Exhibit OO12.bt

**Clinical Staff Executive Committee**

**MEDICAL CENTER POLICY NO. 0115**

A. SUBJECT: Guidelines for the Determination of Death: Including Death by Neurologic Criteria

B. EFFECTIVE DATE: July 1, 2012 (R)

C. POLICY:

The University of Virginia Medical Center abides by the provisions of the Virginia statute regarding the diagnosis of death (Code of Virginia, Section 54.1-2972), as reproduced below in Section D. In addition, it is expected that in so doing, the physician will:

1. Follow the ordinary standards of medical practice, whether the patient dies by virtue of the absence of cardiorespiratory function or by virtue of the absence of brain function.

2. Document all pertinent issues and findings in the medical record.

3. Notify the contracted Organ Procurement Organization (OPO) of all deaths and imminent deaths.

4. Refer all matters related to organ donation, including inquires from families, to the contracted OPO and facilitate the OPO's involvement with family and surrogate decision makers.

5. Discontinue cardiorespiratory support after death has been diagnosed, basing decisions relating to timing of discontinuation of support upon consideration of all relevant ethical issues.

Since ordinary standards of medical practice change over time, the attachment to this policy outlines current guidelines, urging the physician to make use of available experts in diagnostic efforts and in situations of conflict resolution. For information regarding apnea testing see http://www.healthsystem.virginia.edu/docs/manuals/guidelines/cpgguidelines

D. PROCEDURE:

1. The University of Virginia Medical Center abides by the provisions of the Virginia statute (Code of Virginia, Section 54.1-2972) which states that a person is deemed medically and legally dead if:

   a. In the opinion of a physician duly authorized to practice medicine in this Commonwealth, based on the ordinary standards of medical practice, there is the absence of spontaneous respiratory and spontaneous cardiac functions and, because of the disease or condition which directly or indirectly caused these functions to cease, or because of the passage of time since

(SUBJECT: Guidelines for the Determination of Death: Including Death by Neurologic Criteria)

these functions ceased, attempts at resuscitation would not, in the opinion of such physician, be successful in restoring spontaneous life-sustaining functions, and, in such event, death shall be deemed to have occurred at the time these functions ceased; or

b. In the opinion of a physician, who shall be duly licensed and a specialist in the field of neurology, neurosurgery, electroencephalography or critical care medicine, when based on the ordinary standards of medical practice, there is the absence of brain stem reflexes, spontaneous brain functions and spontaneous respiratory functions and, in the opinion of another physician and such specialist, based on the ordinary standards of medical practice and considering the absence of brain stem reflexes, spontaneous brain functions and spontaneous respiratory functions and the patient's medical record, further attempts at resuscitation or continued supportive maintenance would not be successful in restoring such reflexes or spontaneous functions, and, in such event, death shall be deemed to have occurred at the time when these conditions first coincide.

2. Death, as defined in 1.b above, shall be pronounced by one of the two physicians and recorded in the patient's medical record and attested in writing in the patient's medical record by the other physician. One of the two physicians pronouncing or attesting to death by neurologic criteria may be the attending physician regardless of his/her specialty so long as at least one of the physicians is licensed and a specialist in one of the fields specified in D.1.b above.

SIGNATURE:

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

R. Edward Howell, CEO, UVA Medical Center

DATE: 6/22/12

Medical Center Policy No. 0115 (R)
Approved November 1988
Revised September 1993, November 1994, November 1996, September 1999, March 2003, December 2006, June 2008, September 2009, September 2010, June 2012
Approved by Ethics Committee
Approved by Clinical Staff Executive Committee

**Attachment**

(SUBJECT: Guidelines for the Determination of Death: Including Death by Neurologic Criteria)

ATTACHMENT:

I. Diagnosis of Death by Cardiorespiratory Criteria

The diagnosis of death by cardiorespiratory criteria may be made by a physician authorized to practice medicine in the Commonwealth of Virginia when, in the opinion of such physician, attempts at resuscitation would not be successful in restoring spontaneous life-sustaining functions. This decision should be made with consideration of the disease, which directly or indirectly caused the functions to cease, and with consideration of the passage of time since these functions ceased.

II. Diagnosis of Death by Neurologic Criteria

The diagnosis of death by Neurologic Criteria is limited to patients who have been born at term (37 weeks or more post-conception) or older

The diagnosis of death by Neurologic Criteria must be made by a resident or attending neurologist, neurosurgeon, electroencephalographer or intensivist. A second physician, either a resident or attending, of any specialty must confirm the diagnosis of death by neurologic criteria.

Determination of death by neurologic criteria must be made in accordance with the criteria listed below. All observations, tests, and findings must be recorded in the patient's medical record.

Death by neurologic criteria shall mean the irreversible cessation of all functions of the entire brain, including the brain stem.

A. Prerequisites

The following prerequisites must be met:

1. The cause of coma must be established by demonstrating clinical or neuroimaging evidence of a central nervous system injury sufficient to cause irreversible cessation of brain function.

2. The possibility of recovery of any brain functions must be excluded. Complicating medical conditions that may confound clinical assessment should be excluded. Reversible conditions that may mimic death by neurologic criteria include:

   a. Hypothermia, defined as core temperature of less than 32 ºC (90 ºF). (It is recommended that core body temperature be maintained at >35C during apnea testing).
   b. Intoxication
   c. Sedative and hypnotic drugs
   d. Neuromuscular blockade
   e. Severe electrolyte abnormalities
   f. Severe acid-base abnormalities
   g. Shock

3. Where a sufficient cause of coma cannot be established or clinical assessment is confounded, irreversibility can be reliably inferred only after extended observation or ancillary testing.

B. Clinical Examination - The three cardinal findings of death by neurologic criteria are unresponsiveness, absence of brainstem reflexes, and apnea:

1. Unresponsiveness - No cerebral motor response to pain in all extremities after nail-bed pressure and supraorbital pressure stimulus. Seizures, shivering and posturing must be absent, as they imply the presence of brain activity. Spontaneous body movements may be observed during the apnea test, at the time of abdominal incision, or in synchrony with the respirations of the mechanical ventilator. These body movements are generated by the spine and are not inconsistent with the diagnosis of death by neurologic criteria.

2. Absence of Brainstem Reflexes
   a. Absence of pupil response to bright light in both eyes. Round, oval, or irregularly shaped pupils are compatible with death by neurologic criteria. Most pupils in death by neurologic criteria are in middle position (4 to 6 mm), but the size of the pupils may vary.
   b. Absence of spontaneous eye movement, or in response to oculocephalic and oculovestibular testing.
   c. Absence of bulbar musculature including facial and oropharyngeal muscles (corneal, gag, cough, sucking, and rooting reflexes)

3. Apnea Testing performed per Clinical Guideline
   http://www.healthsystem.virginia.edu/docs/manuals/guidelines/cpgguidelines/02-clinical-practice-guidelines/2.030-apnea-testing-guideline-end-of-life/?searchterm=apnea%20(end%20of%20life)

4. When any of the three cardinal findings of death by neurologic criteria cannot be adequately assessed, ancillary tests are required to diagnose death by neurologic criteria, as described in Section C below.

5. Period of Observation - Even when coma is known to have started at an earlier time, the absence of all brain functions must be established by an experienced physician (a neurologist or neurosurgeon, or critical care physician experienced in the evaluation of death by neurologic criteria) at the initiation of the observation period. The duration of the observation period is a matter of clinical judgment. Due to the relative resistance of the child's brain to insults leading to death, an observation period for pediatric patients is recommended as follows:

   a. Term newborn to 30 days of age:
   A period of observation of 24 hours is recommended when an irreversible condition is well established. Ancillary tests may be performed, when indicated, at any time during the observation period and should be ordered in consultation with a neurologist or neurosurgeon. A positive ancillary test would generally support a shorter observation time.

b. Children greater than 30 days to 18 years:
A period of 12 hours is recommended.

C. Ancillary Tests are required when specific components of the clinical examination cannot be reliably performed or reliably evaluated due to coexisting clinical conditions of the patient. Such tests may be performed at any time during the observation period, and should include a cerebral blood flow study.

1. Cerebral angiography must demonstrate the absence of blood flow in intracranial arteries to confirm death by neurologic criteria.

2. Nuclear imaging must demonstrate an absence of intracerebral uptake of the tracer isotope to confirm death by neurologic criteria.

3. Because it is technically difficult and prone to operator variables, transcranial Doppler ultrasonography cannot be used to confirm death by neurologic criteria.

4. The use of computerized tomographic cerebral angiography (CTA), magnetic resonance angiography (MRA), and single photon emission computed tomography (SPECT) are considered investigational and cannot be used to confirm death by neurologic criteria.

5. While an EEG, performed by the electrocerebral silence protocol, and somatosensory evoked potentials (SEP) may be useful in confirming the diagnosis of death by neurologic criteria, they can only reliably be interpreted when all prerequisites for the clinical evaluation of death by neurologic criteria can be met, limiting the situations in which it will clarify the diagnosis.

D. Implementation of Diagnosis of Death by Neurologic Criteria

1. Communication and Documentation
If the responsible physician believes that it is appropriate to implement an evaluation for diagnosis of death by neurologic criteria, he/she should make every reasonable effort to contact the patient's next-of-kin or surrogate by telephone and inform them of his/her intention to test this preliminary diagnosis. During the evaluation process, the physician will record the following information in the progress note of the patient's medical record:

a. All efforts to contact next-of-kin or surrogate regarding implementation of diagnosis of death by neurologic criteria;

b. Any objection raised by family or surrogate to the implementation of the evaluation (see Section D.2, below); and

c. All results of the clinical and laboratory evaluation as performed according to the guidelines outlined above.

d. If the evaluation confirms that the patient is dead based upon neurologic criteria, the responsible physician should note this time in the medical record as the time

of death. At this point the next-of-kin or surrogate should be informed of the patient's death.

e. While the Code of the Commonwealth of Virginia allows the physician to discontinue cardiorespiratory support at the time of death without consent from the next-of-kin or surrogate, the physician's choice of the appropriate moment for discontinuation of cardiorespiratory support may be influenced by family considerations, the possibility of organ donation, and other relevant ethical issues.

f. If the patient is a suitable organ donor, the physician may choose to continue cardiorespiratory support during continued evaluation and preparation for this procedure. The physician will notify the designated hospital personnel in conjunction with the appropriate OPO, in order to initiate and facilitate a systematic process for evaluating potential donors, obtaining consent for donation, and recovering donated organs and tissues as outlined in Medical Center Policy No. 0098, Organ, Tissue and Eye Donation.

g. As in any death in the hospital, the hospital staff or nurse administrator should be notified in order to initiate usual hospital procedures;

h. The final resolution of the case should be noted in the medical record.

2. Family Support

a. Declaring a person brain dead can be very difficult for some families to accept. If this is the case or the family requests time for arrival of other family members it may be reasonable to temporarily continue cardiopulmonary support.

b. If the family continues to have difficulty accepting the death, other medical professionals, hospital chaplains, and/or the Ethics Consultation Service should be contacted.

c. In most cases, this period of continued cardiorespiratory support should not extend beyond 24 hours.

Note: This document follows closely "Evidence- Based Guideline Update: Determining Brain Death in Adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology". Neurology 2010;74(23)1911-1918 and "Guidelines for the Determination of Brain Death in Infants and Children: An Update of the 1987 Task Force Recommendations". Pediatrics 2011;128:e720-740.