains, autopsies, or anatomical gifts.

If a unanimous decision is made to proceed with the proposed intervention/treatment, patients who are not comatose must be notified in writing (see Appendix) that they have been determined to be incapacitated, lack a surrogate decision maker, a medical intervention has been

recommended, and they have an opportunity to seek judicial review of these determinations if they would like.

F. Consent for Investigational Research

Consistent with Medical Center policy #233, all participants in research activities deemed to require informed consent by the IRB must have a valid, signed, and witnessed informed consent specific to the research project in the medical record. Content of the consent will comply with state and federal statute and regulations, as well as IRB requirements.

Use of Interpreters During Informed Consent Process

Informed consent should be conducted in a language the patient understands. If necessary, an interpreter who is used in obtaining informed consent from a patient should be a staff member who the Medical Center has identified as a bilingual interpreter in the needed language. Use of patient's family, friends, or non-Medical Center personnel for interpreter services will be prohibited unless expressly requested by the patient/surrogate or in an emergency. The practitioner must document in the patient's health/medical record: (1) the reason for using a non-Medical Center staff member as an interpreter and (2) the express written permission of the patient/surrogate.

The interpreter who is used in obtaining informed consent from a patient must be identified on the consent form.

The in-person interpreter shall sign the iMedConsent to attest that he or she has:

- Interpreted completely and accurately the practitioner's information and the questions and answers between practitioner and patient/surrogate.
- Read the informed consent to the patient/surrogate completely and accurately in the patient's/surrogate's language, or orally translated the written informed consent, if the informed consent is not in a language understood by the patient.
- Asked the patient/surrogate about the patient's/surrogate's complete understanding of the information and stated that the patient/surrogate has answered affirmatively.

Requirements to be met when the Language Line Service is used for interpretation are found in DHS Policy #314.2.

DEFINITIONS

Practitioner

A Practitioner is defined as any physician, dentist, podiatrist or allied health professional such as Certified Registered Nurse Anesthetist, Certified Nurse Midwife, Registered Nurse Practitioner, Physician Assistant, etc., who performs the treatment or procedure involved, and is within their scope of practice. The term Practitioner includes residents or fellows in an approved graduate medical training program who are deemed competent to participate in performing the treatment or procedure involved.

Decision-Making Capacity

An adult patient presenting him or herself for treatment is assumed to have decision-making capacity unless there is evidence to the contrary. The determination of decision-making capacity shall be made by the Practitioner and may not require a psychiatric consultation or a court hearing.

The adult patient demonstrates capacity to make decisions when he or she has been determined to have the following abilities:

- Ability to understand the given information about diagnosis, treatment, and the relationship of the proposed treatment to his or her medical condition;
- Ability to evaluate the risks, benefits, and alternatives of the proposed treatment and to make choices with appropriate reasons; and
- Ability to communicate his or her choice from the treatment options.

Minor

A minor is a person under 18 years of age. There are certain categories under which a minor may give consent for medical care. One of the following conditions must apply:

- Minors on active duty with United States Forces (Family Code ə 7002)
- Minors receiving pregnancy care (Family Code ə 6925)
- Minors receiving family planning services (Family Code ə 6925)
- Minors 12 years or older suffering from a reportable disease (Family Code ə 6926)
- Minor rape victims 12 years or older (Family Code ə 6927)
- Emancipated minor (Family Code ə 7120)
- Minors 12 years or older undergoing sexually transmitted disease diagnosis and treatment (Family Code ə 6926)
- Minor victims 12 years or older suffering from sexual assault (Family Code ə 6928)
- Minors not married, under 18, over 12, seeking abortion (Health and Safety Code ə 123450)
- Minors under 18, over 12, in need of mental health outpatient treatment (Family Code ə (6924)
- Minors under 18, over 12, with drug or alcohol-related problems (Family Code ə 6929)
- Minors under 18, married or previously married (Family Code ə 7002)
- Self-sufficient minors over 15, not living at home, managing own financial affairs (Family Code ə 6922)
- Minors under 18, no special circumstances, emergency and parents not available (Business and Professions Code ə 2397)
- Minors 12 years or older in need of HIV testing (Family Code ə 6926)
- Minors making a donation of blood (Health and Safety Code ə 1607.5)

For additional details, the California Healthcare Association Consent Manual may be consulted.

RESPONSIBILITY

Administrators
Attending Staff
Residents Allied Health Professionals
Nursing Staff

PROCEDURE DOCUMENTATION

Attending Staff Manual, Rules and Regulations
Departmental Policy and Procedure Manuals

REFERENCES

California Code of Regulations, Title 22, Section 70707 (5), 72528 (e)
California law AB682
California Health and Safety Code Section 120990
California Family Code
DHS Policies #s 314, Informed Consent
314.1, Providing Care To Minors In The Absence Of Parent Or Legal Guardian
314.2, Documenting Use Of Interpretation Services During Informed Consent Discussions
318, Non-English And Limited English Proficiency
Medical Center Policy # 237, Paul Gann Blood Safety Act And Consent For Blood Transfusions
California Healthcare Association Consent Manual
Joint Commission Standards (Ethics, Rights, and Responsibilities)
CMS Conditions of Participation 42 CFR 482.13, 482.51(b)(2), 482.24(c)(2)(v), Tags A-0049 (Patients' Rights), A-0392 (Surgical Services)
38 CFR 17.32
Business and Professions Code section 2397(c)(2) and (3)
Probate Code section 3210(b) and 4716
Welfare and Institutions Code Sections 369(d)

REVISION DATES

April 1, 1995; October 20, 1998; April 9, 2002; November 4, 2002; June 22, 2004; April 19, 2005; October 16, 2008; March 8, 2011; September 11, 2012; April 8, 2014; March 08, 2016; May 19, 2019; November 18, 2019, December 7, 2022

Appendix A: Non-Exclusive List of Procedures That Require Separate, Written Informed Consent

Abortions
Administration of blood and/or blood products
Amniocentesis
Anesthesia and/or deep sedation
Angiography (all)
Arterial Pressure Line
Autopsy
Biopsies (including those done outside of the surgical suite, e.g. uterine, liver, muscle, bone marrow core, pleural, lung-transbronchial and percutaneous, lymph node, skin, nerve, eyelids, external eye, transrectal or perineal prostate biopsy)
Bronchoscopy
Cardiac (all invasive procedures)
Cardioversion (elective)
Chemotherapy for cancer treatment
Cholangiography (transhepatic)
Closed reduction of fractures and dislocations
Colonoscopy
Cryosurgery
Cutdown
Cystoscopy (Retrograde Pyelography)
Dialysis (First episode of dialysis or change in dialysis modality {e.g., formerly hemodialysis now converted to peritoneal, or visa-versa}, require separate written informed consent. Patients who are receiving chronic dialysis (whether hemodialysis or peritoneal) or who have received prior dialysis during the current hospitalization do not require a separate consent to receive additional dialysis sessions.)
Dilatation of Urethral Stricture
Discography
Elective Central Vein Catheterization
Endoscopies requiring conscious sedation
Endoscopies Retrograde Cholangiopancreatography (ERCP)
Esophageal Dilatation
Esophageal Motility
Fluorescein Angiography
General Anesthesia
Induction of Labor (elective)
Intra Uterine Device (IUD) insertion or removal
Intra-Aortic Balloon
Laparoscopy
Laser Procedures
Line Insertions
Local Anesthesia
Lumbar Puncture/Spinal Tap

Myelography
Paracentesis
Percutaneous nephrostomy or gastrostomy or jejunostomy tubes
Pericardiocentesis
Pneumatic Dilation
Polypectomy
Radioactive Isotope Therapy/Therapeutic Doses
Small Bowel Biopsy
Subdural Tap
Surgical Procedures
Swan-Ganz
Thoracentesis
Umbilical Artery & Vein Catheterization

Appendix B: Notification Form for Unrepresented Patient at LAC+USC Medical Center

Patient Name:_____ Medical Record Number:_____ DOB:_____

Your doctor, Dr_____ has carefully evaluated your physical and medical condition and concluded that you don't have the ability to make decisions about your medical treatment.

The hospital has tried to find a family member or friend of yours to make health care decisions for you. The hospital hasn't been able to find anyone to do that. If you have a family member or friend who you want to make health care decisions for you, please tell us.

Your doctor has recommended the following treatment, believing that this is the best treatment for you under the circumstances:

A team of health care professionals, including your doctor and nurses and others, agrees that this is the best treatment for you.

Unless your doctor receives direction otherwise, your doctor intends to proceed with this treatment. You can ask a judge to stop this treatment. You can also ask a judge to let you make your own health care decisions. You can contact a judge at:

Los Angeles County Superior Court

Metropolitan Court House
1945 South Hill Street
Los Angeles, CA 90007

Your assigned hospital social worker, or the LAC+USC patient advocate office, may be able to help you contact a judge. If you are interested in this, please notify your nurse or doctor that you want to talk to a social worker or the hospital's patient advocate.

HOSPITAL EMPLOYEE TO COMPLETE:

I gave a copy of this form to the above-named patient on _____*[date]* at _____ *[time]* a.m./p.m.

Signature:

Print name:

Original to Patient

Copy in Medical Record