

Parent Policies: Determination of Brain Death: Apnea Study	Title: Determination of Brain Death Guideline-Adult	Standard Operating Procedure
		Effective Date: 05/03/2022

**DETERMINATION OF BRAIN DEATH IN ADULT PATIENTS
(18 YEARS AND OLDER)**

Concern for brain death, defined by complete and permanent loss of brain function as defined by an unresponsive coma with loss of capacity for consciousness, brainstem reflexes, and the ability to breathe independently.

- Minimal clinical criteria for establishing brain death**
- The patient must have an established neurologic diagnosis, the nature and severity of which is capable of resulting in the irreversible loss of the capacity for consciousness, the irreversible loss of all brainstem reflexes, and the irreversible loss of the ability to spontaneously breathe.
 - All pathological conditions, confounders, and/or reversible conditions that may mimic brain death must be excluded prior to commencing a determination of brain death.
 - CNS depressant drug effect is absent. If indicated, obtain toxicology screen. If sedating medications are used it is recommended to wait at least 5 half-lives until the start of clinical testing (longer if hepatic or renal insufficiency). If barbiturates have been given serum level must be <10mcg/mL. If alcohol intoxication is suspected or confirmed blood alcohol level must be <80 mg/dL.
 - No evidence of residual paralytics. Check with train of four if paralytics have been used.
 - Absence of severe acid-base, electrolyte, or endocrine abnormalities.
 - Core temperature > 36°C (96.8°F). If targeted temperature management is utilized clinical testing should not be initiated until at least 24 hours following complete rewarming.
 - Systolic blood pressure ≥ 100 mm Hg, or a mean arterial pressure of at least 60 mm Hg. Vasopressors may be required and are permissible.

In EPIC, use the dot phrase .BRAINDEATHEXAM to assist with documentation.

See next page for details regarding the clinical exam, apnea test, confirmatory testing, and notifications.

Pathway A

Two eligible attending physicians independently perform and document a full clinical exam 6 hours apart that establish the loss of function of the entire brain AND a single apnea test confirms the absence of brainstem function.

Official time of death: the time the ABG is drawn for apnea testing

Pathway B

In patients who do not meet minimal clinical criteria for establishing brain death and/or there is uncertainty regarding clinical conditions and/or it is the provider's preference then a confirmatory study can be used to confirm brain death. The preferred confirmatory study is a radioisotope flow study. A clinical exam should still be performed to the fullest extent possible and clearly documented by the primary attending physician. To satisfy WakeMed policy a second eligible attending physician must be consulted and confirm the diagnosis of brain death.

Official time of death: the time the confirmatory study is completed

Primary reference: World Brain Death Project JAMA.2020;324(11)1078-1097.



Clinical testing

If a portion of the exam cannot be performed for any reason the remainder should be completed to the fullest extent possible.

- The patient is comatose. There is no evidence of arousal or awareness to maximal external stimulation.
- Pupils nonreactive to bright light. They are fixed and dilated in the midline position.
- Corneal reflex absent. In the setting of anophthalmia, severe orbital edema, prior corneal transplantation, or scleral edema or chemosis, ancillary testing is recommended.
- Oculocephalic reflex (e.g. doll's eyes) absent. *Test only if C-spine integrity ensured. If the oculocephalic reflex cannot be performed, but the oculovestibular reflex is performed and there are no extraocular movements, ancillary testing is not required.* Severe orbital or scleral edema or chemosis may affect the free motion of the globes, and ancillary testing is recommended. In the setting of anophthalmia, ancillary testing is recommended.
- Oculovestibular reflex (e.g. cold caloric) absent. A fracture of the base of the skull or petrous temporal bone may obliterate the response on the side of the fracture, and ancillary testing is recommended. Severe orbital or scleral edema or chemosis may affect the free motion of the globes, and ancillary testing is recommended. In the setting of anophthalmia, ancillary testing is recommended.
- No movement to noxious stimuli. Specifically, no eye, face, or extremity movement to noxious stimuli. Ancillary testing is recommended if a person has a preexisting severe neuromuscular disorder, such as amyotrophic lateral sclerosis or a preexisting severe sensory neuropathy. Severe facial trauma or swelling may preclude evaluation of facial motor responses, so ancillary testing is recommended. Spinal/peripheral nerve mediated reflexes are permissible.
- Gag reflex absent.
- Cough reflex absent. The efferent limb of the cough reflex includes the phrenic nerve, which may be injured in persons with high cervical cord injuries, so ancillary testing is recommended.

* For more details on how to perform the clinical exam see next page.

Apnea test

- See WakeMed policy 640 for more information: <https://wakemed.policytech.com/dotNet/documents/?docid=675>.
- In Pathway A, only 1 apnea test has to be performed (not 2).
- First, confirm that the patient is not generating any spontaneous breaths on pressure support mode in a normocarbic state.
- Refer to the last ABG result and titrate ventilator rate, if necessary, to achieve a normalized PaCO₂ of 35-45 mmHg. Normalize CO₂ levels in cases of intentional hyperventilation
- Increase FIO₂ on vent to 100%.
- After 5 min, get baseline ABG. Record ABG & baseline vital signs. Continue with ventilator changes until the CO₂ is within normal range.
- Disconnect patient from ventilator and place 14 French suction catheter with suction ports occluded into ET tube. Connect O₂ tubing to the suction catheter and O₂ flow meter and turn flow to 6 LPM. Advance suction catheter to carina and withdraw about 3 cm to avoid catheter insertion into the right main stem bronchus.
- After 5 min, get ABG, print results, and record HR, RR, and BP.
- Repeat at 5-min increments. Note vital signs, respiratory efforts and cardiac irregularities.
- Study is complete when PCO₂ ≥ 60 OR a CO₂ level selected by M.D. is reached in presence of known CO₂ retention.
- If BP falls < 80 mmHg, O₂ saturation <90%, life threatening cardiac arrhythmias occur, or the patient begins spontaneous respirations, place the patient back on the ventilator on previous settings and notify RN and MD.

* Note, apnea testing is contraindicated in the setting of high cervical cord or phrenic nerve injury.

Confirmatory study

The recommended confirmatory test is radioisotope flow study. This is definitive in the face of barbiturates & other conditions mimicking brain death (see appendix below). Brain death is confirmed in the absence of blood flow to the brain.

False negative radioisotope flow study results have been reported (e.g. flow is noted, but clinically the patient meets criteria).

A radioisotope flow study can be used for any reason. Most commonly, a flow study is used to confirm brain death in patients that do not meet all pre-requisites for clinical testing, there is uncertainty regarding clinical conditions, and/or it is the provider's preference (pathway B).

Notifications

- Notify Honor Bridge when initiating a brain death evaluation (1-800-252-2672). Typically, the eICU (0-0625) will assist with this.
- Providers may not discuss organ donation unless they have completed the required training.
- All trauma deaths are reported to the medical examiner. Typically, the eICU (0-0625) will assist with this. The medical examiner is responsible for completing the death certificate.

In accordance with WakeMed policy, somatic support after the declaration of brain death should not be extended beyond 48 hours.

Table 2: World Brain Death
Project JAMA.2020;324(11)1078-
1097.

1. Coma: there is no evidence of arousal or awareness to maximal external stimulation (including noxious visual, auditory, and tactile stimulation).
2. Pupillary reflexes
 - A. Test
 - Shine a bright light into each of the person's eyes, looking for pupillary constriction and measuring the diameter of the pupils. Use of a magnifying glass and/or pupillometer is suggested
 - B. Response consistent with BD/DNC
 - There should be absence of ipsilateral and contralateral pupillary response, with pupils fixed in a midsize or dilated position (~4-6 mm), in both eyes
 - C. Considerations
 - Constricted pupils are not consistent with BD/DNC and suggest the possibility of drug intoxication or locked-in syndrome
 - Pupils can be any shape (round/oval/irregular)
 - Corneal trauma or prior ophthalmic surgery may influence pupillary reactivity and preclude adequate evaluation, necessitating ancillary testing
 - Ocular instillation of drugs may artificially produce transiently nonreactive pupils
 - In the setting of anophthalmia or inability to see the pupils, ancillary testing is recommended
3. Oculocephalic (OCR) and oculovestibular (OVR) reflexes
 - A. Test
 - OCR: Rotate the head briskly horizontally to both sides. There should be no movement of the eyes relative to head movement. Testing vertically is optional
 - OVR: Examine the auditory canal for patency and an intact tympanic membrane. Elevate the head to 30° to place the horizontal semicircular canals in the correct vertical position. Irrigate with at least 30 mL of ice water for at least 60 seconds using a syringe or a syringe attached to a catheter placed inside the canal. Test both sides separately, with a 5-minute interval between to allow the endolymph temperature to equilibrate
 - B. Response consistent with BD/DNC
 - There should be absence of extraocular movements. Detection of any extraocular movements is not compatible with BD/DNC
 - C. Considerations
 - Confirm the integrity of the cervical spine before proceeding with the OCR test. If the OCR cannot be performed, but the OVR is performed and there are no extraocular movements, ancillary testing is not required
 - Ensure the integrity of the tympanic membrane. Presence of a ruptured tympanic membrane does not negate the clinical testing but may risk introducing infections in the ear
 - A fracture of the base of the skull or petrous temporal bone may obliterate the response on the side of the fracture, and ancillary testing is recommended in this instance
 - Severe orbital or scleral edema or chemosis may affect the free motion of the globes, and ancillary testing is recommended in this instance
 - In the setting of anophthalmia, ancillary testing is recommended
4. Corneal reflex
 - A. Test
 - Touch the cornea of both eyes with a cotton swab on a stick at the external border of the iris, applying light pressure and observing for any eyelid movement
 - B. Response consistent with BD/DNC
 - No eyelid movement should be seen
 - C. Considerations
 - Care should be taken to avoid damaging the cornea
 - In the setting of anophthalmia, severe orbital edema, prior corneal transplantation, or scleral edema or chemosis, ancillary testing is recommended
5. Motor responses of the face and limbs
 - A. Test
 - Apply deep pressure to all of the following:
 - i. the condyles at the level of the temporomandibular joints
 - ii. the supraorbital notch bilaterally
 - iii. the sternal notch
 - iv. all 4 extremities, both proximally and distally
 - Insert a cotton swab on a stick in each nostril to perform "nasal tickle" testing
 - B. Response consistent with BD/DNC
 - Noxious stimuli should not produce grimacing, facial muscle movement, or a motor response of the limbs other than spinally mediated reflexes
 - Noxious stimuli above the foramen magnum should not produce any movement in the face or body. Noxious stimuli below the foramen magnum should not produce any movement in the face but may elicit spinally mediated peripheral motor reflexes
 - C. Considerations
 - The clinical differentiation of spinal from brain-mediated motor responses requires expertise. Consultation with an experienced practitioner is recommended if the origin of a response is unclear. Alternatively, if interpretation is unclear, ancillary testing is recommended
 - Ancillary testing is recommended if a person has a preexisting severe neuromuscular disorder, such as amyotrophic lateral sclerosis or a preexisting severe sensory neuropathy
 - Ancillary testing is not required if a person does not have all 4 limbs; absence of a limb does not preclude motor testing to pain on that side of the body
 - Severe facial trauma or swelling may preclude evaluation of facial motor response, so ancillary testing is recommended in this setting
6. Gag and cough reflexes
 - A. Test
 - Gag reflex: stimulate the posterior pharyngeal wall bilaterally with a tongue depressor or suction catheter
 - Cough reflex: stimulate the tracheobronchial wall to the level of the carina with deep endotracheal placement of a suction catheter
 - B. Response consistent with BD/DNC
 - Absence of gag and cough
 - C. Considerations
 - The efferent limb for the cough reflex includes the phrenic nerve, which may be injured in persons with high cervical cord injuries, so ancillary testing is recommended in this setting

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DETERMINATION OF BRAIN DEATH IN ADULT PATIENTS (≥ 18 YEARS OLD)

Brain death requires the IRREVERSIBLE loss of ALL functions of the ENTIRE brain, including the brainstem. It is defined by complete and permanent loss of brain function as defined by an unresponsive coma with loss of capacity for consciousness, brainstem reflexes, and the ability to breathe independently. Brain death determination cannot be made in setting of potentially reversible conditions like hypothermia, shock, or drug intoxication without a confirmatory test.

We recommend that an assessment for the determination of brain death be made regardless of organ donation status. Consent is not required for the performance of clinical evaluation, apnea testing, or confirmatory testing for determination of brain death.

There are two pathways that can be followed to declare a patient brain dead. These pathways differ based on whether or not the patient meets minimal established criteria for establishing brain death:

Pathway A

Two eligible attending physicians independently perform and document a full clinical exam 6 hours apart that establish the loss of function of the entire brain AND a single apnea test confirms the absence of brainstem function. *Official time of death: the time the ABG is drawn for apnea testing.*

Pathway B

In patients who do not meet minimal clinical criteria for establishing brain death and/or there is uncertainty regarding clinical conditions and/or it is the provider's preference then a confirmatory study can be used to confirm brain death. The preferred confirmatory study is a radioisotope flow study. A clinical exam should still be performed to the fullest extent possible and clearly documented by the primary attending physician. To satisfy WakeMed policy a second eligible attending physician must be consulted and confirm the diagnosis of brain death. *Official time of death: the time the confirmatory study is completed.*

MINIMAL CLINICAL CRITERIA FOR ESTABLISHING BRAIN DEATH

- The patient must have an established neurologic diagnosis, the nature and severity of which is capable of resulting in the irreversible loss of the capacity for consciousness, the irreversible loss of all brainstem reflexes, and the irreversible loss of the ability to spontaneously breathe.
- All pathological conditions, confounders, and/or reversible conditions that may mimic brain death must be excluded prior to commencing a determination of brain death.
- CNS depressant drug effect is absent. If indicated, obtain toxicology screen. If sedating medications are used it is recommended to wait at least 5 half-lives until the start of clinical testing (longer if hepatic or renal insufficiency). If barbiturates have been given serum level must be <10mcg/mL. If alcohol intoxication is suspected or confirmed blood alcohol level must be <80mg/dL.

Prepared by: MGR, TRAUMA PROGRAM
Approved by: MEDICAL DIR TRAUMA - RALEIGH

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- No evidence of residual paralytics. Check with train of four if paralytics have been used.
- Absence of severe acid-base, electrolyte, or endocrine abnormalities.
- Core temperature > 36oC (96.8oF). If targeted temperature management is utilized clinical testing should not be initiated until at least 24 hours following complete rewarming.
- Systolic blood pressure > 100 mm Hg, or a mean arterial pressure of at least 60 mm Hg. Vasopressors may be required and are permissible.

CLINICAL TESTING

In EPIC, use the dot phrase .BRAINDEATHEXAM to assist with documentation of the clinical exam. If a portion of the exam cannot be performed for any reason the remainder should be completed to the fullest extent possible.

- The patient is comatose. There is no evidence of arousal or awareness to maximal external stimulation.
- Pupils nonreactive to bright light. They are fixed and dilated in the midline position.
- Corneal reflex absent. In the setting of anophthalmia, severe orbital edema, prior corneal transplantation, or scleral edema or chemosis, ancillary testing is recommended.
- Oculocephalic reflex (e.g. doll’s eyes) absent. Test only if C-spine integrity ensured. If the oculocephalic reflex cannot be performed, but the oculovestibular reflex is performed and there are no extraocular movements, ancillary testing is not required. Severe orbital or scleral edema or chemosis may affect the free motion of the globes, and ancillary testing is recommended. In the setting of anophthalmia, ancillary testing is recommended.
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 - B. Response consistent with BD/DNC
 - Absence of gag and cough
 - C. Considerations
 - The efferent limb for the cough reflex includes the phrenic nerve, which may be injured in persons with high cervical cord injuries, so ancillary testing is recommended in this setting

Table 2: World Brain Death Project JAMA.2020;324(11)1078-1097.

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APNEA TEST

- See WakeMed policy 640 for more information:
<https://wakemed.policytech.com/dotNet/documents/?docid=675>
- In Pathway A, only 1 apnea test has to be performed (not 2).
- First, confirm that the patient is not generating any spontaneous breaths on pressure support mode in a normocarbic state.
- Quick reference:
 - Refer to the last ABG result and titrate ventilator rate, if necessary, to achieve a normalized PaCO₂ of 35-45 mmHg. Normalize CO₂ levels in cases of intentional hyperventilation (Target minute ventilation of 5-7 LPM will generally allow a PaCO₂ within this range).
 - Increase FIO₂ on vent to 100%.
 - After 5 min. get baseline ABG, Record ABG & baseline vital signs. Continue with ventilator changes until the CO₂ is within normal range.
 - Disconnect patient from ventilator and place 14 French suction catheter with suction ports occluded into ET tube. Connect O₂ tubing to the suction catheter and O₂ flow meter and turn flow to 6 LPM. Advance suction catheter to carina and withdraw about 3 cm to avoid catheter insertion into the right main stem bronchus.
 - After 5 min, get ABG, print results, and record HR, RR, and BP.
 - Repeat at 5-min increments. Note vital signs, respiratory efforts and cardiac irregularities.
 - Study complete when PCO₂ ≥ 60 OR a CO₂ level selected by M.D. is reached in presence of known CO₂ retention.
 - If BP falls < 80 mmHg, O₂ saturation <90%, life threatening cardiac arrhythmias occur, or the patient begins spontaneous respirations, place the patient back on the ventilator on previous settings and notify RN and MD.

** Note, apnea testing is contraindicated in the setting of high cervical cord or phrenic nerve injury*

CONFIRMATORY TESTING

The recommended confirmatory test is radioisotope flow study. This is definitive in the face of barbiturates & other conditions mimicking brain death (see appendix below). Brain death is confirmed in the absence of blood flow to the brain.

False negative radioisotope flow study results have been reported (e.g. flow is noted, but clinically the patient meets criteria).

A radioisotope flow study can be used for any reason. Most commonly, a flow study is used to confirm brain death in patients that do not meet all pre-requisites for clinical testing, there is uncertainty regarding clinical conditions, and/or it is the provider's preference (pathway B). CT angiogram is another promising technology but requires additional research.

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Other confirmatory studies include EEG, brainstem evoked potentials, transcranial Doppler, 4-vessel arteriogram, and PET scan. We do not recommend their use.

TIME OF DEATH

The official time of death is the time the ABG is drawn for apnea testing (pathway A) or the time the confirmatory study is completed, not read by radiology (pathway B). The eICU also collects time of CARDIAC standstill. This is used by Honor Bridge for non-heart-beating donations and has no legal meaning.

NOTIFICATIONS

Notify Honor Bridge when initiating a brain death evaluation (1-800-252-2672). Typically, the eICU (0-0625) will assist with this.

Providers may not discuss organ donation unless they have completed the required training.

All trauma deaths are reported to the medical examiner. Typically, the eICU (0-0625) will assist with this. The medical examiner is responsible for completing the death certificate.

In accordance with WakeMed policy, somatic support after the declaration of brain death should not be extended beyond 48 hours.

PRIMARY REFERENCE

The World Brain Death Project has created a comprehensive resource from which this guideline is adapted. Access: World Brain Death Project. JAMA 2020;324(11):1078-97.

APPENDIX

NC LAW G.S. 90-323

The determination that a person is dead shall be made by a physician licensed to practice medicine applying ordinary and accepted standards of medical practice. Brain death, defined as irreversible cessation of total brain function, may be used as a sole basis for the determination that a person has died, particularly when brain death occurs in the presence of artificially maintained respiratory and circulatory functions. This specific recognition of brain death as a criterion of death of the person shall not preclude the use of other medically recognized criteria for determining whether and when a person has died (1979, c. 715, s. 3.).

The WakeMed [Administrative-Patient Care Policy, Determination of Brain Death \(Adult and Pediatric Patients\)](#), effective 12/04/2019, complies with NC law with the following additional requirements:

- NC Law +
- **Requires 2nd confirmatory consultation**
- The examining physicians must be attendings
- One of the examining physicians must be a neurologist, intensivist or neurosurgeon
- Once suspected, the determination of brain death should occur within 48 hours

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Spinal/peripheral nerve mediated reflexes

Movements originating from the spinal cord or peripheral nerve may occur in brain death. These movements occur in up to . of brain-dead patients and may be triggered by tactile stimuli or occur spontaneously. Examples include:

- Triple flexion response with flexion at the hip, knee, and foot when testing for Babinski sign
- Upper limb pronation extension reflex
- Widespread fasciculations of the trunk and extremity
- Finger flexion
- Semirhythmic contractions of facial muscles
- Tonic, whole body flexion, including the neck, arms, and trunk. Often called the “Lazarus sign.”

Conditions mimicking brain death

- Locked-in syndrome
- Neuromuscular paralysis, e.g. severe Guillain-Barre
- Hypothermia
- Drug intoxication

Ordinary and Accepted Standards of Medical Practice

- Harvard Criteria, JAMA 1968;205(6):337-40.
 - Unreceptive & unresponsive
 - No movements or breathing
 - No reflexes
 - Flat EEG (confirmatory)
 - All repeated 24 hours later (arbitrarily selected)
 - MUST exclude hypothermia (32.2°C) & CNS depressants
 - SUGGEST consultation with 1 or more physicians
 - SUGGEST declaration be done by physicians NOT involved in the transplantation of organs
- National Institute for Neurologic and Communicative Disorders & Stroke (NINCDS), JAMA 1977;237(10):982-6.
 - Coma with cerebral unresponsivity
 - Apnea
 - Dilated pupils
 - Absent cephalic reflexes (pupillary light response, oculocephalic or doll’s eyes, oculovestibular or cold caloric, corneal reflex, cough and gag)
 - Spinal reflexes may persist after brain death
 - Electrocerebral silence
 - False negative EEG with drug intoxication, cardiac disease, cerebral trauma, hypothermia & encephalitis
 - MUST exclude hypothermia (32.2°C), CNS depressants, cardiovascular shock & remedial

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- primary disorder
 - RECOMMEND confirmatory test assess cerebral blood flow
- Report of the Medical Consultants on the Diagnosis of Death to the President’s Commission for the Study of Ethical Problems in Medicine and Behavioral Research, JAMA 1981;246(19):2184-6.
 - No cases of recovery after 6 hrs. of cessation & confirmatory test
 - Recommend 12 hrs. if no confirmatory test (24 hrs. for anoxic brain injury)
 - Apnea test (see WakeMed policy No. 640, effective 02/26/2018)
<https://wakemed.policytech.com/dotNet/documents/?docid=675>
 - Must document a pCO2 > 60 mm Hg
- American Academy of Neurology guidelines and checklist
 - Neurology 1995;45:1012-4.
 - Neurology 2010;74:1911-8.
- World Brain Death Project. JAMA 2020;324(11):1078-97.
 - Recommendations for minimum clinical standards for the determination of brain death/death by neurologic criteria (BD/DNC).