I. PURPOSE

The purpose of this policy is to specify the conditions under which a person is pronounced dead; to delineate the procedure for certifying death; to specify the restrictions with regard to physician participation in consent for donor organ or tissue removal or transplant procedures.

II. BACKGROUND

With the passage of the Uniform Determination of Death Act, the Medical Center has adopted policies and procedures in accordance with the various California Health and Safety Codes. It is essential to have the full cooperation of all hospital personnel to compliance with enacted Federal law and California statutes.

III. DEFINITIONS

Organ Procurement Organization (OPO): The Medical Center is contracted with to provide organ procurement services. All references within this policy to “OPO” will be references to .

Determination of Death: Based on current medical standards, an individual who has sustained either (A) irreversible cessation of circulatory and respiratory functions or (B) irreversible cessation of all functions of the entire brain including those of the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards. Note that the policy for brain death is defined separately for adults and infants (See Determination of Death Guidelines: Pediatric Patient).

Imminent Death: A patient with severe, acute brain injury who requires mechanical ventilation and is being evaluated for brain death.

Reasonable Period of Accommodation: A brief period of time that will permit a patient’s family/next of kin to gather at bedside or to have requested religious or cultural practices performed prior to the complete withdrawal of intensive care therapies in cases of death due to cessation of all brain functions. Reasonable Period of Accommodation will be case dependent and based upon bed availability, family needs and patient’s condition.

III. POLICY

A. Death Due To Cessation Of Cardio-Respiratory Function.

1. Responsible person(s):

The responsible person shall be a staff physician or a licensed resident who is functioning as the surrogate for this physician. Also, see issues regarding organ donation below (III.C.).

2. Procedure:
The physician shall examine the patient to determine a lack of cardio-pulmonary function, and then certify death by entering a note in the chart.

3. Criteria:

This assessment will take place after all appropriate resuscitation efforts are completed and have failed. Absence of cardiac function will be demonstrated by the absence of pulses by palpation, and the absence of cardiac contractions by chest auscultation. Absence of respiratory function will be demonstrated by the absence of ventilation by inspection and auscultation. Additional methods of determination may be used to supplement this clinical examination, if appropriate.

4. Documentation:

The physician determining death shall enter and sign a progress note in the chart which details the date, time, and basis of determination of death, and also clearly indicates the physician responsible for this determination. A death certificate must also be completed (see section III.E).

B. Death Due To Cessation Of All Functions of the Entire Brain Including Those of The Brain Stem.

1. Responsible persons:

Two licensed physicians, each from a different service, must agree in the decision. One physician must be from the admitting service and one of the pronouncing physicians must be an attending physician.

a. While California state law does not require that one of the two physicians determining death due to cessation of brain functions be an American Board Certified Neurologist or Neurosurgeon, it is recommended that one of the physicians be skilled in neurological diagnosis.

b. A licensed resident may act as surrogate for one of these two physicians, but only with the specific knowledge and direction of that licensed attending physician.

c. As outlined below (III.C.), these physicians may not participate in the harvesting of donor organs from the patient.

2. Procedure:

Imminent death due to cessation of brain function should be identified as early as possible by the treating physician. When imminent death has been recognized, the patient’s family/next of kin or legal surrogate shall be so informed and provided a reasonably brief period of time to permit the gathering of family members at the patient’s bedside.
The family/next of kin or legal surrogate shall be provided the Family Notification Form (Form ) which identifies the steps involved in determining brain death prior to the withdrawal of intensive care therapies. Following a verbal discussion with the family/legal next of kin, the Family Notification Form (Form ) shall be signed by the attending physician (or licensed physician designee who is functioning as a surrogate for the attending) performing the initial brain death test. The Form will then be provided to the family/legal next of kin by the patient’s social worker or primary nurse.

Determination of brain death should be accomplished as early as practical in the patient's clinical course for the benefit of family and staff. This is a medical decision, which does not require the approval of the family. At the time brain death has been declared, if the patient’s family has requested the Reasonable Period of Accommodation, the hospital may withdraw all measures of life support, other than previously ordered cardiopulmonary support, until the arrival of family members or until requested religious or cultural practices have been performed (e.g. performance of last rites, bedside prayers).

3. Criteria.

a. Clinical criteria to be met:

1. Unreceptivity and unresponsivity to external and internal stimuli should be apparent, including absence of brainstem reflexes, as demonstrated by examination of 1) pupillary response to bright light, 2) oculocephalic reflex (doll's eyes) and/or oculovestibular (cold caloric) in event c-collar remains in place 3) corneal and pharyngeal reflexes, and 4) swallowing or yawning. Further, after auditory or intensively painful stimulation, no motor responses other than spinal reflexes should be present.

2. No spontaneous respiration should be observed during a timed trial (apnea test). This trial should be conducted without respiratory assistance, and in the absence of other clinical conditions which may simulate brain death, etc. (See II.b.iii.b. below). FIO2 should be adjusted to achieve oxygen saturation >90%, if possible. 100% O2 is recommended by some. Prior to completion of this trial, arterial blood gas analyses should demonstrate a pH <7.30 and either a pCO2>60 mm Hg or an increase of >20 mm Hg from pre-test level. This usually is achieved within 10 minutes. Recommend blood gases be taken every 3-4 minutes. In the event the apnea test cannot be practically performed because of the patient’s cardiopulmonary status, another confirmatory test (see III.B. 3.c.) should be done. This apnea or other another confirmatory test would be performed prior to the first drain death note and both notes can refer to the same results.

3. Evidence of irreversible structural brain damage, either grossly or with
supportive studies (see III.B.iii.c. below), which is sufficient to explain the clinical evidence of absent central neurological function.

b. Other clinical conditions to be considered:

The following conditions, which may simulate brain death or obscure its diagnosis, should be determined not to contribute to the diagnosis of brain death:

1. Drugs which are likely to significantly suppress neurologic function, whether administered therapeutically or taken by the patient intentionally, including narcotics and sedatives. Urine toxicology screen should be negative unless confirmatory test performed with the following exceptions:
   a. If pentobarbital level is greater than 5 mcg/ml, confirmatory tests are to be performed.
   b. If pentobarbital level is less than 5 mcg/ml, it is up to the physician’s discretion to perform confirmatory tests.
2. Hypothermia (body temperature below 35°C).
3. Hypotensive for age; hemodynamic instability
4. Metabolic encephalopathy (hypothyroidism, hypercalcemia, electrolyte disorders, renal failure, hepatic failure, or hypercarbia).
5. Hypocapnia or alkalosis -

c. Additional testing to be considered:

Confirmatory and substantiating tests are to be performed as appropriate, which may include one or more of the following:
1. Isoelectric electroencephalogram
2. Cerebral angiogram with absence of cerebral filling.
3. Radioisotope brain scan with absence of cerebral perfusion.
4. Transcranial Doppler indicating no cerebral blood flow.

4. Documentation:

a. Progress notes:

1. For brain death declaration, each physician shall complete the Brain Death Declaration Form (Form ). The physician(s) completing the neurologic/neurosurgical evaluation shall write a progress note in the patient's chart to include the findings, name(s) of concurring physician(s), date and time of findings, and physician signature with medical training status.

b. Death certificate:

1. A death certificate must be completed (see Section III.E.)

2. The death certificate should reflect the date and time brain death was
confirmed, not the time of asystole.

C. **Issues regarding organ donation:**

1. When a part of the donor is to be used for direct transplantation pursuant to the Uniform Anatomical Gift Act, neither the physician nor surgeon making the determination of death, including the time of death, nor a physician making the independent confirmation, shall participate in the procedures for either removal of a part from the donor, or in the transplantation of that part in a recipient.

2. Physicians or nurses, after consultation with the patient's physician, must consider whether or not the patient is a potential organ or tissue donor and, in circumstances where the dying patient has been identified as a potential organ or tissue donor, must make a referral to the Organ Procurement Organization (OPO). California law and Medical Center policies require such documentation in the patient's record.

3. When a patient is confirmed as being a registered organ or tissue donor on the Donate Life California Organ and Tissue Registry, this represents a legally binding consent to donate as outlined in the Uniform Anatomical Gift Act. Unless the patient has a later-executed document of gift which amends or revokes the gift or there is other compelling evidence that the patient has change his/her mind, it is the policy of the Medical Center to make every reasonable attempt to fulfill the patient’s expressed wishes. While the patient’s registered donor status is legally binding and does not require informed consent from the family, it is the expectation of the Medical Center that the OPO will inform the family of the patient’s donor status and will provide information regarding the donation process, and address questions or concerns. If the family objects to the donation, the matter shall be immediately referred to Risk Management.

D. **Issues regarding removal of artificial devices for life support, and coroner's cases:**

1. Once the patient is pronounced dead and the time of death has been established, the disconnection of the respirator or ventilator has no greater medical or legal significance than the removal of any other artificial device (e.g., arterial line, IV, nasogastric tube, shunt, etc.) from the body of a dead patient. If the case has been referred to the coroner's office, the coroner's office is to be consulted as to whether the patient should be retained on the ventilator or respirator temporarily until organs are procured for transplantation.

2. For policy regarding which cases are referred to the coroner's office, refer to the hospital Decedent Affairs criteria provided in deceased packet for reporting deaths, or consult the Decedent Affairs Office. In general, the coroner's office should review deaths of persons dead on arrival at hospitals, deaths occurring in hospitals within 24 hours of admission, and deaths in which the patient sustained an injury while hospitalized.

E. **Certificate of Death, and other forms for all deaths:**

1. The top section of the Report of Death and Permission for Postmortem Examination
Form is to be signed by the physician immediately after death is confirmed. In cases of death due to cessation of brain function, both physicians must sign.

2. The Certificate of Death form, (VS-11), should whenever possible be completed within 8 hours of the time of determination of death, and shall be completed by 15 hours, except in those situations in which a physician believes he/she should not sign the certificate (e.g., coroner's case). The responsibility for assuring that the Certificate of Death is completed and signed rests with the attending physician. This responsibility may be delegated to the chief resident of each service, or another licensed physician knowledgeable of the patient's condition(s), to ensure that the certificate is completed in a timely manner. The signature(s) must be that of a physician licensed to practice in the State of California. The Certificate is then given to the Pathology Department. A photocopy is made and is retained in that office.

3. Documentation of the basis for determining and confirming the death, as well as the signed Report of Death and Permission for Postmortem Examination Form, must be kept in the patient's medical record. If any department makes a request for these forms, for example when permission for postmortem examination has been granted, a photocopy is to be provided them. The original, signed document must remain in the patient's medical record.

IV. RELATED POLICIES AND FORMS

Patient Care Related: Do Not Attempt Resuscitation (DNAR)
Patient Care Related: Donation After Cardiac Death
Organ and Tissue Donation
Brain Death Declaration Form (Form 88090)
Family Notification Form (Form 88339)

V. REFERENCES

State of California Health & Safety Code §1254.4, 7150-7155.5; 7180-7183,
Uniform Determination of Death Act
Medical Center Policy: Decedent Affairs
Uniform Anatomic Gift Act
Forms Used: Report of Death - Permission for Autopsy Consent
Certificate of Death (State of California - Department of Public Health, VS-11.
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 Medicare and biomedical and behavioral research. Neurology
32:395-399.
ACCP/SCCM Consensus Panel. Ethical and moral guidelines for the initiation,

AUTHOR: Risk Management

APPROVALS:
Organ Donor Council 2010
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