POLICY TITLE: Brain Death/ Death by Neurologic Criteria	SYSTEM POLICY AND PROCEDURE MANUAL
POLICY #: 700.00	**CATEGORY:** Administrative
System Approval Date: 4/25/2024 **Site Implementation Date:** 6/03/2024	**Effective Date:** 10/2009 **Last Reviewed/Approved:** 12/2022
Prepared by: Critical Care Services; Office of Legal Affairs	**Notations:** N/A

GENERAL STATEMENT of PURPOSE

The purpose of this document is to establish a best practice for the determination of brain death/death by neurologic criteria.

POLICY STATEMENT

It is the policy of Northwell Health that the diagnosis of brain death is made on the basis of one clinical examination and one apnea test performed by a physician with privileges to do so. It is not necessary in an adult to have a second physician confirm the time of death unless the patient is going to be an organ donor (repeat examination is not required). In children (37 weeks to 18 years of age), two clinicians must each perform a separate and independent examination with a minimum interval of 12 hours separating the two examinations, including two apnea tests. One ancillary test (see below) may be used when clinical examination or an apnea test cannot be performed safely, or there are features of the case that require ancillary testing based on the judgement of the clinical care team. The physicians involved with diagnosing brain death/death by neurologic criteria shall not participate in procuring or transplanting organs should the patient become a donor. Consent is not required and should not be sought for testing to determine brain death/death by neurologic criteria., or for the discontinuation of medical treatments following brain death/death by neurologic criteria determination.

SCOPE

This policy applies to all Northwell Health employees, as well as medical staff, volunteers, students, trainees, physician office staff, contractors, trustees and other persons performing work for or at Northwell Health; faculty and students of the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell or the Hofstra Northwell School of Nursing and Physician

Assistant Studies conducting research on behalf of the Zucker School of Medicine on or at any Northwell Health facility.

DEFINITIONS

Brain Death/ Death by Neurologic Criteria is defined as the permanent loss of all function of the brain, including the brainstem. There are three cardinal findings in brain death/death by neurologic criteria: coma, absence of brainstem reflexes and apnea.

PROCEDURE

Discussion with the patient's family or surrogate about brain death/death by neurologic criteria is appropriate. *The Brain Death/ Death by Neurologic Criteria Checklist, #HS061,* is used for documentation of the brain death/ death by neurologic criteria examination (attached).

I. <u>Diagnostic Criteria for Brain Death/Death by Neurologic Criteria Diagnosis</u>

A. <u>Pre-requisites (prior to initiating a</u> brain death **<u>/death by neurologic criteria protocol the criteria below should be met)</u>**

1. The cause of brain death/death by neurologic criteria is known and permanent. In children < 24 months old, a waiting period of ≥ 48 hours after an acute brain injury is recommended prior to initiating any brain death/death by neurologic criteria testing. In children 24 months of age or older who suffer a hypoxic-ischemic brain injury, wait at least 24 hours prior to the initiation of any brain death/death by neurologic criteria evaluation.

2. Drug levels of CNS depressants (i.e., barbiturates) are below the therapeutic range (e.g., Phenobarbital <5 mcg/ml) or a sufficient period of time has passed to allow for drug elimination. A negative urine toxicology screen is not required for brain death/death by neurologic criteria determination and should not be used to determine timing of examination due to prolonged positivity secondary to metabolites.

3. Core temperature is above 36°C. Wait at least 24 hours after rewarming to 36°C before commencement with evaluation if core body temperature has been < 35.5°C.

4. Systolic blood pressure ≥ 100 mm Hg AND Mean arterial pressure ≥75 mm Hg (for pediatric patients, systolic blood pressure and mean arterial pressure must be ≥ 5th percentile for age). If patient is on VA ECMO, only target mean arterial pressure ≥75 mm Hg. Vasopressors may be used to keep the mean arterial pressures in the acceptable range.

5. Absence of complicating medical conditions that may confound clinical assessment of brain death/death by neurologic criteria (i.e., toxins, locked-in-syndrome).

6. There should be no severe electrolyte abnormalities (defined by severe acidosis or laboratory values markedly deviated from the norm; please see attachments).

Clinical Determination of Brain Death/Death by Neurologic Criteria

1. No behavioral or reflex response that originates from nervous system structures above the cervical spinal cord in response to pain applied to any part of the body.

2. Absent brainstem reflexes.

3. Pupils
   - No response to bright light
   - Size: midposition to dilated (pontine hemorrhage may cause small pupils)

4. Ocular movement
   - Absent oculocephalic reflex (tested only if C-spine integrity ensured)
   - Absent oculovestibular reflex: deviation of the eyes to irrigation in each ear with 30-50 ml cold water with head of bed elevated 30°. Ensure intact tympanic membranes and allow one minute after injection and at least five minutes between testing on each side.

5. Facial sensation and facial motor response
   - No corneal reflex
   - No facial or limb movement in response to deep pressure on nail bed, supraorbital ridge, or temporomandibular joint.

6. Pharyngeal and tracheal reflexes
   - No gag response to posterior pharyngeal stimulation
   - No cough response to tracheobronchial suctioning.

B. Apnea

1. Pre-requisites:
   - The ventilator is adjusted to obtain PaCO2 = 35-45 mm Hg at least 20 minutes prior to testing. If the patient has chronic elevation of PaCO2, this may not be possible due to untoward alkalosis (see #3 of this section). If the patient's baseline chronically elevated of PaCO2 is **unknown**, the apnea test results, if positive, should be followed up with ancillary testing to diagnose brain death/death by neurologic criteria.

   - The patient is pre-oxygenated with FIO2 = 100% for 10 minutes to a PaO2 > 200 mm Hg.

2. The ventilator is disconnected and a small diameter oxygen catheter is placed through the endotracheal tube to the level of the carina delivering oxygen at a rate of 6 liters per minute for 8-10 minutes. During this period, the chest is observed for respiratory activity.

   Alternative methods are valid to perform apnea test, see attached reference, as long as all criteria are met for both pre apnea testing and criteria for a positive test (no spontaneous resp, etc.) are met.

3. The apnea test is consistent with brain death/death by neurologic criteria, if respirations are absent for the duration of the test and with end test PaCO2>=60 mm Hg or there is a 20 mm Hg rise in PaCO2 above the base-line value **AND** pH < 7.30.

4. If the patient develops significant oxygen desaturation, hypotension, or cardiac arrhythmias, an arterial blood gas sample is drawn and the patient is immediately reconnected to the ventilator. If the patient remains apneic during the test and blood gas values meet the stated criteria, then apnea has been demonstrated. If the blood gas values do not meet the criteria, the apnea test is indeterminate and additional (confirmatory) tests are performed (see #II below – Ancillary Tests).

II. Ancillary Tests

Ancillary tests are not required for the determination of brain death/death by neurologic criteria and should not be used when clinical examination and apnea testing can be completed safely. One of the following tests may be used when clinical examination or apnea test cannot be performed safely, or if there are features of the case that require ancillary testing for determination of brain death/death by neurologic criteria by the judgment of the critical care team.

1. Transcranial doppler ultrasonography (TCD) (adults only)
2. Radionuclide perfusion scintigraphy
3. Radionuclide angiography
4. Four vessel catheter angiogram

The following are not acceptable:

1. Electroencephalography (EEG)
2. Computed tomography angiography
3. Magnetic resonance angiography
4. Magnetic resonance imaging

III. Notification and Documentation of Death

1. Reasonable efforts should be made to notify the surrogate that the determination of brain death/death by neurologic criteria is being undertaken.
2. The Organ Procurement Organization must be notified when a healthcare provider judges that brain death/death by neurologic criteria is imminent or the GCS $\leq$ 5. Contact: 800-GIFT-4-NY (800-443-8469).
3. The Brain Death/ **Death by Neurologic Criteria** Checklist may be used but is not required.

IV. Life Sustaining Treatment

1. All life sustaining treatment should be continued upon brain death/death by neurologic criteria determination, until the Organ Procurement Organization has the opportunity to: (i) ascertain whether the patient is on the organ donor registry, in which case the patient's family may not refuse organ donation; or (ii) obtain a valid consent or refusal for organ donation from the patient's health care surrogate. This could include escalation of care in some circumstances, as long as it is not contraindicated by appropriate end of life care (e.g., experiencing repeated arrests in a short period of time and resuscitation would be unsuccessful in restoring cardiac function, ongoing hemorrhage).
    - Physicians who participate in the determination of brain death/death by neurologic criteria may NOT participate in obtaining consent from the family to donate organs or participate in organ recovery.
    - The Death Certificate is completed at the time of brain death/death by neurologic criteria determination and the time of death noted is the time of the final ABG during the first apnea test (for adults) or second apnea test (for pediatric patients), or the time of the documentation of the ancillary test by the radiologist consistent with brain death/death by neurologic criteria.
    - If the patient is an organ donor, a second physician is required to certify death in the medical record.

2. The hospital is required to administer measures necessary to maintain the suitability of the organs for donation. "Measures necessary" could include escalation of care (e.g., administration of medications, cardiac defibrillation, dialysis, invasive hemodynamic monitoring, placement of an arterial/central line). The family should be educated about the need for such measures and their role in preserving the patient's rights and gift of donation.

3. If the patient will not be donating organs, then all life sustaining treatment will be discontinued.

V. Reasonable Accommodation for Religious Objection to Brain Death/Death by Neurologic Criteria Diagnosis

1. The New York State Department of Health Regulation 10 NYCRR Section 400.16 requires that hospitals have an accommodation policy for family members who have a religious objection to the diagnosis of brain death/death by neurologic criteria. Once the diagnosis of brain death/death by neurologic criteria is established at Northwell Health, mechanical ventilation and artificial nutrition and hydration will be continued until cardiac death occurs or organ donation. If the patient is not an organ donor, monitoring, vital signs, testing and dialysis are discontinued upon brain death/death by neurologic criteria determination. In certain situations, an infusion bag of a vasoactive blood pressure agent at a fixed rate or other medication may be allowed to run to completion without renewal in an effort to provide religious accommodation. This provision may be done if bed

availability allows however no monitoring or titration is done. Religious accommodation is not provided if in doing so, the care of other patients is compromised.

2. A brain-dead patient may be transferred out of the ICU to another hospital location for post-mortem care. Although cardiac arrest is expected, a DNR order is not necessary since resuscitation would not be attempted in a brain-dead patient. The death certificate is completed with the date and time of brain death/death by neurologic criteria determination, not cardiac death.

3. Every effort shall be made to support families through the provision of bereavement services, hospital chaplains and psychosocial support providers. Objections based solely on family members' psychological denial that death has occurred do not require reasonable accommodation.

VI. Determination of Brain Death/Death by Neurologic Criteria in Children 37 Weeks to 18 Years of Age

Brain death/death by neurologic criteria determination in children 37 weeks to 18 years of age follows the policy and procedures above. No reliable criteria has been established for those children less than 37 weeks of age.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

- New York Public Health Law: Anatomical Gifts (Article 43 §4306)
- New York State Department of Health Regulation (10 NYCRR §400.16)
- Pediatric and Adult Brain Death/Death by Neurologic Criteria Consensus Guideline. Report of the AAN Guidelines Subcommittee, AAP, CNS, and SCCM. Neurology 2023; 101 :1-21.
- New York State Department of Health Brain Death Guidelines - 2011

CLINICAL REFERENCES/PROFESSIONAL SOCIETY GUIDELINES

N/A

ATTACHMENTS

- Attachment A: Derangements That May Confound Brain Death/Death by Neurologic Criteria Evaluation
- Attachment B: Apnea Testing Guidelines (Clinical Guidance for Performance of the Apnea Test)
- Attachment C: Apnea Testing on ECMO
- Attachment D: Ancillary Testing Recommendations

FORMS

Vital Documents

HS061 – Brain Death/ **Death by Neurologic Criteria** Checklist

APPROVAL:	
Northwell Health Policy Committee	3/26/2024
System PICG/Clinical Operations Committee	4/25/2024

Standardized Versioning History:

Approvals: * =Northwell Health Policy Committee; ** = PICG/Clinical Operations Committee; ✠ = Provisional; ❖ = Expedited

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BRAIN DEATH / DEATH BY NEUROLOGIC CRITERIA CHECKLIST

EXAMINATION	CHECK
Coma, irreversible and cause known	
CNS depressant drug effect absent (if barbiturates given, level < 5 mcg/ml)	
The blood pressure is in an acceptable range	
Absence of conditions or medications which may confound examination	
Core temperature above 36°C	
Absence of motor response to pain in all four limbs	
Pupils nonreactive to bright light	
Absent oculocephalic reflex	
No deviation of eyes to cold caloric testing	
Absent corneal reflex	
No gag reflex or cough response to tracheobronchial suctioning	
Apnea Test: Respirations absent and p_aCO_2 greater than = to 60mmHg or = to or greater than 20mmHg above baseline with pH less than 7.30	

Ancillary Testing

Only perform if clinical examination cannot be performed due to patient factors or if apnea testing inconclusive or aborted (select one).

- Transcranial Doppler (TCD) (adults only)
- 4 vessel catheter angiogram
- Radionuclide perfusion scintigraphy
- Radionuclide angiography

Death Note Date: _____ Time of Death: _____

PHYSICIAN PERFORMING EXAMINATION SIGNATURE	PRINT	DATE	TIME
2ND PHYSICIAN CERTIFYING TIME OF DEATH SIGNATURE (ONLY REQUIRED FOR ORGAN DONORS IN ADULTS)	PRINT	DATE	TIME
2ND 2ND PHYSICIAN CERTIFYING EXAMINATION FOR PEDIATRIC PATIENTS 12 HOURS APART WITH 2ND PHYSICIAN DOCUMENTING DATE/TIME OF DEATH	PRINT	DATE	TIME

Attachment A

Derangements that May Confound Brain Death Evaluation

(Routine measuring of these values may not be necessary unless clinically indicated)

Laboratory Result	Value
Metabolic	
Ammonia	>75 µmol/L
Blood urea nitrogen	>75 mg/dL
Calcium (or ionized calcium)	<7 mg/dL or >11 mg/dL (or <1 mmol/L or >1.3 mmol/L)
Glucose	<70 mg/dL or >300 mg/dL
Magnesium	<1.5 mg/dL or >4 mg/dL
Potassium	<3 mmol/L or >6 mmol/L
Sodium	<130 mmol/L or >160 mmol/L
Acid-Base	
pH	<7.3 or >7.5
Endocrine	
Total T4	<3 mg/dL or >30 mg/dL
Free T4	≤0.4 ng/dL or >5 ng/dL

Clinical Guidance for Performance of the Apnea Test

Prerequisites

1. Ensure the patient is not hypercarbia, hypotensive, hypovolemic, or hypothermic
2. Determine if the patient has baseline CO_2 retention due to pre-existing disease and whether the baseline Pa_{CO_2} is known
    a. In a patient without known baseline CO_2 retention, adjust the ventilator to achieve a normal Pa_{CO_2} (35-45 mm Hg) and pH (7.35-7.45)
    b. In a patient with known baseline CO_2 retention due to pre-existing disease for whom the baseline Pa_{CO_2} is known, adjust the ventilator to achieve baseline pH/ Pa_{CO_2}
    c. In a patient with known baseline CO_2 retention due to pre-existing disease for whom the baseline Pa_{CO_2} is not known, adjust the ventilator to achieve estimated baseline pH/ Pa_{CO_2} (This patient will also require an ancillary test if they do not breathe during the apnea test)

Prior to procedure

1. Preoxygenate for at least 10 minutes with 100% F_{IO_2}, aiming for Pa_{O_2} > 200 mm Hg
2. Check ABG to establish baseline pH, Pa_{O_2}, Pa_{CO_2} within above parameters
3. Ensure respiratory therapist and/or nurse; staff with appropriate expertise in managing the potential cardiopulmonary complications of apnea testing; supplies for multiple ABGs; and vasopressors, inotropes, and/or intravenous fluids are readily available

Disconnect the patient from intermittent mandatory ventilation and provide apneic oxygenation

Techniques for providing apneic oxygenation

1. Tracheal insufflation for patients ≥18 years old
    a. Place a catheter inside the endotracheal or tracheostomy tube such that it approximately terminates just above the level of the carina.
    b. The catheter diameter should be <70% of the diameter of the endotracheal or tracheostomy tube.
    c. Deliver 100% F_{IO_2} at a flow rate of 4-6 L/min.
2. Continuous positive airway pressure for all patients using 100% F_{IO_2} and the same PEEP the patient required prior to the apnea test. The following are acceptable ways to provide CPAP during the apnea test:
    a. Flow inflating bag with functioning PEEP valve
    b. T-piece with functioning PEEP valve
    c. Mechanical ventilator in CPAP mode
        i. Disable default backup apnea ventilation
        ii. Disable apnea alarm or lengthen to maximum allowable limit and assign provider to manually silence alarm
        iii. Remove all condensation from the inspiratory and expiratory limbs of ventilator circuit
        iv. Position the ventilator circuit away from the patient's body to allow for close examination of the chest and abdomen
        v. Adjust the trigger sensitivity to a level that avoids auto-triggering but is sensitive enough to detect a true spontaneous respiratory effort. Auto-triggering may falsely indicate a patient is initiating respiratory effort.
    d. T-piece resuscitator (e.g., Neopuff ventilator for infants)

Monitoring during the apnea test

1. Monitor the patient's cardiopulmonary status via an invasive arterial catheter, 3-5 lead ECG, and pulse oximeter
    a. If unable to obtain invasive arterial access, use blood pressure cuff with frequent cycling
    b. Visual (bare chest and abdomen) and tactile observation of the patient's chest for movement and abdominal musculature for contraction or evidence of spontaneous breathing. Some chest wall movement, which must be distinguished from respiratory effort, can be observed due to cardiac pulsation or contraction of the intercostal muscles due to acidosis
2. If using a flow inflating bag, monitor for respiratory effort by feeling and watching the bag
3. If using the ventilator in CPAP mode, monitor the flow waveforms for a patient-initiated breath
4. Transcutaneous CO_2 monitoring can be used to follow the rise in partial pressure of CO_2 and guide the timing of ABG sampling

Performance of serial arterial blood gasses

1. Pa_{CO_2} increases by approximately 2-3 mm Hg per minute during apnea
2. If point of care blood gas testing is available, perform serial ABG's (approximately every 2 minutes) beginning at approximately 8 minutes of apnea, if the patient does not have hemodynamic instability or hypoxemia, until the ABG results are consistent with the criteria below.
3. If point of care blood gas testing is not available, send an ABG after approximately 8 minutes of apnea, but continue apnea testing/repeat the ABG every 2-3 minutes if the patient is hemodynamically stable until the ABG results are consistent with the criteria below. The duration of testing is typically 10-15 minutes but can be carried out for longer if the patient is stable.

The apnea test is consistent with Brain Death if these conditions are met

1. No respirations or effort occurs, and
2. The arterial pH level is <7.30, and

3a. In patients who are known NOT TO HAVE chronic CO_2 retention, the Pa_{CO_2} level is ≥60 mm Hg AND ≥20 mm Hg above the patient's pre-apnea test baseline level.

3b. In patients who are KNOWN TO HAVE chronic CO_2 retention, and the baseline Pa_{CO_2} is KNOWN, the Pa_{CO_2} level is ≥60 mm Hg AND ≥20 mm Hg above the patient's known chronic elevated premorbid baseline level.

3c. In patients who are SUSPECTED TO HAVE chronic CO_2 retention, but the baseline Pa_{CO_2} is UNKNOWN, the Pa_{CO_2} level is ≥60 mm Hg AND ≥20 mm Hg above the patient's pre-apnea test level, and an ancillary test is required.

Terminate the apnea test for:

1. Spontaneous respirations or effort
2. Hemodynamic instability or hypoxemia
    a. SBP ≤100 mm Hg or MAP ≤75 mm Hg in adults, or SBP or MAP ≤5th percentile for age in children, despite titration of vasopressors, inotropes, and/or intravenous fluids
    b. Decrease in oxygen saturation below 85%
    c. Cardiac arrhythmia with hemodynamic instability
    d. In infants, bradycardia (<60 BPM), since it can occur before hypotension or hypoxemia
3. Unless the test is being aborted due to spontaneous respirations, obtain an ABG before reconnecting the patient to the ventilator if able. If the arterial pH and Pa_{CO_2} criteria (as included above) are achieved, the apnea test is consistent with BD/DNC.
4. After resuming mechanical ventilation, transiently increase minute ventilation to achieve normoxia, normocapnia and a normal acid-base status.
5. If the test is aborted but the completion conditions are not met, the apnea test may be repeated for a longer duration if the patient was stable during testing, or an ancillary test may be performed.

Attachment C

Apnea Testing on ECMO

Clinicians should adhere to the following protocol for apnea testing on ECMO:

1. Preoxygenate by using 100% FiO_2 on the ventilator and through the membrane lung.
2. To achieve an adequate increase in $PaCO_2$ level, either titrate exogenous CO_2 into the ECMO circuit or adjust the sweep gas flow rate to 0.2–1 L/min.
3. Sample ABG measurements from both the patient's distal arterial line and the ECMO circuit postoxygenator for patients on VA ECMO. $PaCO_2$ and pH levels from both locations are required to meet BD/DNC criteria for the apnea test to be consistent with BD/DNC. This ensures that, independent of the mixing point, the $PaCO_2$ and pH levels in the cerebral circulation meet BD/DNC criteria. For patients on venovenous ECMO, sample ABG measurements only from the patient's distal arterial line.
4. Avoid hypotension during apnea testing on ECMO by increasing ECMO flows, intravenous fluid administration, or vasopressor/inotropic support

Ancillary Testing: Tests of Cerebral Blood Flow and Perfusion

Test	Diagnostic criteria	Advantages	Disadvantages	Sensitivity/ specificity	Comments
Digital subtraction angiography/ conventional 4-vessel angiography	Absence of contrast within the intracranial arterial vessels	• Gold standard for ancillary tests	• Requires transport to imaging suite • Invasive (requires technical skills) • Renal susceptibility to contrast • Stasis filling–false negative	100%/ 100%	Persistence of flow does not contradict comprehensive competent clinical diagnosis; Equipment and operator dependence limits practical use–still used as calibration standard
Radionuclide angiography	Absence of radiologic activity upon imaging of the intracranial vault	• Can be performed at bedside • No renal susceptibility to contrast	• Limited evaluation of brainstem • Limited availability • Results can vary based on technique used	98.5%/56%	Persistence of flow does not contradict comprehensive competent clinical diagnosis
Radionuclide perfusion scintigraphy	Absence of radiologic activity indicating metabolic uptake upon imaging of the intra-cranial vault	• Can be performed at bedside (planar imaging)	• Limited availability • Planar imaging may limit brain-stem evaluation • SPECT requires patient transport to scanner	Planar: 77.8%/100% SPECT: 88.4%/100%	Uptake of isotope indicates metabolic activity.
Transcranial doppler ultrasound (adult patients)	Reciprocating flow or small systolic spikes with absent or reversed diastolic flow on initial assessment of intracranial arterial supply, confirmed or proceeding to absent flow velocity signal on second assessment	• Easily performed at bedside • No contrast required • Can assess carotid and basilar circulations	• Operator expertise required • 10% of patients have no acoustic windows	90%/98%	Persistence of flow does not contradict comprehensive competent clinical diagnosis