DETERMINATION OF DEATH OF ADULT PATIENTS BY NEUROLOGIC CRITERIA (BRAIN DEATH)

I. PURPOSE
This policy defines the criteria and procedure by which an IU Health Bloomington patient may be declared dead upon the basis of neurological criteria. In addition, this policy provides healthcare providers with guidelines regarding the handling of the patient’s body once the patient has been declared dead by neurologic criteria.

II. SCOPE
This policy applies to all IU Health Bloomington providers and medical staff members.

III. EXCEPTIONS
This policy does not apply to the care of pediatric (less than 15 years old) patients.

IV. DEFINITIONS

**Accepted Medical Standards for Determining Death by Neurologic Criteria** - The accepted criteria are based on the American Academy of Neurology standards outlined in 2010 and current medical literature.

**Brain death** - The informal and common term used for death by neurologic criteria.

**Death by neurologic criteria** - “An individual who has sustained...irreversible cessation of all functions of the entire brain including the brain stem, is dead” (Indiana Code 1-1-4-3). The determination of death must be made in accordance with accepted medical standards.

**Removal of support** - The cessation of all modalities used to maintain the biologic function of the body of the patient who has suffered death by neurologic criteria. Modalities include but are not limited to artificial ventilation, IV nutrition and hydration, dialysis, implantable devices, and all medication.

**Time of neurologic death** - The time, as documented in the patient’s chart, when the patient has met all criteria for the diagnosis of death by neurologic criteria.
V. POLICY STATEMENTS

A. IU Health Bloomington recognizes the preservation and enhancement of human life by the administration of optimal medical care in accordance with accepted medical standards. In accordance with those standards, IU Health Bloomington accepts that an individual may be declared dead by neurologic criteria, even when cardiac function continues or respiratory function continues via mechanical support.

B. To ensure that the cessation of brain function is irreversible physicians must attempt to determine the cause of coma, exclude mimicking medical conditions and observe the patient for a period of time as determined by the attending physician to exclude the possibility of recovery.

C. Death by neurologic criteria shall be determined in accordance with accepted medical standards, as outlined by the American Academy of Neurology and described here. Deficiencies in the evidence base for determining death by neurologic criteria require that clinicians exercise considerable judgement when applying the criteria in specific circumstances.

D. Under the direct supervision of an attending physician, students and trainees may participate in the testing and clinical exam performed as part of determining death by neurologic criteria.

E. Only attending physician members of the IU Health Bloomington Medical Staff who are experienced in determining death by neurologic criteria and who practice in the areas of critical care, neurology or neurosurgery may declare a patient dead using these criteria.

F. In order to avoid potential or apparent conflict, physicians of any Transplant Service may not be involved in the determination of death by neurologic criteria.

G. All patients suspected to be brain dead or at risk of imminent brain death shall be referred to the Indiana Donor Network (previously known as IOPO) for assessment of the patient’s medical suitability as a potential organ donor, per IU Health Bloomington Policy “Organ and Tissue Donation” (INTER-O-150).

H. The time of the patient’s death is the time when death by neurologic criteria has been established by clinical exam, or exceptional circumstances as described in Procedure B 5 and an attending physician declares the patient brain dead. The clinical exam and all relevant test results must be documented in the patient’s medical record at that time.

I. Once death has been documented, care providers shall follow IU Health Bloomington policy, INTER-D-170 Donation after Circulatory Death (DCD) regarding care of the patient after death. This involves either removal of support or further care of the body in anticipation of organ donation.
J. After the determination of death, but prior to the removal of support, all relevant parties will be informed of the patient’s death – including but not limited to the patient’s family and/or surrogate, and attending physicians involved in the care of the patient.

K. When conflict occurs over the determination of death, either among members of the medical care team or the patient’s family/surrogate, or between members of the medical care team and the patient’s family/surrogate, members of the medical care team are encouraged to call upon the unit medical and nursing leadership, chaplaincy, social work, and/or the ethics consult team to facilitate conflict resolution.

L. Reasonable accommodations may be made for family preferences or needs (e.g., travel time, time to grieve) prior to the removal of support from the body. In general, removal of physiologic support should occur within 8 hours of the declaration of death.

VI. PROCEDURES
A. Physicians involved in the clinical exam and diagnosis of death by neurological criteria and critical care nurses will be educated regarding the contents of this policy, the clinical exam for brain death, and ancillary tests used as an adjunct to the clinical exam.

B. The determination of brain death can be considered to consist of 4 steps: the clinical evaluation prerequisites, the clinical evaluation (neurologic examination), ancillary tests and documentation. In rare circumstances, there may be exceptions to the standard steps to determination of brain death. (See Procedure B.5.)

1. Clinical Evaluation Prerequisites:
   a. Establish irreversible and proximate cause of coma, as determined by history, examination, neuroimaging, and/or laboratory tests.
   b. Exclude the presence of a CNS-depressant drug effect by history, drug screen, calculation of clearance using 5 times the drug’s half-life (assuming normal hepatic and renal function), or, if available, drug plasma levels below the therapeutic range.
   c. There should be no recent administration or continued presence of neuromuscular blocking agents (this can be defined by the presence of a train of 4 twitches with maximal ulnar nerve stimulation).
   d. There should be no severe electrolyte acid base or endocrine disturbance (defined by severe acidosis or laboratory values markedly deviated from the norm).
   e. Achieve normal core temperature (>36°C).
   f. Achieve adequate systolic blood pressure.
2. Neurologic Evaluation: Only one neurologic exam is required to declare a patient brain dead in those over the age of 18. Patients between the ages of 15 years to 18 years shall have a second neurologic evaluation 12 hours after the initial evaluation to confirm brain death.

a. Coma: Patient must lack all evidence of responsiveness. Eye opening or eye movement to noxious stimuli is absent. Noxious stimuli should not produce a motor response other than spinally mediated reflexes.

b. Absence of brainstem reflexes:
   i. Absence of pupillary response to a bright light is documented in both eyes. Usually the pupils are fixed in a midsize dilated position (4-9mm). Constricted pupils suggest the possibility of drug intoxication.
   ii. Absence of ocular movements using oculocephalic testing and oculovestibular reflex testing. Once the integrity of the cervical spine is ensured, the head is briskly rotated horizontally and vertically. There should be no movement of the eyes relative to head movement. The oculovestibular reflex is tested by irrigating each ear with ice water (caloric testing) after the patency of the external auditory canal is confirmed. The head is elevated to 30 degrees. Each external auditory canal is irrigated (1 ear at a time) with approximately 50 mL of ice water. Movement of the eyes should be absent during 1 minute of observation. Both sides are tested, with an interval of several minutes.
   iii. Absence of corneal reflex. Absent corneal reflex is demonstrated by touching the cornea with a piece of tissue paper, a cotton swab, or squirts of water. No eyelid movement should be seen.
   iv. Absence of the pharyngeal and tracheal reflexes. The pharyngeal or gag reflex is tested after stimulation of the posterior pharynx with a tongue blade or suction device. The tracheal reflex is most reliably tested by examining the cough response to tracheal suctioning. The catheter should be inserted into the trachea and advanced to the level of the carina followed by 1 or 2 suctioning passes.

c. Apnea: Absence of a breathing drive in the presence of normotension, normothermia, euvoledea, baseline eucapnia, and absence of hypoxia. To avoid precipitating a clinical deterioration, preparation of the patient is required before conducting this test.
   i. Adjust vasopressors to a systolic blood pressure of 100 mm Hg.
   ii. Pre-oxygenate for at least 10 minute with 100% oxygen.
   iii. Adjust ventilation to achieve a pH of 7.35-7.45.
iv. Reduce positive end-expiratory pressure (PEEP) to 5 cm H2O (oxygen desaturation with decreasing PEEP may suggest difficulty with apnea testing).

v. If pulse oximetry oxygen saturation remains 95%, obtain a baseline blood gas (PaO2, PaCO2, pH, bicarbonate, base excess).

vi. Disconnect the patient from the ventilator.

vii. Preserve oxygenation (e.g., deliver 100% O2 via suction catheter at 6 L/min).

viii. Look closely for respiratory movements for 8–10 minutes. Respiration is defined as abdominal or chest excursions and may include a brief gasp. If respiration is noted, the test should be aborted.

ix. Test may need to be aborted if there is a significant clinical decline in the patient’s condition.

x. Retry procedure with T-piece, CPAP 10 cm H2O, and 100% O2 12 L/min.

xi. If no respiratory drive is observed, repeat blood gas (PaO2, PaCO2, pH, bicarbonate, base excess) after approximately 8 minutes.

xii. If respiratory movements are absent and arterial PCO2 is greater than 60 mm Hg (or 20 mm Hg increase in arterial PCO2 over a baseline normal arterial PCO2), the apnea test result is positive (i.e., confirms the clinical diagnosis of brain death).

xiii. If the test is inconclusive but the patient is hemodynamically stable during the procedure, it may be repeated for a longer period of time (10–15 minutes) after the patient is again adequately preoxygenated.

3. Ancillary Tests: Ancillary tests can be used when uncertainty exists about the reliability of parts of the neurologic examination or when parts of the neurologic examination may not be performed (e.g., facial trauma). In clinical practice, EEG, Cerebral angiography, nuclear scan, TCD, CTA and MRI/MRA may be used. Ancillary tests should not be done in lieu of a rigorous neurologic examination.

a. Conventional angiography: No intracerebral filling at the level of the carotid bifurcation or circle of Willis; patent external carotid circulation, possibly delayed superior longitudinal sinus filling.

b. Electroencephalography: no electrical activity during at least 30 minutes of recording according to the American Electroencephalographic Society guidelines.

c. Transcranial Doppler ultrasonography: small systolic peaks in early systole without diastolic flow or reverberating flow – indicating very high vascular resistance associated with greatly increased intracranial pressure.

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d. **Technetium-99m hexamethylpropyleneamineoxime brain profusion scintigraphy:** (also known as an isotope flow study with brain scan) No flow to brain and no uptake of isotope in brain parenchyma (hollow skull phenomenon) is consistent with brain death.

4. **Documentation:** The time of brain death is documented in the medical record. Time of death is determined by a positive apnea test, or, in the absence under the exceptions in section 5., the time of the interpretation of the confirmatory test. All patients declared dead by neurologic criteria must have the following information documented in the patient’s medical chart at the time of death declaration:
   a. Etiology and irreversibility of patient’s condition
   b. A clinical exam, with findings confirming the absence of brainstem reflexes, an absence of a motor response to pain, a positive apnea test, and the results of any confirmatory tests.
   c. The time of death, documented after completion of the examination and if conducted the ancillary tests (e.g. isotope brain flow studies).

5. **Exceptions in determining death by neurologic criteria:** These exceptions apply to the following situations; 1) traumatic brain injury, or 2) intracerebral hemorrhage, or 3) cerebral infarction. The exceptions must demonstrate consistent neuroimaging AND uncontrolled intracranial pressure despite the therapeutic administration of barbiturates. In these situations the standard clinical exam outlined above may not be reliably interpreted. The following clinical parameters must be satisfied in order to consider the determination of brain death.
   a. **A clinical exam consistent with brain death as described above. In this circumstance an apnea test is not required.**
   b. The patient has a clinical course consistent with intractable intracranial hypertension in spite of therapeutic maneuvers AND evidenced by ICP monitoring
   c. The ancillary test must be interpreted by a qualified specialist functioning independently of the clinical physicians. The results of all ancillary tests performed must be documented in the medical record at the time of declaration of death by neurologic criteria.
   d. The declaration of brain death in this particular clinical situation must be attested to in the medical record by two physicians representing two different specialties (e.g. critical care and neurology, or neurology and neurosurgery). The clinical exam will be independently confirmed by each physician. When two physicians attest to the patient’s condition, time of death shall be declared when the second physician attests that the patient has met criteria to be
declared dead by the concurrence of the two clinical exams and the results of the ancillary test. At the time of attestation, all primary and consulting services for the patient will be notified of the declaration.

C. If the above criteria set forth in Procedure “B” cannot be met then the determination of brain death cannot be made.

D. Inform all relevant parties of the patient death.

E. Arrange disposition of the body, either preparation for organ donation or discontinuation of all medical technologies used to support cardiopulmonary function of the body.

F. Notify unit medical and nursing leadership

VII. CROSS REFERENCES
Donation after Circulatory Death, INTER-D-170
Organ and Tissue Donation, INTER-O-150

VIII. REFERENCES/CITATIONS
American Electroencephalographic Society Guidelines


Indiana State Medical Association Determination of Brain Death Guidelines http://www.ismanet.org/pdf/Brain_death.pdf

IX. FORMS/APPENDICES
None

X. RESPONSIBILITY
IU Health Bloomington Medical Staff

XI. APPROVAL BODY
Trauma Operations Performance Improvement Committee
Trauma Quality Improvement Committee
Patient Care Committee
Medical Executive Committee
XII. APPROVAL SIGNATURES

Dean Lenz, MD
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March 23, 2016

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XIII. DATES

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