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UNIVERSITY HOSPITALS POLICY AND PROCEDURE MANUAL

Title: Informed Consent

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POLICY

The Ohio State University Hospitals respect the patient's right to be informed of surgical or medical procedures which are to be rendered and the patient's right to accept or refuse such surgical or medical procedure. Being consistent with quality patient care, informed consent must be obtained and documented pursuant to this policy before proceeding with surgical and medical procedures, except in emergency situations as defined below.

This policy applies to all surgical and medical procedures that involve material risk to the patient, irrespective of their repetitive nature. Some items require informed consent by law or regulatory standard such as HIV testing and blood/blood product administration. A complete list of procedures requiring informed consent has been approved by the Medical Staff and is available on OneSource under the "Clinical Care" tab.

PROCEDURE

1. OBTAINING INFORMED CONSENT

- a. The attending physician performing or supervising the surgical or medical procedure, or his/her designee, shall be responsible for obtaining informed consent.

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- b. For obtaining informed consent, an attending physician's designee is defined as follows:
 - i. A member of the Limited Staff (e.g., intern, resident or fellow) familiar with the specific procedure for which consent is being obtained;
 - ii. A licensed independent practitioner (LIP) with hospital privileges to perform the specific procedure for which consent is being obtained. An LIP with order-writing authority may also get informed consent for HIV testing and blood/blood product administration;
 - iii. Registered nurses permitted to place PICC lines as a part of their job duties are responsible for obtaining informed consent for that procedure after it is ordered by a physician or an LIP with order-writing authority. Registered nurses are not permitted to obtain informed consent for any other procedure or indication.
- c. The individual obtaining consent must be familiar with both the patient and the surgical or medical procedure for which informed consent is being obtained, and must be capable of accurately answering questions regarding the procedure and its associated risks, benefits and alternatives for that patient.
- d. Medical students may not obtain informed consent for any procedure or other indication.

2. **MECHANISMS OF DOCUMENTING INFORMED CONSENT** Informed consent must be documented by one of the following mechanisms:

- a. A completed Hospitals Informed Consent Form or other hospital-approved Consent Form signed by the patient;
- b. A completed Informed Consent form supplied by the physician signed by the patient;
- c. A written Informed Consent note in the progress notes signed by the patient;
- d. A written Informed Consent form or progress note signed by the patient's legal representative;

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- e. In urgent situations, informed consent may be received by phone from a patient's legal representative if that representative is unable to come to the hospital and unable to sign a faxed consent form. Consent received by phone from a patient's legal representative should be confirmed by a witness who also speaks to the legal representative. The details of the phone consent should be documented in the progress notes and should be signed by the person obtaining the consent and by the witness.

3. REQUIREMENTS FOR INFORMED CONSENT

- a. Consent must be obtained at a time when the patient is fully capable of understanding the procedure so that he/she can make an informed decision regarding consent. For example, informed consent should never be obtained after a patient has received medication for conscious sedation or anesthesia. For multi-stage procedures or when multiple tests requiring consent are contemplated to be done on the same day, informed consent for all parts of the procedure(s) should occur prior to the patient receiving any sedation.
- b. During the informed consent discussion, the following should be discussed with the patient:
 - i. A description of the proposed procedure, including the anesthesia to be used if applicable;
 - ii. The indications for the proposed procedure;
 - iii. Material risks and benefits for the patient related to the procedure and anesthesia if applicable, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;
 - iv. Treatment alternatives, including the attendant material risks and benefits;
 - v. The probable consequences of declining recommended or alternative therapies;
 - vi. Who will conduct the surgical intervention and administer the anesthesia if applicable;
 - vii. Whether physicians other than the attending physician, including but not limited to residents and fellows, will be performing significant tasks related to the surgery or procedure;
 - viii. If students, residents and/or fellows will perform

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significant parts of the surgery/procedure under the supervision of the physician performing the procedure or surgery, the informed consent discussion with the patient or the patient's legal representative is encouraged to include the following:

1. That students, residents and/or fellows will perform portions of the procedure, based on their availability and level of competence;
 2. That it will be decided at the time of the surgery/procedure which students, residents and/or fellows will participate and their manner or participation, and that this will depend on the availability of students, residents and/or fellows with the necessary competence; the knowledge the attending physician has of the student's, resident's and fellow's skill set; and the patient's condition;
 3. Whether, based on the residents' and/or fellows' level of competence, the attending physician is reasonably expected not to be present in the same room for some or all of the tasks performed by residents and fellows.
- ix. Whether qualified medical practitioners who are not physicians (e.g., CRNAs, nurse practitioners, RN first assistants, physician assistants, etc.) will perform significant parts of the surgery or administer the anesthesia and if so, the types of tasks each type of practitioner will carry out. The types of tasks such practitioners will be performing will only be tasks within their scope of practice for which they have been granted privileges.

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- c. The patient should be given an opportunity to ask questions and to have them answered to the patient's or their legal representative's satisfaction.
- d. Documentation of the informed consent must be completed prior to the procedure. Documentation according the details of Section 4 of this policy should be in the patient's medical record as evidence that consent has been obtained.

4. DOCUMENTATION OF INFORMED CONSENT FOR PROCEDURES/SURGERIES

- a. Properly executed informed consent documentation for a surgery, procedure or other treatment requiring informed consent must contain at least the following:
 - i. The name of the hospital where the procedure, surgery, or treatment is to take place;
 - ii. The name of the patient or, when appropriate, the name of the patient's legal representative;
 - iii. The name, nature and purpose of the surgical or medical procedure;
 - iv. A statement that the procedure, surgery or treatment, including the anticipated benefits, material risks and alternative therapies, was explained to the patient or the patient's legal representative;
 - v. Name(s) of the attending physician(s) performing or supervising the surgery, procedure, or treatment requiring informed consent. For PICC lines, the name of the RN performing the procedure will suffice;
 - vi. Acknowledgement by the person giving consent that the procedure was explained to them, that they had an opportunity to ask questions, and that questions have been answered to the satisfaction of the patient or the patient's legal representative;
 - vii. The signature of the patient or his/her representative. The acquisition of both the patient's consent and the consent of his/her representative is acceptable;
 - viii. Date and time the consent form was signed by the patient or the patient's legal representative.
- b. Optional items may be included in the documentation for informed consent, including but not limited to:
 - i. Name and signature of the practitioner who conducted the informed consent discussion with the patient;

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- ii. Date, time and signature of the person witnessing the patient or the patient's legal representative signing the consent form;
- iii. Listing of the specific material risks of the procedure, surgery, or treatment that were discussed with the patient.

5. SPECIAL NON-PROCEDURAL CIRCUMSTANCES REQUIRING INFORMED CONSENT

a. HIV Testing

- i. Informed consent for HIV testing is required by Ohio law except in certain circumstances described in OSU Hospitals Policy 3-11.
- ii. The hospital-approved HIV Informed Consent Form should be used when possible to gain informed consent for HIV testing. Alternatively, a note in the progress note section outlining the informed consent that is signed by the person obtaining consent and the patient will suffice.
- iii. A copy of the signed consent form should be placed in the patient's chart.

b. Blood and Blood Product Administration

- i. Informed consent is required prior to the initial transfusion of blood or any blood product.
 - 1. For inpatients, subsequent administrations of the same blood and/or blood product(s) covered under the original consent during the same admission do not require additional informed consent unless there is a significant change in the risks, benefits or alternatives for the patient in receiving the transfusion.
 - 2. For outpatients, informed consent for blood or blood product administration will have a maximum duration of 12 months. During that period, if there is a significant change in the risks, benefits or alternatives for the patient in receiving the transfusion, the consent process should be redone.
 - 3. In the inpatient or outpatient setting, the patient or their legal representative may withdraw their consent for subsequent transfusions at any time after the initial informed consent is given.
- ii. Initial informed consent must be obtained by the attending physician or a designee as outlined in Section 1.b above.

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- iii. A hospital-approved, pre-printed blood and blood product informed consent form should be used when possible for consent for blood or blood product administration. Prior to an initial transfusion, this form must be completed and signed by the patient and the individual obtaining informed consent. Alternatively, a note in the progress note section outlining the informed consent that is signed by the person obtaining consent and the patient will suffice.
- iv. For both inpatients and outpatients, confirmation that a current, signed informed consent form is in the chart must be done by the nursing staff as a part of the patient identification process prior to the initial and any subsequent transfusions.
- c. Research, Clinical Trials, Investigational Drugs: Informed consent must be obtained and documented prior to enrolling any patient in a research project or clinical trial or prior to treatment with any investigational drugs as required by applicable University Institutional Review Board (IRB) and Office of Responsible Research Practices (ORRP) policies.
- d. Sterilization: Informed consent for sterilization procedures must be obtained using the hospital-approved consent form for sterilization or an equivalent form containing the required information. For Medicaid patients, the informed consent process for sterilization must be completed at least 30 days prior to the procedure.
- e. Transplant and Living Donor Patients
 - i. For transplant patients, the informed consent process must inform the patient regarding, at a minimum, each of the following items:
 - 1. The evaluation process;
 - 2. The surgical procedure contemplated for the patient;
 - 3. Alternative treatments;
 - 4. Potential medical or psychological risks;
 - 5. National and transplant center-specific outcomes for the transplant procedure that is contemplated for the patient from the most recent SRTR center-specific report including but not limited to:
 - a. The transplant center's observed and expected 1-year patient and graft survival rate;
 - b. The national 1 year patient and graft survival



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rate;

- c. Notification about all Medicare outcome requirements not being met by the transplant center;
- 6. Organ donor risk factors that could affect the success of the graft or the health of the patient, including but not limited to the donor's history, condition or age of the organs being used;
- 7. The risk of the organ recipient to contract HIV or other infectious diseases if the disease cannot be detected in an infected donor;

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8. The recipient's right to refuse transplantation;
 9. The fact that if the recipient's transplant is not performed in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his/her drugs paid for under Medicare Part B.
- ii. For living donors, the informed consent process for all prospective living donors must include, at a minimum, the following items:
1. All aspects of living donation including potential outcomes from living donation;
 2. The fact that communication between the donor and the transplant center will remain confidential;
 3. The evaluation process for living donation;
 4. The surgical procedure, including post-operative treatment, contemplated for the patient;
 5. The availability of alternative treatments for the transplant recipient;
 6. The potential medical or psychosocial risks to the donor;
 7. The national and transplant center-specific outcomes for recipients and the national and center-specific outcomes for living donors for the procedure contemplated for the patient;
 8. The possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance might be affected;
 9. The donor's right to opt out of donation at any time during the donation process;

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10. The fact that if a transplant is not provided in a Medicare-approved transplant center, it could affect the transplant recipient's ability to have his/her drugs paid for under Medicare Part B.

6. HOSPITAL STAFF PARTICIPATION

- a. Responsibility for obtaining informed consent from the patient and the appropriate documentation of informed consent rests with the attending physician with the exception of PICC lines as noted above. The attending physician may delegate this responsibility only to the designees outlined in Section 1.b above.
- b. Hospital staff members (including all nurses and other employees) may participate in the informed consent process by witnessing the patient's, the patient's representative, or physician's signature regarding informed consent.
- c. If any staff member has actual knowledge that a patient has not given informed consent or desires to cancel a prior consent, they should report that fact first to the attending physician or his designee, and then to their supervisor. No applicable procedure shall commence without evidence of informed consent.

7. MEDICAL EMERGENCIES

- a. Informed consent is not required in emergency situations. Consent in an emergency will be implied as allowed by law. This rule applies only in cases where a physician must act immediately and the patient is incapable of expressing such consent.
- b. To constitute an "emergency," the threat must be immediate to protect the life, limb, or health of the patient.
- c. The physician must show the need for proceeding without informed consent by documenting in the medical record the reasonable and diligent efforts as time allows to acquire consent from the next of kin or legal representative; and the immediacy and magnitude of the threat to the patient if the medical or surgical procedure were not immediately done.



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8. **INCAPACITY**. For guidance regarding obtaining informed consent for patients that lack capacity, including minors, please see Policy 3-18, Consent for Inpatient and Emergency Department Treatment.
9. **REFUSAL OF CARE**
- a. A competent adult patient or the patient's representative may refuse or may voluntarily withdraw informed consent. Such a request should be honored.
 - b. In such a case, the physician should write in the medical record a statement of the circumstances under which the refusal or withdrawal occurred. The physician is to explain the consequences of refusal to the patient.
 - c. If a patient lacks capacity and the next of kin refuses treatment essential to the patient's life or health, any health care provider may consult Hospital Legal Services.

RELATED HOSPITAL POLICIES AND PROCEDURES

03-24 Do-Not-Resuscitate Orders

03-18 Consent for Inpatient and Emergency Department Care and Treatment

03-11 Management of Human Immunodeficiency Virus Infection in the
Healthcare Facility

03-26 Advance Directives

RELATED CMS RULES AND REGULATIONS FROM THE FEDERAL REGISTER:

42CFR §482.24(c)(2)(v) - Requirement for documentation of informed consent in the medical record

42CFR §482.51(b)(2) - Requirements for documentation of informed consent prior to surgical procedures

42CFR §482.102 - Conditions of participation related to patient and living donor rights for transplant centers