

Main Line Health, Inc. and Main Line Health Inc. Subsidiaries		
Working Together to Serve the Community		
This policy applicable to:	<input type="checkbox"/> All Subsidiaries <input checked="" type="checkbox"/> All Hospitals <input type="checkbox"/> All Acute Care Hospitals	<input type="checkbox"/> BMRH <input type="checkbox"/> Mirmont Treatment Center

ADMINISTRATIVE POLICY AND PROCEDURE MANUAL

Subject: Informed Consent

No. II. 8

Policy

It is the policy of Main Line Hospitals to respect the right of the patient to make decisions regarding his/her medical care. Main Line Hospitals supports the patient's right to consent to or refuse medical or diagnostic treatment options to the extent permitted by applicable state and federal laws. In accordance with legal requirements governing informed consent, the physician must assure that informed consent is obtained and documented for specific treatments and procedures (See Section I for the list of treatments and procedures that require informed consent), prior to the time that such treatments or procedures are performed.

Definitions

Competent: A condition in which an individual, when provided appropriate medical information, communication supports and technical assistance, is documented by a health care provider to do all of the following:

- 1) understand the potential material benefits, risks and alternatives involved in a specific proposed health care decision;
- 2) make that health care decision on his own behalf;
- 3) communicate that health care decision to any other person.

Patients may be found competent to make some health care decisions, but incompetent to make others.

Health Care Agent: An individual designated by the patient in an Advance Directive.

Health Care Power of Attorney (POA): A writing made by the patient designating someone else, known as a health care agent, to make health care decisions for the patient. A health care power of attorney may not override the contents of an operative Advance Directive.

Health Care Representative: An individual authorized by the patient, in writing or verbally, or, absent designation by the patient, as determined by Pennsylvania law to make certain health care decisions for a patient.

Incompetent: A condition in which the patient, despite being provided appropriate medical information, communication supports and technical assistance, is documented by a health care provider to be:

- 1) unable to understand the potential material benefits, risks and alternatives involved in a specific proposed health care decision;
- 2) unable to make health care decisions on his own behalf; or
- 3) unable to communicate that health care decision to any other person.

Patients may be found incompetent to make some health care decisions, but competent to make others.

Patient Surrogate Decision Maker (Authorized Representative): An individual who is authorized to render medical decisions, including informed consent, on behalf of a patient who is either Incompetent to make such decisions or who has designated the surrogate to act on his/her behalf. (See section III.B for who may act as a patient surrogate decision maker).

Procedure

I. Procedures Which Require Consent

A. Consent is required prior to conducting the following:

1. surgical procedures, including inserting a surgical device or appliance
2. anesthesia
3. blood transfusions and/or transfusions of other blood product released from the blood bank
4. chemotherapy
5. radiation
6. experimental procedures, administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner (See Institutional Review Board Policy and Procedure Manual regarding Informed consent related to clinical trials and protocols)
7. invasive procedures (e.g. paracentesis, central line placement, peripherally inserted central catheter, etc.)
8. invasive radiological studies
9. procedures for which consent is required by statute or regulation (e.g. HIV testing)

II. Who May Obtain Consent

- A. The physician who actually performs the procedure or treatment (primary surgeon/practitioner), or his or her physician designee who has reasonable knowledge of the patient and procedure, must provide the patient or the patient's surrogate decision maker with adequate information so that the patient or surrogate may make an informed decision. If consent is obtained by the physician designee, the primary surgeon/practitioner is responsible for assuring that the content of the discussion complies with the requirements of this policy.
- B. The information provided to the patient or the surrogate decision maker should include:
1. an explanation of the nature of the patient's illness/condition;
 2. the nature and purpose of the proposed procedure or treatment;
 3. a description of the associated risks/side effects, potential complications and benefits of the proposed procedure or treatment;
 4. alternative methods of treatment, if any, and the relevant risks/side effects and benefits related to alternatives, including doing nothing;
 5. the likely consequences if the patient does not have the procedure or treatment; and;
 6. the identity of practitioners other than the primary operating surgeon/practitioner who will perform important aspects of the procedure or treatment.
- C. The physician should seek to elicit questions from the patient or surrogate decision maker and should attempt to confirm the patient's or surrogate's understanding of the information provided.

The information must be communicated in terms that the patient or patient surrogate decision maker can reasonably be expected to understand. For patients with a language barrier, interpreters are available through the hospital. See Administrative Policy Interpreter Services; at BMRH, Foreign Language Protocol.

III. Who May Consent

A. Competent Adult Patients

1. Competent adult patients have the right to consent to or refuse proposed medical

treatments or procedures. The right to decide may be qualified by or subject to applicable law in certain circumstances. A psychiatric consultation should be obtained if there is doubt or conflict regarding assessment of a patient's competence.

B. Surrogate Decision Makers (Authorized Representatives) for Adults**

1. If the patient is not competent to give consent, written consent must be obtained from a surrogate decision maker.
2. The following individuals, **in the order listed below**, may be considered the surrogate decision maker/authorized representative of the patient and will have the authority to consent to medical care consistent with this policy and Administrative Policy Advance Directives:
 - Court appointed guardian authorized to make medical decisions on behalf of the patient
 - A health care agent duly appointed to make medical decisions in a Health Care Power of Attorney
 - A health care representative may be designated by the patient in a signed writing (less formal than a Health Care Power of Attorney) or verbally, or, absent a designation, any member of the following classes, **listed in the order of priority**, who is reasonably available are authorized under the law to act as the patient's health care representative
 - Spouse, unless an action for divorce is pending, **and** the adult children of the patient who are not the children of the spouse
 - Adult child
 - Parent
 - Adult brother or sister
 - Adult grandchild
 - Adult who has knowledge of the patient's preferences and values

****See Administrative Policy: Advance Directives and Health Care Decision Making for explanation of the extent of authority of and decision making process for Health Care Agents and Health Care Representatives; disagreements of surrogate decision makers; patient countermands and revocations, etc.**

3. If attempts to locate a surrogate decision maker are unsuccessful, it may be necessary to obtain a court order for treatment, or the appointment of a guardian. See Administrative Policy: Emergency Guardianships/Guardianships; at BMRH- Obtaining Court Orders, Emergency Guardianships.
4. If there is any question as to the authority or decision-making ability of the surrogate decision maker, unresolved disagreement among surrogate decision makers, and/or concern that the surrogate decision maker is not acting in the best interest of the patient the Patient Safety Officer/Risk Manager or hospital legal counsel should be contacted. When appropriate, hospital counsel will determine whether court guidance should be sought.

C. Minors

Children under 18 years of age are presumed by law to be incompetent to make health care decisions, except in certain statutorily prescribed circumstances described below. Accordingly, parents or legal guardians or other duly appointed parties standing in loco parentis (e.g. children and youth agency) must make medical decisions on behalf of minors.

1. Any minor who has graduated from high school, been married, or been pregnant may give informed consent to medical, dental and health services for himself or herself, and the consent of no other person shall be necessary.
2. Any minor who has been married or has borne a child may give informed consent to medical, dental and health services for his or her child.
3. Any minor may give informed consent for medical and health services to determine the presence of or to treat pregnancy, venereal disease and other diseases reportable under the act known as the Disease Prevention and Control Law, and the consent of no other person shall be necessary.
4. Medical, dental and health services may be rendered to minors of any age without the consent of a parent or legal guardian when, in the physician's judgment, an attempt to secure consent would result in delay of treatment which would result in risk to the minor's life or health.
5. The Abortion Control Act mandates prior consent of a parent or legal guardian before the performance of an abortion on a minor.
5. Under the Mental Health Procedures Act, children 14 years and older who believe they are in need of mental health treatment and substantially understand the nature of voluntary treatment may consent to examination and treatment.
6. A minor who suffers from the use of a controlled or harmful substance may give consent to medical care or counseling related to diagnosis or treatment.

IV. Implied Consent in Emergency Situations

Consent to treatment will be implied when the procedure is necessary for the diagnosis and/or treatment of a condition that, if not treated immediately, can lead to death or permanent disability; and the patient is not capable of providing informed consent to treatment (i.e., the patient lacks decision-making capacity and no surrogate can be located to provide consent). In such cases, the responsible attending physician must document the circumstances in the patient's medical record.

* If the patient has made specific health care choices in a Living Will, **see Administrative Policy: Advance Directives and Health Care Decision Making.**

V. Documentation

A. The agreement of the patient to undergo the proposed treatment or procedure must be documented in the medical record using the hospital's Surgical, Medical or Diagnostic Procedure and Blood Transfusion Consent Form (Attachment A), or any other form approved by the Main Line Hospitals Forms Committee or BMRH MR Committee for the procedure or treatment being performed ("Consent Form"). Where required by law, applicable consent forms must be used. The primary surgeon/practitioner must complete all applicable blank lines on the Consent Form. In addition, it is advisable for the primary surgeon/practitioner or designee to document the informed consent discussion in the progress notes. In the case of PICC line placement, the ordering practitioner will document consent in the CPOE order and the PICC team RN will finalize the consent document. Obtaining informed consent for PICC line placements done in procedural areas (non PICC team insertions) such as Interventional Radiology is the responsibility of the Proceduralist inserting the PICC line.

B. Any modification to the consent form must be initialed and dated by both the patient or patient surrogate

decision maker and the responsible physician.

C. If a patient refuses consent for a treatment or procedure, such refusal must be honored if the patient is competent to make medical decisions. The physician must document the patient's refusal and reason for refusal in the medical record. **See Administrative Policy: Against Medical Advice/Refusal of Treatment.**

D. Main Line Hospitals' consent forms may be used only for procedures performed at a Main Line Hospitals facility.

VI. Telephone/Facsimile Consent

Consent may be obtained by telephone or facsimile only if the patient surrogate decision maker is unavailable in person. Telephone consent may be obtained to prevent an unreasonable delay in patient care. Telephone consent should be obtained by the primary operating surgeon/practitioner or his/her physician designee and should be witnessed by a hospital employee. The conversation must be documented in the patient's medical record and the "Verbal Telephone Consent" section of the Consent Form must be completed and signed by the physician obtaining telephone consent and the witness to the telephone consent.

VII. Witnesses

The signature of the patient or patient surrogate decision maker must be witnessed by someone other than the responsible physician. The purpose of the witness is to verify the authenticity of the patient's or patient surrogate decision maker's signature, not the adequacy of the consent.

VIII. Duration of Consent

Written informed consent must be obtained prior to the performance of any treatments and procedures set forth in Section I. Such consent remains valid unless revoked orally or in writing for the duration of that designated treatment course. In the case of blood transfusions, such consent remains valid for the duration of time specified in Blood Transfusion Paragraph of the Consent Form.

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Consent Form- see MLH intranet/forms