XXXXXXXX MEDICAL CENTER

ATTENDING STAFF POLICY & PROCEDURE

Subject:	Original Issue Date:	Policy #:
DECLARATION OF BRAIN DEATH	XXXX, 2003	**XXXXXX**
	Supersedes: XXXX, 2008	Effective Date: XX/XX/2013

Departments Consulted & Approved:	Reviewed & Approved by:	Approved by:
Brain Death Committee Office of Risk Management Ethics Resource Committee Fetal, Infant, Child Ethics Committee	Credentials and Privileges Advisory Committee Attending Staff Association Executive Committee	President, Attending Staff Association

PURPOSE

The purpose of this policy is to govern the process for determining brain death in the XXXXXXXX Medical Center.

POLICY

Death occurs when either circulatory and respiratory functions or whole brain neurological functions have ceased and will not spontaneously resume. Therefore death can be determined by either **Cardiopulmonary** or **Neurological** Criteria. Determination of death shall be limited to qualified physicians acting in conformity with the procedures set forth below.

Special Circumstances:

Occasionally, patients may be transported to the hospital who exhibit unmistakable signs of death (e.g. decapitation, rigor mortis, livido, decomposition). Such patients may be declared dead on arrival by an attending or resident physician without further cardiopulmonary or neurological evaluation.

I. DECLARATION OF DEATH BY CARDIOPULMONARY CRITERIA

PHYSICIAN QUALIFICATIONS:

Any attending physician with active staff privileges and any resident physician in a training program at XXXXXXXX Medical Center may declare death by cardiopulmonary criteria in accord with the procedures set forth below.

PROCEDURES

1. Declaration of death by cardiopulmonary criteria requires the determination of both **cessation** of cardiopulmonary functions and **irreversibility**.
   A. **Cessation** of functions is determined primarily by an appropriate clinical examination and confirmed, only when necessary, by hemodynamic monitoring:
      i. The clinical examination must demonstrate absence of responsiveness, absence of heart sounds, absence of pulse, and absence of respiratory effort.
   B. **Irreversibility** is determined by persistent cessation of circulatory function during an appropriate period of observation.
      i. A **five (5) minute observation** time after cessation of circulatory function establishes irreversibilty.

2. When donation of organs after cardiac death (DCD) is planned there is a need to precisely establish the moment of circulatory cessation. In this situation confirmatory hemodynamic monitoring is **mandatory**.
    A. Absence of circulatory function can determined by:
        i. Loss of pulse pressure on arterial catheter monitoring

        or

        ii. Doppler echo study adequate to define the moment of blood flow cessation.

        or

        iii. ECG silence
            a. Note: Cardiac electrical activity may persist after blood flow has ceased, therefore ECG silence is **not necessary** for the determination of cessation of function. (For example pulse-less electrical activity and ventricular fibrillation can be identified as non-perfusing states using the objective measures of blood flow mentioned above)

3. Declaration of death must be made by a qualified physician and documented in the medical record. The documentation must include at a minimum the clinical determinants of death, the time and date of death, and the physician's signature.
    A. When the declaration of death precedes possible donation of organs, the confirmatory hemodynamic determinants and the 5 minute observation period ensuring irreversibility must also be documented.
    B. It is recognized that the actual "time of death" is rarely known with objective certainty. Therefore to standardize the process of documentation, the time of death will be defined as a time no less than 5 minutes from the time of loss of circulatory function.
4. Caveat: If organ donation after cardiac death is a consideration, the physician caring for or declaring and documenting the death of the patient must have no involvement with the recovery or use of organs for transplant.

Resources

1. Report of a national conference on donation after cardiac death. Am J Transplant: 2006; 6(2):281-291

II. DECLARATION OF DEATH BY NEUROLOGICAL CRITERIA: BRAIN DEATH DETERMINATION POLICY

Determination of brain death shall be limited to qualified physicians acting in conformity with the procedures set forth below.

PHYSICIAN QUALIFICATIONS:

1. **Attending physicians**

For attendings in the Departments of Neurology, Neurosurgery, Nuclear Medicine, and

Radiology, and for attendings granted privileges to provide intensive care in any of the Medical Center's intensive care units, the granting of this privilege will require reading this policy and the Brain Death Syllabus (Attachment 106A).

For attendings in other clinical departments, the granting of this privilege will require the reading of this policy and the Brain Death Syllabus (Attachment 106A) and successful completion of the Competency Exam (Attachment 106B).

2. **Resident physicians**

Residents must be licensed and deemed competent to perform the brain death examination through appropriate departmental procedures. At a minimum, all residents must read this policy and the Brain Death Syllabus (Attachment 106A) and successfully complete the Competency Exam (Attachment 106B) to be deemed competent.

3. **Physician disqualification**

Neither the physician making the determination of brain death nor the physician making the independent confirmation may participate in procedures for the removal or transplanting of organs after death.

PROCEDURES

1. INITIATION OF EVALUATION FOR BRAIN DEATH

An evaluation for brain death may be initiated by a patient's health care team when the patient is comatose and:

a. There is a confirmed mechanism and/or degree of injury consistent with the level of coma and the injury is deemed irreversible.

b. There has been a search for and conclusive analysis of all possible confounding factors.

c. The physical examination is consistent with brain death.

2. PERIOD OF ACCOMMODATION

a. As soon as the decision is made to initiate an evaluation for brain death, a member of the patient's treatment team shall inform the patient's legally recognized health care decision maker, if any, or the patient's family or next of kin, if available, that if brain death is diagnosed and confirmed according to hospital procedure all ongoing medical interventions, including mechanical ventilation will be stopped at that time.

b. According to *Section 125.4 of the Health and Safety Code* a family may request a period of accommodation to facilitate personal, cultural or spiritual needs after the diagnosis has been made and prior to the removal of medical support. They are also entitled to a written statement of hospital policy in this regard upon request.

c. Period of accommodation statement:

Upon request, and provided that the needs of other patients and prospective patients in need of urgent care permit, ventilatory support will be maintained for a reasonably brief period after brain death has been declared to permit those close to the patient to gather at the bedside before that support is discontinued.

When a period of accommodation has been requested, its exact duration will be determined in the light of existing circumstances by the attending physician of record in consultation with the authorized patient representative. It is expected that this time interval will be less than 24 hours.

In case of dispute, the final determination will be made by the medical director of the service.

3. BRAIN DEATH DETERMINATION IN ADULTS > 17 YEARS OF AGE

a. Diagnosis based on a complete clinical examination

In the event there is no contraindication to or limitation to the performance of a complete clinical brain death examination, a diagnosis of brain death may be made after:

i. *Determination* of brain death by a clinical examination the findings of which satisfy all the requirements of the Brain Death Form (Attachment C) and Syllabus (Attachment A).

ii. *Confirmation* of brain death by either

(1) a second complete clinical examination at least 2 hours later by a second qualified physician

or

(2) by an accepted objective test or study (see Attachment B) demonstrating absence of intracranial perfusion or absence of brain activity (no time interval required). The results of the study must be interpreted by a qualified attending physician, and documented as diagnostic of brain death.

iii. If death is diagnosed by 2 clinical examinations, at least one examination must be performed by a qualified attending physician. A single apnea test performed by an attending physician according to hospital policy may be accepted by the second independent examiner and noted on the brain death documentation form.

b. Diagnosis when a complete clinical examination cannot be performed

In the event that a complete clinical brain death examination cannot be performed, a diagnosis of brain death may be made only after:

i. *Determination* of brain death by an objective test or study of cerebral blood flow that shows no intracranial perfusion or a study that shows absence of brain activity. The results of the study must be interpreted by a qualified attending physician, and documented as diagnostic of brain death.

ii. *Confirmation* by a clinical examination as complete as circumstances allow adequate to confirm that there is no contraindication to the determination.

c. Time of death

The dated and timed documentation of the independent confirmation of death, whether by objective test or examination, will be the official pronouncement of death in the medical record.

4. BRAIN DEATH DETERMINATION IN CHILDREN > 37 WEEKS GESTATION TO 17 YEARS OF AGE

a. Diagnosis based on a complete clinical examination

In the event there is no contraindication to or limitation to the performance of a complete clinical brain death examination a diagnosis of brain death may be made after:

i. *Determination* of brain death by a clinical examination the findings of which satisfy all the requirements of the Brain Death Form (Attachment C) and Syllabus (Attachment A).

ii. *Confirmation* of brain death by a second clinical examination, including a second apnea test, performed at the following time intervals based on age:

- age 37 weeks gestation to 30 days: 24 hours
- age 31 days to 17 years: 12 hours

iii. Additional confirmatory testing is not required when two complete exams and apnea tests have been performed as above. See section 5 below for indications for ancillary confirmatory testing.

iv. BOTH clinical examinations must be performed by different, qualified Attending physicians.

b. Diagnosis when a complete clinical examination is not possible

In the event that a complete clinical brain death examination cannot be performed, a diagnosis of brain death may be made only after:

i. *Determination* of brain death is made by a combination of a clinical exam, as complete as circumstances allow, that shows no contraindication to the diagnosis, followed by a study of cerebral blood flow that shows no intracranial perfusion or by a study showing absence of brain activity. The results of the study must be interpreted by a qualified attending physician and documented as diagnostic of brain death.

ii. *Confirmation* of brain death is made by a second clinical examination, performed by an independent qualified physician, as complete as circumstances allow, that also demonstrates no contraindication to the diagnosis of death. The second exam can follow the diagnostic ancillary study without time interval restriction.

c**. Time of death**

The dated and timed documentation of the second independent confirmatory examination will be the official pronouncement of death in the medical record.

5. BRAIN DEATH DETERMINATION IN INFANTS LESS THAN 37 WEEKS GESTATIONAL AGE

No determination of brain death will be made prior to the 37th week of gestational age.

6. CAVEAT IN THE USE OF OBJECTIVE TESTS OF BRAIN PERFUSION OR FUNCTION

Ancillary objective testing is required when

1) components of the examination or apnea test cannot be safely completed,

2) there is uncertainty about the examination,

3) a medication effect may interfere with the clinical examination or

4) there is a desire to shorten the interval between clinical examinations.

Objective tests may be used as described above to determine or confirm brain death, if and only if, the qualified attending reading the test is able to give a diagnostically definitive reading. Readings that are noted to be anything less than definitive (i.e. merely "suggestive of…") can not be used to determine or confirm brain death.

7. DOCUMENTATION

Physicians determining and confirming brain death should complete the Brain Death Documentation Form (Attachment 106C) in its entirety or document in the progress notes a clear diagnosis of brain death according to the provisions outlined in the Brain Death Documentation Form.

ATTACHMENTS

Attachment 106A: Brain Death Syllabus

Attachment 106B: Brain Death Competency Exam

Attachment 106C: Brain Death Documentation Form

REFERENCES

California Health and Safety Code: (sections 7180-7182)

An individual who has sustained irreversible cessation of all functions of the entire brain, including the brain stem, is dead. (Section 7180) (a)(2)

When an individual is pronounced dead by determining that the individual has sustained an irreversible cessation of all functions of the entire brain, including the brain stem, there shall be independent confirmation by another physician (Section 7181)

When a part of the donor is used for….transplantation…and the death of the donor is determined by determining that the individual has suffered an irreversible cessation of function of the entire brain, including the brainstem, neither the physician making the determination of the death nor the physician making the independent confirmation may participate in the procedures for removing or transplanting a part. (Section 7182)

California Health and Safety Code, Sections 7180, 7181 and 7182

REVISIONS:

2003; 2005; 2006, 2008, 2012, XX, 2013

XXXXXXXX Medical Center ASA 106 A
Brain Death Determination Syllabus

Background

The diagnosis of brain death is made according to criteria that are determined at the level of individual hospitals. Federal and state legislation defer to physicians regarding criteria and determination of brain death.
Most brain death laws in the United States are based on the Uniform Determination of Death Act, drafted by the National Conference of Commissioners of Uniform State Laws in 1980 at the Commissioner's Annual Conference in Kauai, Hawaii.
In its Prefatory Note the Act states: "this act is silent on acceptable diagnostic tests and medical procedures. It sets the general legal standard for determining death, but not the medical criteria for doing so. The medical profession remains free to formulate acceptable medical practices and to utilize new biomedical knowledge, diagnostic tests, and equipment".
The California legislature has delegated to hospitals responsibility for brain death determination and documentation “in accordance with accepted medical standards" when there is "irreversible cessation of all functions of the entire brain, including the brain stem."
The Brain Death Determination Policy ASA 106 was first approved by the Executive Committee of the Attending Staff Association at XXXXXXXX Medical Center in April 2003.

Examiner Qualification

License

California Law stipulates that brain death must be determined and independently confirmed by two California licensed physicians.

Attending Physicians

XXXXXXXX policy requires that attending physicians be specifically credentialed and be granted privileges to determine or confirm brain death. Attending members of one of the neuroscience departments, Neurology or Neurosurgery, attending intensivists in one of the Medical Centers ICUs and attending members of the departments of Radiology and Nuclear Medicine can be granted privileges upon completing a required reading of the policy and this syllabus. Members of other clinical departments can be credentialed after reading the policy and syllabus and passing an accompanying competency examination with a score of at least 80%. In accordance with Bylaws and Network policy 541 the attending physician must have been recommended by the department chair, Credentials and Privileges Advisory Committee, Executive Committee of the Attending Staff Association and the Director of DHS.

Resident Physicians

Licensed resident physicians can be deemed competent by their department chair to perform the brain death examination via accepted departmental procedures. Such procedures will also require at a minimum a reading of the policy and syllabus as well as successful completion of the competency exam with a score of at least 80%.

Principles

Documentation of brain death must certify that each of the following areas of concern have been appropriately addressed:
1. Etiology of coma
2. Interfering confounding factors ruled out
3. "Whole brain" neurologic examination
4. Irreversibility

Etiology of coma

A mechanism of injury consistent with the level of coma should be documented. Examples of etiologies include: “motor vehicle accident”, “gunshot wound to the head”, “brain abscess”, “meningitis” or “intracerebral hemorrhage”.

Confounding factors

Prior to initiating a brain death evaluation the examining physician must assess for the presence of reversible factors that could be significantly contributing to coma such as metabolic abnormalities, presence of toxins, central nervous system depressants, hypoxia, and hypercarbia. In addition, two specific stipulations are included in the brain death declaration form: 1) the patient's body temperature must be greater than 35^{0} C and 2) the patient must have a normal blood pressure for age.

A determination of Brain Death can be made in the presence of minor abnormalities but the examining physician must document on the Brain Death Form or in an accompanying Progress Note that he or she feels the abnormality is not significantly contributing to the absence of brain function on neurological examination.

Whole brain neurologic examination

The function of the entire brain including brainstem must be absent. This is demonstrated by a comprehensive examination that tests for cerebral and brainstem function.

Each of the following must be documented in the list of neurologic findings reported in the brain death note: **Test**	**Technique**	**Finding**	**Anatomy**	**Criterion for death**
Motor response to noxious stimulation (central and peripheral)	Firm pressure to supraorbital nerve, supratrochlear nerve, etc	Movement of face, body, or an extremity	Spinal, brainstem, basal ganglia, and cortical pathways	Absence of non-reflexive movement
Pupil response to light	Light shown onto retina	Pupil constricts or dilates	Midbrain	Fixed, mid position
Fifth and seventh nerve sensory and motor reflex	Light touch to cornea	Eye blinks	mid pons	No eye blink
Gag reflex	Touch oropharyngeal wall	Elevation of uvula and cough	IX, X: lower pons	No gag
Oculo- vestibular (caloric) reflex	Irrigation of tympanic membrane with ice water. Observe for eye movement.	Absence of nystagmoid eye deviation	VII, VIII: lower pons	No eye movement
Oculo- cephalic reflex * * This test is not required and should be omitted when a C-spine injury is suspected	Turn head side to side while observing for movement of eyes.	Doll's eyes (painted on): stay fixed forward No doll's eye	VIII: lower pons	Doll's eyes (no oculo- cephalic reflex)
Apnea The apnea test need only be performed once for adult pts when performed by an attending physician. Two anpea tests are required for pediatric pts < 18 years of age The test should be started from a baseline PCO2 of ~35 – 45 mmHg	Maintain oxygenation, induce hypercarbia / respiratory acidosis to stimulate breathing center	Absence spontaneous breaths	Medulla	Absence of spontaneous breath in spite of severe acidosis (PCO2 $\geq$ 60mmHg and 20mmHg above starting point

Pitfalls

SPINAL REFLEXES -The most common confusing finding on examination for brain death is the presence of "spinal reflexes" where the patient moves an extremity in response to noxious stimulation. This is why a central noxious stimulus, for example to the supraorbital nerve, is preferred over peripheral stimulation alone. Rarely, it has been reported that a brain dead person may even sit up in bed and perform a complex set of movements such as crossing the arms across the chest (Lazarus phenomenon) in the absence of any brain activity. If there is any

question about the significance of movements or other responses an objective confirmatory test should be performed.

APNEA TEST- Another common mistake is failure to correctly perform the apnea test. The apnea test is performed by pre-oxygenating the patient with 100% oxygen and then allowing the patient's pCO2 to rise to 60mmHg or greater. In the un-ventilated patient pCO2 rises approximately 3mmHg per minute. Assuming that a patient's pCO2 is 30mmHg at the time that the ventilator is disconnected, a pCO2 of 60mmHg should be reached after 10 minutes (3mmHg/min x 10 minutes = 30mmHg). Occasionally, the apnea test will not be tolerated by some patients whose cardiopulmonary status is unstable. In these patients brain death cannot be determined on clinical grounds alone. See "Inability to perform a complete examination" below.

ISOLATED BRAIN STEM INJURY- Pt with brain stem injury without evidence of higher cortical injury warrant very careful evaluation because they may present with signs and symptoms consistent with a locked in syndrome. Consultation with neurosciences is recommended.

Irreversibility

Irreversibility can be defined either by an objective confirmative test or by an appropriate time interval between two clinical exams The interval between two clinical exams at XXXXXXXX Medical Center is 2 hours for adults. The interval for pediatric patients age 37 weeks gestational age to 30 days is 24 hours and for children >30 days through 17 years it is 12 hours. Time interval requirements do not apply if ancillary confirmatory testing is diagnostic in the presence of a physical exam as complete as possible that is consistent with brain death.

Use of Objective Diagnostic or Confirmatory Tests

A number of objective tests are available for confirming the absence of brain activity or absence of intracranial perfusion. These include angiography (including MR angiography), transcranial doppler, radionuclide flow study, and EEG. These tests are used in two ways: either to confirm the results of a complete clinical examination or to actually demonstrate brain death in situations where a complete clinical examination cannot be performed. When these tests are used to determine brain death, (i.e. when a complete neurological evaluation cannot be performed), they are termed diagnostic. When they are used to supplement a complete neurological evaluation they are termed confirmatory.

When two complete physical examinations are diagnostic, the use of these tests in a confirmatory manner is optional. Never the less, any time an objective test of cerebral function or flow is used, either in a diagnostic or confirmatory manner, certain stipulations must be met: 1) the study must be read by an attending physician, 2) the physician must have privileges to declare brain death and 3) the results and interpretation must be diagnostically definitive and properly documented by this physician on the Brain Death Form or progress notes.

If a patient receives an ancillary test that shows cerebral blood flow or electrical activity, brain death can not be diagnosed at that time.

The use of diagnostic tests when a complete clinical examination cannot be performed

Frequently one of the accepted objective tests will be used to determine the presence or absence of brain death in cases where a complete brain death examination cannot be performed (for example, in a patient is too unstable to tolerate an apnea test).

In the event that a complete brain death examination cannot be performed, determination of death by clinical criteria alone is not possible. However, a diagnosis of brain death may be made using objective studies of brain perfusion or function if; 1) the study, as interpreted and documented by an attending physician according to the provisions in the previous section, shows conclusively that there is absence of cerebral perfusion or brain activity and 2) there has been a clinical examination, by an independent qualified physician, as complete as circumstances allow and adequate to confirm that there is no contraindication to the determination of brain death.

Documentation

Brain Death Documentation Form

Use of the brain death determination form is the preferred method for documenting the results of examinations for brain death. Each item on the checklist form adopted by the Brain Death Committee must be addressed. The time and date of the second independent confirmatory test or examination will configure the official pronouncement of death in the medical record.

Family Notification and Period of Accommodation

It is often difficult for family members to fully understand the diagnosis of brain death and it is very important for medical providers to use language that clearly communicates the fact that a loved one, if declared dead by neurologic criteria, is truly dead. Avoiding terms like removal of "life support" when mechanical ventilation is to be removed is essential to avoid further familial confusion.

Furthermore, California law grants that a family may request a period of accommodation to facilitate personal, cultural or spiritual needs after the diagnosis has been made and prior to the removal of medical support. They are also entitled to a written statement of hospital policy in this regard upon request. The period of accommodation should be reasonably brief (generally on the order of hours, not days) and is determined by both familial needs and the existing circumstances within the hospital at the time of the request. If providers encounter a difficulty in finding an agreeable time to remove mechanical support, the case should be referred to the unit director for resolution.

Challenges

Challenges to a Brain Death Determination will be mediated by the Brain Death Committee. In the event that a committee member is not accessible the Medical Officer of the Day (MOD) or Medical Director will mediate.
Risk Management should be notified of all Brain Death declaration challenges.

Review

All determinations of brain death will be reviewed for Quality Improvement purposes by the Brain Death Committee.

References

1. Whole-brain criterion of death first proposed by the "Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death" in a "Special Communication" published in JAMA in 1968.
2. Guidelines for the determination of death: Report of the medical consultants on the diagnosis of death to the president's commission for the study of ethical problems in medicine and biomedical behavioral research. JAMA 1981; 246 (19): 2184-2186.
3. Practice parameters for determining brain death in adults in 1995 by the Quality Standards Subcommittee of the American Academy of Neurology (Neurology, 45:1012, 1995). The Academy qualifies this protocol as "an educational service... [not] intended to exclude any reasonable alternative method" of brain death determination.
4. The diagnosis of brain death. New England Journal of Medicine 2001, 344 (16): 1215-1221.
5. Variability in brain death determination practices in children. JAMA 1995, 274 (7): 550-553.

6. California Health and Safety Code: (sections 7180-7182). An individual who has sustained irreversible cessation of all functions of the entire brain, including the brain stem, is dead. (Section 7180) (a)(2)
When an individual is pronounced dead by determining that the individual has sustained an irreversible cessation of all functions of the entire brain, including the brain stem, there shall be independent confirmation by another physician (Section 7181)
When a part of the donor is used for….transplantation…and the death of the donor is determined by determining that the individual has suffered an irreversible cessation of function of the entire

brain, including the brainstem, neither the physician making the determination of the death nor the physician making the independent confirmation may participate in the procedures for removing or transplanting a part.

106C: Brain Death Documentation Form

Brain Death Determination / Confirmation using Clinical Examination	Results / Comments
Mechanism consistent with brain death	
No other cause of coma, exclude the following:	
Toxins / drugs (no contributory abnormalities)	
Metabolic parameters (no contributory abnormalities)	
Vital signs	
Temperature (> 35 ^{o} C)	
Blood pressure normal for age	
Neurological Examination	
Response to verbal stimuli absent	
Pupils fixed	
Corneal reflex absent	
Oculocephalic reflex absent (test only if C-spine injury NOT suspected) Note: Omitting the oculcephalic test in the presence of c-spine injury is permitted as long as the oculovestibualr reflex is tested and absent.	
Oculovestibular reflex absent	
Gag reflex absent	
Motor response to noxious stimulation absent	
Sucking/rooting reflexes absent (for infants)	
Apnea test (pCO2 ≥ 60 mmHg AND 20 mmHg above baseline PCO2 35-45)	
(Only one apnea test is required for adults≥18 yrs if performed by an attending)	

☐ I certify that I have performed a complete clinical exam according to hospital policy and that this patient is brain dead.

☐ I certify that I have performed a clinical examination as complete as circumstances permit. This will constitute an independent exam determining brain death only if confirmed by an objective test of cerebral blood flow or function.

California licensed physician [1] (Signature) **(Staff ID Number)** **(date)** **(time)**

Brain Death Determination-Confirmation using Objective Tests	Check Test Used below
4-vessel cerebral angiography	
Radionuclide cerebral blood flow study	
EEG	
Doppler/Ultrasound	

☐ I certify that a diagnostic study was achieved. The result of this test meets objective criteria for brain death.

California licensed physician [1] (Signature) **(Staff ID Number)** **(date)** **(time)**

[t1] The dated and timed documentation of the independent confirmation of death, whether by objective test or examination, will be the official pronouncement of death in the medical record.

IMPRINT I.D. CARD (NAME, MRUN CLINIC/WARD)