UNIVERSITY of VIRGINIA HEALTH SYSTEM

Clinical Staff Executive Committee

MEDICAL CENTER POLICY NO. 0024

A. SUBJECT: Informed Decision-making

B. EFFECTIVE DATE: October 1, 2013 (R)

C. POLICY:

Patients 18 years of age or older who are capable of making an informed decision shall provide consent to healthcare for themselves. A patient is capable of making an informed decision when the patient is able to demonstrate an understanding of the nature, extent and probable consequences of a proposed medical decision or is able to make a rational evaluation of the risks and benefits of a proposed medical decision as compared with the risks and benefits of alternatives to that decision.

No examination or demonstration shall be done solely for teaching purposes (no discernible therapeutic or diagnostic benefit) unless the patient has consented to the specific examination or demonstration.

The attending physician proposing a treatment plan or procedure or his/her designee is responsible for obtaining consent prior to provision of care. The attending physician is responsible for explaining the outcome of any treatment or procedure once care has been provided.

D. PROCEDURE: (See also Summary Flow Charts, Figures 1 and 2, which are attached).

1. Informed consent shall be obtained before the initiation of care or treatment that poses a risk of harm greater than that ordinarily encountered during the performance of routine physical or psychological examinations, tests or treatments. Such situations include all procedures performed in the operating room, all procedures under anesthesia or moderate/deep sedation, and invasive procedures performed outside of the operating room where there is more than minimal risk to the patient.

   Attachment A is a listing of those procedures which require the completion of an approved consent form. A properly executed informed consent form contains documentation of a patient's or surrogate decision maker's understanding of and agreement for care, treatment, or services through written signature, electronic signature or, when a patient or surrogate decision maker[1] is unable to provide a signature, documentation of verbal agreement by the patient or surrogate decision maker written on the consent form itself.

   When a surrogate decision maker is not physically present to provide a signature and consent is sought by telephone, the telephone conversation must be witnessed by a practitioner or staff

[1] "Surrogate decision maker" has the same meaning as such terms as "legal representative", "patient's authorized agent", "healthcare agent", and "legally authorized representative" appearing in other Medical Center policies.

member working within the Medical Center. This person signs the consent in the appropriate place and is witnessing that the conversation took place and the name of the person providing consent for the patient.

Documentation of the telephone conversation and the surrogate's consent must be written on the consent form itself. The consent form must then be placed in the patient's record.

Consent for abortion and non-therapeutic sterilization must be authenticated consent from the patient. Surrogate decision makers do not have authority to consent to these procedures/treatments. Virginia law does not allow verbal consent for these procedures/treatments.

Consent for electroconvulsive therapy (ECT) must be authenticated consent from the patient or surrogate decision maker. Virginia law does not allow verbal consent for ECT.

Procedures to obtain consent for patients participating in human subject research must be approved by the Institutional Review Board for Health Sciences Research (IRB-HSR) as part of the protocol review process. See http://www.virginia.edu/vpr/irb/hsr/

Individual clinicians or departments may choose to use a form to obtain informed consent for other procedures or treatments not listed in Attachment A. In those situations, the form should include the patient or surrogate's written signature, electronic signature or, as specified above, when a patient or surrogate decision maker is unable to provide a signature, documentation of verbal agreement by the patient or surrogate decision maker written on the consent form itself.

2. In seeking informed consent from patients, the attending physician or his/her designee shall provide:

   a. an explanation of the nature and purpose of the proposed actions(s) to be taken and the benefits, risks and consequences of the proposed action(s), including the likelihood of success of achieving goals and potential problems that might occur during recuperation;

   b. a discussion of benefits, risks and consequences of alternatives to the proposed action(s) and the benefits, risks and consequences if no treatment or an alternative treatment is rendered;

   c. the name of practitioner(s) performing the procedure/treatment and, when indicated, an explanation that other qualified practitioners, including residents, may perform important tasks related to the surgery within the scope of their practice and for which they have been granted clinical privileges;

   d. as appropriate, a discussion of any limitations on the confidentiality of information learned from or about the patient;

   e. an offer to answer inquiries and an explanation of how questions and concerns can be raised; and

   f. notification that the individual is free to refuse or withdraw his or her consent

3. When documenting consent for procedures involving laterality the terms “Right”, “Left” or “Bilateral” shall be used. Use of abbreviations (i.e., “R”, “L”, or “B”) is prohibited.

4. When obtaining patient consent for a clinical procedure, the patient shall be informed of the presence and role of any vendors, sales or service representatives during the performance of the procedure. The procedure consent form shall include this disclosure. (See Medical Center Policy No. 0013 “Vendors, Sales and Service Representatives”)

5. Patient consent shall also be obtained when photographing, recording or filming will occur for purposes other than the identification, diagnosis or treatment of the patient. (See Medical Center Policy No. 0030 “The Use of Cameras and other Electronic Devices and Media”)

6. Procedures for obtaining consent from patients who are under the age of 18 (“minors”) are set out in Attachment B.

   When a parent of a minor or surrogate decision maker is not physically present to provide a signature and consent is sought by telephone, the telephone conversation must be witnessed by a practitioner or staff member working within the Medical Center. This person signs the consent in the appropriate place and is witnessing that the conversation took place and the name of the person providing consent for the patient.

7. An adult patient is “incapable of making an informed decision” when the patient is unable to understand the nature, extent and probable consequences of a proposed healthcare decision or is unable to make a rational evaluation of the risks and benefits of a proposed medical decision as compared with the risks and benefits of alternatives to that decision, or is unable to communicate such understanding in any way. (see Summary Flow Chart, Figure 1) If two physicians or one physician and one clinical psychologist have, upon personal examination determined that a patient is incapable of making an informed decision for a specific course of treatment, the procedures set out in Figure 2 shall be followed. The second physician or psychologist shall not be otherwise involved in the treatment of the patient, unless such an independent physician or psychologist is not reasonably available.

   The second capacity assessment is **not** required if the patient is unconscious or experiencing a profound impairment of consciousness due to trauma, stroke, or other acute physiological condition.

8. If the patient is determined to be incapable of making an informed decision, the patient shall be notified, as soon as practical and to the extent he/she is capable of receiving such notice, that such determination has been made before providing, continuing, withholding or withdrawing health care. The patient's healthcare agent shall also be notified as soon as practicable.

9. When a patient has not appointed a healthcare agent in an Advance Directive, the individuals set out in Figure 2, in the order of priority specified, may authorize healthcare decisions for the patient.

10. After review and approval by the Patient Care Consulting Subcommittee:

    a. an adult who: (a) has exhibited special care and concern for the patient and (b) who is familiar with the patient’s religious beliefs and basic values and any preferences previously

expressed by the patient regarding healthcare may authorize healthcare decisions for the patient.

b. an adult approved under this provision shall **not** be authorized to make decisions in which the proposed treatment recommendation involves the withholding or withdrawing of a life-prolonging procedure.

c. an adult may not be approved under this category if there is a willing and capable individual in a higher priority class.

11. A single physician may at any time, upon evaluation of the patient, determine that a patient who has been previously determined to be incapable is now capable of making an informed decision.

12. If a patient who lacks capacity to make an informed decision protests the authority of an agent, except for an appointed guardian, the agent shall have no authority for decision making unless an advance directive explicitly confers decision-making authority even over a later protest. Otherwise, decision making would be determined as noted in Figure 2.

13. When an emergency procedure is medically indicated, informed consent, consistent with the requirements of Paragraph 1 above, shall be obtained unless time and circumstances required to obtain such consent will jeopardize the patient's health. An emergency procedure is medically indicated when a delay in providing medical or surgical treatment will likely cause death, disability or a serious irreversible condition. Such medical emergencies shall be documented in the patient's chart along with a statement that the harm from failure to treat is imminent.

14. When the consent obtained contemplates, at the time such consent was obtained, a series of the same procedures, written consent need only be obtained once every six months for all procedures contemplated. Should additional operative procedures be required that were not contemplated at the time consent was obtained, a new written informed consent form must be obtained.

15. Once medical care and/or treatment has been provided, the attending physician shall discuss with the patient and/or their representative the outcomes and implications of that care. When discussing the outcome of treatment with patients and families, the physician shall also discuss any unanticipated outcomes (i.e., unanticipated modifications or variances in the care and/or treatment of the patient) whenever those outcomes differ significantly from the anticipated outcomes.

16. For further guidance on discussions of the outcome of treatment, see Medical Center Policy No. 0293 "Disclosure of Outcomes"; additional information and/or guidance regarding informed consent and disclosure of outcomes may also be obtained from the Patient Safety & Risk Management Office in the Quality and Performance Improvement Department.

(SUBJECT: Informed Decision-making)

SIGNATURE:

Robert S. Gibson, M.D., President, Clinical Staff

R. Edward Howell, CEO, UVA Medical Center

DATE: 9/24/13

Medical Center Policy No. 0024 (R)
Approved March 1984
Revised August 1987, September 1993, September 1996, October 1999, November 2002, December 2003, June 207, June 2008, February 2009, June 2009, June 2010, March 2011, September 2011, September 2012, September 2013
Approved by Quality Committee
Approved by Clinical Staff Executive Committee

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Figure 1: Summary Flow Chart
Does the patient have the capacity to make his or her own health care decision?

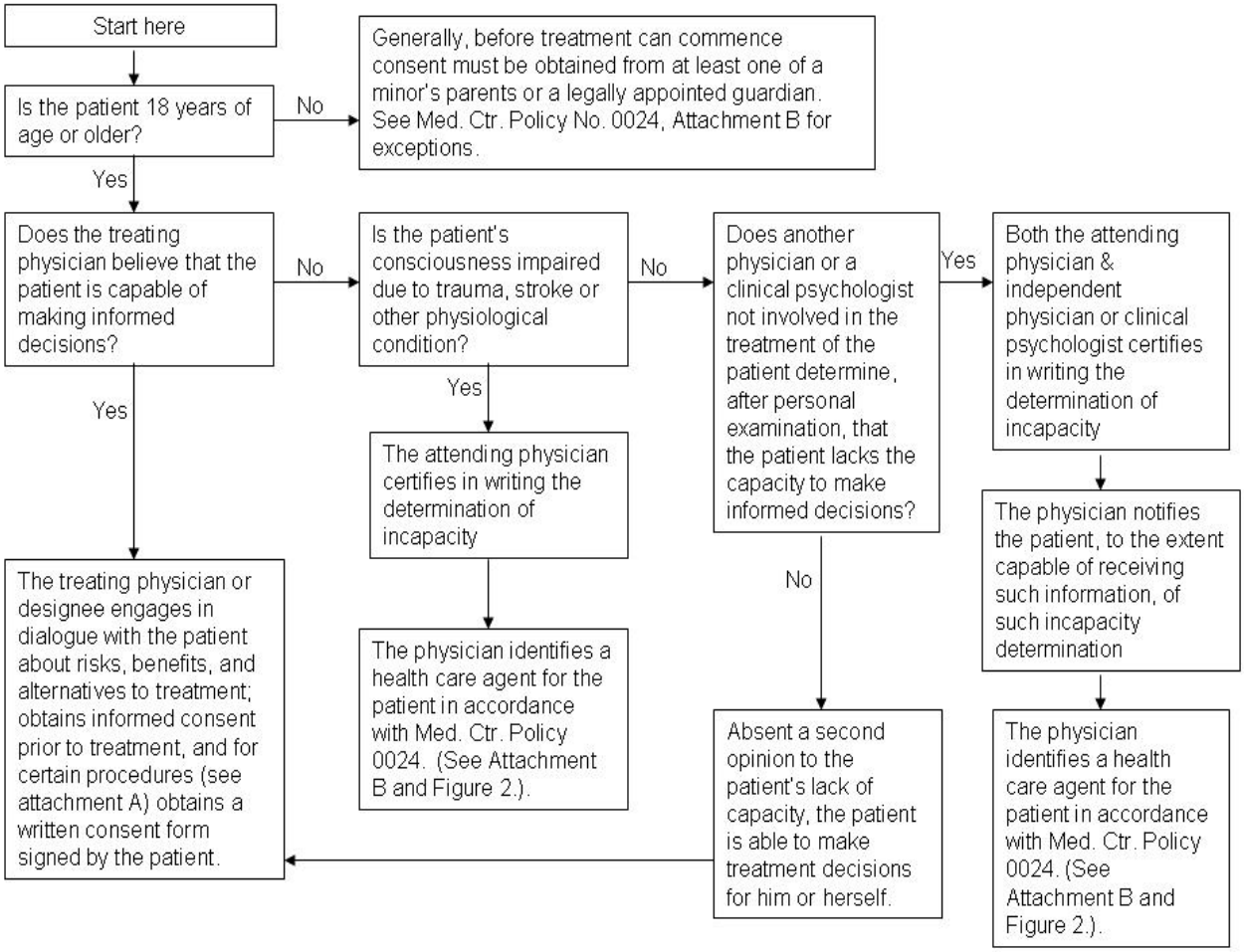

Exhibit OO12.bm

Figure 2: Summary Flow Chart
How are Health Care Decisions Made for the Adult Patient Lacking Capacity?

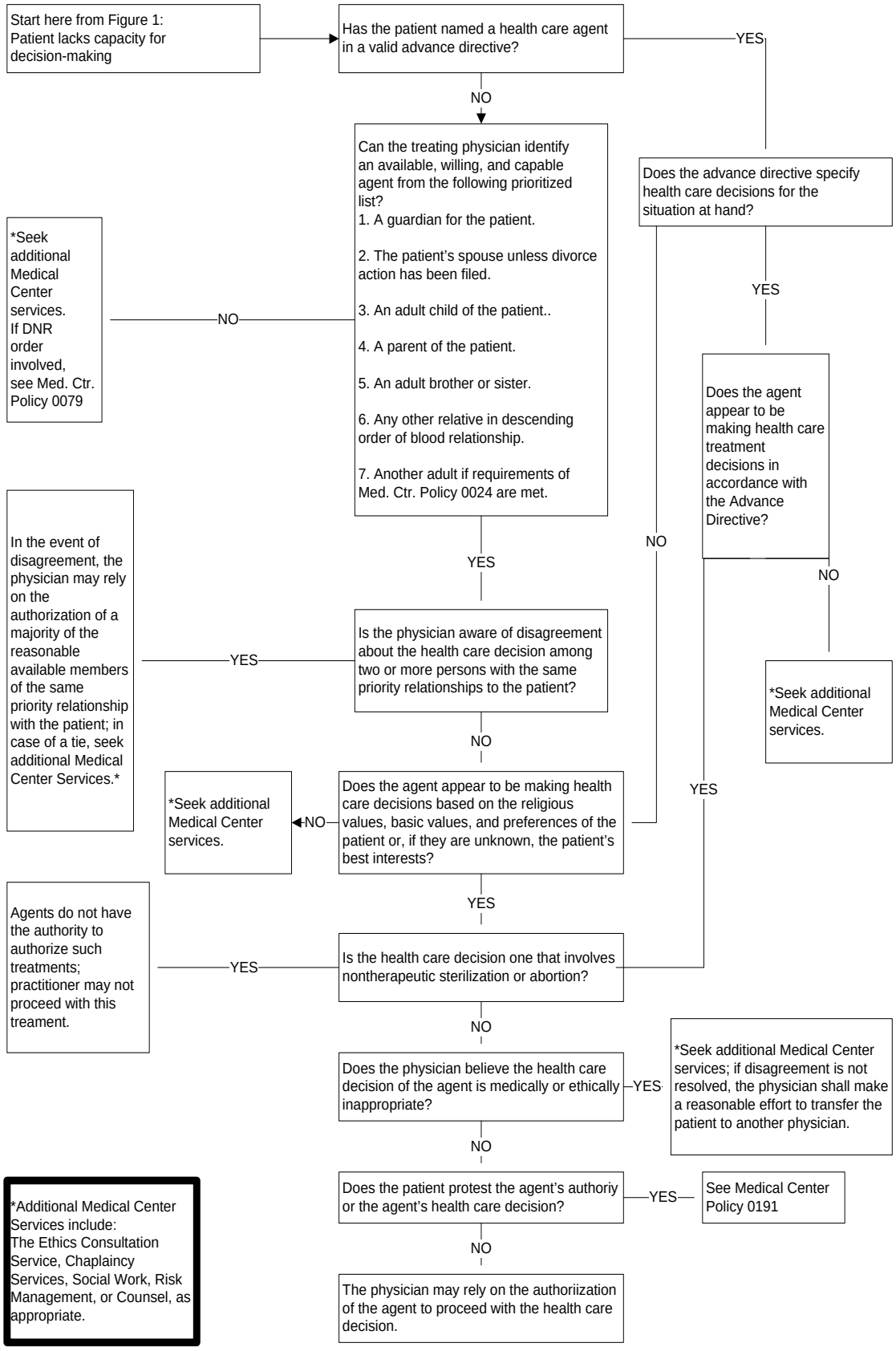

Exhibit OO12.bm

Attachment A

Informed consent forms shall be used for all of the procedures/treatments below.

CARE/TREATMENT	COMMENTS
1. Abortion	Consent required by Virginia law – VA Code 18.2-76 (Written signature required, Verbal consent not acceptable).
2. Anesthesia - Use of general, spinal and/or epidural	Consent may be documented in conjunction with procedure consent documentation.
3. Blood and blood product use	• A transfusion episode for an inpatient is defined as the total number of transfusions of blood and blood components administered during a single hospitalization. • In the case of ongoing administration of blood or blood components in an outpatient setting, informed consent must be obtained at reasonable intervals as defined by the attending physician. • Informed consent for transfusion must be obtained again if a new infectious agent, transmissible by transfusion, poses new risks, as defined by the Transfusion Committee and/or Infection Protection and Control Committee • Previously signed consent for outpatient transfusion for a particular disease or disorder will suffice for blood products administered during a hospitalization for the same diagnosis if a copy of a previously signed consent form is available on the inpatient record prior to the time of transfusion.
4. Cancer Chemotherapy	For patients receiving chemotherapeutic agents for the treatment of neoplasm.
5. Cardiac Catheterizations and Angiography	No additional requirements.
6. Dialysis – Extracorporeal and peritoneal	Consent obtained at initiation of service.
7. Electroconvulsive Therapy (ECT)	Consent required by Virginia law. – 17 VAC 35-115-70 (Written signature required, Verbal consent not acceptable).
8. Investigational Procedures/Drug Studies and other human research studies	Study and consent or waiver of consent process must be approved by the Institutional Review Board for Health Sciences Research (http://www.virginia.edu/vpr/irb/hsr/).
9. Non-therapeutic Sterilization	• Consent required by Virginia law – VA Code 54.1-2974, 54.1-2975 and 2976 (Written signature required, Verbal consent not acceptable). • Medicaid patients must be 21 years of age and there is a 30 day waiting period. • A court order is required to perform this procedure on minors 14-18 years of age and on mentally incompetent adults.
10. Radiation Therapy	No additional requirements.
11. Radiology – Invasive Procedures	Invasive is defined as a procedure in which a sharp object, other than an IV, penetrates tissue (i.e., biopsy, angiogram, myelogram).
12. Procedures performed under general/spinal and regional anesthesia and moderate sedation	No additional requirements.
13. Sedation - Use of moderate or deep sedation associated with a diagnostic or therapeutic procedure	Consent may be documented in conjunction with procedure consent documentation.

Attachment B

Healthcare practitioners should discuss with each patient, regardless of the patient's ability to provide consent, the care and treatment that will be provided.

Patient Under the Age of 18

General rule, unless exceptions below apply.	Consent must be obtained from at least one of a minor's biological or adoptive parents or a legally appointed guardian.
Minors who have decision-making capacity can give consent for certain treatment	* Medical or health services needed to diagnose or treat venereal disease or other infectious/contagious disease that is reported to the Virginia Dept. of Health. * medical or health services required in the case of birth control, pregnancy or family planning except for sexual sterilization. Consent for abortion must be obtained as required by Virginia law. * Medical or health services needed for outpatient care, treatment or rehabilitation of substance abuse. * Medical or health services needed for outpatient care, treatment or rehabilitation for mental illness or emotional disturbance.
Minors who have decision-making capacity and are married	Consent for all treatment for themselves.
Emancipated minors who have decision-making capacity	Upon presentation of a court order documenting emancipation, can provide consent for all treatment for themselves.
Pregnant minors who have decision-making capacity	Consent for hospital admission and all treatment for themselves and her child provided during the delivery of the child. Consent to subsequent surgical and medical treatment for the child.