Keywords: informed consent, consent, patient decision maker, patient caregiver, patient surrogate

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### I. OBJECTIVES

This policy provides the information necessary to obtain informed consent for an intervention (procedure/treatment/anesthesia/blood transfusion) from the patient/decision maker (health care agent, legal guardian, or surrogate decision maker).

### II. INDICATIONS FOR USE

A. Informed consent is the process to honor the competent patient’s or their surrogate’s right to exercise self determination about their healthcare. The goal of the informed consent process is for the person to understand information relevant to the decision, alternatives and their consequences, and allow the person to freely choose to accept or reject the recommended treatment based on their goals of care (refer to Goals of Care Policy). This process is grounded in the ethical and legal principles of patient autonomy, The law does not allow a health care provider to substitute his/her judgment for that of the patient in the matter of consent. Therefore, interventions that require consent shall not be performed on a patient until consent of the patient/decision maker is obtained, except in an emergency (see Section III E). Failure to obtain informed consent for an intervention may impose liability on the hospital and the health care provider.

B. Examples of interventions requiring informed consent and a consent form are listed in Appendix A (this list is not all-inclusive). Consent must be obtained by a healthcare provider authorized to obtain informed consent (see Definitions).

### III. DEFINITIONS

| Health Care Provider Authorized to Obtain Informed Consent | Authorized prescribers; Registered Nurses with specialized training See Appendix A; Technologists with specialized training - See Appendix A |
### Health Care Agent/ Durable Power of Attorney
- An adult appointed by the patient under an advance directive in accordance with Maryland law (a copy of the document must be in the Legal section of the medical record).

### Incapable of Making an Informed Decision
- A condition in which the patient is unable to understand the nature, extent or probable consequences of the proposed treatment; is unable to make a rational evaluation of the burdens, risks, and benefits of a proposed treatment, or non-treatment; or is unable to communicate by any means using verbal, written, electronic, or expressive means. Assessment of decision making capacity is made by clinicians.

### Informed Consent
- A process accomplished by a dialogue between the patient/decision maker and a provider of services during which the patient/decision maker is given information and an opportunity to ask questions. This dialogue culminates in the understanding by the patient/decision maker of the risks, benefits, and alternatives to the procedure under discussion and leads to agreement by the patient/decision maker.

### Research Informed Consent
- Informed consent obtained per the Institutional Review Board’s informed consent guidelines (irb.jhmi.edu/Policies/116_1.html). See section III J.

### Minor
- A person under the age of 18; requires surrogate decision making except in special circumstances as defined in III G

### Surrogate Decision Maker for Adult Patients
- An individual recognized by law to make health care decisions for another. See section III D.

### IV. RESPONSIBILITY

#### A. Health Care Provider Authorized to Obtain Informed Consent
1. In order to obtain informed consent, there must be a dialogue between the patient/decision maker and a health care provider responsible for the treatment/procedure. The health care provider has a duty to inform the patient in understandable language of important information regarding the intervention, as defined below in Procedure, III A. The informed consent must be free of coercion, duress or fraud. Through dialogue, the health care provider ensures that the patient/decision maker understands the procedure, its risks, benefits and alternatives.
2. The health care provider shall assure that the patient has decision making capacity at the time that consent is obtained. If the patient is incapable of making a decision, the health care provider shall follow the procedure for surrogate decision making in section IIIID.
3. For information on obtaining research consent see [http://irb.jhmi.edu/Policies/116_1.html](http://irb.jhmi.edu/Policies/116_1.html)

#### B. Health Care Provider Performing Test/Treatment/Procedure
1. Ensure informed consent is obtained prior to performing treatment/procedure. - Ensure time out is documented (Refer to “Patient, Procedure Site Verification and Time-out Policy: ICPM Policy # PAT017)
2. The bottom of the consent form is one area that the time out can be documented. (See Appendix C).

#### C. Registered Nurse
1. Ensures informed consent is obtained prior to administering any sedatives, for procedures requiring informed consent.
a. If multiple procedures requiring separate consents will occur on the same day, consent for each procedure must be obtained prior to sedating pre-medication.

2. Validates:
   a. Properly completed consent form available in the Medical Record prior to procedure.
   b. Procedure documented on the consent form and the patient/decision-maker’s verbal understandings of the procedure are consistent (when possible).
   c. For OR cases, ensure OR posting schedule matches consent form and patient/decision maker’s verbal understanding (when possible).
   d. Notify the person performing the procedure if there are any discrepancies noted.

3. Informs the attending physician or other health care provider designee if the patient verbalizes any concern regarding performance of the intended procedure/operation. For procedures completed by RN, ensure time out is documented. The bottom of the consent form is one area where the time out can be documented.

D. Treatment Team (Attendings, residents, physician assistants, nurse practitioners, nurse midwives, nurse and/or technicians who are present for the invasive procedure)
   1. Participate in time out prior to start of procedure. Any member of the treatment team may document completion of the time out. Signature verifies that all elements of the time out were reviewed prior to start of procedure. (Refer to “Patient, Procedure Site Verification and Time-out Policy: ICPM Policy #PAT017)

E. Witness Signature for Informed Consent (Any individual, including employees, aged eighteen (18) or older, excluding the provider obtaining the consent).
   1. Observes the patient/decision maker signing the document or verifies the signature with patient or health care agent. The witness is not required to be present during informed consent dialogue or to assure patient or decision maker understanding of content within the informed consent document.
   2. Signs the “witness” line on the consent form.
   3. Contacts the physician if during the witnessing of the patient’s signature, or anytime there after, the patient has questions about the forthcoming procedure, treatment or test.
   4. Contacts the physician if the procedure to be performed is not filled in on the consent form. Witness can not enter type of procedure to be performed on the consent form.
   5. The witness should be chosen with respect to the patient’s privacy.

F. Witness for Telephone Consent (Must be a registered nurse, physician, physician's assistant, nurse practitioner, nurse anesthetist, or nurse midwife).
   1. Identifies self to the decision maker on the telephone.
   2. Verifies the identity of the decision maker.
   3. Assures that the decision maker has had all of their questions answered to their satisfaction and is willing to approve the procedure.
   4. Signs the “witness” line on the consent form.

V. PROCEDURE
   A. INFORMED CONSENT PROCESS
      1. The responsibility to see that informed consent is obtained rests with the attending physician or other health care provider credentialed to perform the procedure. When there are two health care providers performing different procedures on the same patient, both providers must obtain informed consent. (e.g., mastectomy performed by one surgeon, flap completed by second surgeon).
2. Informed Consent for invasive procedures, which are performed in a diagnostic laboratory (e.g., cardiac catheterization, endoscopy, etc.), shall be obtained by a physician or health care provider from that respective area.

3. A mentally competent person who is age eighteen (18) years or older may give a valid consent for treatment or may appoint a health care agent to act on their behalf (see ICPM Advance Directive Policy, MEL001). In some situations minors may consent as adults (see Section III G).

4. The consent for an intervention continues to be valid as long as there have been no changes in the indication for the procedure, the risks, the alternatives, or the probability of success. If such a change occurs, consent is no longer valid and a new consent must be obtained.

5. Federal regulation requires the signing of a special consent form at least thirty (30) days prior to a sterilization procedure if funded under a State Medical Assistance Program (see Section III H. 1.a below).

6. Patients will not be pre-medicated for a procedure with a sedating medication before an informed consent discussion has been held and a consent form has been properly completed (see Section III B).

7. For patients with DNR orders who require informed consent to undergo invasive diagnostic or therapeutic procedures or surgery, the physician obtaining consent must meet with the patient’s attending physician and the patient/decision maker:
   a. Discuss the patient’s goal of care regarding the procedure or surgery and preferences concerning resuscitation in the event of a cardiopulmonary arrest during the peri-operative/procedure period.
   b. The patient’s attending physician shall document the patient’s or surrogate’s decision in the medical record.
      See ICPM Policy # PAT005 Do Not Resuscitate policy and ICPM Policy #MEL017 Establishing Goals of Care

8. Non-English speaking patients or deaf patients shall have a verbal or hand sign language interpreter involved in the informed consent process. In some cases, patients may ask that a family member or friend serve in this capacity. It is strongly encouraged that a qualified interpreter be present during the informed consent discussion to verify the accuracy of the information being expressed. See ICPM Policy #PAS002 - Interpreting Services.

9. Consent may be withdrawn or modified by the patient/decision maker at any time prior to or, if possible, during the intervention. The authorized prescriber, or designee, shall be informed of the patient’s consent modification which shall be documented in the patient’s medical record by the authorized prescriber, or designee. http://www.insidehopkinsmedicine.org/operations_integration/patientBOR.pdf

B. Documentation of Informed Consent

1. There must be documentation in the medical record of the informed consent discussion. This documentation shall occur on a Johns Hopkins Hospital approved consent form and shall include the following:
   a. Indications and nature of the proposed procedure, treatment or test, including:
      • The operative site and side (right or left), if applicable.
      • The anesthesia (requires separate consent form) or sedation options with attendant risks.
      • The need for and the risk of blood transfusion and available alternatives to be used, if applicable. Requires a separate consent form; See Appendix D.
   b. Description of potential risks, benefits, and complications inherent in or collateral to the procedure, treatment or tests, and the probability of success.
   c. First and last name of the physician(s) or other health care provider(s) who will be performing and/or supervising the given procedure, treatment or test.
   d. Alternatives, including risks and benefits of the alternatives.
   e. The probable consequences of declining recommended or alternative therapies, including side effects and possible outcome.
   f. Any limitations on the confidentiality of information learned from or about the patient.
g. The right of the patient to refuse treatment

2. Consent for an intervention is only for that specific intervention (EXCEPTION: See Bundled ICU Consent, Section C below). However, a serial consent may be obtained if the health care provider informs the patient/decision maker that consent is for a series of interventions and it is documented on the informed consent form (e.g., skin grafts, ECT, etc.). New consent for the same procedure/treatment must be obtained if the risks to the patient have changed (e.g., change in level of care). - When a serial consent is kept in a procedural area for future procedures, a copy of the consent form shall be made and placed in any documents that are sent to Medical Records after each procedure.

3. The consent form must be signed, dated, and timed by the patient/decision maker, whose signature is witnessed (see Responsibilities section above). - If the informed consent form has no witness signature, the prospective witness confirms with the patient that the signature on the form belongs to the patient, and then signs the witness signature area using current date and time.

4. The health care provider obtaining the informed consent shall read and explain the form, through an interpreter if necessary (see III A #9 above), to any patient/decision maker who cannot read or understand the form's contents. See ICPM Policy #PAS002 - Interpreting Services.

5. The health care provider securing the consent must print and sign the consent form with their first and last name. With the exception of telephone consent (see Section III F) the patient/decision maker will also print and sign the consent form with their first and last name. All signatures shall be dated and timed.

6. Abbreviations may not be used to describe the intervention on the consent forms.

7. If a patient/decision maker does not wish to have observers or to be photographed/videotaped during a procedure, they may cross out this area of the consent form with single line. This cross out will be initialed by both the patient/decision maker and the provider obtaining consent

8. Prior to initiating procedure, page two of the consent form or another document that is part of the medical record (e.g., procedure/progress note, procedural flowsheet, checklist, ORMIS) will be used to verify that all elements of the time out are completed. See Patient, Procedure, and Site Verification and Treatment, ICPM Policy #PAT 017.

C. Bundled ICU Consent

1. The ICU areas may choose to utilize the Consent for Procedures Performed in the Adult Intensive Care Unit form, which allows for consent for any or all of the following:
   • Central Line Insertion
   • Arterial Line Insertion
   • Pulmonary artery catheter insertion
   • Lumbar puncture
   • Thoracentesis
   • Chest tube placement

2. This consent form is only for the current ICU stay. upon transfer or discharge from an ICU, bundled consent is no longer valid. If a patient is re-admitted to an ICU, new bundled consent shall be obtained.

3. Once a bundled ICU consent is obtained, a new consent is not required for the same procedure unless the patient’s condition changes causing significant changes in the risks of the procedures/tests.

D. Surrogate Decision Making for Adults

1. Based on respect for persons who are no longer able to communicate on their own behalf, another person can be authorized to make decisions that the patient would have made if the patient was able to communicate on their own behalf. Maryland law has established a procedure to be followed in obtaining informed consent for an adult who is incapable of making an informed decision. A Surrogate Decision Maker may make decisions about health care
for a person who have been certified by two Maryland licensed physicians as being incapable of making medical decisions (see definition, IC above).

2. Decision Makers: The following individuals/groups, in the specified order of priority, may make decisions about healthcare for a person who has been certified to be incapable of making an informed decision. Surrogates in a particular class may be consulted to make decisions only if all individuals in the next higher class are unavailable, are incapacitated/unwilling to make decisions, or have failed to respond to the health care provider.

- **Health Care Agent:** An adult appointed by the patient under an advanced directive in accordance with Maryland law (a copy of the document must be in the Legal section of the medical record).
- **Hierarchy of Surrogates:**
  - Legal Guardian of the person - An adult appointed by the court to make medical decisions for the patient (a copy of the document must be in the Legal section of the medical record);
  - The patient's spouse, or domestic partner;
  - An adult child of the patient;
  - A parent of the patient;
  - An adult brother or sister of the patient; or
  - A friend or other relative of the patient who signs an affidavit demonstrating that the person has maintained regular contact with the patient and is familiar with the patient's activities, health and personal beliefs. A copy of the affidavit (Appendix B) shall be placed in the Legal section of the medical record.

3. A surrogate may not authorize:
   a. Sterilization;
   b. Treatment for a mental disorder;
   c. Treatment if the health care provider is aware that the patient has expressed disagreement, or
   d. The withholding or withdrawing of life/sustaining procedures except as outlined below.

4. Dispute among surrogates: If persons with equal decision-making priority disagree about a healthcare decision, the case shall be referred to The Johns Hopkins Hospital Ethics Service and Committee. The attending physician may act in accordance with the recommendation of the Ethics Service and Committee or may contact The Johns Hopkins Health System Legal Department for possible guardianship proceedings. See K: Resources below.

5. Certification of Incapacity (for emergencies, see Section E1 below)
   a. Prior to providing, withholding, or withdrawing treatment or procedures on the basis of surrogate decision making, the attending physician and a second physician, one of whom shall have examined the patient within two hours before making the certification, shall certify in writing that the patient is incapable of making an informed decision regarding the treatment. The certification shall be based on a personal examination of the patient. Efforts should be undertaken to restore decision making capacity when ever possible such as removing physiologic or medication related impediments. If there are underlying psychiatric conditions that may interfere with decision making, consultation with a psychiatrist or other mental health professional is recommended.
   b. If a patient is unconscious or unable to communicate by any means, the certification of a second physician is not required.

6. Certificate of Condition - A health care provider can not withhold or withdraw life-sustaining procedures (e.g. CPR, mechanical ventilation, dialysis) on the authorization of a surrogate (as distinguished from a Health Care Agent see, #2 above) unless:
   - The patient's attending physician and a second licensed physician have certified that the patient is in a terminal condition or has an end-stage condition OR
Two licensed physicians, one of who is a neurologist, neurosurgeon or other physician who has special expertise in the evaluation of cognitive functioning, certify that the patient is in a permanent vegetative state.

7. If there is a dispute between a Healthcare Provider directly involved in the patient's care and a surrogate with regard to the patient's preferences, the person on-call for ethics consultations should be contacted.

E. Treatment in an Emergency
1. A health care provider may treat an individual who is incapable of making a medical decision without consent when all of the following apply:
   a. The treatment is of an emergency nature;
   b. A person who is authorized to consent is not immediately available (III, D); and
   c. A licensed physician determined that, with a reasonable degree of medical certainty, the life or health of the patient would be affected adversely by delaying treatment. The licensed physician must document this decision. Under these circumstances, the health care provider may proceed with the intervention, documenting in the medical record the nature of the emergency.

2. This section does not authorize any treatment, even in an emergency, if the health care provider knows that the treatment is against the wishes of the patient.

3. Minor patients may give consent for their own treatment in an emergency if the delay in treatment would adversely affect their life or health.

F. Informed Consent by Telephone
1. In special situations when the patient is unable to give consent, and the decision maker cannot be physically present, the informed consent dialogue between the health care provider and the decision maker may be communicated by telephone. The following protocol must be followed:
   a. The name and relationship of the decision maker shall be properly identified on the consent form with "telephone consent" written next to the decision maker's name.
   b. The physician or health care provider shall provide the decision maker (see Section III D- Surrogate Decision Making) information, which has been described in Section III B. Documentation of the information discussed shall appear on the consent form and the health care provider will sign the “Healthcare Provider Securing Consent” line on the consent form. Whenever possible, the decision maker shall send a facsimile or telegram to the physician/health care provider or admitting office of the hospital confirming the substance of the discussion and agreement for the staff to proceed with the intervention.
   c. A witness, who must be a registered nurse, physician, physician’s assistant, nurse practitioner, nurse anesthetist, or nurse midwife, identifies self to the decision maker on the telephone, verifies the identity of the person, and assures that the person giving consent has had all of their questions answered to their satisfaction and is willing to approve the procedure. This witness shall sign the “witness” line on the consent form.

G. Treatment of a Minor
1. General rule for minors
   a. For patients under the age of 18, except in certain circumstances as outlined in G-2 below, consent shall be obtained in the following order:
      • Either parent, unless parental rights have been terminated or limited by a court order or separation/divorce agreement,
      • Legal Guardian;
      • Court appointed custodian or
      • Informal kinship care affidavit (see G-5 below)
b. If the parent or individual identified above (collectively known as the “decision maker”) refuses to consent to a life-saving procedure/treatment for the child that has a high probability of benefit and low risk or burden, the physician shall proceed with the necessary procedure/treatment and contact the Johns Hopkins Health System Legal Department. In cases where there is uncertainty about the probability of benefits, consequences or effectiveness of a treatment, parents have greater discretion to choose among ethically justified options. If disputes arise, ethics consultation and legal advice should be sought.

c. Minor children shall be involved in a process of understanding their diagnosis, treatment, and consequences within their developmental, cognitive, and psychological capacities. Assent may be sought.

2. Minor capacity to consent

a. A minor has the same capacity as an adult to consent to medical treatment if the minor is married or the parent of a child. This means that if the minor is married or the parent of a child (refer to “Incapable of making an informed decision” in Definitions)) and otherwise has capacity, the minor may consent to medical treatment. If there are disputes about the capacity or authority of a minor to consent to treatment, the legal department shall be contacted. Ethics Committee consultation may be sought.

b. A minor has the same capacity as an adult to consent to medical treatment if, in the judgment of attending physician, the life or health of the minor would be affected adversely by delaying treatment to obtain the consent of another individual.

c. A minor may seek treatment or advice for the following conditions without parental or guardian consent and give consent, when indicated:
   • drug abuse;
   • alcoholism;
   • sexually transmitted disease;
   • pregnancy;
   • contraception other than sterilization;
   • physical examination and treatment or injuries from an alleged rape or sexual offense
   • physical exam to obtain evidence of an alleged rape or sexual offense.

d. Consent cannot be over-ridden by parents or guardian.

e. When a circumstance as listed in G 2-c. exists, the attending physician may, but is not obligated to, inform the parent or other decision maker. This communication may authorize the communication of information to the parents or other decision maker. If such communication is made, the presenter will inform the patient before such communication is made.

f. Maryland law provides that minors who are sixteen (16) years old or older (“mature minors”) are capable of consenting as adults for consultation, diagnosis and treatment of a mental or emotional disorder by a physician, psychologist or a clinic (“mental health services”). However, the law further provides that although a parent/guardian/custodian may not override the consent of a mature minor to mental health services, a mature minor may not refuse to consent to mental health services for which his/her parent/guardian/custodian has consented. In other words, even if the mature minor says “no” to mental health services, if the parent says “yes” to mental health services, this is legally effective consent for the provider to render the mental health services.


4. Immunization for Minors:

a. Maryland law allows certain persons other than the parent or individual identified in Section G-1-a to consent for a minor’s immunizations under the following conditions:
• A parent may delegate the authority to consent, verbally or in writing, to an adult relative or any other adult who has care or control of the minor, whose name must be documented in the medical record.
• An adult who has had the authority delegated to them by the parent, and who has become the child care provider, may delegate to another adult, in writing or verbally, the authority to consent for immunization.
• The following individuals, not in order of priority, may consent to the immunization of a minor if the parent is not readily available, and the authority to consent has not been denied:
  • A grandparent;
  • An adult brother or sister;
  • An adult aunt or uncle;
  • A stepparent;
  • Any other adult who has care and control of the minor
  • A court, which has jurisdiction of a lawsuit affecting the parent-child relationship
• Minors may consent to the following immunizations:
  • Human papillomavirus
  • Hepatitis

5. Informal kinship care affidavit
   a. A relative providing informal kinship care (a living arrangement in which relative provides for the care and custody of the child due to serious family hardship) for a child may consent to health care on behalf of a child if:
      • A court has not appointed a guardian for the child or awarded custody of the child to an individual other than the relative providing informal kinship care; and
      • The relative verifies the informal kinship care relationship through a sworn affidavit (www.peoples-law.org/children/emancipation/kinship_care.htm) that is filed with the Department of Social Services Administration (a copy of the affidavit must be filed in the legal section of the medical record). This affidavit must be renewed annually.

H. Special Considerations
  1. Sterilization
     a. No sterilization will be performed on a patient under the age of 18 or adult patient who has been declared incompetent unless medically indicated and ordered by the court. Any competent adult, 18 years or older, shall give his/her own consent for sterilization; however, if the individual is a recipient of the State Medical Assistance Program, he/she must have reached the age of 21 years. Special consent forms must be used for Medical Assistance patients for:
        • Sterilization (tubal ligation, vasectomy);
        • Therapeutic abortion
        • Hysterectomy.
        • These forms may be obtained in the Department of Gynecology and Obstetrics.
  2. Abortion
     a. ADULTS: Before a prescriber performs an abortion, the woman undergoing the procedure shall be advised of:
        • Financial and other material assistance to carry the pregnancy to term
        • Financial and other material assistance available to raise and support her child, and
        • Resources to contact if assistance from a licensed and regulated adoption agency is desired.
        • Informed consent shall be obtained from the patient. No other approval or consent is necessary.
     b. MINORS:
• Married Minors: A married minor with proof of marriage may consent to an abortion in the same manner as an adult. No notice to the married minor’s parents is required, or allowed without the married minor's consent.
• Unmarried Minors: Physicians may not perform an abortion on an unmarried minor unless the physician first gives notice to a parent or guardian of the minor. The postal receipt, sent by Certified Mail, return receipt requested, bearing a post mark from the United States Postal Service, to the last known address and attached to the notice is sufficient for Evidence of Notice.
• Exceptions to Notice:
  • A physician may perform the abortion without giving notice to a parent or guardian if:
    1. The minor does not live with a parent or guardian, and
    2. A reasonable effort to give notice to a parent or guardian is unsuccessful
  • A physician may perform an abortion on a minor if in the professional judgement of the physician one of the following exists:
    1. Notice to the parent or guardian may lead to physical or emotional abuse for the minor;
    2. The minor is mature and capable of giving informed consent to an abortion; or
    3. Notification would not be in the best interest of the minor.
• If the physician desires to waive the notice requirement based on one of the exceptions listed above, the physician must document his/her judgement in the medical record in the Progress Note.

3. HIV Testing
   a. HIV Testing for the presence of HIV Infection requires informed consent:
      • Informed consent from the patient/decision maker must be obtained by the health care provider prior to obtaining a fluid or tissue sample for the testing for the presence of HIV infection.
      • Before obtaining a sample, the health care provider shall provide the individual with pretest counseling.
      • The health care provider shall document the verbal informed consent in the medical record, including information that the patient has had an opportunity to refuse to be tested, that consent was obtained, and that they will be informed of the results.
   b. HIV Testing After Exposure of a Health Care Provider:
      • Informed consent or substitute consent by a decision maker shall be sought prior to testing the patient’s blood for HIV when there has been exposure of a health care provider (See Appendix E).
      • If informed consent by the patient or consent by a decision maker to test the patient’s blood is sought and the patient/decision-maker is unavailable or unable to consent, a designated infectious disease/communicable disease officer shall order HIV testing and testing shall be done without informed consent and the attempts to obtain consent shall be documented in the medical record.
      • In the event the patient/decision maker refuses to give consent for HIV testing, a test can be performed on a previously drawn blood sample if:
        • The health care worker has followed appropriate procedure regarding reporting exposure
        • The designated infectious disease/communicable disease officer (HEIC Infectious disease or Occupational Health on call physician) determines that HIV testing would be helpful in managing the risk of disease and health outcome of the healthcare provider.
        • The patient/decision maker is informed of the provision to test as defined in Health-General 18-338.3.

I. Consents Concerning Deceased Patients
   1. Consent for postmortem examination (autopsy)
a. Prior to asking for consent for autopsy, determine if the death is a Medical Examiner’s case. If the case is a Medical Examiner’s case (Refer to ICPM Policy #ADT009), an authorized prescriber will notify the decision maker. Informed consent is not required and the body can be transferred to the Medical Examiner.

b. If the Medical Examiner will be signing the death certificate but will not be doing an autopsy, the next of kin shall be asked whether he/she would like a hospital autopsy. If the next of kin agrees to an autopsy, informed consent must be obtained (JHH Form 15-145-020).

c. In order to perform an autopsy at The Johns Hopkins Hospital, informed consent must be obtained by an authorized prescriber (JHH Form 15-145-020). The following individuals, in the specified order of priority, may give consent for autopsy if they have also assumed control of the body for its final disposition. Individuals in a particular class may be consulted to make the decision only if all individuals in the higher classes are incapacitated or unavailable.
   - The person's legal guardian (a copy of the document must be in the Legal section of the medical record)
   - The patient's spouse
   - An adult child of the patient
   - An adult brother or sister of the patient
   - A friend or other relative of the patient who has assumed responsibility for the body for its final disposition. If the Maryland State Anatomy Board assumes control of the body, consent shall be given by them.
   - The role of Health Care Agent/ Durable Power of Attorney ceases upon the death of the patient. The individual named in any such document may therefore not give consent for autopsy unless he/she is also the highest-ranking individual in the list above.
   - The Hospital will accept appropriately completed paperwork previously signed by the patient under the Uniform Anatomical Gift Act.

d. Consent shall be obtained after the patient has been declared dead.

e. Consent shall be obtained in person, via facsimile, by telegram, or by a recorded telephonic message.

f. The Autopsy Service accepts completed, signed consent forms by facsimile to the Admitting Office (410-502-5392).

g. The Autopsy Service accepts telegraphic consent through American Telegraph, collect to the Admitting Office. The telegram shall include the name and birth date of the deceased, any restrictions to the autopsy, the name and address of the consenter, and his/her relationship to the deceased. These requirements are on file with American Telegraph (1-800-343-7363).

h. Where there is disagreement about autopsy between two persons in the highest available class (see above), autopsy shall not be performed.

i. On cases released to the Hospital by the Medical Examiner, permission for postmortem examination is preferred but not required.

2. Consent for disposition of fetuses and neonates
   a. After the death of a fetus over 20 weeks gestation, a younger fetus with a fetal death certificate, or a baby less than one month old, the parent, guardian, or other next-of-kin must decide whether to assume full responsibility for the funeral arrangements or to give permission to the Maryland State Anatomy Board to perform the final disposition (cremation and burial of ashes).

   b. This decision shall be recorded on the Disposition Consent Form (JHH 15-145-050), which must be returned to the Admitting Office along with the death certificate, chart, and other paperwork.

   c. The patient must sign the consent form for disposal of the individual listed above.
3. Consent for Anatomical (Gift of Body) Donation
   a. Any individual who is 18 years or older and who is competent to execute a will may give all or any part of his/her body for any one or more of the purposes specified in the Maryland Anatomical Gift Act.
   b. When living persons wish to make a donation of this type, use JHH Form 15-145080. On the permission form, the Section for Next-of-Kin shall be noted as “Not Applicable” and the word “myself” is to be entered in the space for “relationship”. The patient, who must be 18 years of age, will then sign his/her own name in the space provided for legal signature. The form must be signed by the health care provider as a witness, countersigned by the Admitting Officer on duty, and filed in the patient’s medical record.
   c. Unless he/she has no knowledge that contrary directions have been given by the decedent, the following persons, in the order of priority stated, may give all or any part of the decedent’s body for any one or more of the purposes specified in the Maryland Anatomical Gift Act. If there is a controversy with a class the gift cannot be accepted.
      • The spouse, if one survives;
      • An adult son or daughter;
      • Either parent;
      • An adult brother or sister;
      • The guardian of the decedent at the time of his/her death;
      • A friend or other relative of the decedent, if the individual: (1) is a competent individual; and (2) presents with an affidavit similar to the one described above in III D.2 (a copy of the affidavit shall be placed in the legal section of the medical record).
      • Any other person or agency authorized or under obligation to dispose of the body.

4. Organ and Tissue Donation
   a. In compliance with Maryland State Law, all persons meeting the criteria of death or near death must be referred to the Maryland Donor Referral Line for consideration as a possible organ and/or tissue donor. The determination of donor medical eligibility can only be determined by the Living Legacy Foundation (LLF). The decision maker of each patient who meets the medical criteria of eligibility as a potential organ and/or tissue donors will be approached by LLF staff about the option of consent for donation.
   b. According to Maryland State Law the request for consent for organ donation must be a collaborative effort between the LLF and the physician. Physicians are not allowed by law to approach a family for the purpose of seeking consent for organ donation without the collaboration and support of the LLF. In compliance with the law, all requests for Organ and Tissue Donation are to be done by a “trained requestor”.
   c. Request for organ and/or tissue donation will be made by the LLF to the decedent’s decision maker via telephone after they have determined potential donor eligibility. Tissue consent will be documented by the LLF. The consent of the decedent’s decision maker is not necessary if the decedent’s driver’s license or identification card contains a notation that the decedent is an organ donor; or the decedent has consented to the gift of all or any part of the decedent’s body in accordance with the provisions of the Maryland Anatomical Gift Act or an advance directive containing a statement that the decedent consents to the gift of all or any part of his/her body for anatomical donation.
   d. Consent for organ donation may only be requested after it has been determined that a patient is brain dead (refer to ICPM Policy #MEL006-Organ Donation After Brain Death) or meets the criteria of potential organ donation following cardiac death (refer to ICPM Policy #MEL011-Organ Donation following Cardiac Death policy) or a family member expresses an interest in donation to the Johns Hopkins Hospital staff.
organ donation is documented on the consent form provided by the LLF and is the responsibility of the LLF staff. A copy of this form shall be placed in the patient’s medical record.

e. Authorization for removal of organs and tissues:
   • Authorization for removal of organs and tissues, from a living donor (JHH Form 15-145020), is to be completed by the Transplant Surgeon or his/her designated representative and the living donor.
   • Forms are available in the General Operating Rooms, Weinberg Operating Rooms General Recovery Room, Intensive Care Units, office of the Transplant Resident, Renal Dialysis Unit, and the office of the Transplant Coordinator.
   • If the decedent’s decision maker is unavailable, the Chief Medical Examiner, the Deputy Chief Medical Examiner or an assistant medical examiner may provide the organ on request of the LLF with assistance of the staff of the Johns Hopkins Hospital if:
     • The medical examiner has charge of a decedent who may provide a suitable organ for the transplant;
     • A reasonable, unsuccessful search for a decision maker has been made by the treating physician and the hospital in which the patient is located and LLF;
     • Efforts to locate a decision maker shall be well documented.
     • A patient advocate is assigned to the case to advocate on behalf of the patient in the context of their personal, cultural, religious and spiritual interests.
     • Removal of the organ for transplant will not interfere with the subsequent course of an investigation or autopsy

J. Clinical Investigation
   1. When the patient is a subject in an approved clinical investigation, informed consent must be obtained per the Institutional Review Board’s informed consent guidelines, unless the requirement is waived by the institutional review board. All clinical investigational studies must be approved by a Johns Hopkins Medicine Institutional Review Board. Human subject research applications must be submitted through an electronic system, eIRB. eIRB access is available through the JHIMIRB Web site (http://irb.jhmi.edu). Each project must have either an IRB approved study-specific consent form or have obtained a waiver of consent. The consent of parents of minors able to consent on their own behalf may or may not be required in any specific protocol in order for the minor to participate in the protocol (see Section G-2).
   2. All signatures on clinical investigation informed consent forms in the medical record shall be dated and timed.

K. Resources
   1. The Johns Hopkins Hospital Ethics Service and Committee (paging operator 5-4331 or pager 3-6104)
   2. The Johns Hopkins Health System Legal Department (5-7949, or paging operator 5-4331).

VI. REPORTABLE CONDITIONS
   Document in Patient Safety Net any failure to obtain informed consent for non-emergent procedures.

VII. DOCUMENTATION
   A. Document in medical record when surrogate decision making is to occur, including certification that patient is incapable of making informed decision regarding treatment.
   B. Document elements of informed consent on Hospital approved consent forms.

VIII. EDUCATION AND COMMUNICATION
   This policy will be communicated to the appropriate JHH personnel via the following channels:
1. Important aspects of the policy will be communicated via Medical Staff and Nursing publications.
2. Important aspects of the policy will be discussed at Risk Management seminars presented to physicians and nurses.
3. This policy will be placed in the Interdisciplinary Clinical Practice Manual on the JHH Intranet site http://www.insidehopkinsmedicine.org/icpm. Paper distributions will be made to the Functional Unit Nursing offices in the event of web access difficulty.

IX. SUPPORTIVE INFORMATION

See Also:
The Johns Hopkins Hospital, Interdisciplinary Clinical Practice Manual
- Advance Directives, MEL001
- Interpreting Services, PAS 002
- Organ Donation after Brain Death, MEL006
- Organ Donation following Cardiac Death, MEL011
- Patient, Procedure, and Site Verification and Timeout Policy, PAT 017
- Establishing Goals of Care MEL017

The Johns Hopkins Hospital, Corporate and Administrative Manual
- Patient Bill of Rights

References:
2. Centers for Medicare & Medicaid Services, CoP 42 CFR 482.13, 482.24, 482.51, Tags A-0049
3. Health General, section 18-336, 18-338.1 and 18-338.3

Sponsor:
- Risk Management Committee

Developer:
- Risk Management Committee
- Ethics Committee

Review Cycle - Three (3) years
Medical Board - Approval Date: 2/22/11; Effective Date: 3/1/11

Vice President for Nursing & Patient Services
Vice President for Medical Affairs

Date: ____________________________ Date: ____________________________