

**The Miriam Hospital
Administrative Manual**

Subject:
Informed Consent Policy

File Under: Medical Staff
MS-05 and A-09

Issuing Department:
Risk Management

Latest Revision Date:
4/6/93; 5/30/96; 6/2/03

Original Procedure Date:
10/1/79

Page 1 of 4

Approved By:

(Director)

(Executive)

I. Policy

The Miriam Hospital supports the patient's right to make healthcare decisions in collaboration with physicians and other healthcare professionals involved in their care and treatment. To this end, patients have the right to accept, discontinue or refuse any medical or surgical treatment or procedure, and to be informed of the expected consequences as well as the complications associated with the medical or surgical treatment or procedure which is recommended. It is the policy of The Miriam Hospital that surgical procedures and certain other procedures and treatment require documented evidence of the patient's acknowledgment of consent. It is the responsibility of the physician or practitioner performing the procedure to obtain the patient's consent.

II. Purpose

To document that the patient/surrogate decision-maker has been informed of the risk, benefits, alternatives, including the alternative of no treatment at all for the recommended procedure or treatment.

III. Procedure

Prior to surgery or other invasive procedures, the physician or practitioner performing the procedure must have a full discussion with the patient or surrogate including the nature of the patient's condition, the proposed procedure, the material risks and benefits of the procedure and the feasible alternatives to the procedure, including the alternative of no treatment at all and the material risks of those alternatives. Information should be presented in lay terms. Patients should be given the opportunity to have questions answered to their satisfaction. The consent process must be documented on The Miriam Hospital Consent for Surgical or Other Invasive Procedures form or the department form developed for other than surgical procedures. The function of this consent form is, in part, to preserve evidence of informed consent to substantiate the oral consent obtained during the discussion between the patient and the physician/practitioner.

This form must be signed by both the patient (or the surrogate decision-maker if the patient does not have the capacity to make the decision or is under 18 years of age) and the physician/practitioner prior to any surgical or other invasive procedure being done. The form must be filled out completely, including the date and time of the signing. A lay description of the procedure or treatment should be included, as well as documentation of the site (left or right) of surgery if indicated. Physicians are also encouraged to document the fact of the discussion in the patient's medical record.

If the patient does not have the capacity to make medical decisions or is under eighteen (18) years of age, please refer to the Policy on Medical Decision Making (A-22) to determine an appropriate decision maker.

Emergency Situations

When a physician determines that immediate treatment is necessary to preserve the life of the patient or to prevent an impairment of the patient's health, and it is not possible to obtain the consent of the patient or the patient's surrogate decision-maker, the physician may initiate the procedure. Documentation concerning the emergency nature of the situation and the effort made to obtain consent must also be included in the patient's medical record when treatment is initiated without consent being obtained.

Treating Minors in the Emergency Department

In situations when a minor presents to the Emergency Department with a non-emergent condition, consent for treatment should be obtained from a parent or legal guardian. Verbal telephone consent may be obtained if the parent/guardian is not present. If the parent/guardian cannot be reached, consent may be obtained from the adult who accompanied the minor. If the minor is not accompanied and is between 16 and 18 years old, the minor may consent, but continued efforts should be made to reach a parent. All efforts to contact a parent should be documented in the medical record.

A minor parent may consent to the treatment of his/her child. Married minors may consent to their own treatment. A minor of any age may consent to examination and treatment for venereal disease.

Telephone Consent

There are times when it is not possible to get an informed consent form signed because the patient is unable to give consent and the surrogate decision-maker is some distance away and either unable to come to the hospital or the seriousness of the patient's medical condition precludes the possibility of incurring further delay. In such cases, informed consent from the surrogate decision-maker may be taken over the telephone by the physician. In addition to the discussion of risks and benefits, the physician should read the entire form to the person giving consent. Once informed consent is acknowledged by the surrogate decision-maker, the physician

will sign the consent form and indicate the date and time the informed consent was obtained. The name of the person consenting to the procedure as well as their relationship to the patient must be identified on the consent form, and it should be noted that the discussion occurred by telephone. A third person should be on the line to witness the telephone discussion. The witness should sign the form to confirm the fact that the discussion took place.

Changes Made in Consent Form

The physician and patient may mutually agree to change part of the standard consent form. Any such additions or deletions must be initialed by both the patient and physician. An example would be a patient who does not want a medical student participating in the surgical procedure. Barring unforeseen circumstances or complications, the hospital will comply with this type of agreement. The physician is responsible for coordinating the plan to conform with the patient's wishes.

Communication Issues

Some patients may have difficulty understanding the discussion due to language problems or impairments. The physician should be cognizant of the patient's ability to comprehend the discussion needed for informed consent and use an interpreter as appropriate (see Policy on Providing Assistance to Non-English Speaking Patients in Need of Health Care, ITS-01)

The interpreter should sign and date and time the consent form. The physician should document the fact that an interpreter was used in the medical record. For hearing impaired patients, see the Policy on Providing Assistance to the Hearing Impaired in Need of Health Care, ITS-02). If an interpreter is used to assist with the discussion, the physician should document the use of the interpreter and the interpreter's name.

Consent for Blood Transfusions

It is important that patients who need blood and/or blood component transfusions or their surrogate decision-makers, as appropriate, be informed of the risks, benefits and alternatives to blood and/or blood component transfusions. Patients also have the right to refuse blood transfusion and the possible consequences of refusing blood and/or blood components need to be discussed with the patient by the physician as part of the consent process. The Acknowledgment of Consent to Surgical or Other Invasive Procedure form documents that these discussions have occurred prior to the procedure. A Consent for Transfusion of Blood Components is used for other medical or surgical patients requiring blood and/or blood component transfusion.

The transfusion consent is considered valid for one admission for inpatients, or one episode of care for outpatients, while the patient diagnosis and indications for blood transfusion remains the same. In a situation which is viewed as an emergency, that is to preserve the life of the patient or to prevent an impairment of the patient's health, the physician has the right to render necessary treatment without attempting to obtain consent unless a competent adult objects. If the patient is a minor, and the parent refuses consent for blood, the physician should contact the Social Work Department to coordinate involvement of the Department of Children, Youth and their Families

(DCYF). Written documentation concerning the emergency nature of the situation and the effort to obtain consent from the patient or surrogate must also be included in the patient's medical record when treatment is initiated without consent being obtained.

Time Limitations

The Hospital Consent form must be signed by the patient or surrogate and the physician prior to any procedure done in the inpatient or outpatient operating rooms. The consent discussion should take place at a date reasonably near to the procedure. If there is a delay of more than 45 days between the discussion/signing of the consent and the procedure, the physician and patient shall initial and date the original signed consent provided that the patient's medical condition remains the same and the patient remains competent. If the patient's condition has changed, a new consent form and discussion of risks, benefits and alternatives must take place.

Other Consent Forms

Many departments have developed additional consent forms for acknowledgment of consent for other than surgical procedures. The general process for obtaining the patient's consent should be the same. Physicians may elect to use the Acknowledgment of Consent to Surgical or Other Invasive Procedure form for diagnostic or therapeutic procedures that, in the physician's judgment, presents special or unusual risks to the patient.

If the department or physician choose to develop a consent form to document acknowledgment of consent for a specific procedure, the form must be approved by the Risk Management Department and presented to the Medical Records Committee for approval.

Cross Reference Policies

Policy on Medical Decision Making, A-22
Advance Directives, A-27