

GUIDELINES FOR
DETERMINING BRAIN DEATH

**NEW YORK STATE
DEPARTMENT OF HEALTH**

AND

**NEW YORK STATE
TASK FORCE ON LIFE
& THE LAW**

November 2011

GUIDELINES FOR DETERMINING BRAIN DEATH

BACKGROUND

This document provides guidance for determining brain death, aims to increase knowledge amongst health care practitioners about the clinical evaluation of brain death, and reduces the potential for variations in brain death determination policies and practices amongst facilities and practitioners within New York State. The Department of Health hopes that the issuance of these guidelines not only will help educate health care providers regarding such determinations, but also will increase the public's confidence that such determinations are made after a thorough and careful evaluation in accordance with accepted medical standards.

The guidelines contained in this document, which revise and update New York's 2005 guidelines, represent a broad consensus on the criteria for determining brain death. They incorporate the guidelines of the American Academy of Neurology (AAN), initially released in 1995 and revised in 2010. They also draw upon a consensus-building process that included ethical, legal and clinical review by the New York State Task Force on Life and the Law, as well as recommendations by an outside working group of expert physicians from across the State.

Revisions to the 2005 Brain Death Determination Guidelines

These updated guidelines make two significant modifications to the 2005 guidelines, as well as a number of smaller changes to certain clinical parameters. First, the 2005 guidelines recommended two clinical assessments of brain stem reflexes before an apnea test was performed, whereas these guidelines recommend one comprehensive clinical assessment prior to an apnea test. Evidence has revealed several disadvantages – and no concomitant benefits – to requiring the second brain stem assessment prior to the apnea test. Extensive review of medical journals and studies conducted to date supports the use of a single proper brain function assessment after an appropriate waiting period, and an apnea test the results of which are diagnostic of brain death, in order to declare death.

In addition, conducting a second brain stem assessment within a reasonable timeframe is sometimes not possible, particularly in facilities that have only one physician who is privileged to perform brain death determinations. These delays have been shown to be traumatic to families watching their loved one in intensive care and waiting for confirmation of their death. In addition, while waiting for a second assessment, patients are especially susceptible to cardiac arrest and vulnerable to rapid deterioration of other organ systems, which could lead to a needlessly prolonged confirmation of death. Accordingly, these updated guidelines contained in this document allow for an apnea test to be performed after a single, rigorous clinical examination showing that brain function has ceased.

Second, these updated guidelines, like the 2005 guidelines, include a waiting period to exclude the possibility of recovery, but differ in important ways from previous waiting period requirements. The 2005 guidelines recommended an arbitrary waiting period of six hours and placed the waiting period between the first and second examinations of brain stem reflexes.

Studies have since shown that there is insufficient evidence to pinpoint a minimally-acceptable number of hours to ensure that brain function has permanently ceased. To address this issue, these guidelines recommend that physicians wait an appropriate period of time, sufficiently long as is relevant to the individual patient's condition (in practice, usually several hours), after the onset of the brain insult to exclude the possibility of recovery, and requires that this possibility be ruled out prior to proceeding to the brain stem reflex exam.

Adding a waiting period early in the process – before the clinical assessment of brain death is initiated – provides greater assurance that there is little potential for improvement and is consistent with current clinical practice. Only after it is clear that the patient will not likely recover should the brain stem reflex test and apnea test be conducted. In all cases, these guidelines advocate a high degree of caution and vigilance to ensure that there is no possibility of a patient's recovery.

Please note that the guidelines for the determination of brain death in children contained in this document do not substantively alter the State's 2005 iteration.

DEFINITION

New York State regulation defines brain death as the irreversible loss of all function of the brain, including the brain stem. *See* 10 N.Y.C.R.R. § 400.16. The three essential findings in brain death are coma, absence of brain stem reflexes, and apnea. An evaluation for brain death should be considered in patients who have suffered a massive, irreversible brain injury of identifiable cause. A patient properly determined to be brain dead is legally and clinically dead.

The diagnosis of brain death is primarily clinical. No other tests are required if the full clinical examination, including an assessment of brain stem reflexes and an apnea test, is conclusively performed. In the absence of either complete clinical findings consistent with brain death or ancillary tests demonstrating brain death, brain death cannot be diagnosed.

Hospital Responsibilities Regarding Brain Death Determination

10 N.Y.C.R.R. § 400.16 requires all New York State hospitals to establish and implement written policies for determining brain death, including:

- The tests and procedures required for determining brain death;
- Notification of the next of kin or other person closest to the patient (collectively, the "Surrogate Decision-maker") that brain death determination is in progress; and
- Reasonable accommodation of an individual's or Surrogate Decision-maker's religious or moral objection to use of the brain death standard to determine death.

In addition, hospitals should create written policies for privileging physicians to make brain death determinations in accordance with accepted medical standards.

Each of these responsibilities is addressed in further detail on the following pages.

Brain Death Determination Policies

Hospitals are required to establish written policies that specify the process for determining brain death, including a description of examinations and tests to be employed. The following pages provide additional information on the clinical steps that should be conducted and on various ancillary tests available as guidance to clinicians and facilities. The Department recommends hospitals use these guidelines in developing their own written policies while tailoring ancillary testing to the specific resources available in their facility.

Notification

New York State law requires hospitals to make reasonable efforts to notify the Surrogate Decision-maker that the process of evaluating brain death has begun. Staff notifying such persons should be prepared to respond to basic questions concerning the patient's condition and the procedures for determining brain death.

Reasonable Accommodation

Hospitals must establish written procedures for the reasonable accommodation of the individual's religious or moral objections to use of the brain death standard to determine death when such an objection has been expressed by the patient prior to the loss of decision-making capacity, or by the Surrogate Decision-maker. Policies may include specific accommodations, such as the continuation of artificial respiration under certain circumstances, as well as guidance on limits to the duration of the accommodation. Policies may also provide guidance on the use of other resources, such as clergy members, ethics committees, palliative care clinicians, bereavement counselors, and conflict mediators to address objections or concerns. Since objections to the brain death standard based solely upon psychological denial that death has occurred or on an alleged inadequacy of the brain death determination are not based upon the individual's moral or religious beliefs, "reasonable accommodation" is not required in such circumstances. However, hospital staff should demonstrate sensitivity to these concerns and consider using similar resources to help family members accept the determination and fact of death.

Privileging

The application of the clinical criteria described in this policy requires the sound judgment of a physician competent in determining brain death. The privileging of physicians is essential to ensuring the proper conduction of brain death examinations. Each hospital should establish a process for identifying and privileging physicians to make brain death determinations and a mechanism by which all nursing and medical staff can verify physicians' privileges. Hospital policies should specify rigorous standards for training and assessing competency to determine brain death and should include procedures for periodic review of clinicians' credentials under the applicable standards to ensure that such physicians are qualified and that their knowledge reflects current scientific understanding and generally-accepted clinical practice.

A physician need not be, or consult with, a neurologist or neurosurgeon in order to determine brain death. However, privileged physicians should have appropriate medical knowledge and understanding of the procedures and testing involved in determining brain death.

A patient's attending physician should participate in the determination of brain death whenever possible. If the attending physician is not privileged by the hospital in the determination of brain death, another physician having such privileges must perform the assessment and make the final determination.

Responsibilities of Physicians Determining Brain Death

The diagnosis of brain death is primarily clinical, and consists of three essential findings: irreversible and unresponsive coma, absence of brain stem reflexes, and apnea. No other tests are required if the full clinical examination, including an assessment of brain stem reflexes and an apnea test, is conclusively performed. In the absence of either complete clinical findings consistent with brain death, or ancillary tests demonstrating brain death, brain death cannot be diagnosed and certified. These guidelines apply to patients one year of age or older. *Please see Appendix 1 for the determination of brain death in children less than 1 year old.*

The steps for determining brain death are summarized below, and explained in more detail in the following pages:

1. Establish proximate cause and irreversibility of coma and monitor the patient for an appropriate waiting period in order to exclude the possibility of recovery;
2. Initiate the hospital policy for notifying the patient's Surrogate Decision-maker;
3. Conduct and document the clinical assessment of brain stem reflexes;
4. Perform and document the apnea test;
5. Perform ancillary testing, if indicated;
6. If the individual's religious or moral objection to the brain death standard is known, implement hospital policies for reasonable accommodation;
7. Certify brain death; and
8. Discontinue cardio-respiratory support in accordance with hospital policies, including those for organ donation.

Step 1: Establish Proximate Cause and Irreversibility of Coma

A prerequisite to the determination of brain death is the identification of the proximate cause and irreversibility of coma. Severe head injury, intracerebral hemorrhage, aneurysmal subarachnoid hemorrhage, hypoxic-ischemic brain insults and fulminant hepatic failure are potential causes of irreversible loss of brain function. The physician should assess the extent and potential reversibility of any damage, and also exclude confounding factors such as drug intoxication,

neuromuscular blockade, hypothermia, or metabolic abnormalities that cause coma but are potentially reversible.

Establishing the cause and irreversibility of coma requires the physician to wait an appropriate period of time sufficiently long as is relevant for the individual patient (in practice, usually several hours) in order to rule out any confounding factors and the possibility of recovery. The evaluation of a potentially irreversible coma should also include, as may be appropriate to the particular case:

- Clinical or neuro-imaging evidence of an acute CNS catastrophe that is compatible with the clinical diagnosis;
- Exclusion of complicating medical conditions that may confound clinical assessment (*e.g.*, no severe electrolyte, acid-base, or endocrine disturbance);
- Exclusion of significant hypothermia or hypotension;
 - Normal core temperature should be:
 - (age $\geq$ 18 years) $> 36^{\circ}\text{C}$ (96.8°F)
 - (age $\geq$ 1 year $<$ 18 years) Consider age specific norms
 - (age $<$ 1 year) See Appendix 1
 - Normal systolic blood pressure should be:
 - (age $\geq$ 18 years) ≥ 100 mm Hg (Option: mean arterial pressure ≥ 65 mm Hg)
 - (age $\geq$ 1 year $<$ 18 years) Consider age specific norms
 - (age $<$ 1 year) See Appendix 1
- Exclusion of drug intoxication or poisoning. Patients admitted for the treatment of drug overdose should have confirmatory tests to ensure that drug levels have decreased to clinically insignificant levels.

Where hypothermia was induced previously in a patient, additional vigilance is recommended. In such cases, a prolonged waiting period after the re-warming phase is completed may be appropriate.

If intoxicants such as barbiturates, benzodiazepines, or opioids are present, levels need not be zero, but should be in a range that would not normally be expected to interfere significantly with consciousness. Since it is impossible to stipulate specific levels for every drug, experienced clinical judgment is necessary. If levels are unknown, a reasonable practice is to wait 5 half-lives (assuming normothermia and normal hepatic and renal function), or in the case of alcohol usage, the legal limit for driving (blood alcohol content 0.08%) may serve as a practical threshold below which an examination to determine brain death could reasonably proceed. A cerebral blood flow study that demonstrates absent intracranial blood flow is consistent with the diagnosis of brain death even in the presence of CNS depressants.

If neuromuscular junction blocking agents have been used, there should be evidence of neuromuscular transmission, *i.e.*, deep tendon reflexes, other clinical muscle function, or responses to electrical stimulation of motor nerves (presence of a train of 4 twitches with maximal ulnar nerve stimulation), before beginning the determination of brain death.

Step 2: Notify Surrogate Decision-maker

The facility must make diligent efforts to notify the patient's Surrogate Decision-maker that the process for determining brain death is underway. Consent need not be obtained but requests for reasonable accommodation based on religious or moral objections should be noted and referred to appropriate hospital staff. Where family members object to invasive ancillary tests, physicians should rely on the guidance of the hospital's counsel and ethics committee.

Step 3: Clinical Assessment of Brain Stem Reflexes

If an appropriate period of time has passed since the onset of the brain insult to exclude the possibility of recovery, one clinical assessment of brain function and an apnea test should be sufficient to pronounce brain death. Only after the possibility of recovery has been excluded should the brain function and apnea test be performed. However, if the possibility of recovery has not been excluded, these examinations should be deferred.

- Note: Repeat brain death examinations are advisable before proceeding to an apnea test in young children. *Please see Appendix 1 for the determination of brain death in children less than 1 year old.*

In addition, for patients who are 18 years or older, normal core temperature ($> 36^{\circ}\text{C}$ (98.8°F)) should be achieved, particularly in patients who have been hypothermic. In addition, normal systolic pressure (≥ 100 mm Hg) (option: mean arterial pressure ≥ 65 mm Hg) should be achieved before assessing brain stem reflexes.

Where these conditions are met, the following clinical indications verify the occurrence of brain death:

- Coma: No 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.
- Absence of brain stem reflexes:
 - Absence of pupillary response to bright light in both eyes. Usually the pupils are fixed in midsize or dilated position (4-9 mm).
 - Absence of ocular movements using oculoccephalic testing (only when no fracture or instability of the cervical spine or skull base is apparent or may be suspected clinically) and oculovestibular reflex testing.
 - Absence of corneal reflexes.

- Absence of facial muscle movement in response to a noxious stimulus.
- Absence of pharyngeal (gag) and tracheal (cough) reflexes.

Confounding Factors: The following conditions may interfere with the clinical diagnosis of brain death. In such instances, ancillary tests may be necessary.

- Severe facial or cervical spine trauma, or facial deformity confounding cranial nerve assessment.
- Toxic levels of CNS-depressant drugs or neuromuscular blocking agents.
- Severe electrolyte, acid-base, or endocrine disturbance (defined by severe acidosis or laboratory values markedly deviated from the norm).
- Severe chronic pulmonary disease or severe obesity resulting in chronic retention of CO₂.

Clinical observations compatible with the diagnosis of brain death: The following manifestations are occasionally seen and should not be misinterpreted as evidence for brain stem function:

- Spontaneous movements of limbs (when due to spinal activity).
- Deep tendon reflexes; superficial abdominal reflexes; triple flexion response.
- Babinski reflex.
- Respiratory-like movements (shoulder elevation and adduction, back arching, intercostal expansion without significant tidal volumes).
- Sweating, flushing, tachycardia.
- Normal blood pressure without pharmacologic support or sudden increases in blood pressure.
- Absence of diabetes insipidus.

Step 4: Apnea Test

Generally, the apnea test is the final step in the determination of brain death, and is performed after establishing the irreversibility and unresponsiveness of coma, and the absence of brainstem reflexes.

Before performing the apnea test, the physician must determine that the patient meets the following conditions:

- Core temperature $> 36^{\circ}\text{C}$ or 96.8°F .
- PaCO_2 35-45 mm Hg.
- Normal PaO_2 . Option: pre-oxygenation for at least 10 minutes with 100% oxygen to $\text{PaO}_2 > 200$ mm Hg.
- Normotension. Adjust fluids and (if necessary) vasopressors to a systolic blood pressure ≥ 100 mm Hg (option: mean arterial pressure ≥ 65 mm Hg).

After determining that the patient meets the prerequisites above, the physician should conduct the apnea test as follows:

- Connect a pulse oximeter.
- Disconnect the ventilator.
 - Apnea can be assessed reliably only by disconnecting the ventilator, as the ventilator can sense small changes in tubing pressure and provide a breath that could suggest breathing effort by the patient where none exists.
- Deliver 100% O_2 , 6 L/min by placing a catheter through the endotracheal tube and close to the level of the carina. Option: use a T-piece with 10 cm H_2O CPAP and deliver 100% O_2 , 12 L/min.
- Draw a baseline arterial blood gas.
- Look closely for respiratory movements (abdominal or chest excursions that produce adequate tidal volumes) for 8-10 minutes.
- Measure PaO_2 , PaCO_2 , and pH after approximately 8-10 minutes and reconnect the ventilator.
- If respiratory movements are absent and PaCO_2 is ≥ 60 mm Hg (*option*: 20 mm Hg increase in PaCO_2 over a baseline normal PaCO_2), the apnea test supports the diagnosis of brain death.
- If respiratory movements are observed, the apnea test result is negative (*i.e.*, does not support the diagnosis of brain death).
- Connect the ventilator if, during testing, the systolic blood pressure becomes < 90 mm Hg (or below age-appropriate thresholds in children less than 18 years of age) or the pulse oximeter indicates significant oxygen desaturation ($< 85\%$ for > 30 seconds), or cardiac arrhythmias develop; immediately draw an arterial blood sample and analyze

arterial blood gas. If PaCO₂ is ≥ 60 mm Hg or PaCO₂ increase is ≥ 20 mm Hg over baseline normal PaCO₂, the apnea test result supports the diagnosis of brain death; if PaCO₂ is < 60 mm Hg and PaCO₂ increase is < 20 mm Hg over baseline normal PaCO₂, the result is indeterminate. If adequate blood pressure and oxygenation can be maintained, the apnea test can be repeated for a longer period of time (10-15 minutes) or an ancillary test can be considered if the result is indeterminate.

Step 5: Ancillary Testing as Indicated

When the full clinical examination, including the assessment of brain stem reflexes and the apnea test, is conclusively performed, no additional testing is required to determine brain death. In some patients, however, facial or cervical injuries, cardiovascular instability, or other factors may make it impossible to complete parts of the assessment safely. In such circumstances, an ancillary test verifying brain death is necessary. These tests may also be used to reassure family members and medical staff. Based on clinical indications, ancillary testing may sometimes precede other aspects of the determination of brain death.

Documentation should indicate which parts of the clinical examination could not be completed safely, along with the reason. Even when ancillary testing is consistent with brain death, as when absent cerebral blood flow is documented, brain death protocols still require assessment of coma, brain stem reflexes, and an apnea test, except in the circumstances where such tests cannot be performed.

Any of the suggested tests may produce similar results in patients with catastrophic brain damage who do not (yet) fulfill the clinical criteria of brain death. The diagnosis of brain death rests on the clear determination of the cause of coma, the elimination of potentially confounding factors, the results of the clinical examination and those of ancillary tests as indicated.

The choice of an ancillary test is dictated in large part by practical considerations, *i.e.*, availability, advantages, and disadvantages. Currently available ancillary tests are listed below, in alphabetical order, along with the findings consistent with brain death and complicating factors. For more details, see Appendix 2.

- Angiography (conventional, computerized tomographic, and magnetic resonance): Brain death confirmed by demonstrating the absence of intracerebral filling at the level of the carotid bifurcation or Circle of Willis. On CT angiography, opacification may be seen in proximal portions of the anterior and middle cerebral arteries. The external carotid circulation is patent, and filling of the superior sagittal sinus may be delayed.
 - MRI angiography can be quite challenging in an ICU patient because of magnet incompatibility with lines, ventilator tubing and other hardware.
 - CT angiography commonly demonstrates blood flow in patients who are brain dead.
 - Cerebral arteriography is often difficult to perform in a critically ill, unstable patient.

- Electroencephalography (EEG): Brain death is confirmed by documenting the absence of electrical activity during at least 30 minutes of recording that adheres to criteria listed in Appendix 2.
 - The ICU setting may result in false readings due to electronic background noise creating innumerable artifacts.
- Cerebral Scintigraphy (HMPAO) (Nuclear Brain Scanning): Brain death is confirmed by absence of uptake of isotope in brain parenchyma and/or vasculature, depending on isotope and technique used. ("hollow skull phenomenon"). (See reference 3 below.)
- Transcranial Doppler Ultrasonography: Brain death confirmed by small systolic peaks in early systole without diastolic flow, or reverberating flow, indicating very high vascular resistance associated with greatly increased intracranial pressure.
 - Since as many as 10% of patients may not have temporal insonation windows because of skull thickness, the initial absence of Doppler signals cannot be interpreted as consistent with brain death.

Step 6: Reasonable Accommodation

When an objection to brain death based on religious or moral grounds is raised, physicians and hospital staff should follow hospital policy for providing reasonable accommodation. Please refer to the Reasonable Accommodation section under Hospital Responsibilities Regarding Brain Death Determination.

Step 7: Certification of Brain Death

Brain death can be determined by a single physician privileged to make brain death determinations. However, before a patient can become an organ donor, New York State law requires that the time of brain death must be certified by the physician who attends the donor at his death and one other physician, neither of whom shall participate in the procedures for removing or transplanting organ(s). This requirement ensures that the clinical assessment and any ancillary testing meet the accepted medical standards, and that all participants can have confidence that brain death determination has not been influenced by extraneous factors, including the needs of potential organ recipients.

When two physicians are required to certify the time of death, *i.e.*, when organ donation is planned, the second physician should review and affirm that the medical record and data fully support the determination of brain death. Any aspect of the clinical assessment, apnea test, or ancillary test (if applicable) may be performed again if the second physician believes it is indicated to make his or her determination concerning brain death. The second physician must have attending privileges as a member of the medical staff of the hospital, but need not be privileged to perform brain death determinations. However, he or she should have a thorough understanding of the tests involved.

Medical Record Documentation: All phases of the determination of brain death must be documented in the medical record. The medical record must indicate:

- Etiology and irreversibility of coma.
- Absence of cerebral responsiveness.
- Absence of brain stem reflexes.
- Absence of respiration with $\text{PaCO}_2 \geq 60$ mm Hg (or ≥ 20 mm Hg increase over baseline normal PaCO_2).
- Justification for, and result of, ancillary tests if used.

A sample checklist is provided at the end of this document (see Appendix 3). Use of this or any other checklist is optional.

Step 8: Discontinue Cardio-respiratory Support in Accordance with Hospital Policies, Including Those for Organ Donation

When a patient is certified as brain dead and the ventilator is to be discontinued, the family should be treated with sensitivity and respect. If family members wish, they may be offered the opportunity to attend while the ventilator is discontinued. However, family members should be prepared for the possibly disturbing clinical activity that they may witness. When organ donation is contemplated, ventilatory support will conclude in the operating room and family attendance is not appropriate.

References:

1. American Clinical Neurophysiology Society. Guideline three: Minimum technical standards for EEG recording in suspected cerebral death. *J Clin Neurophysiol*. 2006; 23(2): 97-104.
2. Combes JC, Chomel A, Ricolfi F, d'Athis P, Frevsz M. Reliability of computed tomographic angiography in the diagnosis of brain death. *Transplant Proc*. 2007; 39(1): 16-20.
3. Donohue KJ, Frey KA, Gerbaudo VH, Nagel JS, Shulkin B. Guideline for Brain Death Scintigraphy. *J Nucl Med*. 2003; 44(5): 846-51.
4. Greer DM, Panayiotis V, Haque S, Wijdicks EF. Variability of brain death determination guidelines in leading US neurologic institutions. *Neurology*. 2008; 70(4): 284-9.
5. Lustbader D, O'Hara D, Wijdicks EF, MacLean L, Tajik W, Ying A, Berg E, Goldstein M. Repeat brain death examinations may negatively impact organ donation. *Neurology*. 2011; 76(2): 119-24.
6. Quality Standards Subcommittee of the American Academy of Neurology. Practice parameters for determining brain death in adults (summary statement). *Neurology*. 1995; 45(5): 1012-4.
7. Quesnel C, Fulgencio JP, Adrie C, Marro B, Payen L, Lember N, El Metaoua S, Bonnet F. Limitations of computed tomographic angiography in the diagnosis of brain death. *Intensive Care Med*. 2007; 33(12): 2129-35.
8. Task Force for the Determination of Brain Death in Children. Guidelines for the determination of brain death in children. *Neurology*. 1987; 37(6): 1077-78.
9. Webb A, Samuels O. Reversible brain death after cardiopulmonary arrest and induced hypothermia. *Crit Care Med*. 2011; 39(6): 1-5.
10. Wijdicks EF. Determining brain death in adults. *Neurology*. 1995; 45(5): 1003-11.
11. Wijdicks EF. The diagnosis of brain death. *N Engl J Med*. 2001; 344(16): 1215-21.
12. Wijdicks EF, Varelas PN, Gronseth GS, Greer DM. 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): 1911-18.

Appendix 1: Determination of Brain Death in Children Less Than One Year of Age

1. General Policy Statement.

The brains of infants and young children have increased resistance to damage and may recover substantial functions even after exhibiting unresponsiveness on neurological examination for longer periods as compared to adults. When applying neurological criteria to determine death in children younger than one year, longer waiting periods are required.

2. The patient must not be significantly hypothermic or hypotensive for age.

3. Waiting Periods According to Age.

The recommended waiting period depends on the age of the patient and the laboratory tests utilized. Ages listed assume the child was born at full term. Between the ages of 2 months and 1 year, an interval of at least 24 hours should be used. Between the ages of 7 days and 2 months, the minimum interval should be 48 hours.

- Reliable criteria have not been established for the determination of brain death in children less than 7 days old.
- Seven days to two months: Two examinations and electroencephalograms (EEGs) should be separated by at least 48 hours.
- Two months to one year: Two examinations and EEGs should be separated by at least 24 hours. A repeat examination and EEG are not necessary if a concomitant radionuclide or other angiographic study demonstrates no visualization of cerebral arteries.

Appendix 2: Methods of Ancillary Testing for the Determination of Brain Death

Cerebral Angiography

- The contrast medium should be injected in the aortic arch under high pressure and reach both anterior and posterior circulations.
- No intracerebral filling should be detected at the level of entry of the carotid or vertebral artery to the skull.
- Opacification may be seen in proximal portions of the anterior and middle cerebral arteries.
- The external carotid circulation should be patent.
- The filling of the superior longitudinal sinus may be delayed.

Electroencephalography

- A minimum of 8 scalp electrodes should be used.
- Interelectrode impedance should be between 100 and 10,000 Ω .
- The integrity of the entire recording system should be tested.
- The distance between electrodes should be at least 10 cm.
- The sensitivity should be increased to at least 2 μ V for 30 minutes with inclusion of appropriate calibrations.
- The high-frequency filter setting should not be set below 30 Hz, and the low-frequency setting should not be above 1 Hz.
- Electroencephalography should demonstrate a lack of reactivity to intense somatosensory or audiovisual stimuli.

Transcranial Doppler Ultrasonography (TCD)

- TCD is useful only if a reliable signal is found. The abnormalities should include either reverberating flow or small systolic peaks in early systole. A finding of a complete absence of flow may not be reliable owing to inadequate transtemporal windows for insonation. There should be bilateral insonation and anterior and posterior insonation. The probe should be placed at the temporal bone, above the zygomatic arch and the vertebrobasilar arteries, through the suboccipital transcranial window.
- Insonation through the orbital window can be considered to obtain a reliable signal. TCD may be less reliable in patients with a prior craniotomy.

Cerebral Scintigraphy (Nuclear Brain Scan) (technetium Tc 99m hexametazime (HMPAO))

- The isotope should be injected within 30 minutes after its reconstitution.
- Anterior and both lateral planar image counts (500,000) of the head should be obtained at several time points: immediately, between 30 and 60 minutes later, and at 2 hours.
- A correct IV injection may be confirmed with additional images of the liver demonstrating uptake (optional).
- No radionuclide localization in the middle cerebral artery, anterior cerebral artery, or basilar artery territories of the cerebral hemispheres (hollow skull phenomenon).
- No tracer in superior sagittal sinus (minimal tracer can come from the scalp).

Appendix 3: Optional Sample Checklist for Determination of Brain Death for Adults

Prerequisites (each item must be checked) (Steps 1 and 2 of the Guidelines)

YES NO

- | | | |
|--------------------------|--------------------------|--|
| ☐ | ☐ | Coma, irreversible and cause known |
| ☐ | ☐ | Appropriate waiting period has been followed (_____ hours)
If patient was previously induced into hypothermia, additional vigilance is recommended |
| ☐ | ☐ | Neuroimaging is compatible with the diagnosis, if applicable |
| ☐ | ☐ | CNS depressant drug effect absent (if indicated toxicology screen; if barbiturates given, serum level < 10 µg/mL) (_____ serum level) |
| ☐ | ☐ | No evidence of residual paralytics (electrical stimulation if paralytics used) |
| ☐ | ☐ | Absence of severe acid-base, electrolyte, endocrine abnormality |
| ☐ | ☐ | Normothermia or mild hypothermia (core temperature > 36°C) (_____ temperature) |
| ☐ | ☐ | Systolic blood pressure ≥ 100 mm Hg (option: mean arterial pressure ≥ 65 mm Hg) (_____ mm Hg) |
| ☐ | ☐ | No spontaneous respirations |
| ☐ | ☐ | Reasonable efforts have been made to notify the patient's Surrogate Decision-maker of the intention to initiate the determination of brain death |

Explanation/comments for any of the prerequisites above: _____

Clinical Neurological Examination (each item must be checked) (Step 3 of the Guidelines)

YES NO

- | | | |
|--------------------------|--------------------------|--|
| ☐ | ☐ | Pupils nonreactive to bright light |
| ☐ | ☐ | Corneal reflex absent |
| ☐ | ☐ | Oculocephalic reflex absent (tested only if C-spine integrity ensured) |
| ☐ | ☐ | Oculovestibular reflex absent |
| ☐ | ☐ | No facial movement to noxious stimuli at supraorbital nerve, temporomandibular joint |
| ☐ | ☐ | Gag reflex absent |
| ☐ | ☐ | Cough reflex absent to tracheal suctioning |
| ☐ | ☐ | Absence of motor response to noxious stimuli in all 4 limbs (spinally mediated reflexes are permissible) |

Explanation/comments for any of the examination steps above: _____

Apnea Testing (check if performed) (Step 4 of the Guidelines)

- ☐ Core temperature $> 36^{\circ}\text{C}$ (_____ temperature)
- ☐ Systolic blood pressure ≥ 100 mm Hg (option: mean arterial pressure ≥ 65 mm Hg) (_____ mm Hg)
- ☐ Ventilator adjusted to provide normocarbida (PaCO_2 35–45 mm Hg) (PaCO_2 _____ mm Hg)
- ☐ Patient preoxygenated with 100% FiO_2 for ≥ 10 minutes to $\text{PaO}_2 > 200$ mm Hg, if applicable
- ☐ Draw a baseline arterial blood gas
- ☐ Provide oxygen via a catheter to the level of the carina at 6 L/min or attach T-piece with CPAP at 10 cm H_2O at 12 L/min
- ☐ Connect a pulse oximeter
- ☐ Disconnect ventilator
- ☐ If tolerated, leave the patient off the ventilator for 8–10 minutes
- ☐ Observe the patient for respiratory movements
- ☐ Measure PaO_2 , PaCO_2 , and pH at the end of 8–10 minutes, and reconnect the patient to ventilator

Explanation/comments for any of the apnea testing steps above: _____

Results of the Apnea Test:

- ☐ Confirms brain death: If respiratory movements are absent and PaCO_2 is ≥ 60 mm Hg or PaCO_2 increase is ≥ 20 mm Hg over baseline normal PaCO_2 , the apnea test result supports the diagnosis of brain death.

OR

- ☐ Does not confirm brain death: If respiratory movements are observed, the apnea test result does not support the diagnosis of brain death.

OR

- ☐ Results are indeterminate:
 - ☐ If PaCO_2 is < 60 mm Hg and PaCO_2 increase is < 20 mm Hg over baseline normal PaCO_2 , the result is indeterminate. If adequate blood pressure and oxygenation can be maintained, the apnea test can be repeated for a longer period of time (10-15 minutes) or an ancillary test can be considered.
 - ☐ The patient does not tolerate the apnea test, as evidenced by significant drops in blood pressure and/or oxygen saturation, or the development of cardiac arrhythmias, or an apnea test cannot be performed on the patient. If possible, the apnea should be repeated, or an ancillary test can be considered.

Comments to the results of the apnea test: _____

Ancillary Testing (to be ordered only if clinical neurological examination cannot be fully performed due to patient factors, or if apnea testing is inconclusive, aborted, or is not performed due to patient factors; only one ancillary test needs to be performed) (Step 5 of the Guidelines)

- ☐ Cerebral angiogram (includes CT or MR angiogram)
- ☐ Nuclear Brain Scan (HMPAO SPECT)
- ☐ EEG
- ☐ TCD
- ☐ Other

What was the interpretation of the test? _____

DOCUMENTATION OF BRAIN DEATH

A physician shall certify a patient as brain dead when the patient fulfills the criteria described in these guidelines. Before a patient can become an organ donor, a second physician certification is required.

Certification of Physician:

Date and time of death: _____

Print name of physician: _____

Signature: _____

Certification of Second Physician, who shall not participate in the procedures for removing or transplanting organ(s) (required for organ donation only):

Date and time of death: _____

Print name of physician: _____

Signature: _____

Members of the Task Force on Life and the Law

Nirav R. Shah, M.D., M.P.H.

Commissioner of Health, New York State

Karl P. Adler, M.D.

President and CEO, New York Medical College

Adrienne Asch, M.S., Ph.D.

Director, Center for Ethics, Yeshiva University

Donald P. Berens, Jr., J.D.

Former General Counsel, New York State
Department of Health

Father Thomas Berg, Ph.D., M.A.

President and Executive Director, Westchester
Institute for Ethics and the Human Person

Rabbi J. David Bleich, Ph.D.

Professor of Talmud, Yeshiva University
Professor of Jewish Law and Ethics,
Benjamin Cardozo School of Law

Kathleen M. Boozang, J.D., L.L.M.*

Associate Dean and Professor of Law,
Seton Hall University School of Law

Karen A. Butler, R.N., J.D.

Partner, Thuillez, Ford, Gold, Johnson &
Butler, LLP

Lyla J. Correoso-Thomas, M.D.*

Medical Director, Bronx Hospice Team,
Visiting Nurse Service of New York

Nancy Neveloff Dubler, LL.B.

Senior Associate Montefiore-Einstein Bioethics
Center and Consultant for Ethics New York
City Health and Hospitals Corporation

Paul J. Edelson, M.D.

Professor of Clinical Pediatrics, Columbia
College of Physicians and Surgeons
Quarantine Medical Officer, CDC NY

Joseph J. Fins, M.D., F.A.C.P.

Chief, Division of Medical Ethics,
Weill Medical College of Cornell University

Alan R. Fleischman, M.D.*

Senior Vice President and Medical Director,
March of Dimes Foundation

Rev. Francis H. Geer, M.Div.

Rector, St. Philip's Church in the Highlands

Samuel Gorovitz, Ph.D.

Professor of Philosophy, Syracuse University

**Cassandra E. Henderson, M.D., C.D.E.,
F.A.C.O.G.**

Chief of Maternal-Fetal Medicine,
Our Lady of Mercy Medical Center

Hassan Khouli, M.D., F.C.C.P.

Chief, Critical Care Section,
St. Luke's – Roosevelt Hospital

**Rev. H. Hugh Maynard-Reid, D.Min.,
B.C.C., C.A.S.A.C.**

Director, Pastoral Care Department,
North Brooklyn Health

John D. Murnane, J.D.

Partner, Fitzpatrick, Cella, Harper & Scinto

Samuel Packer, M.D.

Chair of Ethics, North Shore-LIJ Health
System

Barbara Shack

Health Policy Consultant

Robert Swidler, J.D.

General Counsel, Northeast Health

Sally T. True, J.D.

Partner, True, Walsh and Schubert

* Former Task Force Member

Task Force Staff

Beth E. Roxland, J.D., M.Bioethics

Executive Director

Special Advisor to the Commissioner on Stem Cell Research Ethics

Susie A. Han, M.A., M.A.

Principal Policy Analyst

Valerie G. Koch, J.D.

Senior Attorney

Carrie S. Zoubul, J.D., M.A.

Senior Attorney

Angela R. Star

Administrative Assistant

Outside Physician Consultants

James Zisfein, M.D.

Chair, N.Y. State Brain Death Guideline Panel
Chief, Division of Neurology, Lincoln Hospital

Gregory Bennett, M.D.

Erie Niagara Neurosurgery

Jennifer Frontera, M.D.

Medical Director, Neurosurgical Intensive Care
Unit, Mount Sinai Hospital

Michael Gruenthal, M.D., Ph.D.

Professor and Bender Chair of Neurology,
Albany Medical College
Director, Neurosciences Institute, Albany
Medical Center

Robert G. Holloway, M.D.

Professor of Neurology, University of
Rochester Medical Center

**David M. Landsberg, M.D., F.A.C.P.,
F.C.C.P.**

Assistant Chief of Medicine, Crouse Hospital
Associate Program Director, Internal Medicine
SUNY Upstate Medical University

Julius Gene S. Latorre, M.D., M.P.H.

Director, Neurocritical Care Service, Upstate
Medical University Hospital

Dana Lustbader, M.D., F.C.C.M., F.C.C.P.

Chief, Palliative Medicine
Intensivist, Critical Care Medicine,
North Shore Long Island Jewish Health
System

Stephan Mayer, M.D.

Professor of Clinical Neurology and
Neurological Surgery Critical Care,
Neurology, Division Head, Neurological
Institute

Margaret Paroski, M.D.

Executive Vice President, Chief Medical
Officer, Neurologist, Kaleida Health

Tia Powell, M.D.

Director, Montefiore-Einstein Center for
Bioethics

Sophia Socaris, M.D.

Professor, Surgery/Critical Care Medicine,
Albany Medical Center

Department of Health Staff Reviewers

Sue E. Kelly, M.S., M.S.

Executive Deputy Commissioner of Health

Richard M. Cook

Deputy Commissioner, Office of Health
Systems Management

James E. Dering, J.D.

General Counsel, Division of Legal Affairs

Lisa McMurdo, R.N., M.P.H.

Director, Division of Quality and Patient Safety,
Office of Health Systems Management

David Quist, J.D.

Associate Attorney, Division of Legal Affairs

Kim Valente, R.N.

Health Policy Associate, Transplant Services

Thomas Conway, J.D.**

General Counsel, Division of Legal Affairs

John Morley, M.D.**

Medical Director, Office of Health Systems
Management

**** Former DOH employee**