DETERMINATION OF BRAIN DEATH

POLICY©

DOCUMENT SUMMARY/KEY POINTS

- Staff responsible for diagnosing and those caring for potentially brain dead patients should read this document.
- Determination of brain death requires understanding of the pathology that lead to cessation of whole brain function.
- Before brain death testing can occur preconditions must be met, prior to and maintained, during the 4 hours period of observation. During this time the patient must be intubated and ventilated and demonstrate to have loss of neurological function (pupils fixed and dilated, no cough, no gag, no spontaneous respiration).
- In cases of acute hypoxic ischemic injury a period of 24 hours must elapse following return of spontaneous circulation before the 4 hour observation period can commence prior to brain death testing.
- TWO separate tests must be performed by two different medical practitioners. The tests MUST be done separately but can be done consecutively. Only in the case of a neonate (≥36 wks gestation and ≤30days of age) are the two tests to be done 24 hours apart.
- The time of death should be documented at the time of completion of the second clinical test.
- A patient must meet the preconditions prior to Brain Death testing. If the patient cannot meet the criteria then imaging of cessation of blood flow to the brain can be considered.
- ALL components of the clinical test must be performed to confirm the diagnosis of brain death. If the patient cannot complete all aspect of the test then imaging of cessation of blood flow to the brain is to be considered.
- The clinical test is comprised of three main components
  - COMA
  - ABSENT Brain Stem Reflexes
  - APNOEA

This policy should be used in conjunction with the policy on Organ and Tissue Donation. On occasion, organs can be removed from a person after death when the circulation has ceased irreversibly, this is called "Donation after Cardiac Death – DCD" and in this case brain death testing is not required. The policy on DCD is currently being reviewed by SCHN OTDS staff.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1st March 2014	**Review Period:** 3 years
Team Leader:	Staff Specialist Organ & Tissue Donation Service	**Area/Dept:** Intensive Care Unit, CHW

This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.

CHANGE SUMMARY

- Updated the document based on the ANZICS "Statement on Death and Organ Donation 3.2" 2013. The amendments are to the following topics:
    - Preconditions
    - Observation period prior to testing
    - Effect of therapeutic hypothermia on brain death testing
    - Demonstrating the Absence of Intracranial Blood Flow
- Amend flow chart – Appendix 1
- Insertion of form "Certification of brain death form" – Appendix 2

READ ACKNOWLEDGEMENT

- ALL medical practitioners that perform clinical test for the diagnosis of brain death should read and acknowledge this document
- Training/Assessment Required – for registrars/fellows in PICU
- Nursing staff looking after potential brain dead patients should read this document.

TABLE OF CONTENTS

This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.

This policy should be used in conjunction with the policy on Organ and Tissue Donation. On occasion, organs can be removed from a person after death when the circulation has ceased irreversibly, this is called "Donation after Cardiac Death – DCD" and in this case brain death testing is not required. The policy on DCD is currently being reviewed by SCHN OTDS staff

Policy Statement

In cases where organs/tissues are to be removed for transplantation, cessation of brain function will be certified according to ANZICS recommendations.

The following information is based on the document: "The ANZICS statement on Death and Organ Donation – Edition 3.2; 2013, Australian & New Zealand Intensive Care Society".

A copy of the document is available at the following website:
http://www.anzics.com.au/death-and-organ-donation

The above mentioned statement reviews evidence from:

- the UK "the criteria for determination of brain death, outlined in the joint statement of the Medical Royal Colleges and their Faculties of the United Kingdom"
- the USA "the criteria for determination of brain death in the Report of the Medical Consultants on the Diagnosis of Death to the President's Commission"
- peer reviewed published literature.

Legal definition of death

Death is legally said to occur when there is irreversible cessation of circulation of blood in the body of a person, or irreversible cessation of all function of the brain.

The term "brain death" should be used when death is certified using the brain function criteria.

Determination of brain death requires:

- understanding of the pathology that lead to cessation of **whole** brain function.
- Cessation of **whole** brain function is represented by the clinical testing (performed only if preconditions are met) and documentation of:
    - irreversible coma
    - irreversible loss of brain stem reflex responses and respiratory centre function

If clinical testing preconditions (detailed below) cannot be met then brain death can be determined by:

- demonstration of cessation of intracranial blood flow.

This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.

Clinical Diagnosis of brain death

Brain death means death.

Testing is carried out to diagnose brain death in order to prove death in the presence of a beating heart. This confirms for staff and families that death has occurred and that continuation of treatment serves no purpose for the child. Brain death testing should be performed irrespective of the donor status of the child.

Formal brain stem death testing is a legal requirement in the removal of organs for transplantation, from a deceased person who has a beating heart.

Preconditions to be met prior to formal brain stem function testing

The following conditions must be met before clinical brain death testing may be performed. If any of the following are not met then clinical brain death testing cannot proceed until **all** the preconditions are met.

- The **cause** of severe brain injury must be known (either by clinical or neuro-imaging).
- **Normothermia** – core temperature >35°C.
- **Normotensive** – inotropes can be used to achieve an age appropriate mean blood pressure.
- **Exclusion of effects by sedative drugs** – care must be taken when considering the continued effects of sedative drugs and in particular the increased metabolic clearance rate of the drugs when therapeutic hypothermia has been used. In the case of barbituates, either levels should be shown to be below clinically significant levels (10mg/L) or demonstration of absent cerebral blood flow. If there are concerns of the effects of benzodiazepines or opiates the appropriate reversal agent should be administered.
- **Absence of electrolyte, metabolic or endocrine imbalances.**
- **Intact neuromuscular conduction** – if neuromuscular blocking agents have been administered as part of the treatment management of the patient, then peripheral nerve stimulator should be used to confirm normal neuromuscular conduction.
- **Ability to examine brain stem reflexes** – ability to examine at least one eye and one ear. Care must be taken to ensure that NO dilating eye drops have been used. If they have, then then a period of at least 24 hours should elapse or consultation with ophthalmology should occur to meet preconditions.
- **Ability to perform apnoea test** – may not be able to perform if the patient also has severe respiratory failure such as ARDS.

Clinical Testing of Brain Stem Function

This is divided into two sections: (1) Observation and (2) Formal examination.

Observation

The patient must have met the preconditions stated above, before the **4 hour** period of observation can commence. The preconditions must be met during the entire observation period. This observation period must occur before brain death testing can be performed. During this time the patient must show:

This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.

- No spontaneous breathing efforts and must be intubated and ventilated.
- Pupils not responding to light (fix and dilated).
- No cough or gag reflexes.

In the event of a **hypoxic ischaemic injury**, such as a cardiorespiratory arrest, the observation period should be delayed by **24 hours** from return of spontaneous circulation.

In an infant >30 days of age the above guidelines have been seen to be adequate. In the case of a term neonate (≥36 weeks gestation and ≤30 days old) the first clinical test should occur either after 48 hours from birth or 24 hours from insult and the first test must be separated from the second clinical test by a minimum of 24 hours.

In the event that therapeutic hypothermia following cardiorespiratory arrest, brain death testing should be delayed by 24 hours AFTER rewarming, but may be confirmed prior by demonstration of absent cerebral blood flow.

Formal examination

Two medical partitioners carry out the clinical examinations for determination of brain death. The two tests must be performed separately but may be done consecutively, except for the case of term neonates (as described above).

The legislation in NSW stimulates that each practitioner must:

- *Have practiced medicine for not less than 5 years in the preceding 8 years*
- *One must be a designated specialist for the hospital*
- *They MUST NOT be the designated officer*
- *They MUST NOT be involved in tissue removal*
- *They ideally SHOULD NOT be responsible for care of the intended recipient*

All of the components of the clinical test must be performed to determine brain death. The clinical test **must confirm all** of the following:

- Coma
- Absence of brain-stem reflexes
- Apnoea

Time of death is recorded as the time when certification of brain death is completed, i.e. following the second examination.

The clinical test is comprised of the following components:

1. **Coma**
   - i. **Test:** Apply noxious stimulus to the cranial nerve distribution, sternum and all four limbs (e.g. deep nail bed pressure).
   - ii. **Response:** No flexor or extensor motor response. GCS of 3. Spinal reflexes can be elicited with painful stimulus.
   - iii. **NOT brain dead:** True extensor or flexor motor response demonstrated on stimulation ➔ STOP test.

This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.

2. **Brain stem reflexes**

- *Pupillary reaction to light*
  - i. **Test:** Shine bright light into the eye and look for pupillary constriction, Pupils must be ≥ 4mm in size.
  - ii. **Response:** No pupillary constriction.
  - iii. **NOT brain dead:** Pupils constrict ➔ STOP test.
- *Corneal reflexes*
  - i. **Test:** Touch the Cornea with a soft cotton wool or gauze. Ensure to be gentle as corneas may damage easily.
  - ii. **Response:** No blink reflex.
  - iii. **NOT brain dead:** blink reflex is observed ➔ STOP test.
- *Pain reflex*
  - i. **Test:** Apply pain over trigeminal nerve distribution (e.g. supraorbital ridge).
  - ii. **Response:** No facial or limb response.
  - iii. **NOT brain dead:** Movement of face or limbs ➔ STOP test.
- *Vestibulo-ocular reflexes (caloric testing)*
  - i. **Test:** Use an otoscope to visualize the ear drum (ruptured ear drum does not preclude the test but wax must be removed before the test may proceed). Head must be at 30° and 50ml of ice cold water should be instilled into the ear canal using a syringe. Eye lids must be held open to observe eye movement for a minimum of 60 seconds.
  - ii. **Response:** No eye movement.
  - iii. **NOT brain dead:** ANY eye movement ➔ STOP test.
- *Gag reflex*
  - i. **Test:** Stimulate the back of the pharynx with a cotton swab or tongue depressor.
  - ii. **Response:** No gag.
  - iii. **NOT brain dead:** Gag present ➔ STOP test.
- *Cough reflex*
  - i. **Test:** Stimulate the tracheal wall with a suction catheter.
  - ii. **Response:** No cough.
  - iii. **NOT brain dead:** Cough present ➔ STOP test.

3. **APNOEA** – *Proceed ONLY if all of the above reflexes are ABSENT*.

   i. **Test:** Preoxygenate with 100% oxygen for 5 minutes. Blood gas should be collected prior to the start of the test. The patient should be disconnected for the mechanical ventilator but oxygen can be administered via a catheter inserted into the endotracheal tube (oxygen flow 1-2 L/min). PEEP may be administered throughout the apnoea test to avoid hypoxia (turn OFF apnoea ventilation mode). A blood gas should be collected at the end of the test. The arterial pCO_2 should be >60 mmHg and arterial pH should be <7.30 (with oxygenation throughout the test) to provide adequate stimulus to spontaneous ventilation and

This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.

in the case of chronic hypercarbia the pCO_2 should have risen by 20 mmHg (~>60mmHg) and a pH <7.30.

ii. **Response:** No spontaneous breaths.

iii. **NOT brain dead:** Spontaneous breathing ➔ STOP test.

Observations compatible/incompatible with the diagnosis of brain death

Compatible with the diagnosis of brain death:

- **Spinal reflexes**
  - Lazarus sign
  - Deep tendon reflexes
  - Undulating toe reflex
  - Respiratory – like movement with no significant tidal volumes
  - Head turning
- **Sweating, blushing, tachycardia**
- **Normal blood pressure** – absence of the need for inotropes
- **No diabetes insipidus**

Incompatible with the diagnosis of brain death:

- Decerebrate or decorticate posturing
- True extensor or flexor motor response to painful stimulus
- Seizures

In cases where clinical criteria cannot be met

For example:

- Cardiovascular instability or severe hypoxaemic respiratory failure precluding the apnoea test.
- Possible metabolic or drug effect.
- Cranial nerves cannot be adequately tested.

In such cases, two medical practitioners (not including the medical practitioner who performed the investigation) provide certification of brain death. Said practitioners, having examined the patient and in the knowledge of the circumstances of the onset of coma, are further assisted in making the diagnosis of brain death by evidence of absent intracranial blood flow. The imaging should ONLY be performed once adequate blood pressure is achieved (with or without the use of inotropes). The time of death should be recorded at the time the second clinician confirms absence of flow.

This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.

If aspects of the testing cannot be completed due to trauma or pathology, then preconditions, observation period and components tested should be documented prior to proceeding to imaging.

Four vessel intra-arterial catheter angiography is considered to be the gold standard to demonstrate the absence of blood flow to the brain parenchyma. The contrast medium is injected directly into both carotid and vertebral arteries.

A **radionuclide scan** can also be used as an objective confirmation of brain death, in cases where clinical criteria cannot be met, by demonstrating absence of perfusion. It is important to remember that the radio-nucleotide used needs to cross the blood-brain barrier.

Contrast CT or CT angiography is another mode of imagining that has been used. There are no large studies that have demonstrated the specificity and sensitivity of this mode of study. There have not been any reported cases of absent blood flow as detected by CT angiography that were NOT declared brain dead via clinical test or four vessel catheter angiography. Larger studies with matched controls are needed.

MRI has been used to demonstrate the absence of flow into the brain parenchyma. Caution must be used when interpreting these scans as in some cases slow flow may mimic absence of flow. These false positive depend on a large number of variables, consequently the ANZICS statement on brain death does not recommend the use of MRI to determine absence of flow to the brain.

Transcranial Doppler is an imaging technique that can be used as a screening tool to optimise timing of a contrast study but should not be used to determine absence of flow to the brain.

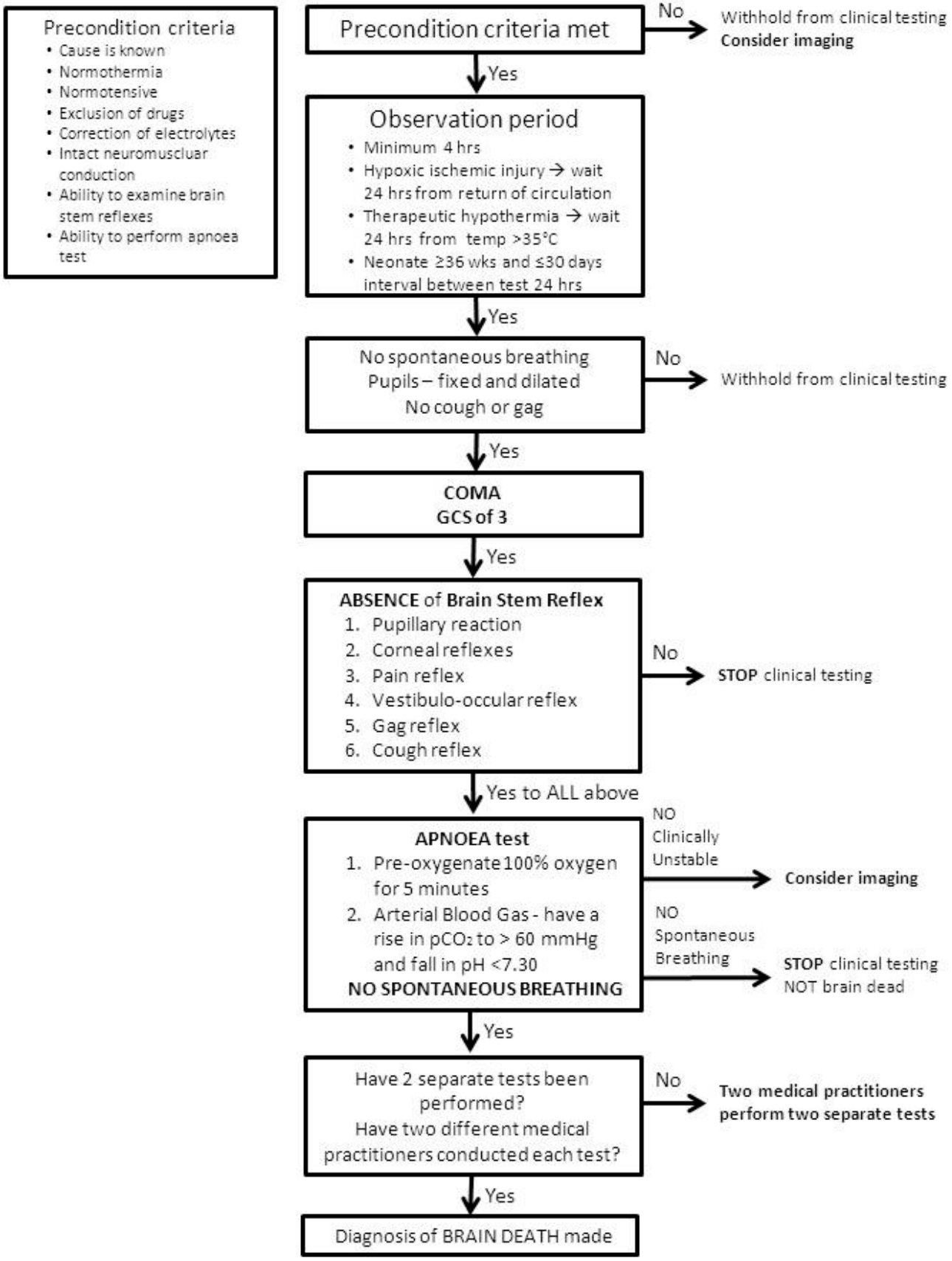
Documentation

Accurate documentation is paramount and all preconditions and components of the test need to be documented. To aid in this process the NSW Health PD2013-001 (page 27) had developed a “Certification of brain death” form. This form is available in the ICUs across the network (Appendix 2) otherwise please contact the OTDS staff form more information.

Copyright notice and disclaimer:

The use of this document outside The Sydney Children's Hospital Network (SCHN), or its reproduction in whole or in part, is subject to acknowledgement that it is the property of SCHN. SCHN has done everything practicable to make this document accurate, up-to-date and in accordance with accepted legislation and standards at the date of publication. SCHN is not responsible for consequences arising from the use of this document outside SCHN. A current version of this document is only available electronically from the Hospitals. If this document is printed, it is only valid on the date of printing.

Appendix 1 – Flow chart for Determination of BRAIN DEATH



This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.

Appendix 2:– SCHN "certification of brain death" form (example only)

NSW Health

Facility:

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

D.O.B. ____/____/____ | M.O.

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

SMR010517

CERTIFICATION OF BRAIN DEATH

For the purposes of the law of NSW, a person has died when there has occurred: (a) irreversible cessation of all function of the person's brain. (s 33 Human Tissue Act 1983) A designated officer shall not give an authority to remove tissue from a deceased person for it's use for transplantation unless each of 2 medical practitioners has certified in writing that the following has occurred.

Known cause of irreversible loss of brain function

There is acute brain pathology consistent with the irreversible loss of brain function

Doctor A: *Specify condition* _____

Doctor B: *Specify condition* _____

Period of continuous observation of apparent loss of neurological function

There has been at least a 4 hour period of observation (24 hours for hypoxic-ischaemic encephalopathy) and mechanical ventilation during which the patient has unresponsive coma, with pupils nonreactive to light, absent cough/tracheal reflex and no spontaneous breathing efforts.

This period began at (Date and time) _____

Determination of brain death by clinical examination * Preconditions	Doctor A Please √	Doctor B Please √
1. Hypothermia is not present – temperature is > 35°C Specify Temperature:	_____°C	_____°C
2. Blood pressure is adequate (eg MAP>60 in an adult)	☐	☐
3. Sedative drug effects are excluded	☐	☐
4. There is no severe electrolyte, metabolic or endocrine disturbance	☐	☐
5. Neuromuscular function is intact	☐	☐
6. It is possible to examine the brain-stem reflexes (including at least one ear and one eye)	☐	☐
7. It is possible to perform apnoea testing	☐	☐
Clinical Testing		
1. There is no motor response in the cranial nerve distribution to noxious stimulation of the face, trunk and four limbs and there is no response in the trunk or limbs to noxious stimulation within the cranial nerve distribution	☐	☐
2. There are no pupillary responses to light	☐	☐
3. There are no corneal reflexes	☐	☐
4. There is no gag (pharyngeal) reflex	☐	☐
5. There is no cough (tracheal) reflex	☐	☐
6. There are no vestibulo-ocular reflexes on ice-cold caloric testing	☐	☐
7. Breathing is absent (despite arterial pCO_2 > 60mmHg (8pKa) and arterial pH < 7.30)	pCO_2 _____	pCO_2 _____
8. Specify pCO_2 in **mmHg** or **kPa** (*circle one*) and pH at end of apnoea	pH _____	pH _____

Determination of brain death when clinical examination cannot be done:	Doctor A Please √	Doctor B Please √
1. There is no intracranial blood flow	☐	☐
2. *(Delete one as appropriate)* This has been demonstrated by *either* **intra-arterial angiography** *or* **other suitably reliable method**		

Other (Specify) _____

We have determined, according to the above procedures, that irreversible cessation of all function of the person's brain has occurred

Doctor A (Name): _____ | Doctor B (Name): _____

Designation: _____ | Designation: _____

Signature: _____ | Signature: _____

Date and time of assessment: _____ | Date and time of assessment: _____

Date and time of death (End of the assessment by second doctor): _____

*Based on criteria developed by the Australian New Zealand Intensive Care Society, the ANZICS statement on Death and Organ Donation, edition 3.1, 2010

NO WRITING

Page 1 of 1

Holes Punched as per AS2628.1 2012

BINDING MARGIN - NO WRITING

CERTIFICATION OF BRAIN DEATH

SMR010.517

NH9006617 050213

Example only

This Policy/Procedure may be varied, withdrawn or replaced at any time. Compliance with this Policy/Procedure is mandatory.