

**LOUISIANA STATE UNIVERSITY HEALTH CARE SERVICES DIVISION
BATON ROUGE, LA**

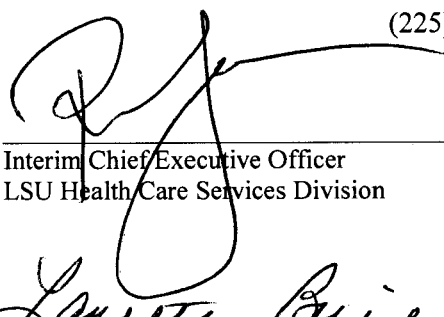
POLICY NUMBER: 5501-12

CATEGORY: Medical Services


CONTENT: Informed Consent for Medical Treatment: To familiarize LSUHCSD staff with requirements for obtaining consents. To assure compliance with Louisiana State Law and requirements of various accrediting agencies (The Joint Commission, CMS, etc.). To protect the patient's right to give informed consent and to ensure that patients are adequately informed prior to giving consent.

EFFECTIVE DATE: Issued: June 19, 1996
Revised and Reissued: October 8, 2001
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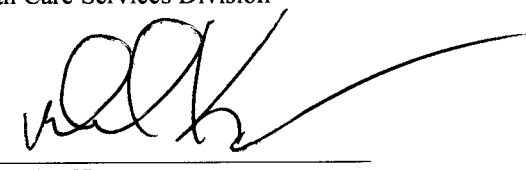
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Interim Chief Executive Officer
LSU Health Care Services Division

2/28/12
Date


Deputy Chief Executive Officer
LSU Health Care Services Division

2/28/12
Date


Chief Medical Officer
LSU Health Care Services Division

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Date

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Policy 5501-12
Page 5501-12.1

Policy Subject: Informed Consent for Medical Treatment

Policy purpose:

- To protect the patient's right to give informed consent
- To ensure patients are adequately informed prior to giving consent
- To familiarize LSU HCSD staff with requirements for obtaining consents
- To assure compliance with Louisiana State Law and accrediting agencies

Policy Statement

General Consent

All patients at LSU HCSD hospitals must have a valid consent prior to receiving treatment.

Exceptions:

- A. Patients requiring emergency, life-saving treatment are not required to have informed consent prior to treatment.
- B. Consents are not required for most outpatient visits, except when a procedure is performed that would otherwise require informed consent.

Who May Give Consent?¹

I. Competent Adult (18 and above)

II. Someone acting on behalf of an incompetent patient, minor, or otherwise incapacitated person²

When the patient is incompetent, not of legal age, or otherwise not in a condition to consent, the following hierarchy is used to determine who may provide consent:

- a) Judicially appointed tutor or curator of the patient, if one has been appointed
- b) An agent acting pursuant to a valid mandate, specifically authorizing the agent to make health care decisions (power of attorney)
- c) Spouse, if not judicially separated
- d) Adult child of patient
- e) Either parent, whether adult or minor, for a minor child

¹ Louisiana Medical Consent Law, Revised Statute 40:1299.53

² R.S. 40:1299.55 – The relationships of those who may consent include marital, adoptive, foster, and step-relations as well as the natural whole blood. The healthcare provider is justified in relying on the representation of any person purporting to give such a consent, including, but not limited to, identity, his age, marital status, emancipation, and relationship to any other person for whom the consent is purportedly given.

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- f) An adult brother or sister³
- g) The patient's other ascendants or descendants
- h) Any other person temporarily standing in loco parentis whether formally serving or not, for the minor under his care and any guardian for his ward with a properly executed affidavit. (A copy of the affidavit should be attached to the record.)⁴

Note: If there is more than one person within the above named class, the consent is given by a majority of those class members available for consultation.

Minors (Age <18)

When can minors consent to treatment?

Minors may consent without parental authorization for

- A. *Emergency procedures*
- B. *Treatment of self for substance abuse*⁵
- C. *Treatment of self for venereal disease*⁶
- D. *Treatment of self for any procedure associated with pregnancy or childbirth*
- E. *Donation of blood -Must be seventeen years old and must not receive compensation for the donation of blood*⁷
- F. *Any medical or surgical procedure if he/she believes himself/herself to be afflicted with an illness or disease*⁸
- G. *Emancipated minors may consent without parental consent for all procedures/treatments*

Minors may not consent to be sterilized.

Notes:

Consent should be obtained from the parents if they are available.

The physician may choose to give information to or withhold information from the spouse, parent, or guardian without the minor's consent and over the express objection of the minor.

The physician must assure that the minor understands the content of the consent.

When the parent is present and objecting, a minor has no right to refuse treatment when that treatment is consented to by his parents and proposed by a licensed physician. R.S.40:1095 states no suit may be brought

³ "Steps" are considered the same – e.g. stepbrother and stepsister

⁴ Non-legal Custodian Law, L.S. 975, Paragraph B.(1) "No person who acts in good faith reliance on a non-legal custodian properly executed affidavit, having no actual knowledge of any facts contrary to those stated in the affidavit, shall be subject to civil liability or criminal prosecution, or to professional disciplinary procedure, for any action which would have been proper if the facts had been as he believed them to be. This Paragraph shall apply even if medical or educational services are rendered to a child in contravention of the wishes of the parent or legal custodian of that child. However, the person rendering the services must not have actual knowledge of the wishes of the parent or legal custodian."

⁵ R.S. 40:1096

⁶ R.S. 40:1065.1

⁷ R.S. 40:1097

⁸ R.S. 1095

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under the Minor Consent Law except for negligence, thus, obtaining only the minor's consent will not result in legal liability for any defect in obtaining consent to perform a procedure.

Prisoners

When can prisoners consent to treatment?

Consents for procedures should be obtained from prisoners for all procedures that require informed consent just like all other patients.

Juvenile Offenders

Juvenile Offenders have the same rights as other juvenile patients. Consents should be dealt with in the same manner as any other minor with consent obtained from the parent, when possible.

When can prisoners refuse treatment?

Prisoners may refuse any and all treatment, except in exceptional circumstances:

- A. Their condition relates to certain contagious or infectious diseases.
- B. Mentally ill and mentally challenged inmates may be treated for 15 days if necessary to prevent harm or injury to the inmate or others. This is allowed after a properly completed physician's emergency commitment (PEC) declaration has been completed. Beyond 15 days, a court order is required. (R.S. 15.830). Additionally a court order is always required before a major surgical procedure or for electroconvulsive therapy

Alcohol Testing in the ER

For a person in police custody, alcohol testing requires the patient's permission except if a death or serious bodily injury has occurred.⁹

Mentally Ill Patients

When Can Mentally Ill Patients Refuse Treatment?

Patients under Physician Emergency Commitment (PEC) are incompetent to give consent. With the exception of electroconvulsive therapy or surgical procedures which require a court order, any medical/psychiatric procedures and/or treatment may be performed without the patient's consent¹⁰.

Who may obtain consent?

A. General Consent

The "Consent for Medical Treatment" is obtained by Admitting Department Staff and is valid for the entire hospital stay.

⁹ L.R.S. 32:666

¹⁰ R.S. 20:52§ (k).

B. Specific Providers¹¹

1. Physicians
2. Nurse Practitioners may obtain consents for procedures they are credentialed to perform¹².
3. Physicians Assistants may obtain consents when that duty/responsibility for performing the procedure has been delegated to him by his supervising physician¹³.
4. Other Health Care Providers may obtain consent for procedures that are within their scope of practice.
5. The Informed Consent form must be signed by the Health Care Provider prior to the performance of the procedure.

C. For Specific Procedures

A. Blood Transfusions

Transfusion consents may be obtained by the physician or other health care provider who will perform the procedure. (Give the transfusion).

Transfusion consent: If the original transfusion consent states "further transfusions", or "multiple transfusions may be required", a separate consent will not be required for each transfusion.

B. Radiological Procedures

Consent for radiological studies requiring the injection of radiopaque contrast media should be obtained by the person performing the procedure. For instance, the radiology technician if he/she is injecting contrast and performing the study. (e.g. CT Scan with contrast, IVPs, etc.)

C. Immunizations

An immunization consent (HCSD 1501 IMM) must be obtained before the first immunization is provided to either an adult or child and remains in effect until cancelled in writing. Before each immunization, appropriate written information, specific to the vaccine to be administered, must be provided to the patient or parent, appropriately documented, and all questions answered. Patients and parents have the right to refuse any immunization, as long as that refusal is documented and the dangers of contracting the specific disease explained.

Who may witness consent?

- A. Another physician
- B. Medical student
- C. Nurse
- D. Secretary
- E. Nursing assistant
- F. Any adult

¹¹ R.S. 40:1299.40 allows the health care provider who will perform the procedure to obtain the consent.

¹² Louisiana State Board of Nursing

¹³ Louisiana Revised Statute 37:1360.31

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Notes:

Being a witness to the signing of the consent means that the patient's identity has been verified and that the patient was not coerced. Witnessing does not indicate or imply responsibility for informed consent.

How long is the informed consent valid?

There is no specific time for an informed consent to be valid.

When must a new consent be obtained?

Treatment protocols, such as chemotherapy or radiation therapy, require informed consent prior to initiation but not with each subsequent visit for the same treatment protocol.

Different Operation:

When the planned procedure is different from the original operation or changes in a material way.

Cancelled Procedure:

If the procedure is cancelled following the induction of anesthesia.

New Operative Event:

If the original consent includes, for example, multiple incision and drainage procedures, a new consent would not be required each time the patient goes to the Operating Room (OR). This is not considered a new event.

If the patient returns to the OR for a procedure unrelated to the original procedure or due to complications of the original procedure, this is a new operational event and a new consent would be required. Any time a new procedure presents substantially different material risks a new consent should be obtained.

How long must one wait to obtain consent if the patient has received a narcotic or sedative?

There is no set time. The provider uses his/her judgment to determine if the patient is capable of making an informed consent decision and documents that fact in the medical record.

How is consent obtained if the patient cannot give consent and no authorized person is present?

You may obtain the consent by fax, telephone, or e-mail.

These routes may be used only in an emergency and the person authorized to consent for the patient cannot timely come in and sign a consent.

- A.** Provider who is capable and credentialed to do the procedure must provide information to the person who is going to give consent.

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Policy 5501-12

Page 5501-12.6

The person giving consent must:

- ☐ Identify himself/herself
- ☐ Affirm his/her relationship to the patient
- ☐ Grant or deny his/her approval of the proposed procedure
- ☐ State any restrictions

For telephone consents, the provider making the call and another staff member must hear and document the information listed above.

The information in the written, informed consent should be included in the information provided to the person giving the consent.

The person giving consent must be given the opportunity to ask any questions and have those questions answered.

Where are completed consents kept?

Consents are placed in the medical record as soon as possible after signing and are a part of the patient's permanent record.

Changes In The Consent

What procedure is used to make changes to the informed consent?

Any alteration is acceptable as long as it is legible.

Any alteration is made by drawing a single line through the text to be changed and writing the corrected text. (No text is to be obliterated.)

Both the patient and the physician/Health Care Provider must initial, date and time any alterations prior to the procedure.

The Health Care Provider who identifies a need for a change in the consent should call the physician who obtained consent as soon as possible and prior to the start of the planned procedure.

Emergency Consents

What procedure is followed in an emergency when the patient or someone authorized to consent for him/her is not able/available to give written, telephone, facsimile, or e-mail consent?

Two licensed independent practitioners must sign the consent. The nature of the emergency must be documented in the patient's progress notes.

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Policy 5501-12

Page 5501-12.7

Withdrawal of Consent

What if the patient has reservations or is hesitant about the procedure or indicates he/she was not informed?

Report the situation promptly to the provider planning to perform the procedure. The patient may refuse the procedure at any time. Patients should know that there are no consequences for changing their mind.

HIV Testing

HIV diagnostic testing does not require a separate informed consent when it is a part of routine medical screening, unless the patient declines or “opts out” of testing. If a patient declines testing, it shall be noted in the medical record. Before routine testing, oral or written information should be provided to the patient including an explanation of HIV infection and the meanings of positive and negative test results, and the patient shall be offered an opportunity to ask questions.

Eligibility for Reproductive Sterilization

Patients eligible for reproductive sterilization must be at least 21 years of age and legally competent.

Patients requesting reproductive sterilization will not be denied sterilization because of their marital status, number of children, age, ethnicity, religion, as long as they are over 21 and are legally competent.

Spouses are encouraged to participate in the decision for sterilization. However, one can not require that a married individual have a spouse present or sign the consent as a prerequisite to the performance of the procedure.

The procedure must not be medically contraindicated.

Initial consent may not be elicited from a patient during admission or hospitalization for childbirth or abortion or other medical treatment. Consent obtained during these times will be presumed involuntary.

Tubal Sterilizations

In order to meet the requirements of informed consent and federal requirements, every patient must receive an informational session by a non-physician counselor in addition to any information she may have received from a physician. This information session will include discussion of all methods of birth control and the advantages and disadvantages of each.

The patient will also receive information about the permanence of sterilization and the incidence of regret which may accompany the procedure.

The patient will be informed, as required by federal regulations, that her consent may be withdrawn at any time prior to the procedure without threat of loss of health services or other benefits.

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Policy 5501-12

Page 5501-12.8

The patient will also reaffirm her understanding of the reproductive sterilization procedure and its implications by signing a second written consent which must be signed within 48 hours prior to the procedure.

Consent Time Line

Consent for reproductive sterilization is unique among consents because it has specific time requirements.

Reproductive sterilization may not be performed sooner than thirty (30) day following the giving of the initial informed consent by the patient except in special circumstances.

Note:

A woman who has completed the appropriate forms and information sessions and who signs the required consent form thirty (30) days prior to her anticipated delivery date may be sterilized in less than thirty days if she delivers prior to her anticipated date or she is undergoing abdominal surgery, as long as the consent was signed seventy-two (72) hours before the procedure or delivery.

The consent is good from 30 to 180 days after its proper completion.

2nd Consent

All patients must sign a statement reaffirming their request and consent to reproductive sterilization upon admission for the procedure.

Right to Refuse Sterilization

All patients must be given assurance orally and in writing that if they choose not to be sterilized, they will not lose any benefits or medical services and that they can change their mind at any time prior to the operation.

Medical services cannot be delayed or withheld while a person is considering reproductive sterilization.

Form Requirements

The federally approved consent form must be used.

All counseling should be documented in the patient's medical record.

The consent forms should be placed in the patient's permanent record.

The federally approved consent form must be read orally in the presence and hearing of a witness.

If a woman appears for delivery, full-term or pre-term, at a hospital other than that at which she has completed the appropriate forms and information session, the receiving hospital shall contact the hospital at which the forms and procedures were completed for verification. This must be noted in the record, with the name and title of the person providing the information, the date that the consent form was signed, and the anticipated delivery date. If the consent form was signed thirty days prior to the anticipated delivery date, this will be sufficient to enable the receiving hospital to perform the sterilization. If the patient presents a

duplicate copy of the initial consent duly signed, witnessed and dated at least thirty days prior to the anticipated delivery date, verification may be waived.

Consents for Investigational Research and/or Clinical Trials

All participants in a research project or clinical trial must have an informed consent specific to the project. Informed consent is an individual's voluntary agreement to become a subject of research after having been informed of

- a. the purpose of the study,
- b. the procedures that are experimental, and
- c. potential discomforts, risks or benefits to reasonably be expected

A legally effective consent form is read to or by the subject and signed by the subject or his/her legally authorized representative

Additional information which must be given to the patient includes:

- a. expected duration of the patient's participation
- b. selection of patients
- c. alternative treatment procedures available
- d. extent of record confidentiality, and
- e. all financial issues
- f. That they may refuse and refusal will not compromise their access to the hospital's services

Computer Consent Management:

We require each hospital to use the server to obtain mandatory consents.

Accessing Consents on the Server:

From www.lsuhs hospitals.org website:

Click on the "Health Care Effectiveness" tab, under the "HCE Site Links" on the right hand side of the page you can either:

Click "Forms"
Click "English Consents" or "Spanish Consents"
OR
Click "Intranet"
Click "Consents"

Server Downtime Procedure:

An original hard copy of the consents most commonly used should be kept on file in the particular patient care area

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Policy 5501-12
Page 5501-12.10

These originals are to be used to make copies as needed only when the server is down.

Each unit is responsible for insuring that they have the most current consent forms.

To add a new consent or to modify an existing consent, do the following:

- A. Print a blank consent (or the appropriate existing consent)
- B. Complete all appropriate blanks – legibility is required
- C. Obtain Chief of Service written approval
- D. Consent will be reviewed by the “Consent Committee”
- E. If approved, the consent will be added to the server.

Consents in Spanish and other languages- Consents are available in Spanish. When printing a consent in a language other than English the English version of the consent will also print. Have the patient sign the foreign language translation. Have the provider and witness sign the foreign language translation. Place both in the patient’s medical record.

Definitions and Notes:

“General Consent for Medical Treatment: “

Signed when a patient presents to the facility for emergency services or is admitted to the facility.

Does not provide consent for specific procedures.

Provides consent for reasonable and necessary services, including but not limited to, pathology and radiology.

Authorizes release of information needed to file a claim for payment.

Authorizes payment for services provided to be made on the patient’s behalf.

Informs the patient that medical career students (medical, allied health, nursing, residents with training, fellows) and/or residents may be involved in his/her care.

Patient’s signature verifies that patient has read and understands the consent.

Typical procedures covered by “the general consents for medical treatment” include, but are not limited to:

- Arterial Blood Gas
- Dressing Change
- General Medication Administration
- I-V Placement
- Non-Contrast X-Ray
- Insertion of In-dwelling Urinary Catheter
- Splinting/Casting
- Ultrasound
- Venipuncture

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Policy 5501-12

Page 5501-12.11

The HCSD Informed consent has been designed:

To meet legal requirement¹⁴. (Louisiana Revised Statute 40:1299.40)

Utilizes the format designated by the Louisiana Department of Health and Hospitals Medical Disclosure Panel.

Is required for procedures/treatments specified by the Louisiana Medical Disclosure Panel and required by the HCSD facilities for other procedures/treatments.

A specific consent should include: (All that apply)

Specific treatment or procedure

Purpose of the treatment or procedure

Specific site, including left or right when appropriate

Patient's diagnosis or condition for which the procedure or treatment is indicated

Risks identified by the Louisiana Medical Disclosure Panel

Risks determined by the patient's physician

Additional risks particular to the patient due to a complicating medical condition

Risks generally associated with any surgical treatment/procedure

Reasonable therapeutic alternatives

Patient's acknowledgement that:

No guarantees have been made

No information that is inconsistent with the information in the consent document has been presented.

An opportunity to disclose and discuss particular concerns/risks/consequences with the physician and

An opportunity to ask and have answered any questions has been provided.

Presence of a technical representative in the patient care area to provide information on a specific instrument and/or product.

Consent to audiotaping, video, and/or still photography of procedures and/or any medical condition.

¹⁴ LRS 40:1299.40

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Informed consents are required for the following:

Anesthesia¹⁵
Blood/blood product administration
Chemotherapy
Moderate Sedation (also known as conscious procedural sedation)
Immunizations
Interventional radiology
Investigational Therapies
Lumbar Puncture
Spinal Tap
Sterilization procedures
Surgical Operative/Invasive procedures

Definitions:

Minor

Anyone under the age of eighteen

Emancipated Minor:

One who is emancipated by legal decree or by marriage

Emergency: (R.S. 40:1299.55)

Any delay in treatment could reasonably be expected to jeopardize the life or health of the person affected, or could reasonably result in disfigurement or impair faculties. A situation wherein in competent medical judgement, the proposed surgical or medical treatment or procedures are reasonably necessary, and a person authorized to consent is not readily available.

Loco parentis:

"Instead of parent" or "in place of a parent," this phrase identifies a foster parent, a county/parish custodial agency or a boarding school which is taking care of a minor, including protecting his/her rights.

New Operative Event:

Any subsequent procedure unrelated to the initial operative event or one undertaken to treat a complication of the original procedure.

¹⁵ Anesthesia – Deep/Moderate Sedation

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