Subject: Procedure for Determining the Health Care Decision-Maker for Research

Procedure:
This procedure outlines the responsibilities of the Institutional Review Board (IRB) and the Investigator in the approval and appropriate utilization of a Health Care Decision-Maker in the context of research.

I. Specific Terminology Associated with Health Care Decision-Maker.

A. Health Care Decision: A decision made by or on behalf of a patient regarding the patient's health care, including but not limited to:
   1. The selection and discharge of health care providers and institution;
   2. Approval or disapproval of diagnostic tests, surgical procedures, programs of administration of medication, and orders not to resuscitate;
   3. Directions to provide, withhold or withdraw artificial nutrition and hydration and all other forms of health care; and/or
   4. Transfer to other health care facilities.

B. Health Care Decision-Maker (HCDM): For patients that are either incompetent or lack decision-making capacity, the HCDM is one of the following in order of priority:
   1. The patient’s health care agent, as specified in the patient’s Durable Power of Attorney for Healthcare; or
   2. The patient’s court-appointed legal guardian or conservator with health care decision-making authority; or
   3. The patient’s Health Care Decision-Maker determined in accordance with this Procedure and VUMC Operations Policy 20-10.08.

C. Incompetent: Refers to a patient who has been adjudicated incompetent by a court of competent jurisdiction and who has not been restored to legal capacity.

D. Lack of Decision-Making Capacity: A patient demonstrates a lack of decision-making capacity when the patient’s attending physician and another physician factually demonstrate that the patient is unable to understand:
   1. A proposed health care procedure, treatment, intervention, or interaction;
   2. The risks and benefits of such procedure, treatment, intervention or interaction; and
   3. The risks and benefits of any available alternative to the proposed procedure, treatment, intervention or interaction.

D. Institutional Ethics Committee: A committee of a licensed health care institution, which renders advice concerning ethical issues involving health care. For Vanderbilt, the Clinical Ethics Consultation Service performs as the Institutional Ethics Committee.

E. Surrogate Consent Rider: An addendum to an informed consent document to obtain consent from a designated HCDM.

II. Investigator Responsibilities.

A. IRB Approval.
   1. New studies. The Investigator must indicate in the IRB application that the protocol will utilize consent by a Health Care Decision-Maker and submit the
**surrogate consent rider.**

2. **Ongoing studies.** If the Investigator later decides to utilize consent by a Health Care Decision-Maker, an amendment must be submitted requesting the use of surrogate consent along with a revised informed consent document that incorporates the surrogate consent rider.

**B. Verifying/Identifying the Health Care Decision-Maker (HCDM).**

1. Per this procedure and VUMC Operations Policy 20-10.08, the identification of a HCDM is the responsibility of the treating physician, the consulting physician(s) and/or other involved members of the healthcare/clinical team.
   a) When a HCDM has already been clinically assigned, the investigator and research team should verify that the HCDM Identification Documentation Form is in the patient's medical record prior to obtaining consent for participation in research.
   b) When a HCDM is needed, but has not yet been clinically identified, the Investigator/research team becomes responsible for completing this form, as outlined in section II.D below prior to obtaining consent for participation in research.

2. The HCDM identified to make health care decisions on the patient’s behalf is generally the individual who should make decisions regarding the patient’s participation in IRB-approved clinical research studies.

3. In the case of adult patients who are incompetent or lack decision-making capacity, AND who do not have a valid Durable Power of Attorney for Healthcare (“DPOA”) or a court-appointed guardian or conservator, the Health Care Decision-Maker should be an adult who has exhibited special care and concern for the patient, who is familiar with the patient’s personal values, and who is reasonably available.

4. Consideration shall be given, if possible, in order of descending preference for service as a Health Care Decision-Maker to:
   a) The patient’s spouse;
   b) The patient’s adult child;
   c) The patient’s parent;
   d) The patient’s adult sibling;
   e) Any other adult relative of the patient; or
   f) Any other adult who satisfies the requirements under item 1, above.

5. Health Care Decisions made by an HCDM must be made in accordance with the patient’s individual health care instructions, if any, and other wishes, if known to the HCDM. If the patient has not given individual health care instructions, and the patient’s specific wishes are not known, decisions are to be made in accordance with the HCDM’s determination of the patient’s desires or best interests in light of the patient’s personal values and beliefs to the extent they are known.

**C. No Appropriate Health Care Decision-Maker Available.**

1. If none of the individuals eligible to act as a Health Care Decision-Maker under B.2 or B.3 above is reasonably available, the patient’s treating physician may make health care decisions for the patient after the treating physician either:
   a) Consults with and obtains the recommendations of the Clinical Ethics Consultation Service; **OR**
   b) Consults with a second physician who:
      (1) Is not directly involved in the patient’s healthcare; **AND**
      (2) Who either:
Does not serve in a capacity of decision-making, influence, or responsibility over the treating physician; OR
(b) For whom the treating physician does not exert decision-making, influence, or responsibility over the treating physician; AND
(c) Concurs with the treating physician’s decision.

2. In the event that the patient’s treating physician is acting in the role of Health Care Decision-Maker (as defined in IV.C. above), and is also the Principal Investigator in a proposed clinical research study, before enrolling the patient in a clinical research study, the physician must do one of the following so that there is an independent determination of the appropriateness of enrolling the patient in the research study. The physician must either:
   a) Withdraw as treating physician and transfer the patient’s care to another treating physician; OR
   b) Allow the decisions regarding whether to enroll and continue the patient in the study to be made by either:
      (1) Consulting with and obtaining the recommendations of the Clinical Ethics Consultation Service; OR
      (2) Consulting with a second physician who:
         Is not directly involved in the patient’s health care; AND
         (b) Who either:
         Does not serve in a capacity of decision-making, influence, or responsibility over the treating physician; OR
         (ii) For whom the treating physician does not exert decision-making, influence, or responsibility; AND
         (iii) Concurs with the treating physician’s decision.

3. A Clinical Ethics Consult should be obtained in all situations where the physician is acting as Health Care Decision-Maker and the patient is being considered for enrollment in a clinical research study. The recommendations(s) of the Clinical Ethics Consultation Service and/or the consulting physician shall be documented as to the appropriateness of enrolling the patient in the clinical research study, and this recommendation shall be determinative as to whether or not the patient should be enrolled.

D. Required Documentation. In all cases involving adult patients who are incompetent or lacks decision-making capacity for healthcare decisions and consent by a Health Care Decision-Maker is utilized, the treating physician, the consulting physician(s) and other involved members of the healthcare team (or the Investigator/research team, if applicable, per section II.B.1.b of this procedure) shall document in the medical record:

1. The basis for their determination that the patient lacks decision-making capacity in accordance with I.D. of this procedure;
2. The identity of the HCDM and the rationale for the selection of the individual as HCDM, which shall be documented on the Healthcare Decision-Maker Identification Documentation Form;
3. The process by which a treating physician is determined to be the HCDM if no other appropriate individuals are identified, as well as the recommendations of the Clinical Ethics Consult Service and/or consulting physician when the treating physician is identified as the HCDM, if applicable; and
4. The process by which the patient was enrolled or declined to be enrolled in the clinical research.
III. IRB Committee Responsibilities.
   A. The IRB Committee, the Chairperson, or his/her designee will review the informed consent documents with the attached surrogate consent rider in accordance with HRPP Policy IV.A and HRPP Procedure IV.A.1 and IV.A.2.
   B. The IRB Committee, the Chairperson or his/her designee will review the Investigator’s rationale for the need to utilize consent by a Health Care Decision-Maker assuring:
      1. There are appropriate safeguards in place for cognitively impaired participants;
      2. The Investigator has a thorough understanding of the appropriate use of consent of a Health Care Decision-Maker in clinical research; and
      3. The Investigator has detailed how re-consenting will take place when and if an individual becomes competent to consent for oneself.
   C. The IRB should consider whether and when to require a reassessment of decision-making capacity. Additionally, after taking into account the study’s anticipated length and the condition of the individuals to be included, whether and when periodic re-consenting of the HCDM should be required to assure that a participant’s continued involvement is voluntary.

IV. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA will conduct a pre-review of the informed consent document with the surrogate consent rider submitted with a new study application to determine that the correct forms have been submitted for the targeted population, assess the readability of the document, and verify all required elements are present for adequate informed consent, including if any additional elements are appropriate.
   B. If additional information regarding the informed consent process or documentation is needed, the RCA will contact the Investigator and request the additional information.
   C. The RCA will assure that the HRPP database is updated appropriately to reflect IRB approval for the use of consent by a Health Care Decision-Maker for the research.
   D. The RCA will draft all approval letters for signature by the Chair or his/her designee. In addition, the RCA will date stamp the informed consent document in accordance with HRPP Policy IV.D.

References:
TAR 1200-8-1
TCA § 33-3-219-221
TAR 0940-4-03.01
Healthcare Decision Making Policy OP 20-10.08