	POLICY: Informed Consent
Facility: Inova-wide	**Key Words:** Voluntary, benefits, risks, alternatives, waivers
Applies To: Clinical areas	
Policy Manual: Administrative	
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Approved by:	
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I. Purpose

This policy outlines the process of providing and documenting informed consent, including the elements to be shared and discussed with the patient and a list of the procedures, treatments and services requiring informed consent.

Separate policies should be consulted for Informed Consent requirements mandated by state law regarding Sterilization, HIV testing, Electroconvulsive Therapy, Participation in Human Research and Termination of Pregnancy.

II. Policy

1. Treating practitioners and Attending Physicians will obtain informed consent for specified surgeries, procedures and treatments from all adult patients and emancipated minors who have the capacity to participate in the process of making decisions about their own care and treatment (refer to the addendum Treatments, Procedures, Operations Requiring Informed Consent as needed).

2. For unemancipated minors and patients who are deemed incapable or incompetent to participate in their own decision-making, the practitioner will generally obtain informed consent from their designated decision-maker. However, an unemancipated minor may consent in certain limited situations (see Procedure section IV.D - Patient Capacity, Minor Patients, and Designated Decision-Makers).

III. Applies to

Clinical areas

IV. Definition of Terms

Attending Physician	The attending physician is the physician treating either inpatients or outpatients who orders a procedure or test requiring informed consent under this policy and has the same privileges as the treating practitioner to perform the procedure or test.
Benefits	The outcomes expected from the proposed surgery, procedure, or treatment to stabilize, ameliorate, palliate or improve the patient's medical condition.
Best Interests	The standard to be used by designated decision-makers to guide health care decisions when the patient's specific values and wishes are unknown. The designated decision-maker in consultation with the health care team utilizes this standard to determine the interventions most likely to produce the optimal outcomes for patients. The designated decision-maker must also take into account the patient's cultural, ethnic and religious beliefs, if known.
Designated Decision-Maker	The person designated under the laws of the Commonwealth of Virginia to make decisions for the patient in the event that the patient lacks capacity to make decisions for him/herself. The designated decision-maker relies on previous preferences for treatment expressed by the patient or, in the absence of information on the patient's preferences, on the best interests of the patient, to guide decisions. The hierarchy of designated decision-makers is listed in Procedure section IV.F - Patient Capacity, Minor Patients, and Designated Decision-Makers
Decision-Making Capacity	A clinical determination which must be diagnosed and certified in writing by the patient's attending physician and a second physician or a licensed clinical psychologist who was not previously involved in the patient's care after personal examination of the patient. Decision-making capacity for health care decisions has four major elements: • **Understanding:** The patient or designated decision-maker must be able to understand the known benefits and risks of the recommended surgery, procedure, or treatment options, as well as any reasonable alternative options including no treatment. Understanding may be enhanced with the use of a certified interpreter and a variety of teaching materials/media. • **Appreciating:** The patient or designated decision-maker must be able to appreciate the nature and expected consequences of each health care decision. • **Formulating:** The patient or designated decision-maker must be able to formulate a judgment. • **Communicating:** The patient or designated decision-maker must be able to communicate a clear decision concerning

	health care. Patients may have physical or mental disabilities that limit their ability to participate in the process of decision-making as they may preclude communication or impair judgment (examples include mental retardation, dementia, lack of consciousness). For purposes of this policy, patients who are deaf, dysphasic, or have other communication disorders, who are otherwise mentally competent and able to communicate by means other than speech, shall be considered capable of making an informed decision.
Emancipated Minor	An individual at least 16 years of age but less than 18 years of age who has been emancipated by a court order. Emancipated minors are treated as adults for the purpose of giving informed consent. The emancipated minor must provide the order of court or the identification card issued by the Department of Motor Vehicles stating that said minor is emancipated. Any minor who is married or has been married shall be treated as an adult for informed consent purposes, regardless of emancipation status, except for the purposes of sexual sterilization.
Risks	The possible undesirable outcomes of the proposed surgery, procedure or treatment including side effects, complications, serious social or psychological harms or other adverse outcomes.
Treating Practitioner	The practitioner who will be performing the proposed surgery, procedure or treatment and who has approved clinical privileges to perform the proposed surgery, procedure, or treatment. If the treating practitioner is not the attending physician, the process for informed consent may involve consultation and advice to the patient or designated decision-maker from the attending physician. Residents and Fellows working under the supervision of the treating practitioner or attending physician may obtain informed consent.

V. Expected Outcomes

Health care providers will obtain informed consent from patients / designated decision-makers in accordance with Virginia law.

VI. Procedure

I. Informed Consent Process

A. The patient or designated decision-maker will be informed by the treating practitioner or the attending physician of:
   1. The nature of the patient's condition and the nature of the surgery, procedure, or treatment to be performed;
   2. The benefits that can reasonably be expected from the surgery, procedure or treatment to be performed;
   3. The nature and probability of the risks involved in the surgery, procedure, or treatment considering the patient's total physical condition, including any side effects.
      a. The type and number of risks to be disclosed should depend on the significance that the patient would attach to such risks in deciding whether to consent to the surgery, procedure or treatment.
      b. The patient's values, overall goals for treatment and cultural background may influence his/her consideration of risks;
   4. The likely result of the surgery, procedure or treatment; the likelihood of the patient achieving his/her goals; and any potential problems that might occur during recuperation.
   5. Available alternatives to the surgery, procedure or treatment including benefits, risks, and side effects, for each alternative;
   6. The likely outcome if the surgery, procedure or treatment is not performed;
   7. Any circumstances under which information about the patient must be disclosed or reported (such as reportable diseases).
   8. What treatment will continue to be provided if the patient exercises his/her right to refuse the proposed surgery, procedure or treatment; and
   9. Surgical patients or their decision-maker shall be informed of the following:
      a. When practitioners other than the primary surgeon (including but not limited to residents) will perform important parts of the surgery;
      b. Other practitioners will have the appropriate skill sets to participate in the procedure and will be under the supervision of the primary surgeon.
      c. The patient may obtain the names of all who participated in their procedure by requesting a copy of his/her medical record.
      d. How photographs will be identified, utilized, and stored;
      e. When and why a vendor or medical equipment representative may be present during surgery;
      f. How recovered tissues, body parts, or organs may be used for scientific research or disposed of.

B. The treating practitioner or attending physician will:
   1. Determine that the patient has sufficient capacity to understand the information and to make an informed decision (see Procedure section IV – Patient Capacity, Minor Patients, and Designated Decision-Makers);
   2. Complete the appropriate informed consent form (if one is available for the surgery, procedure, or treatment) with his/her signature and the patient or decision-maker's signature before the surgery, procedure, or treatment is performed. A copy of the signed consent is acceptable if consent was obtained at a prior time.

3. If an appropriate informed consent form is not available or is not completed, document in the medical record:
    a. The names of those present for the discussion.
    b. The content of the discussion.
    c. That the patient or designated decision-maker was offered the opportunity to ask questions and request additional information, and that all questions were answered and requested information was provided.
    d. That the patient or designated decision-maker expressly consented to the proposed surgery, procedure or treatment.
4. Disclose any potential conflicts of interest related to research and economic interests related to the proposed surgery, procedure or treatment. (Professional fees do not require disclosure.)

C. The staff will:
1. Review the informed consent form for completion including the signatures of the patient or designated decision-maker and the practitioner performing the procedure or treating the patient;
2. Place the informed consent form in the appropriate section of the patient's medical record (in the case of surgery, it should be placed in the patient's medical record prior to surgery, except in emergencies);
3. Witness a signature (if requested) by either observing the patient/decision-maker sign the form or, if the form has already been signed, by asking the patient/decision-maker to verify that the signature on the form is theirs and their question(s) were addressed.
4. Note on the Boarding Pass (for surgical patients) that the signed informed consent form is in the medical record.
5. Refer to their supervisor for resolution of any concerns regarding the informed consent. If the supervisor cannot resolve the concern, contact Risk Management (Pager # 77475 on weekends, evenings, nights).

II. Scope

A. The scope of informed consent may be limited to a one-time, single surgery, procedure, or treatment, or may encompass consent for routine care for chronic conditions, or for a series of treatments as decided by the practitioner and patient or their designated decision-maker. Patients or their designated decision-makers may refuse recommended treatments. The scope of informed consent also includes providing a full range of information regarding discharge planning (refer to the Discharge Planning, Multidisciplinary Team policy as needed). When the proposed plan of care involves multiple or recurrent surgeries, procedures, or treatments, it may not be necessary to repeat the process of informed consent for each treatment. Risk Management may be consulted if there is a question about obtaining consent. (Refer to the addendum Treatments, Procedures, Operations Requiring Informed Consent as needed.)

B. The informed consent discussion should be repeated and a new consent shall be obtained when:
1. There is a significant deviation from the treatment plan to which the patient originally consented; or

2. There is a change in the patient's condition or diagnosis that should reasonably be expected to alter the original informed consent.

C. For a single surgery, procedure and/or treatment, the consent is valid for 30 days from date of signature.

D. For a series of treatments documented on the form with date range and for blood transfusions, consent is valid for 180 days for the same admission or outpatient course of treatment.
   1. A new blood consent must be obtained if the reason for the blood has changed from the original consent.
   2. A single informed consent may cover multiple transfusions over the course of an inpatient admission, to include transfer to another operating unit (OU) if:
      a. they are part of a single course of treatment, ***and***
      b. the consent is in the electronic health record (EHR) or available on the unit.
   3. A single informed consent may cover multiple outpatient transfusions if:
      a. they are part of a single course of treatment, ***and***
      b. the consent is in the electronic health record (EHR) or available on the unit

III. Revocation of Consent

The patient or designated decision-maker may revoke a prior consent, even if that decision may increase the risk of serious illness or death, without prejudice to the patient's access to future health care. If the treating practitioner or attending physician disagrees with the patient's or designated decision-maker's decision to revoke consent, he/she should consult the Risk Manager and Ethics Committee for advice.

IV. Patient Capacity, Minor Patients, and Designated Decision-Makers

A. Patients including adults over the age of 18 and emancipated minors under the age of 18 have the legal and ethical right to consent to or refuse proposed surgeries, procedures and/or treatments.

B. In relation to decision-making capacity, "competency" is a legal determination made by a court of law, that a patient has the requisite capacities to make a medical decision. This is in contrast to the term "decision-making capacity", which is a clinical determination made by the physician and/or licensed clinical psychologist.

C. General exceptions for capacity are as follows:
   1. For persons deemed incompetent by a court of law, health care decision-making power is vested in the appointed guardian.
   2. For unemancipated minors, the parent(s), guardian or court holds decision-making authority, depending on the circumstances. (The Informed Consent – Minors policy provides guidance. If there is a question as to who may give consent or if there is a dispute between parents, consult Risk Management.)

D. In the following situations, an unemancipated minor is considered to be an adult for the purpose of consent and thus it is not necessary to obtain parental/guardian consent for:
   1. Medical or health services needed to determine the presence of or to treat sexually-transmitted diseases or any infectious or contagious disease that the State Board of Health requires to be reported;
   2. Medical or health services required in case of birth control, pregnancy or family planning except for the purpose of sexual sterilization;
   3. Medical or health services needed in the case of outpatient care, treatment or rehabilitation for substance abuse;
   4. Medical or health services needed in the case of outpatient care, treatment or rehabilitation for mental illness or emotional disturbance;
   5. Any minor who is or has been married, except for the purposes of consenting to sexual sterilization;
   6. A pregnant minor may consent for herself and her child to surgical and medical treatment relating to the delivery of her child when such surgical or medical treatment is provided during the delivery of the child or the duration of the hospital admission for the delivery.
   7. After the delivery of her child, a minor mother may consent to surgical and medical treatment of her child.
   8. Parental consent to donate blood by any minor 17 years of age is not required so long as the minor receives no payment or other consideration for his/her blood donation and the procurer of the blood is a non-profit, voluntary organization.

E. If the patient who lacked decision-making capacity regains decision-making capacity, then the patient will make decisions for his/her care.

F. The hierarchy of designated decision-makers as outlined by Virginia law is:
   1. Legal guardian or agent appointed by advance directive/durable power of attorney (DPOA) for health care decisions;
   2. Patient's spouse (except when a divorce action has been filed);
   3. Adult child of patient;
   4. Parent of patient;
   5. Adult brother or sister of patient;
   6. Any other relative of the patient in descending order of blood relationship.
   7. Except in cases in which the proposed treatment recommendation involves the withholding or withdrawing of a life-prolonging procedure, any adult who qualifies may be a decision maker.
      a. The adult must be someone who:
         i. Exhibits special care and concern for the patient and
         ii. Is familiar with the patient's religious beliefs and basic values and any preferences previously expressed by the patient regarding health care, to the extent that they are known.
      b. The adult may not be any director, employee, or agent of a health care provider currently involved in the care of the patient.
   8. If such a person is available, the patient care consulting committee of the Ethics Committee shall determine whether this person meets the criteria and shall document the information relied upon in making such determination.

G. If two or more of the designated decision-makers in one class with equal decision-making priority inform the attending physician that they disagree as to a particular treatment decision, the attending physician may rely on the authorization of a majority of the reasonably available members of that class. The attending physician should consult the Risk Manager and Ethics Committee to help resolve disputes as appropriate.

H. In order to facilitate emotional support during hospitalization, the patient may select one to two (1-2) adult Patient Care Companions (PCC) to function in a supportive role during the patient's hospitalization.
   1. The PCC is primarily a supportive role to the patient.
   2. The PCC is not a medical decision-maker unless the PCC also is the agent appointed by advance directive/medical power of attorney (POA) for that patient or is the next of kin as outlined in the hierarchy above in Procedure section IV.F.

I. Substituted Judgment is the standard to be used by the patient's designated decision-maker who has specific knowledge of the patient's values and preferences for health care treatment. This standard requires that the designated decision-maker make decisions based on what the patient would have wanted if he or she were capable of expressing their preferences and the patient's best interests. That decision may not necessarily coincide with what the designated decision-maker and the health care team otherwise would consider optimal for the patient.

J. Telephone consents may be obtained from a designated decision-maker who is not immediately available to sign the consent form and when delay of care may cause potential harm to the patient. One licensed clinician can listen to the consent over the phone and sign the form on the TELEPHONE CONSENT line of the form. Staff may witness a signature by either listening to the telephone conversation as the licensed clinician obtains informed consent or by calling back and asking the patient/decision-maker to verify that the consent discussion occurred and/or signature on the form is theirs.

K. If, after a good faith and reasonable effort, none of the aforementioned designated decision-makers can be contacted and the patient is incapable of making an informed treatment decision, the treating practitioner or attending physician should document this information in the medical record. For additional consultation and to facilitate decision-making, the treating practitioner or attending physician should contact the Risk Manager. The Risk Manager will evaluate the situation, assess the urgency, and coordinate legal services as necessary. In all cases, efforts should continue to locate a designated decision-maker. Emergent care needs will be provided as appropriate. For urgent care, a court order and/or the appointment of a legal guardian to make medical decisions for the patient may be sought.

V. Exceptions to Obtaining Informed Consent

A. Patient Request – A patient may request that he/she not be informed of the risks, etc. of a particular surgery, treatment or procedure. The treating practitioner or attending physician should fully document in the medical record:
   1. That the patient has decision-making capacity;

2. The patient's request and reason for request;
3. What, if any, information was disclosed to the patient; and
4. The name and contact information of the person that the patient has designated as his/her decision-maker and that the person has agreed to be the decision-maker. The treating practitioner or attending physician should continue to inquire if this remains the patient's choice. Family members may not ask that the patient not participate in the informed consent process unless the patient agrees. If there is a conflict regarding disclosure, the treating practitioner or attending physician should consult the Ethics Committee.

B. Emergency Care/Treatment

1. When, in the reasonable judgment of the treating practitioner or attending physician, a delay in treatment would likely result in imminent harm to the patient and the patient is unable to give informed consent, the law recognizes an exception to the requirement for obtaining informed consent, provided the following conditions are met:
   a. If the patient is unable to consent and has a designated decision-maker available, the treating practitioner or attending physician shall obtain the informed consent from the designated decision-maker when informed consent cannot be obtained from the patient, ***or***
   b. Informed consent cannot be obtained in a timely manner, ***and***
   c. The treating physician or attending physician, using his/her reasonable judgment, determines that a delay in obtaining consent would likely result in imminent harm to the patient.
2. Whenever delay in providing medical or surgical treatment to a minor may adversely affect such minor's recovery and no person authorized to consent to such treatment for the minor is available within a reasonable time under the circumstances, the law recognizes an exception to the requirement for obtaining informed consent, but states that in the case of a minor 14 years of age or older who is physically capable of giving consent, such consent should be obtained first.
3. The emergency exception to the requirement of informed consent does not extend to a conscious, capable adult patient who is able to give his/her own informed consent and who has refused to consent to a surgery, procedure or treatment.
4. The need for immediate treatment should be documented in the patient's medical record. The documentation should include all information establishing the nature, immediacy and magnitude of the problem, and the fact that informed consent either could not be obtained or could not be obtained in a timely manner. All notes should also show the date and time that these determinations were made.
5. Questions regarding whether the emergency exception described above is applicable may be referred to Risk Management to facilitate the informed consent and decision-making processes. Options for resolution may include a court order to treat and/or the appointment of a legal guardian to make health care decisions for the patient.
6. If the patient has AND/DNAR or DDNR status, consult the AND/DNAR/DDNR policy for guidelines.

C. Research Protocol Patients

The informed consent for participation in a research study protocol may substitute for the standard written informed consent. Consult the applicable Institutional Review Board (IRB) Consent Policy for detailed information.

Related Attachments

- Informed Consent Form – Surgical Patients
- Informed Consent Form – Nonsurgical Patients
- Informed Consent Form – Blood / Blood Product Transfusions
- Addendum – Treatments, Procedures, and Operations Requiring Informed Consent
- Addendum – Informed Consent Process Flowchart