

# University of Michigan Hospitals and Health Centers

## Policy 62-10-001

### Informed Consent for Invasive Procedures and Treatments Involving Substantial Risk of an Adverse Outcome

(Issued: 9/82; Last Reviewed: 9/04; Last Revised: 5/08)

#### I. POLICY

It is the policy of the University of Michigan Hospitals and Health Centers (UMHHC) to obtain voluntary and informed consent from all patients (or for incompetent patients, their legally authorized representatives) for all proposed invasive procedures and treatments involving substantial risk of adverse outcome.

In non-emergency situations, a patient shall receive a clear explanation of his or her condition and of all proposed invasive procedures and treatments involving a substantial risk of adverse outcome. Patients shall be informed of the possible benefits of the treatment, possibilities of any substantial risks of side effects of the treatment, and alternative forms of treatment. Special rules apply for emergency situations and are discussed below.

The purpose of obtaining informed consent is to support full disclosure to the patient regarding treatment options. This is a process of information exchange that allows the patient to make an informed choice.

#### II. DEFINITIONS

**A. Voluntary** - Being freely chosen or undertaken of one's own free will.

**B. Informed Consent** - The permission granted by a patient or a patient's legally authorized representative after being fully informed about the possible benefits, possible substantial risks, possible alternative treatments, and the probability of success of the treatment or procedure. Informed consent may be for invasive procedures, non-invasive procedures or special treatments, such as immunization or blood product administration.

**C. Invasive Procedures** - Most procedures involving puncture or incision of the skin, or insertion of an instrument or foreign material into the body, including, but not limited to, percutaneous aspiration of abscesses or fluid collections, biopsy, cardiac or vascular catheterization, endoscopy, angioplasty, and implantation of a device. For the purposes of this policy, venipuncture, injections (unless consent is specifically required by the type of treatment being delivered through injections), insertion of medical devices into body cavities or orifices such as endotracheal tubes, Foley urinary catheters and naso-gastric and other orally placed feeding tubes and peripheral intravenous line placement are not considered invasive procedures.

**D. Substantial Risk** - A risk that a reasonable individual would find important in determining his or her course of action.

**E. Competent** - Understanding the nature and consequences of one's actions.

1. Components of competence include the ability to:

- Comprehend the information intellectually.
- Process information.
- Understand the consequences of the decision at hand.

2. Medications can impair competence temporarily; it is the physician's responsibility to determine whether a patient who has received medication is competent for the purpose of giving consent in any given situation.

3. Adults are considered competent unless determined otherwise. Minors generally are not considered competent.

**F. Legally Authorized Representative** - One who by a durable power of attorney for healthcare or by statute or by judicial action is authorized to make decisions for an individual unable to make decisions for him- or herself.

**G. Emergency** - A sudden, unexpected occurrence in which there is an imminent danger to an individual's life or limb and that demands immediate medical attention.

**H. Adult** - An individual age 18 or older.

**I. Minor** - A minor is an individual under age 18. A minor may be recognized as able to consent in the circumstances specified in the policy on consent for minors: [UMHHC Policy 03-07-018 Minors: Consent and Access to Confidential Health Care](#).

### III. STANDARDS

A. Types of consent:

1. Operation/Invasive procedure.

a. Informed consent will be obtained prior to the performance of operations or invasive procedures or treatments that have a substantial risk of serious injury to the patient or that have a low frequency of occurrence but are serious in nature.

b. The attending physician performing or in charge of the treatment or procedure shall ensure that the patient is properly informed regarding the treatment or procedure and for documenting this process.

c. Another licensed health care professional with knowledge of the treatment or procedure may conduct the discussion and may document the patient's written consent on a standard consent form ([Exhibit 1](#)). This may include appropriately trained registered nurses, advanced practice nurses, residents in training, physician assistants, technologists and technicians.

2. Non-invasive Treatments of a Diagnostic or Therapeutic Nature, and Specialized Consents.

a. Where a substantial risk of harm exists, the attending physician performing or in charge of the treatment or procedure shall ensure that the patient has been properly informed regarding the treatment or procedure and for documenting this process.

b. Another licensed health care practitioner with knowledge of the treatment or procedure may document the patient's written consent on the standard consent form ([Exhibit 1](#)). This may include appropriately trained Registered Nurses, advanced practice nurses, residents in training, physician assistants, and technologists and technicians.

c. Documentation of informed consent on the standard consent form ([Exhibit 1](#)) must include the signature of the clinician who obtained consent and the signature of the patient or legal authorized representative.

d. A patient's refusal of a recommended operative or invasive procedure or treatment should be documented on the Refusal of Blood or Treatment form ([Exhibit 2](#)) or elsewhere in the medical record.

e. Factors for the clinician to consider when deciding whether to use a standard consent form include:

i. Does the recommended treatment or procedure carry a high probability of risk of complications to the patient by its nature?

ii. Does the recommended treatment or procedure carry a lesser probability of risk of complication to the patient, but have severe consequences should the complication occur, (eg. blindness, paralysis)?

iii. Does the status of a particular patient, in the judgment of the clinician, render her or him more vulnerable to risk of complication than the usual patient, (eg. immunosuppression)?

### 3. Research consent.

a. Informed consent will be obtained prior to any treatment or procedure that is part of a research study if required by and in accordance with University of Michigan Medical School IRB (IRBMED) requirements and the IRBMED approved protocol. See: <http://www.med.umich.edu/IRBMED> and federal regulations contained in the Department of Health and Human Services Policy for Protection of Human Research Subjects found at <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.116>.

b. The investigator or another appropriate individual with knowledge of the research shall properly inform the patient regarding the experimental procedures or treatment as required by federal regulations and by the IRBMED approved protocol and consent form.

### 4. Anesthesia

a. Consent for anesthesia required for operation is obtained when consent for the operation itself is obtained. Separate written consent for anesthesia is not required in these instances.

b. Specific written consent is required for independent diagnostic and therapeutic anesthesia procedures, such as therapeutic nerve blocks.

### 5. Sedation

a. Consent for sedation associated with a procedure, operation or treatment shall be obtained in conjunction with the consent obtained for the procedure or treatment itself.

b. Consent for sedation is not implied. Documentation of consent for sedation should be included in the procedure/treatment consent form.

c. In those instances where signed consent for the procedure or treatment is not required, separate consent for sedation should be obtained and documented on a standard consent form. Examples of such situations include pediatric cardiac ECHO studies. See <http://www.med.umich.edu/i/anes/sedation/contents.htm>

6. Specialized consents: Consent will be obtained for treatments or procedures that although common, may have rare but serious side effects or consequences. This applies for example, to blood transfusions ([Exhibit 1, page 2](#)) and to certain types of immunizations.

7. Consents required by law: In certain cases consent is mandated by State or Federal law. For example:

a. HIV, genetic tests and alternative treatments for breast cancer are required by state law. MCLA 333.5133.

b. State law requires a special process of consent for termination of pregnancies. MCLA 333.5133.

8. Tissue consents: Separate consent will be obtained for the procurement of tissue to be used in cancer-related research and documented on Optional Tissue Research form attached to the standard consent ([Exhibit 1](#)). Standards contained within this policy regarding who obtains consent, the frequency and duration of the consent, and signature of the clinician obtaining consent will be followed. There will be NO emergency exceptions to obtaining consent for tissue procurement.

B. Elements of the process of informed consent for treatment ([Exhibit 3](#)):

For all treatment, including operations, invasive procedures and non-invasive treatment or procedures, the process of informed consent with the patient or legally authorized representative (e.g. a parent for a minor patient) will be conducted that includes the following points:

1. Detailed explanation of the procedure, including:

a. The nature, expected duration, and purpose (reason for procedure)

b. The preparation required and period of time before normal activities can be resumed.

2. The potential benefits the patient may expect to receive from the procedure.

3. Risks and complications: Possible harmful effects that a reasonable person would find important in determining his or her course of action, as well as possible side effects.

4. The potential necessity for related or additional procedures associated with the procedure

5. The approximate location of the surgical incision (operative field).

6. The risks of anesthesia or sedation analgesia.

7. Alternative management, including the consequences of not proceeding with the procedure/treatment.

8. Donation and authorization of any excess tissues, specimens, or parts of organs.

9. Authorization of the use of additional personnel to participate in the diagnosis and treatment of this condition.

10. Following the discussion, the patient is allowed to ask questions and once satisfied, the patient makes a choice.

C. Consent form ([Exhibit 1](#)):

1. In addition, if the patient chooses to proceed, for all operations and invasive procedures that carry substantial risk, an official standard consent form will be completed by the clinician and

signed by the patient or authorized representative before that treatment is begun. This form will be completed no more than 6 months in advance of the beginning of treatment, operation or procedure. The form will be signed by the clinician who obtained consent as described in III. A. 1. d., and a note may be placed in the medical record documenting the discussion.

2. For non-invasive procedures that carry substantial risk of adverse outcome, the clinician may use the standard consent form to document the patient's choice in addition to documenting the consent process as outlined in this policy in III.H. 2. The form will be signed by the clinician who obtained consent as set forth in III.A.2 c, and a note may be placed in the medical record setting forth the discussion.

3. For sedation, consent should be documented on the consent form used for the procedure or treatment or on a separate copy of the standard consent form.

4. Exceptions are emergency situations. See Section III.F.

5. If the patient refuses the recommended treatment, the Refusal to Blood or Treatment form ([Exhibit 2](#)) should be used to document the refusal. The form should then be placed in the medical record. When refusal is documented, the expected or possible consequences of refusal of treatment should be written on the form. Alternatively, a note may be placed in the medical record setting forth the discussion.

#### D. Frequency of Obtaining Consent

1. The patient's informed consent must be obtained for each procedure or may be used for the duration of each course of treatment as long as the risk remains unchanged.

2. Consent must be obtained not earlier than a reasonable interval between the discussion and the proposed treatment, and not to exceed six months before the procedure is performed or the course of treatment is begun.

3. The informed consent process will be reviewed whenever the course of treatment or the patient's condition is substantially altered or when the interval between the initial informed consent discussion and the procedure or between the initial informed consent discussion and the beginning of treatment exceeds six months.

4. Consent for Serial Procedures: A single consent process and form may be used for a series of (nearly) identical treatments or procedures for the same condition. The single consent for serial, (nearly) identical treatments or procedures may be used for a period of up to six months as long as the risk to the patient remains unchanged. Serial consents involving laterality where the procedure for each side of surgery are performed on different operative dates are not acceptable. Because of the possible confusion of laterality, each sided procedure requires a separate consent indicating the laterality specific to that operative date's procedure.

5. Research consents: Informed consent shall be obtained as required by federal regulation and by the IRB policy and the IRBMED approved protocol.

#### E. Persons From Whom Consent Must Be Obtained

1. Competent adult patients shall give their own consent. In the event a competent adult patient is physically unable to sign or cannot write, the patient should make a mark such as a "X" in the presence of a witness. The witness should then write a brief note next to the mark indicating the mark was made by the patient of their own free will.

2. If an adult patient is not competent, that individual's legally authorized representative shall grant or withhold consent.

3. If a patient is a minor, his or her legally-authorized representative shall grant or withhold consent except as provided by state or federal law. See [UMHHC Policy 03-07-018 Minors: Consent and Access to Confidential Health Care](#) and [Exhibit 4](#).

4. If an adult patient is not competent or if the patient is a minor and a legally authorized representative is not physically present at UMHHC, the legally authorized representative may give consent by telephone, following the procedure outlined in Exhibit 5. Special procedures apply for telephone consent for research projects. See <http://www.med.umich.edu/irbmed/InformationalDocuments/TelephoneConsent.htm>

#### F. Emergency Situations

If an emergency exists, i.e., imminent threat to life or limb, the licensed health care professional may render immediate and appropriate emergency treatment even though consent has not been obtained. Waiver of informed consent for participation in a research study requires specific IRBMED approval, which is rarely granted. See <http://www.med.umich.edu/irbmed/HIPAA/Waiver-Request-INSTRUCT.htm>

#### G. Approval of Informed Consent Forms

Informed consent forms for non-research procedures and treatments may be developed by clinical departments in order to document that the patient has been properly informed and has consented to the treatment or procedure. Such forms shall be reviewed prior to use at UMHHC by the Medical Information Committee, Subcommittee on Medical Record Forms, with the advice of the Health System Legal Office and the Chief of Clinical Affairs prior to use at UMHHC. For more information on the approval process see [UMHHC Policy 03-09-002](#).

#### H. Approval of Informed Consent Forms

##### 1. Documentation of Written Informed Consent in Research

The IRBMED requires a copy of the research informed consent document be provided to the subject. An original research informed consent document must be retained in the investigator's research record. A copy of the signed research informed consent document should be placed in the UM medical record of subjects, particularly when the research intervention may affect other treatment or care. However, doing so may not be appropriate in all cases (for example, if identification of the subject as a study participant might put the subject at risk of criminal prosecution or harm to reputation.) The IRBMED must approve the exclusion of the research informed consent document from the UM medical record.

2. All other consents for treatment, invasive and non-invasive -- The informed consent discussion may be documented in the medical record as a narrative dictated or written note (inpatient or outpatient progress as appropriate) by the licensed health professional who had the informed consent discussion with the patient. Such documentation should include:

- The date of the discussion.
- The proposed treatment or procedure.
- Indications for the proposed treatment or procedure.
- Anticipated benefits of the proposed treatment or procedure.
- Risks and potential complications of the proposed treatment or procedure.

- Alternatives to the recommended procedure and their risks.
- Who was present for the discussion and who participated in it if applicable.
- Additional information given to the patient such as printed material, web site citations and videotaped information, if applicable.
- That the patient's questions were answered.
- That the patient wishes to consent to or refuses the proposed treatment or procedure.

### 3. Emergency situation:

In an emergency when the usual consent process cannot be followed, the physician shall document in a progress note in the patient's chart:

- a. The circumstances that do not allow consent to be obtained.
- b. The efforts by the UMHHC to obtain such a consent.
- c. The circumstances that constitute an emergency need for treatment to proceed.

4. Refusal of blood or blood products: The documentation of a patient's refusal of blood product administration is addressed in [UMHHC Policy 62-10-002 Blood/TX/DX Refusal](#).

## IV. EXHIBITS

[Exhibit 1: Request and Consent to Medical, Surgical, Radiological and Other Procedures](#)

[Exhibit 2: Refusal for Blood or Treatment](#)

[Exhibit 3: Elements of Informed Consent: A Checklist](#) (not for research use)

[Exhibit 4: Consent and Guardianship Rules for Incompetent or Mentally Ill Adults](#)

[Exhibit 5: Procedure for Telephone Consent](#)

## V. REFERENCES

Joint Commission on the Accreditation of Hospitals, Comprehensive Accreditation Manual for Hospitals: 2001, "Patient Rights and Organization Ethics."

University of Michigan Hospitals, Medical Staff Bylaws, "The University of Michigan Policy on the Use of Human as Subjects in Research and Instructional Investigations," XXXI-1.

[UMHHC Policy 06-01-001 Patient Rights and Responsibilities](#)

[UMHHC Policy 03-07-018](#)

[Minors: Consent and Access to Confidential Health Care Services](#)

[UMHHC Policy 02-02-001 Prevention of Wrong Site, Wrong Procedure and Wrong Person Surgery](#)

Additional questions regarding informed consent shall be referred to the Health System Legal Office (4-2178).

Author/Consultant: UMHS Compliance Office; Informed Consent Committee; Office of Clinical Affairs

Revised by: Carrie M. Wright, Patient Safety Analyst, Office of Clinical Affairs, September 24, 2004. These revisions are of a minor nature dictated by the Legal Office and do not require ECCA approval.

Revised September 8, 2005 - Request and Consent to Medical, Surgical, Radiological and Other Procedures.

Revised May 7, 2008 - Exhibit 1 revised 8/2007

Approved by: Executive Committee on Clinical Affairs - October 23, 2001; January 27, 2004; April 27, 2004

Approved by: Director and Chief Executive Officer, UMHHC - October 31, 2001; February 23, 2004; June 15, 2004; September 28, 2004

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