I. PURPOSE

This document outlines the policy and protocol for determination of brain death at Stanford Hospital and Clinics (SHC). It includes information on how to approach the patient's family and/or legal representatives, as well as how to manage care for a pregnant woman who is declared brain dead.

II. POLICY

A determination of brain death must be made in accordance with accepted medical standards. Pronouncement of brain death requires the independent confirmation by two licensed physicians as defined in this policy. This policy and the implementing procedure describe recommended actions to comply with statutory or regulatory requirements. For questions, consult the Risk Management office.

III. PROCEDURES

A. Pronouncement of brain death requires the independent confirmation by two licensed physicians, one of whom must be either an attending on the Neurosurgery or Neurology service, Chief Resident or a PGY3 or above neurosurgery resident.

B. A determination of brain death must be made in accordance with accepted medical standards. The definition of brain death is irreversible cessation of all function of the entire brain, including the brain stem.

C. Specific confirmatory tests, such as a technetium 99m hexamethylpropyleneamineoxime brain scan, electroencephalography or cerebral blood flow studies, may be performed to aid in the diagnosis of brain death at the discretion of those called upon to formally declare that brain death has occurred. Brain death is a clinical diagnosis. Confirmatory tests are desirable in patients in whom specific components of clinical testing cannot be reliably performed or evaluated.

1. The following conditions may interfere with the clinical diagnosis of brain death, so that the diagnosis cannot be made with certainty on clinical grounds alone. Confirmatory tests may be considered in the following circumstances:

a. Severe facial trauma.

b. Preexisting pupillary abnormalities.

c. Toxic levels of any sedative drugs, aminoglycosides, tricyclic antidepressants, anticholinergics, antiepileptic drugs, chemotherapeutic agents, or neuromuscular agents.

d. Sleep apnea or severe pulmonary disease resulting in chronic retention of CO2.

D. The physicians making a determination of brain death shall document in the patient's medical record compliance with this protocol and the manner in which the determination of brain death was accomplished.

E. This protocol describes the criteria for brain death and the steps of the clinical examination necessary to determine brain death.

1. Criteria for performing clinical brain death examination

a. Clinical or radiographic evidence of an irreversible central nervous system catastrophe that is compatible with the clinical diagnosis of brain death and that is caused by a known mechanism of trauma or medical injury.

b. Normothermia, with a minimum temperature of 36.5°C.

c. Drugs:

(1) No sedative or paralytic agents within 3 half-lives of drug.

(2) No drug intoxication or poisoning.

d. Systolic blood pressure greater than 90 mm Hg

e. No severe electrolyte, acid-base or endocrine disturbances

2. Clinical brain death examination

a. The initial examination should be performed by a neurology, neurosurgery or intensive care unit attending physician, or their fellows, chief resident or resident with three or more years of post-graduate training.

b. The initial clinical examination should consist of the following:

(1) Determination of coma or unresponsiveness: no cerebral motor response to pain in all extremities and to supraorbital pressure.

(2) Pupilliary light reflext (direct and consensual): no response to bright light. Size of pupils: midposition (4mm) to dilated (9mm).

(3) Corneal reflex

(4) Oculocephalic reflex

(5) Vestibulo-ocular reflex. (Instill a minimum 20 ml ice water in the ear. The patient should be 30° upright with the head in the neutral position. Allow five minutes to elapse between testing of each ear.)

(6) Gag reflex

(7) Apnea test

(a) Pre-requisites

(i) Corrected diabetes insipidus or positive fluid balance for the past 6 hours

(ii) Systolic blood pressure greater than 90mmHg

(iii) Normalized PCO_2 (40-44) documented by arterial PCO_2 blood gas (ABG). In patients with chronic CO_2 retention, the PCO_2 should be at the patient's baseline and the pH should be normal.

(iv) Preoxygenatation with 100% O_2 for ten minutes or arterial pO2 greater than 200 mmHG.

(b) Disconnect the ventilator and place a suction catheter down the tracheal tube through which oxygen is delivered at a flow of 8 liters O_2 per minute (higher flows have been associated with spontaneous pneumothoraces).

(c) During the apnea test, the patient should maintain an oxygen saturation greater than 97% and a systolic blood pressure greater than 90 mm Hg without malignant rhythms. Failure to meet any of these conditions should result in immediate termination of the apnea test and institution of mechanical ventilation

(d) Observe the patient for eight minutes. There should be no movement of the abdomen/chest wall in a potential respiratory fashion and an ABG documenting a PCO_2 greater than 60 mm Hg in patients with a normal baseline PCO_2 or a 20mm Hg increase in PCO_2 over the baseline PCO_2 in chronic CO_2 retainers.

3. Second, confirmatory examination

a. Neurology, neurosurgery or intensive care unit attendings, or their fellows or residents with more than three years of postgraduate training may perform a confirmatory examination.

b. The second, confirmatory examination should be performed more than one hour after the first exam.

c. The confirmatory examination does not need to include an apnea test.

4. Time of death is from the second examination. The Death Certificate must be completed by the attending physician of record or designee.

F. For Transplant Donors

1. It is recognized that there may be a potential conflict of interest if a physician involved with declaration of brain death is also involved with care of a transplant recipient. In those situations, another physician not involved with care of a transplant recipient should be asked to do the brain death examination.

2. All potential organ donors will be referred to the California Transplant Donor Network 1-800-55-DONOR (800-553-6667). See "Organ and Tissue Donation" in the *Stanford Hospital and Clinics Administrative Manual.*

3. A prospective organ donor who has not been declared brain dead according to California law or suitable for donation after cardiac death may not be admitted directly or transferred to the medical or surgical transplant service.

4. The Brain Death Policy applies to transplant donor patients not previously pronounced legally dead at another facility.

G. Withdrawal of Medical Intervention for Declared Brain Dead Patients and Interaction with Family

1. The Uniform Determination of Death Act states that an individual, who has sustained irreversible cessation of all functions of the entire brain, including the brain stem, is dead. The intent is to allow physicians and the medical team to withdraw medical intervention once a patient is declared brain dead. Ideally, the patient's family and/or legal representative will concur that since the patient is dead, medical intervention should cease. In cases where the family and/or legal representative disagree, the physician is encouraged to explore the reasons for disagreement and to try to resolve the dispute as described below.

2. Written Notification to Family

In accordance with Health and Safety Code 1254.4 (Appendix A), family or next of kin will be allowed a “reasonably brief period” of time to gather at the patient’s bedside. The patient’s legally recognized health care decisionmaker, if any, or patient’s family or next of kin, if available, will be provided with a written statement of the policy (Appendix B), upon request, but no later than shortly after the treating physician has determined that the potential for brain death is imminent.

3. The medical team should thoroughly discuss withdrawal of support with the patient's family and/or legal representative and seek their assent prior to discontinuing all medical intervention. Family consent for this withdrawal is not required. However, if the family objects, reasonable accommodation should be attempted as outlined below. The discussion with family should not include the language of withdrawing "life support" as this may be interpreted as a contradiction to the pronouncement of death.

4. Family Objections

Objections to withdrawal of support may arise due to lack of understanding regarding the meaning or significance of brain death, on the basis of religious or cultural beliefs, the news may come suddenly as in the case of trauma, or the belief that the diagnosis is mistaken.

a. In cases where the family disputes the diagnosis, a qualified SHC privileged physician of their choice could be requested to render a

timely additional confirmation of the determination of irreversible brain death. If the diagnosis remains disputed and the family disagrees with withdrawal, Risk Management should be consulted about next steps.

b. In the rare instance that the physician requested by the family or legal representative does not confirm the diagnosis, or that despite confirmation the family or legal representative still objects to withdrawing medical intervention, an attempt should be made to resolve the dispute within the hospital. It may be useful to involve trusted person(s) such as a chaplain, Social Worker or Ethics Committee consultant(s).

c. If the diagnosis is **not** disputed, yet the family or legal representative objects to the withdrawal of medical interventions and all reasonable attempts have been made to resolve the dispute, then the family and/or legal representative will be informed that within a limited designated time frame the withdrawal of medical intervention will proceed.

5. Once a patient has been declared brain dead, the Transplant Network Coordinator should be contacted to discuss organ/tissue donation with the patient's family and/or legal representative. This should be done at an appropriate time interval after the family and/or legal representative has been informed of the diagnosis of brain death.

H. Medical Intervention when a Pregnant Woman is Declared Brain Dead:

1. When a pregnant woman is declared brain dead, the medical team must determine the gestational age and condition of the fetus before withdrawing medical intervention. The team should include representatives from the ICU, the primary service group and/or the primary care provider, neonatology, and obstetrics. All four groups should be consulted before any decisions are made or communicated to the family. The Ethics Committee should be consulted, if appropriate.

2. In appropriate cases, the medical team may continue artificial support of the vital functions of the brain-dead patient, including ventilation and perfusion, in order to support the fetus. Artificial support should not continue unless all 3 of the following criteria are met:

a. The team members believe that the fetus can survive until it is both viable and has a reasonable prognosis for a good neurologic outcome;

b. The team members believe they can artificially maintain the brain-dead patient's vital functions until that point;

c. The family (or surrogate) requests continued artificial support for the benefit of the fetus. The team may continue support to allow time to locate family members or surrogates. If there is no family or advance directives, proceed to Section 7 below.

3. In deciding whether to continue artificial support, it should be recognized that these are extraordinary measures:

a. Artificial support of a brain-dead patient has practical limitations because the patient's cardiovascular system will eventually collapse. Maintaining support for even 1 or 2 weeks after brain death is a difficult endeavor;

b. An infant delivered earlier than 24 weeks gestation and weighing under 500 grams is very unlikely to survive;

c. The likelihood of both survival and good neurologic outcome improves significantly with a gestation period of at least 26 weeks and preferably 30 weeks. Thus, the team should consider whether the mother's cardiovascular system is likely to withstand artificial support until 26-30 weeks of gestation.

4. If the team members continue artificial support, they should estimate the earliest date they expect to deliver the fetus. If the brain-dead patient's physiological condition deteriorates prior to that date, the team should reevaluate whether the efforts are still appropriate.

5. Consulting the Family

a. If the medical team determines that artificial support is medically appropriate, the team should help the family understand the current data on whether the baby is likely to survive after delivery and what the likelihood is that the baby will be born with significant neurologic damage due to extreme premature delivery. In addition, the team should help the family understand the range of medical procedures that the baby may face after delivery so that the family can weigh the benefits and burdens of continued artificial support of the fetus and the brain-dead mother. The family should be offered resources in areas such as patient finances, social services and family counseling to help evaluate the long-term effects of any decision.

b. In weighing the interests of the brain-dead mother, members or surrogates must determine whether the mother made any oral or written advance directives about continued use of her body after brain death. In weighing the interests of the fetus, family members or surrogates should weigh the benefits and burdens to the fetus of the extraordinary course of medical intervention that will occur prior to and after birth.

c. If the family members or surrogates decide that the burdens outweigh the benefits the team should not continue support. If the practitioners believe that the fetus has a good prognosis, there should be further discussions with the family about continuing support.

6. Regardless of what the family or surrogates decide, the medical team should document the discussion and the decision in the mother's chart.

7. If the patient and the fetus have no family members or surrogates to request continued intervention and participate in the neonatal medical decisions, the team should consult the Ethics Committee and the *Health Care Decisions for Patients Who Lack Capacity and Lack Surrogates* policy for guidance in decision making. The team should continue artificial support if the fetus is already viable and has a reasonable prognosis for a good neurologic outcome. The team may continue artificial support in the course of performing an emergency cesarean section.

8. Identifying Family Members and Resolving Disagreements

a. If the medical team determines that artificial support is medically appropriate, the team should consult family members or surrogates who represent the interests of the fetus and the brain-dead mother. If possible, such family members or surrogates should include the biological father of the fetus or those who represent the interests of the biological father.

b. If family members or surrogates disagree with each other concerning whether to continue artificial support, the medical team should involve the assistance of appropriate consultants (e.g., spiritual care services, social services, or ethics committee).

c. If disagreements persist, the medical team should refer the matter to the ethics committee for emergency consultation. If the ethics consultation does not resolve the conflict, the medical team should contact Risk Management.

9. If the members of the medical team disagree about whether continued artificial support is appropriate, they should follow the procedures in the policy for resolving disputes within the medical team.

10. Withdrawing Medical Intervention

a. If the team determines that continued intervention is not appropriate, the team should inform family members or surrogates and then follow the procedures outlined above for withdrawal of medical intervention when a patient is brain dead.

b. If the brain-dead patient's cardiovascular system collapses before the estimated delivery date, no effort should be made to resuscitate the patient except for those efforts necessary to perform an emergency cesarean section for a viable fetus with a reasonable prognosis for a good neurologic outcome.

11. If the team delivers the fetus:

a. After the delivery, the team should follow the procedures outlined above for withdrawal of medical intervention when a patient is brain dead; and

b. Unless custody is clear, the neonatal team should contact Risk Management to determine who has legal custody of the baby.

IV. COMPLIANCE

A. All workforce members including employees, contracted staff, students, volunteers, credentialed medical staff, and individuals representing or engaging in the practice at SHMC are responsible for ensuring that individuals comply with this policy;

B. Violations of this policy will be reported to the Department Manager and any other appropriate Department as determined by the Department Manager or in accordance with hospital policy. Violations will be investigated to determine the nature, extent, and potential risk to the hospital. Workforce members who violate this policy will be subject to the appropriate disciplinary action up to and including termination.

V. RELATED DOCUMENTS

A. Death of Patient in the *SHC Administrative Manual*
B. Medically Ineffective Health Care in the *SHC Administrative Manual*
C. Organ and Tissue Donation in the *SHC Administrative Manual*

VI. APPENDICES

A. California Health And Safety Code Section 1254.4
B. Family Notification Form

VII. DOCUMENT INFORMATION

A. Legal Authority/References
   1. Health and Safety Code Section 7180 et. Seq.
   2. Health and Safety Code Section 1254.4

B. Author/Original Date
   May 1991, L. Gunderson, Assistant Director of Nursing, ICU

C. Gatekeeper of Original Document
   Administrative Manual Coordinators and Editors

D. Distribution and Training Requirements
   1. This policy resides in the Administrative Manual of Stanford Hospital and Clinics.

2. New documents or any revised documents will be distributed to Administrative Manual holders. The department/unit/clinic manager will be responsible for communicating this information to the applicable staff.

E. Review and Renewal Requirements

This policy will be reviewed and/or revised every three years or as required by change of law or practice. Ethics Committee chairs will be consulted in the review process for minor revisions; full Ethics Committee review will be obtained for significant revisions..

F. Review and Revision History

January 1994, L. Gunderson, Assistant Director of Nursing, ICU
August 1995, to reflect Stanford Health Services title
October 1995, T. Jenkins, Assistant Nurse Manager
February 1999, E. Young, PhD, Chair, Ethics Committee
April 2000, C. Taylor, RN, to incorporate the Brain Death Protocol
March 2001, M.L. Polan, MD, PhD and M. Druzin, MD, Department of Gynecology and Obstetrics
September 2003, coordinated by C. Taylor, Patient Care Policy and Procedure Coordinator
January 2007, Sheetal Shah, Director Risk Management
August 2009, Matson Sewell, Director Risk Management

G. Approvals

May 1991, ICU/IICU Committee
January 1994, ICU/IICU Committee
March 1994, Medical Board
March 1994, Hospital Board of Directors
April 1997, Ethics Committee
November 1997, Medical Board
December 1997, UCSF Stanford Health Care Board of Directors
March 1999, SHC Medical Board
April 2000, ICU Committee
January 2001, L. Smith, Vice President, Director of Risk Management
February 2001, SHC Medical Board
February 2001, SHC Hospital Board
March 2001, M.L. Polan, MD, PhD, and M. Druzin, MD, Department of Gynecology and Obstetrics
March 2001, ICU Committee
October 2003, Ethics Committee

February 2004, Quality Improvement Patient Safety Committee
March 2004, SHC Medical Board
March 2004, SHC Hospital Board
January 2007, SHC Critical Care Committee
March 2007, Quality Improvement and Patient Safety Committee
April 2007, SHC Medical Board
April 2007, SHC Hospital Board
November 2009, Quality, Patient Safety & Effectiveness Committee
December 2009, SHC Medical Executive Committee
December 2009, SHC Board Credentials, Policies & Procedures Committee