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POLICY:

Only those patients who have voluntarily and knowingly consented to surgical and other intensive and/or invasive procedures shall receive those treatments at Beaumont Health- Royal Oak, Troy, and Grosse Pointe. Appropriate documentation of informed consent shall be required before commencing those treatments.

SCOPE:

Informed consent is required, in general, when treatment is undertaken where a substantial risk of harm exists, where mandated by statute or by hospital policy or when treatment is of an experimental nature under the purview of Beaumont's Human Investigation Committee. This requirement includes, but is not limited to invasive major diagnostic or operative procedures that involve puncture and/or incision of the skin, and/or insertion of an instrument or foreign material into the body.

No documentation of informed consent is required for routine care, routine examination, or non-invasive treatment that involves an insubstantial risk of harm to the patient because the patient has consented to such care upon signing the General Consent to Treatment form. This routine care includes, but is not limited to venipuncture, peripheral IV line placement, arterial puncture, accessing a mediport, insertion of a nasogastric tube/Corpak, insertion of indwelling urinary catheter/straight catheter, and/or enema.

In the event of an emergency situation, this policy would not apply.

ELEMENTS OF INFORMED CONSENT

1. **Capacity:** The patient must have the capacity to consent. Capacity is determined by a physician. Competency is determined by a Court.
2. **Sufficient Information:** The patient must have sufficient information upon which to base the consent. This must include information about the patient's medical condition; proposed and reasonable alternative treatments, including their risks, benefits, significant complications and side effects; the consequences of foregoing treatment; prospects for recovery; potential problems during recuperation and the likelihood of achieving the patient's goals.
3. **Documentation:** The patient's receipt of the information and consent to the treatment must be documented.

PROCESS FOR OBTAINING AND DOCUMENTING INFORMED CONSENT

1. **When the Process is Initiated in Physician's Office**
 - a. The physician must document in the office records that the patient has been given sufficient information concerning the proposed treatment, alternatives, risks, benefits, complications, prognosis and goals. Except where a specific consent form is required by statute, regulation or

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<p>Hospital policy, a copy of the Physician's documentation of informed consent need not be provided to the Hospital.</p>		
<p>b. If a specific consent form required by statute, regulation or Hospital policy is signed in the physician's office prior to Hospitalization:</p> <ul style="list-style-type: none"> • The patient must be admitted within the effective time frame if specified in the regulation, statute or Hospital policy, and • A copy of the specific consent form must be provided to the Hospital and in the Hospital medical record at the time of admission. (See Medicaid regulations for sterilization). 		
<p>c. The patient must complete the Acknowledgment of Informed Consent ("Form #232") at the Hospital prior to the treatment. The patient's signature must be witnessed by a treating physician, a nurse or a designated Hospital employee. The signed Form #232 is maintained in the Hospital medical record.</p>		
<p>2. When the Process is Initiated at the Hospital</p> <p>a. If a specific consent form <u>IS NOT</u> required by statute, regulation or Hospital policy:</p> <ul style="list-style-type: none"> • The attending physician or his/her designee must document in the Hospital medical record that he/she has discussed the proposed treatment, alternatives, risks, benefits, complications, prognosis and goals with the patient and that the patient consents to the treatment; and • The patient must sign the Form #232. The patient's signature must be witnessed by a physician, a nurse or designated Hospital employee. The signed Form #232 is maintained in the Hospital medical record. <p>b. If a specific consent form, other than the Form #232, <u>IS</u> required by Hospital policy, statute or regulation, for example, for sterilization, transfusions, or human investigation research:</p> <ul style="list-style-type: none"> • The specific consent form must include the sufficient information upon which the patient's consent is based and must document that the patient has consented. Specific consent forms must be approved in accordance with the Hospital policy on approval of new consent forms; and • The attending physician shall be available to discuss the content of the specific consent form with the patient; and • The patient must sign the specific consent form. The patient's signature must be witnessed by a physician, nurse or designated Hospital employee. The signed specific consent form shall be made a part of the Hospital medical record. • Consent for transfusion of blood or blood products may be obtained by the ordering physician or that physician's designee who may be a mid-level provider or nurse. 		

RESPONSIBILITY FOR PROVIDING INFORMATION TO THE PATIENT

1. Physician

- a. As a general rule, the physician performing the procedure or serving as the attending physician shall ensure that the patient has sufficient information about the procedure and that the appropriate documentation exists as to the informed consent procedure.
- b. In the event that a procedure involves administration of an anesthetic, the physician administering the anesthetic shall be responsible for ensuring that the patient has sufficient

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<p>information regarding the anesthesia to be used during the procedure and for documenting that the information was given to the patient in accordance with the anesthesia consent.</p>		
<p>2. Health Care Worker</p> <ul style="list-style-type: none"> a. The health care worker may provide additional information to patients per Hospital policy. b. In general, if a patient requires additional information or displays confusion or hesitation about a scheduled treatment, it is the health care worker's responsibility to notify the attending physician. c. If the attending physician fails to resolve the problem to the satisfaction of the reporting health care worker, the health care worker shall report the incident to his/her supervisor. d. If the attending physician fails to resolve the problem to the satisfaction of the supervisor, the supervisor shall report the incident to the Chairman of the Department. If the Chairman of the Department is unavailable, the supervisor shall report the incident to the Hospital Administrator and Medical Administrator on call. See Patient Care – Corporate Policy #312 – Patient Care Concerns/Chain of Command. 		
<p>DOCUMENTATION REQUIREMENTS RELATED TO INFORMED CONSENT</p> <ol style="list-style-type: none"> 1. With respect to Form #232, the role of the health care worker is to witness the signature of the patient, not the obtaining of informed consent. 2. All dates, times, and signatures must be in ink. If the signature is other than the patient's, then the relationship of the signer to the patient should be noted below the signature. 3. In the event of a technical flaw in a specific consent form, the physician need not re-obtain the patient's consent, but may proceed with the treatment after appropriate documentation in the medical record. 4. In general, the specific consent form remains effective for the duration of the hospitalization and is valid if: <ul style="list-style-type: none"> a. The nature or scope of the treatment, and the patient's diagnosis, prognosis and medical condition is unchanged, and b. The patient or legal representative continues to demonstrate a willingness to undergo the treatment. 5. Where consent for a definite treatment is obtained pursuant to a court order, the consent is valid until the treatment has been accomplished. 6. Barriers to receipt of information and documentation of consent must be resolved. <ul style="list-style-type: none"> a. If a patient's disability presents a barrier to communicating his/her understanding of the content and purpose of the Form #232, the law requires the use of special equipment and /or personnel to enable the disabled patient to give informed consent. b. If the patient or legal representative has a hearing disability, auxiliary aids, including a video phone and/or a relay service, or a qualified oral or sign language interpreter must be provided. See, Corporate Policy #315, "Interpreters for Deaf and Hard of Hearing Patients and their companions." c. If the patient or legal representative has a visual impairment, the Physician or nurse should read the form to the patient or legal representative, and document that the reading took place. 		

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<p>d. If the patient's ability to speak, read, or understand English is limited, an interpreter must be provided. See, Corporate Policy #316, "Translators for Patients with Limited English Proficiency."</p>			
<p>EXCEPTIONS TO INFORMED CONSENT</p>			
<p>1. Emergencies. In an emergency situation, the Physician must document the nature of the emergency and the reasons why he/she was unable to obtain written or verbal consent from the patient or the patient's legally authorized representative. Consent is implied unless the physician or other health care worker has reason to know that the patient would not consent to the treatment, such as where there is an Advance Directive declining the treatment.</p> <p>a. Competent Adult</p> <ul style="list-style-type: none"> i. Consent is implied where a patient is unconscious and unable to give his/her consent and immediate treatment is necessary to preserve the patient's life or to prevent serious impairment of the patient's health. ii. Consent is implied not only in medical emergencies, but also for unanticipated events. A physician is justified in performing a procedure different from that which the patient agrees to when an unanticipated event or condition arises that is or may become life-threatening as a result of surgery or due to an unexpected complication discovered during surgery, and it is impractical or impossible to obtain the consent of the patient or one authorized to act in his/her behalf. <p>b. Incompetent Adult: Consent to treat an incompetent adult is implied in an emergency and attempts to obtain appointment of a legal guardian would delay treatment and cause permanent harm. If available, parents of an incompetent adult, who is incompetent from birth or becomes incompetent during minor years, may give consent.</p> <p>c. Minors</p> <ul style="list-style-type: none"> i. Consent to treat a minor is presumed in an emergency just when attempts to reach the parents or legal guardian for consent would delay treatment and cause permanent harm. ii. If the minor is not living at home, and does not have a legal guardian, consent should be implied in an emergency, where attempts to reach the Michigan Department of Human Services to obtain a legal guardian would delay treatment and cause harm to the patient. iii. An abortion may be performed upon a minor in an emergency without a parent's written consent or Court order waiving parental consent. An emergency is a situation in which continuation of the pregnancy would create an immediate threat and grave risk to the life of the minor, as certified in writing by a physician. <p>2. Therapeutic Privilege. If a psychiatrist chooses to withhold information from a patient based upon therapeutic privilege, he/she must document in the medical record his/her reasons for invoking such a privilege. By law, "therapeutic privilege" applies only to psychiatry.</p> <p>3. Assumption of the Risk. The physician must document in the medical record any occurrence where the patient refuses to allow the physician to explain the risks, benefits, and reasonable alternatives of a proposed operation or medical intervention, but insists upon signing the written consent form. The physician should then have this discussion with a person authorized by the patient to hear this information and seek that person's concurrence. The physician must also document when the patient orally consents to treatment.</p>			

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4. **Telephone Consent.** Consent and authorization for treatment may be obtained by telephone if no reasonable opportunity to obtain written consent exists. The medical record should reflect who consented, the nature of the consent given, the date and time, and the names of two (2) witnesses to the obtaining of telephone consent.
5. **Police Department.**
 - a. If a police officer requests that a test be performed on a patient to determine the amount of alcohol or presence of a controlled substance, or both, in the patient's blood, the police officer is responsible for obtaining written consent of the patient, or his/her representative (EC Form #2323). If the patient refuses to submit to the test, the Hospital shall honor the patient's wishes and not proceed with the test unless the police officer obtains and presents a court order/search warrant.
 - b. Assuming a court order/search warrant has been obtained, the Hospital shall abide by it. The Hospital department in receipt of a court order/search warrant must refer to the Department of Legal Affairs before complying.
 - c. In the event that the patient becomes combative and refuses to remain at the Hospital, it is the police officer's responsibility, not the Hospital's, to restrain the patient.
6. **First Responders.** A First Responder who has either transported an emergency patient (the "Source Patient") to the Hospital or assisted a Source Patient who is later transported to the Hospital for purposes of medical treatment may request that the Source Patient be tested for HIV and/or HBV if it is believed that the First Responder has sustained a percutaneous, mucous membrane or open wound exposure to the Source Patient's blood or other body fluids. See RO EC Policy#312 – First Responder Exposure.

WHO MAY CONSENT

1. **Competent Adult.** A competent adult is one who is eighteen (18) years of age or older and can understand his/her medical condition, proposed treatment, alternatives, risks, benefits, complications, prognosis and goals.
 - a. Before proceeding with treatment, the consent of a competent adult must be obtained. A competent adult has the right to refuse any treatment.
 - b. An adult psychiatric patient is not presumed to be incompetent to consent to medical treatment. The patient's psychiatrist and attending physician (if applicable) should make the determination as to whether the patient can understand his/her medical condition and proposed treatment. The determination should be documented in the medical record.
2. **Incompetent Adult.** An incompetent adult is one who, though eighteen (18) years of age or older, cannot understand his/her medical condition, proposed treatment, alternatives, risks, benefits, complications, prognosis and goals.
 - a. An adult is presumed to be competent. If the treating physician questions whether the patient is competent, he/she should request the appropriate consultation, e.g., psychiatric or geriatric as appropriate to the patient's condition/status. After consultation, the treating physician should assess whether the patient has sufficient capacity to make informed decisions regarding treatment and document that assessment in the medical record.
 - b. If the treating physician concludes that the patient is not competent to give or refuse consent, treatment decisions may be made by one of the following surrogate decision makers:

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<p>i. Legal Guardian: If a patient is declared incompetent by a Probate Court, consent of the court appointed guardian (“Legal Guardian”) is necessary for non-emergent medical/surgical treatment and, if readily available, for emergency treatment. The Legal Guardian may or may not be a family member and will have a Letter of Guardianship evidencing the appointment. Once appointed, only the Legal Guardian has authority to consent to or refuse medical/surgical treatment. If there is a difference of opinion between the family and the Legal Guardian, the Legal Guardian prevails. If there are any questions related to the Letter of Guardianship, please contact the Department of Legal Affairs. A copy of the Letter of Guardianship must be made part of the patient’s medical record.</p> <p>ii. Patient Advocate Acting Under a Durable Power of Attorney for Health Care: A Durable Power of Attorney (“DPOA”) is a written document by which a competent adult patient gives another adult the power to make medical treatment, psychiatric treatment and personal care decisions for the patient when the patient is unable to participate in treatment decisions. The adult designated by the patient is called the Patient Advocate.</p> <ol style="list-style-type: none"> 1. If the patient has executed a DPOA and is subsequently found to be incompetent, the consent of the Patient Advocate is necessary for non-emergent medical/surgical treatment or psychiatric treatment and for emergency treatment if readily available. <ol style="list-style-type: none"> a. For medical/surgical treatment, incapacity is determined and documented by two physicians or by one physician and a licensed psychologist. b. For psychiatric treatment, incapacity is determined and documented by two physicians, one of whom is a licensed psychiatrist. 2. Before the Patient Advocate may make treatment decisions for the patient, the Patient Advocate must sign an Acceptance Form. Both the DPOA and the Patient Advocate’s Acceptance Form must be part of the patient’s medical record. <p>iii. Family</p> <ol style="list-style-type: none"> 1. If it is determined that the patient is incompetent and the patient does not have a legal guardian or a Patient Advocate acting under a DPOA, then the next of kin may consent to medical/surgical treatment provided all of the following conditions are met: <ol style="list-style-type: none"> a. The treating physician, relying on his/her medical judgment, believes the treatment, though not emergent, should not be delayed until the patient recovers sufficiently to give consent; and b. The treating physician documents these reasons in the patient’s medical record; and c. Neither the physician nor the next of kin knows, or has reason to know, that the patient, if competent, would be opposed to the proposed medical/surgical treatment, given the specific set of circumstances. 2. Consent should be obtained from the closest next of kin in the following order of priority: <ol style="list-style-type: none"> a. Spouse b. Adult son or daughter c. Either parent 		

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<p>d. Adult sibling</p> <p>3. When the person with the highest priority is not available, the next in order should be contacted. It is strongly recommended that the consent of persons, other than those listed above, be used with caution. The more distant the relationship between the patient and the next of kin, the greater the probability that the procedure should be delayed until consent can be obtained from a person authorized to give consent, such as a Legal Guardian.</p> <p>4. The opinion of a patient's domestic partner, including those of the same sex as the patient, should be considered for purposes of consent. If conflict arises between a domestic partner and the next of kin, then an Ethics consultation should be obtained and Legal Affairs should be contacted.</p> <p>5. If the patient's lack of competency is long-term or unrelated to the present illness, appointment of a Legal Guardian should be discussed with the family.</p> <p>c. If the patient is not competent and there is no surrogate decision maker, the treating physician should contact the Department of Legal Affairs to request appointment of a Legal Guardian.</p> <p>d. If a question arises regarding consent on behalf of an incompetent patient or there is disagreement among next of kin or between the treating physician and surrogate decision maker, the treating physician should contact the Department of Legal Affairs.</p> <p>3. Medicated Patients. A patient should never be informed of the proposed treatment, alternatives, risks, benefits, complications prognosis and goals if he/she is mentally impaired by virtue of medication or abused substances. If a patient has been given an anesthetic agent, the patient is incapable of giving consent until 24 hours after administration of the anesthetic agent.</p> <p>a. If the physician will attest in the medical record that the patient received sufficient information and did consent to the treatment prior to receiving the medication, the proposed treatment may proceed without a Form #232 being signed.</p> <p>b. If the physician cannot document that sufficient information was given prior to the administration of the medication, the treatment will be delayed until the patient is capable of understanding and consenting.</p> <p>c. Sterilization/therapeutic abortion may not proceed unless a Form #232 is signed prior to pre-operative medication.</p> <p>4. Minors. Except in emergency cases, the consent of a parent, Legal Guardian, or person acting in place of the parents is required in providing medical or surgical treatment to an individual under age eighteen (18). The assent of the minor, as appropriate for age, should be sought in conjunction with obtaining parental consent and the minor's assent, or lack thereof, should be documented in the medical record. If the minor does not assent, Clinical Ethics consultation should be considered.</p> <p>a. Minor Living at Home but Parent Unavailable: If a minor requires medical and/or surgical care and the parents are temporarily unavailable, the physician should obtain consent from the minor's nearest available adult relative or person with a written delegation of parental rights acting in place of the parents. The medical record should reflect the fact that attempts were made to contact the minor's parents. In addition to providing discharge instructions to the responsible adult, a copy of relevant discharge instructions should be mailed to the minor's parents at their home address.</p> <p>b. Minor's Parents are Divorced or Legally Separated: If the parents are legally separated or divorced, the court will have awarded custody. If parents have joint legal custody, then either</p>		

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parent may consent. If one parent has been awarded legal custody of the minor, then that parent's consent should be obtained. In the event of a dispute, the parents should be required to produce a written Judgment of Divorce and the Department of Legal Affairs must be contacted immediately.

- c. Parental Refusal of Treatment: If, in the opinion of the attending physician, a minor requires medical treatment and the parents refuse to consent, a court order may be obtained under the Child Abuse and Neglect Act. Contact the Department of Legal Affairs immediately.
- d. Minor Not Living at Home and Without Legal Guardian: If a minor is not living with his/her parents and does not have a Legal Guardian, consent to routine non-surgical medical care may be obtained from the Circuit Court – Family Division or the Michigan Department of Human Services. If a question arises in this circumstance, the Department of Legal Affairs should be contacted.
- e. Minor Lives in Foster Home or Residential Care Facility
 - i. Consent for minors in foster care depends upon the nature of the proposed treatment and the type of placement as follows:

Type of Care	Type of Placement	Who May Consent
Routine, non-surgical care (other than contraceptive treatment, services, or devices)	Involuntary placement by Court	Court, child placing agency, Michigan Department of Human Services, or the residential care provider to which they have delegated such authority in writing
Routine, non-surgical care (other than contraceptive treatment, services, or devices)	Voluntary placement by parent/Legal Guardian	Parent/Legal Guardian
Emergency medical or surgical care	Involuntary placement by Court	Court, child placing agency, Department of Human Services, or the residential care provider to which they have delegated such authority in writing
Emergency medical or surgical care	Voluntary placement by parent/Legal Guardian	Residential care provider to which parent must delegate such authority in writing
Non-emergent, elective surgery	Voluntary or Involuntary placement	Parent/Legal Guardian OR If parental rights have been permanently terminated, then the Court or Department of Human Services

- ii. Although the consent of the parent or Legal Guardian is typically required for minors prior to commencing treatment, Michigan law permits a minor in some instances to consent to medical or surgical treatment on his/her own behalf.
- f. Emancipated Minors: Emancipation means a parent is no longer legally responsible for a minor. It occurs in the following instances:

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<p>i. Where a minor is legally married.</p> <p>ii. During the period when a minor is on active duty with the Armed Forces of the United States.</p> <p>iii. For the purpose of consenting to routine, non-surgical medical care or emergency care, when the minor is in the custody of a law enforcement agency and the minor's parent or Legal Guardian cannot be promptly located.</p> <p>iv. Upon entry of an emancipation order by the Circuit Court – Family Division</p> <p>g. Substance Abuse, Venereal Disease or HIV: Minors may consent to medical advice or treatment for substance abuse, venereal disease or HIV (AIDS, ARC) without parental consent.</p> <ul style="list-style-type: none"> i. Substance Abuse: The minor must consent for a treating physician to inform the parents of treatment. ii. Venereal Disease or HIV: A treating physician may inform the parents of treatment, even if the minor specifically requests that the physician not inform his/her parents of the treatment. <p>h. Birth Control Information and Devices: Minors may obtain birth control information, medication and devices without parental consent.</p> <p>i. Mental Health Services: Minors over the age of 14 may seek and receive outpatient mental health services, excluding pregnancy termination referral services and the use of psychotropic drugs, without parental consent for up to twelve (12) sessions or four (4) months.</p> <p>j. Abortions: A minor may not obtain an abortion without the written consent of one (1) parent or the minor's Legal Guardian, unless the Circuit Court – Family Division has entered a written order waiving the parental consent requirement. A parent's written consent or the Court's order waiving parental consent must be included in the medical record together with the written consent of the minor.</p> <p>k. Prenatal and Pregnancy Related Health Care: A minor female may seek and consent to prenatal and pregnancy related health care and to the provision of health care for her child without the consent of her parents.</p> <ul style="list-style-type: none"> i. Prenatal and pregnancy related "health care" is defined by law as "only treatment or services intended to maintain the life and improve the health of both the minor and the minor's child or fetus." Prior to treatment, the Hospital or physician is required to inform the minor that while the physician is not obliged to notify the spouse, parent, Legal Guardian, or putative father of the child, the law does not prevent such notification. ii. The physician, for medical reasons, may inform the spouse, parent, Legal Guardian, or putative father of the child regardless of the minor's consent or lack thereof. iii. The medical record should reflect the fact that the minor has been informed that notification of others regarding her treatment may occur. <p>l. Blood Donation: A person 17 years of age or over may donate blood in a voluntary and non-compensatory blood program without the necessity of obtaining the permission or authorization of a parent or Legal Guardian.</p> <p>m. Sterilization: The law is silent as to whether a married minor may consent to be sterilized without spousal or parental consent. The Department of Legal Affairs should be contacted in all cases involving sterilization of minors. For the patients who are Medicaid recipients, federal regulations prohibit funding for any person under age 21.</p>		

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