

# NEW YORK CITY HEALTH AND HOSPITALS CORPORATION

## CORPORATE BRAIN DEATH POLICY

### **PURPOSE:**

To describe the guidelines, procedure, and documentation requirements for:

- Initiation of a brain death evaluation,
- Determination of brain death,
- Pronouncement of death based on brain death,
- Removal of medical and ventilator support, and
- Cases that present special considerations such as pregnant patients, young children, or objections by an appropriate individual to a determination of brain death.

### **POLICY:**

- Brain death shall be determined according to generally accepted medical practice.
- Brain death evaluation is performed according to the Guidelines for Determining Brain Death, published by the New York State Department of Health and the New York State Task Force on Life and the Law, November 2011 (Attachment A).
- The patient's next of kin and/or other person closest to the patient (such as a surrogate or health care agent) shall be notified when a brain death evaluation is being performed and again when a determination of brain death is made.
- Reasonable accommodation shall be made for the religious or moral objections of the patient to the use of the brain death standard to determine death, when such an objection has been expressed by the patient prior to loss of decision-making capacity, by next of kin, or other person closest to the patient (such as a surrogate or health care agent).
- Organ donation shall be considered in all cases.
- Patient and family shall be treated with sensitivity and respect.
- Compliance with applicable laws and regulations is required.

### **DEFINITIONS:**

- Brain death: the irreversible loss of all functions of the brain, including the brain stem.
- Brain death evaluation: the process of determining that a patient is brain dead, including performance and interpretation of ancillary tests needed for the determination of brain death.

# NEW YORK CITY HEALTH AND HOSPITALS CORPORATION

## CORPORATE BRAIN DEATH POLICY

- Legally Authorized Representative: For purposes of this policy, the patient's next of kin and/or other person closest to the patient (such as a surrogate or health care agent).

### **GUIDELINES:**

New York State regulation defines brain death as the irreversible loss of all functions of the brain, including the brain stem. The three essential findings in brain death are coma, absence of brain stem reflexes, and apnea.

- A. Brain death evaluation is initiated when a patient:
  1. Is unresponsive,
  2. Has unreactive pupils, and
  3. Requires a ventilator.
- B. Legally Authorized Representative is notified (or reasonable attempts are made to notify the Legally Authorized Representative) that a brain death evaluation is being performed.
  1. Notification of the Legally Authorized Representative should occur early in the brain death evaluation process.
  2. If notification of the Legally Authorized Representative is unsuccessful or if a Legally Authorized Representative cannot be identified, assistance of hospital administration should be obtained.
  3. Brain death evaluation does not require consent or permission from the Legally Authorized Representative.
- C. New York Organ Donor Network (NYODN, 1-800-GIFT-4-NY) is notified that a brain death evaluation is being performed.
  1. NYODN determines if the patient would be a medically suitable organ donor.
- D. Brain death evaluation is performed under the direction of a physician who is privileged to make that evaluation.
  1. The hospital should have a privileging mechanism to identify physicians who are competent to perform brain death evaluations. For specialists in neurology, neurosurgery, critical care medicine, and critical care surgery, determination of brain death and performance of apnea tests for brain death are to be included as core privileges.
  2. The physician performing the brain death evaluation must not be a member of the organ transplant team.

# NEW YORK CITY HEALTH AND HOSPITALS CORPORATION

## CORPORATE BRAIN DEATH POLICY

3. Brain death evaluation is performed according to the Guidelines for Determining Brain Death, published by the New York State Department of Health and the New York State Task Force on Life and the Law, November 2011 (Attachment A).
    - a. If a sufficient period of time has passed since the onset of a brain insult to exclude the possibility of recovery (in practice, usually several hours), a single neurologic examination and an apnea test should be adequate to determine brain death.
  4. If the patient is an infant or child, additional considerations may apply (Attachment A, Appendix 1).
  5. The time of death is recorded as the time brain death is determined.
- E. The Legally Authorized Representative is notified (or reasonable attempts are made to notify the Legally Authorized Representative) of the determination of death before medical support is removed.
1. If there is an objection to the determination of death or to the removal of medical support by the Legally Authorized Representative, Risk Management shall be informed.
    - a. Ethics consultation is also recommended.
    - b. The determination of brain death must still be made and the pronouncement documented.
  2. If there is an objection by the Legally Authorized Representative to a brain death determination that is on a religious or moral basis, reasonable efforts to accommodate the objection shall be undertaken.
    - a. Reasonable accommodation after the determination of death includes the continued provision of ventilator support and routine nursing care for a reasonable period (generally not to exceed 72 hours from the time of pronouncement). Treatment for an indefinite period of time after the determination of death is not required.
    - b. Reasonable accommodation after the determination of death does not require performance of any diagnostic or therapeutic procedures, including (but not limited to): blood tests, radiologic tests, physiologic monitoring, administration of medications for any purpose, nutrition or hydration support, cardio-pulmonary resuscitation (notwithstanding absence of a DNR order), or treatment in a critical care unit.
  3. If there is an objection by the Legally Authorized Representative to a brain death determination that is not based on a religious or moral basis, reasonable efforts to accommodate the objection are not required. After discussion with Risk Management, medical support may be removed. However, hospital staff should demonstrate

# NEW YORK CITY HEALTH AND HOSPITALS CORPORATION

## CORPORATE BRAIN DEATH POLICY

sensitivity to family members and help them to accept the determination and fact of death.

4. If there is a request by the Legally Authorized Representative to delay removal of ventilator support pending arrival of another family member, such delay is permitted (in general, not to exceed 24 hours from the time of pronouncement) based on the availability of hospital resources for patients.
  5. If the patient is pregnant, medical support shall be removed only after consultation with Risk Management.
- F. Consent for organ donation is sought if a brain dead patient may be a medically acceptable organ donor. Consent is requested from an individual only after he or she has been informed of the patient's death.
1. Consent for organ donation may be given by:
    - a. The deceased adult patient who properly executed an organ donor card, driver's license authorization or other written authorization to make an anatomical gift, or by prior enrollment in an organ or tissue donor consent registry. Such authorization for donation shall not be rescinded by an objection of a member of any of the classes set forth below (F1 (b)-(h)); except upon a showing that the adult patient revoked the authorization.
    - b. The person designated as the patient's health care agent, subject to any written statement in the health care proxy form,
    - c. The person designated as the patient's agent in a written instrument, subject to any written statement in the written instrument,
    - d. The spouse, if not legally separated from the patient, or the domestic partner,
    - e. A son or daughter eighteen years of age or older,
    - f. Either parent,
    - g. A brother or sister eighteen years of age or older,
    - h. A guardian of the person of the patient at the time of his/her death.
  2. The designated requester may seek consent for an anatomical gift from any of the individuals, specified in F1 (b)-(h) in the order of priority stated, when persons in prior classes are not reasonably available, willing, and able to act, at the time of death, and in the absence of actual notice of contrary indications by the patient, or actual notice of opposition by a member of the same class or prior classes as specified in F1 (b)-(h).

# NEW YORK CITY HEALTH AND HOSPITALS CORPORATION

## CORPORATE BRAIN DEATH POLICY

- a. A list of designated requesters should be maintained by the Administrator on Duty and by NYODN.
3. Generally speaking, brain death may be determined by a single physician privileged to make brain death determinations. However, before a patient may become an organ donor, New York State law requires that the time of death must be certified by the physician who attends the donor at his/her death and one other physician, neither of whom shall participate in the procedures for removing or transplanting the organs.
  - a. In the case of potential organ donation: 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.
  - b. When two physicians are required to certify the time of death, the second physician should review and affirm that the medical record and data fully support the determination of 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.
4. Ventilator support shall not be removed until:
  - a. Reasonable Accommodation (See Paragraph E) is not applicable,
  - b. Organ recovery has been completed, or
  - c. The patient is no longer being considered as an organ donor.

### **PROCEDURE:**

#### **RESPONSIBLE STAFF:**

1. The patient's attending physician.
2. If the patient's attending physician is not privileged in the determination of brain death; a consulting physician who is privileged in the determination of brain death.
3. If the patient is potentially an organ donor: a second attending physician shall certify to the time of death. (Please refer to section F (3) for more specific details).

# NEW YORK CITY HEALTH AND HOSPITALS CORPORATION

## CORPORATE BRAIN DEATH POLICY

### **ACTION TO BE PERFORMED BY RESPONSIBLE STAFF:**

#### **(PRINCIPALLY THE ATTENDING PHYSICIAN)**

1. Utilizes the Guidelines for Determining Brain Death, published by the New York State Department of Health and the New York State Task Force on Life and the Law, (November 2011) (Attachment A).
2. Initiates the brain death evaluation.
3. Notifies the Legally Authorized Representative of the initiation of a brain death evaluation and informs that person of the patient's status.
4. Obtains assistance of hospital administration if notification of the Legally Authorized Representative is unsuccessful or if a Legally Authorized Representative cannot be identified.
5. Verifies that NYODN (1-800-GIFT-4-NY) has been notified of the brain death evaluation. Notification of NYODN can be performed by any member of the care team.
6. Writes a pronouncement of death note in the medical record. The determination of brain death must be performed by a physician who is privileged to make that determination.
7. Notifies the Legally Authorized Representative of the determination of death.
8. Notifies the Risk Manager if there is an objection by the Legally Authorized Representative to the use of the brain death standard or to the removal of medical support.
9. Functions as clinical liaison with the Transplant Coordinator and maintains optimal donor management.
10. Consults with a second attending physician to confirm and certify the time of death only if organ donation is contemplated.
11. Directs removal of medical support/ventilator support if the patient is not a potential organ donor.
12. Ensures that emotional and pastoral support is provided to the family.

#### **DOCUMENTATION REQUIREMENTS:**

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

# NEW YORK CITY HEALTH AND HOSPITALS CORPORATION

## CORPORATE BRAIN DEATH POLICY

- a. Etiology and irreversibility of coma.
  - b. Absence of cerebral responsiveness.
  - c. Absence of brain stem reflexes.
  - d. Absence of respiration with PaCO<sub>2</sub> ≥ 60 mm Hg (or ≥ 20 mm Hg increase over baseline normal PaCO<sub>2</sub>) or confirmation of brain death by a confirmatory test if the apnea test cannot be completed.
  - e. Justification for, and result of, ancillary tests if used.
2. Reports of any laboratory or radiology tests that were used to determine brain death.
  3. Document notification of the Legally Authorized Representative of the brain death evaluation and the determination of death. If identification or notification of the Legally Authorized Representative was unsuccessful, document the reasonable efforts that were made.
  4. Document any objections by Legally Authorized Representative to the determination of death or removal of medical or ventilator support.
  5. Document requests for reasonable accommodation.
  6. Document the request for organ donation.
  7. A licensed physician shall document the pronouncement of death in the medical record with the date and time.
  8. Document cause of death, if known.
  9. Before a patient may become an organ donor:
    - a. The time of death must be certified by the physician who attends the donor at his/her death and one other physician, neither of whom shall participate in the procedures for removing or transplanting the organs.
    - b. The second physician should review and affirm that the medical record and data fully support the determination of death.
  10. Document the date and the time ventilator support was removed and the name and the title of the physician who authorized it.
  11. Adhere to documentation requirements required by other applicable law or regulation.

**NEW YORK CITY HEALTH AND HOSPITALS CORPORATION**  
**CORPORATE BRAIN DEATH POLICY**

**ATTACHMENTS:**

- A. 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**

**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 I 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)  $> 36^{\circ}\text{C}$  ( $96.8^{\circ}\text{F}$ )
    - (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)  $\geq 100$  mm Hg (Option: mean arterial pressure  $\geq 65$  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 ( $> 36^{\circ}\text{C}$  ( $98.8^{\circ}\text{F}$ )) should be achieved, particularly in patients who have been hypothermic. In addition, normal systolic pressure ( $\geq 100$  mm Hg) (option: mean arterial pressure  $\geq 65$  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 CO<sub>2</sub>.

*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  $96.8^{\circ}\text{F}$ .
- $\text{PaCO}_2$  35-45 mm Hg.
- Normal  $\text{PaO}_2$ . 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  $\geq 100$  mm Hg (option: mean arterial pressure  $\geq 65$  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%  $\text{O}_2$ , 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  $\text{H}_2\text{O}$  CPAP and deliver 100%  $\text{O}_2$ , 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  $\text{PaO}_2$ ,  $\text{PaCO}_2$ , and pH after approximately 8-10 minutes and reconnect the ventilator.
- If respiratory movements are absent and  $\text{PaCO}_2$  is  $\geq 60$  mm Hg (*option*: 20 mm Hg increase in  $\text{PaCO}_2$  over a baseline normal  $\text{PaCO}_2$ ), 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 PaCO<sub>2</sub> is  $\geq 60$  mm Hg or PaCO<sub>2</sub> increase is  $\geq 20$  mm Hg over baseline normal PaCO<sub>2</sub>, the apnea test result supports the diagnosis of brain death; if PaCO<sub>2</sub> is  $< 60$  mm Hg and PaCO<sub>2</sub> increase is  $< 20$  mm Hg over baseline normal PaCO<sub>2</sub>, 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  $\geq 20$  mm Hg increase over baseline normal  $\text{PaCO}_2$ ).
- 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.

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## **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  $\Omega$ .
- 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  $\mu$ 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 vertebrbasilar 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: \_\_\_\_\_

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#### 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: \_\_\_\_\_

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

- Core temperature > 36°C ( \_\_\_\_\_ temperature)
- Systolic blood pressure  $\geq$  100 mm Hg (option: mean arterial pressure  $\geq$  65 mm Hg) ( \_\_\_\_\_ mm Hg)
- Ventilator adjusted to provide normocarbia (PaCO<sub>2</sub> 35–45 mm Hg) (PaCO<sub>2</sub> \_\_\_\_\_ mm Hg)
- Patient preoxygenated with 100% FiO<sub>2</sub> for  $\geq$  10 minutes to PaO<sub>2</sub> > 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<sub>2</sub>O 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<sub>2</sub>, PaCO<sub>2</sub>, 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: \_\_\_\_\_

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**Results of the Apnea Test:**

- Confirms brain death: If respiratory movements are absent and PaCO<sub>2</sub> is  $\geq$  60 mm Hg or PaCO<sub>2</sub> increase is  $\geq$  20 mm Hg over baseline normal PaCO<sub>2</sub>, 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<sub>2</sub> is < 60 mm Hg and PaCO<sub>2</sub> increase is < 20 mm Hg over baseline normal PaCO<sub>2</sub>, 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: \_\_\_\_\_

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