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<td>KEY TERMS</td>
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<td>SUMMARY</td>
<td>To inform staff of the process and</td>
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<td>requirements for multi-organ and appears</td>
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<td>donation after brain death has been</td>
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1. **POLICY STATEMENT**

To inform staff of the process and requirements for multi-organ and tissue donation, after brain death has been determined, based on irreversible cessation of all function of the person’s brain within South Eastern Sydney Local Health District.

2. **BACKGROUND**

The principles in this document are consistent with the National Health and Medical Research Council (NHMRC): Organ and Tissue Donation after Death, for Transplantation: Guidelines for Ethical Practice for Health Professionals.

The fundamental principles for organ and tissue donation within Southern Eastern Sydney Local Health District include:

- Donation of organs and tissues is an act of altruism and human solidarity that potentially benefits those in medical need and society as a whole.
- Organs and tissues for transplantation should be obtained in ways that:
  - Demonstrate respect for all aspects of human dignity, including the worth, welfare, rights, beliefs, perceptions, customs and cultural heritage of all involved
  - Respect the wishes, where known, of the deceased
  - Give precedence to the needs of the potential donor and the family over the interests of organ procurement
  - As far as possible, protect the recipients from harm
  - Recognise the needs of all those directly involved, including the donor, recipient, families, carers, friends and health professionals.
- Organs and tissues should be allocated according to just and transparent processes.
- The choice not to donate should be respected and the family shown understanding for the decision.

### 2.1 Definitions

**AODR:** Australian Organ Donor Register

**Medicare Australia**

**ARCBS:** Australian Red Cross Blood Service

**Brain Death:** The term ‘brain death’ should be used when death is certified using the NSW Human Tissue Act 1983 definition “irreversible cessation of all function of the person’s brain”

**Child:** A person who has not attained the age of 18 years and who is not married.

**Child in care:** Means a child or young person under the age of 18 years:

- Who is under the parental responsibility of the Minister administering the Children and Young Persons (Care and Protection) Act 1998
- For whom the Director-General of the Department of Family and Community Services or a designated agency has the care responsibility under section 49 of the Children and Young Persons (Care and Protection) Act 1998
• Who is a protected person within the meaning of section 135 of the Children and Young Persons (Care and Protection) Act 1998
• Who is the subject of an out of home care arrangement under the Children and Young Persons (Care and Protection) Act 1998
• Who is the subject of a sole parental responsibility order under section 149 of the Children and Young Persons (Care and Protection) Act 1998
• Who is otherwise in the care of a service provider.

**Designated Office**: Appointed by the Governing Authority to legally authorise, in writing, non-coronal post-mortem examination; the release of a body for anatomical examination and the removal of tissue from a body for transplant or other therapeutic, medical or scientific purpose.

**Designated Specialist**: Appointed by the Governing Authority of appropriately qualified and experienced medical specialists for the purposes of certifying brain death. The following classes of medical practitioners are prescribed:
• Fellows of the Australasian College of Emergency Medicine
• Fellows of the Australian and New Zealand College of Anaesthetists
• Fellows of the College of Intensive Care Medicine of Australia and New Zealand
• Fellows of the Royal Australasian College of Physicians
• Fellows of the Royal Australasian College of Surgeons
• Fellows of the Royal Australian College of Obstetricians and Gynaecologists.

**NSW Organ and Tissue Donation Service (NSW OTDS)**: Is the NSW agency responsible for the coordination of organ and tissue donation for transplantation based at Kogarah within SESLHD. Paging service for the DSC is **02 9963 2801**.

**DSC**: Donation Specialist Coordinator based at NSW OTDS
**DSM**: Donation Specialist Medical employed within SESLHD
**DSN**: Donation Specialist Nurse employed within SESLHD

**ED**: Emergency Department

**G.I.V.E. Clinical Trigger**: G=GCS ≤ 5, I=Intubated, V=Ventilated, E=End of life discussions.

The Clinical Trigger is met in patients from ED or ICU with an irrecoverable neurological injury where GCS ≤ 5, Intubated and ventilated with whom end of life decisions have been initiated.

**ICU**: Intensive Care Unit

**Medical or scientific purpose**: The use of a body or tissue for medical or scientific purposes includes educational and/or research purposes connected with medicine or science.

**Potential donor**: Is a critically ill patient in an emergency department or intensive care unit meeting G.I.V.E. clinical trigger.
Principal Care Officer (PCO): PCO of the designated agency has full case management responsibility for the child or young person, automatically becomes the person with responsibility for consent for organ and tissue donation for transplantation. The Act does not allow for organs and tissues to be retained for research or other medical scientific or therapeutic purposes in these cases. The PCO must use reasonable efforts to contact persons who have been significant in the child’s or young person’s life and who the PCO considers to be appropriate to assist in the decision making process. This may include:

- Birth parents
- Foster parents
- Extended family
- If the child/young person is Aboriginal or Torres Strait Islander, appropriate persons from the child’s or young person’s Aboriginal and/or Torres Strait Islander community
- Other persons considered relevant by the PCO.

The PCO will determine whose approval is required and may determine that more than one person’s approval is necessary. A PCO must not give consent unless all relevant parties have been consulted and have given their approval to the organ and tissue donation.

RMS: Roads and Maritime Services, an agency which brings together the former Roads and Traffic Authority (RTA) and NSW Maritime. Donor preferences on RMS can be accessed for a further five years from November 2012.

SANOK: Senior Available Next-of-kin: as defined in the NSW Human Tissue Act 1983. In relation to a deceased adult:

- Spouse of the deceased (which includes de facto and same sex partner)
- Son or daughter of the deceased (18 years of age or over), where above is not available
- Parent of the deceased where none of the above is available
- Sibling of the deceased (18 years of age or over), where none of the above is available.

And

In relation to a deceased child:

- Parent of the child (both parents have equal standing)
- Sibling of the child (18 years of age or over), where a parent is not available
- Guardian of the child at the time of death where none of the above is available.

Delegate: Somebody who is chosen to represent or given the authority to act on behalf of the SANOK. The delegate must be of the same order of hierarchy (as per Human Tissue Act) as the person who authorised him or her to exercise the functions of a next of
kin. The following form must be competed: Authorisation to Delegate Responsibilities of the Next of Kin.

SEALS: South Eastern Area Laboratory Service

3. RESPONSIBILITIES
   - Hospital Network Executive
   - Stream / Site / Service Executive
   - Senior Nurse Managers
   - Organ and Tissue Donor Coordinators
   - Intensive Care Units Nursing and Medical Staff
   - Emergency Departments Nursing and Medical Staff
   - Operating Theatre Nursing and Medical Staff
   - Social Work, Multicultural and Aboriginal Health Care Workers

4. PROCEDURE
4.1 Identification of a potential organ donor
   Patients that are in the ICU or the ED who meet the G.I.V.E clinical trigger (as per definition) and exhibit clinical signs consistent with brain death are potential organ donors.
   - Each potential donor is assessed on a case-by-case basis and there is no expectation that the treating clinician should determine medical suitability.

4.2 Notification of potential organ donor
   Contact the local area DSN:
   St George and Sutherland Hospitals       Prince of Wales Hospital
   P. 9113 3520                              P. 9382 4872
   M. 0413 009 332                          M. 0457 409 836
   Switchboard: 9113 1111                   Switch board: 9382 2222

   Notification of a potential donor can also be made to NSW OTDS paging service on 02 9963 2801, at any time.

   Early notification is preferable to:
   - Ascertain any recorded intent of the deceased from the RMS and AODR databases
   - Assist with advice and support regarding organ donation
   - On-site family discussion and informed decision making
   - Assessment of medical suitability
Facilitation of organ donation process
Coordination of referral and retrieval process
Support of the family
Support of medical and nursing staff.

4.3 **Determination of brain death**

Patient is confirmed deceased by brain death criteria, as recommended by the ANZICS Statement on Death and Organ Donation, that:

- There must be definite clinical or neuro-imaging evidence of acute brain pathology (e.g. traumatic brain injury, intracranial haemorrhage, hypoxic encephalopathy) consistent with the irreversible loss of neurological function
- Unresponsive coma (GCS 3)
- The absence of brain-stem reflexes
- The absence of respiratory centre function, in the clinical setting in which these findings are irreversible. In particular, there must be definite clinical or neuro-imaging evidence of acute brain pathology (e.g. traumatic brain injury, intracranial haemorrhage, hypoxic encephalopathy) consistent with the irreversible loss of neurological function.
- All preconditions are satisfied.

4.3.1 **Preconditions are:**

- Diagnosis of severe brain injury and coma, which is consistent with progression to brain death (the clinical diagnosis is usually confirmed by neuro-imaging)
- Normothermia (Temperature > 35 C)
- Normotension (as a guide, systolic blood pressure > 90 mmHg, mean arterial pressure (MAP) > 60 mmHg in an adult)
- Exclusion of effects of sedative drugs (self-administered or otherwise) — the time taken for plasma concentrations of sedative drugs to fall below levels with clinically significant effects depends on the dose and pharmacokinetics of drugs used, and on hepatic and renal function. If there is any doubt about the persisting effects of opioids or benzodiazepines, an appropriate drug antagonist may be administered
- Absence of severe electrolyte, metabolic or endocrine disturbances — these include: marked derangements in plasma concentrations of glucose, sodium, phosphate or magnesium; liver and renal dysfunction; and severe endocrine dysfunction
- Intact neuromuscular function — if neuromuscular-blocking drugs have been administered, a peripheral nerve stimulator or other recognised method (e.g. electromyography) always be used to confirm that neuromuscular conduction is normal
- Ability to adequately examine the brain-stem reflexes — it must be possible to examine at least one ear and one eye
• Ability to perform apnoea testing.

4.3.2 Clinical testing of brain stem reflexes
They are:
• Pupillary responses to light (Cranial nerves II and III)
• Corneal reflex (Cranial nerves V and VII)
• Responses to painful stimuli applied within the cranial nerve distribution (Cranial nerves V and VII)
• Vestibulo-ocular reflex (Cranial nerves III, IV, VI, VIII)
• Gag reflex (Cranial nerves IX and X)
• Cough/Tracheal reflex (Cranial nerve X)
• Respiratory function (Apnoea test)

For the apnoea test, firstly pre-oxygenation with 100% oxygen (for at least five minutes) followed by cessation of mechanical ventilation. While mechanical ventilation is stopped, place suction catheter in the tracheal tube and supply oxygen at 1-2 L/min. Apnoea must persist without mechanical ventilation and in the presence of an adequate stimulus for spontaneous ventilation i.e.: an arterial PCO2 > 60mmHg, and an arterial pH <7.30. (For those with pre-existing hypercapnia, it is recommenced to wait for a rise of 20mmHg above their chronic level with a pH <7.30).

Clinical Testing Procedure
• A minimum of four hours observation and mechanical ventilation during which the patient is in an unresponsive coma (Glasgow coma score 3), absence of brain stem reflexes and absence of respiratory centre function. All preconditions must be fulfilled before and throughout the four hour waiting period of observation, before clinical examination can begin. The above observations of lack of function should be recorded by the attending nursing or medical staff.
• Two sets of tests are performed separately. Each doctor is responsible for performing one set of tests. The tests may be done consecutively. Both practitioners may choose to be present at both examinations, but each practitioner must actually perform, and be responsible for, one of the two examinations.
• Certification of irreversible cessation of all brain function must be completed by two medical practitioners, one of which must be a Designated Specialist.
• Each of the two medical practitioners have practised medicine for a period or periods totalling not less than five years during the eight years immediately preceding that time and not be associated with the organ procurement or transplantation process.
• In cases of acute hypoxic-ischemic brain injury, clinical testing for brain death is to be delayed for 24 hours subsequent to the cardio respiratory arrest.
4.3.3 Medical Imaging

- When clinical criteria cannot be met, four vessel angiography and/or nuclear scan may be used to demonstrate absent intracranial blood flow.
- Documentation of no evidence of cerebral blood flow by angiogram must be reported by a specialist in radiology or nuclear medicine.
- Determination of brain death by medical imaging is provided by two medical practitioners who have examined the patient, who have knowledge of the circumstances of the onset of coma and are further assisted in determining brain death by evidence of nil intracranial blood flow reported by specialist in radiology or nuclear medicine.

4.3.4 Documentation of Brain Death

- Confirm and document brain death using Criteria for Diagnosing Brain Death Form.
- The time of death should be recorded as the time when the second clinical examination to determine brain death is completed whether this is by clinical examination or imaging to confirm the absence of intracranial blood flow.
- Documentation should also include entry into the patient's medical progress notes.

4.4 Seeking Consent

The process of authorisation for organ and tissue donation involves seeking consent from the following:

- The deceased
- Senior available next-of-kin (SANOK) or delegate
- Coroner (where applicable)
- Designated Officer
- PCO (where applicable)

4.4.1 The Deceased

The AODR are to be accessed to ascertain the wishes of the deceased; contact the DSN with the following details: full name, date of birth, current address, medical history and cause of death.

- Please note: A registered refusal does not necessarily mean organ and tissue donation cannot proceed under NSW Legislation. As of November 2012, families may overrule any such registered refusal where the more recent wishes of the potential donor are known with some certainty.

4.4.2 SANOK/delegate

If there is no senior available next of kin:

- Indication of prior consent on RMS and AODR is authorisation for organ and tissue donation to take place once verified by the Designated Officer.
• The consent will nominate the specific organs and tissues to be donated.

If there is senior available next of kin:
• Consent is indicated by signing the Consent and Authority for Removal of Tissue after Death or by taped verbal consent if obtained over the phone
• The consent will nominate the specific organs and tissues to be donated.

4.4.3 Coroner
If the death is reportable to the Coroner, the DSC will consult with the police and the “on call” Forensic Pathologist before approaching the Coroner. The DSC will inform the referring hospital if coronial consent has been granted, restrictions in place or withheld.
• Police and next-of-kin will identify the deceased patient prior to organ donation/retrieval surgery
• The Medical Officer must complete Report of Death of a Patient to the Coroner and organise Report of Death Associated with Anaesthesia/Sedation (if applicable).

4.4.4 Designated Officer
• To locate a Designated Officer of the hospital contact the DSN or Nursing Administration/Bed Manager/After-hours Bed Manager
• A Designated Officer must authorise in writing the removal of tissue after death:
  a) When the adult person during their lifetime has given his or her consent in writing to the removal after death of tissue, (and has not revoked the consent)
  OR
  b) When the person during their lifetime has not given written consent or was a child (apart from a child in care of the state) or the adult person in their lifetime had expressed an objection to the removal of tissue after death and based on the most recent views expressed by the adult person, he or she no longer objects to the tissue from their body, the Designated Officer can:
• Verify a senior available next of kin has given consent in writing or in any other manner prescribed by the legislation
• The Designated Officer has ascertained that there is no ‘senior available next-of-kin’ of same standing or higher order who objects
• It has been established that the deceased has not expressed an objection during their lifetime or if the deceased had expressed an objection, based on the most recent view he or she no longer objects to the removal of tissue from his or her body after death.

Designated Officer - A child in care of the State
• If a Designated Officer for a hospital is satisfied, after making such inquiries as are reasonable in the circumstances in relation to a child in the care of the State who has died in the hospital or whose dead body has been brought into the hospital, that:
• The deceased child had not, during the child's lifetime, expressed an objection to the removal of tissue from the child's body for the purpose of its transplantation to the body of a living person
• The Principal Care Officer for the child has given their consent in writing, or in any other manner prescribed by the regulations, to the removal of tissue from the child's body for the purpose of its transplantation to the body of a living person.

The Designated Officer may, by instrument in writing, authorise the removal of tissue from the deceased child's body for the purpose of its transplantation to the body of a living person in accordance with the terms and any conditions of the consent referred to in paragraph (b).

• A Designated Officer who is unsure as to the status of the child may need to verify this status. If verification of the status of a child is necessary, an application for information can be made to the Local Police Command to ascertain the status of the child from the Department of Family and Community Services.

4.4.5 Principle Care Officer (PCO)
• The PCO automatically becomes the person with responsibility for consent for organ and tissue donation for transplantation. The PCO will determine whose approval is required and must use reasonable efforts to contact persons who have been significant in the child’s or young person’s life.

4.5 Referral of Potential Donor
Once written consent has been obtained from SANOK, bloods for virology, serology and cross matching can be collected.

4.5.1 Blood Collection for virology, serology and cross matching:
Follow the guide to blood taking and packaging within the lab-mailer containers in the ICU.
• Two lab-mailer containers with a total of 21 tubes encased are located in each Intensive Care Unit
• Place patient ID label lengthways, time and date of collection on each blood tube and initial. Place tubes in designated containers provided. Do not pack in ice. In lab mail container labelled SEALS, follow instructions on chemical ice pack to activate
• The bloods are to be transported URGENTLY. The DSN will contact the DSC to arrange for a courier to collect the above blood samples.

4.5.2 Pathology and Investigations post confirmation of Brain death
• FBC, UECs, LFTs, BSL, Amylase/Lipase, CK, Troponin, Coags, Beta HCG (if woman of child bearing age) and ABG (to be taken after 20 minutes on FiO2 1.0, ideally with PEEP at 5 cmH2O on 100% )
• CXR
• ECG
• Height, weight and abdominal girth
• Cardiac Echo, the cardiac echo report is to specifically mention: Wall thickness; Global systolic function; Regional wall motion; Ejection fraction; Structural heart disease (valvular/congenital), and a preliminary summary report. Use NSW OTDS cardiac echo form.
• Specific requests from the transplant teams will be relayed as appropriate from the DSC.

4.6 Hospital staff in collaboration with the DSN needs to ensure the following:
• DSN will arrange operating theatre time and confirm time of arrival of retrieval teams with ICU and operating theatre staff and organise any special theatre requests
• Contact Anaesthetist on-call with estimated theatre time
• Ensure following paperwork is complete:
  o Criteria for Diagnosing Brain Death Medical Certificate Cause of Death
  o Cremation Certificate (if applicable)
  o Report of Death of a Patient to the Coroner Report of Death Associated with Anaesthesia/Sedation (if applicable)
  o Consent and Authority for the removal of tissue after death
  o Preoperative checklist - Confirm patient identification and two x hospital identification bands placed on patient limbs (one upper limb, second on lower limb).
• For those patients that have had craniotomies and bone flaps in storage are to contact the tissue bank to reunite the bone flap with the patient
• Use clippers if patient requires removal of hair from chest and/or abdomen. Clipping should be attended to as close as possible to the scheduled operative time.

4.7 Donor Management
• Maintain patient homeostasis as per NSW Ministry of Health Guideline - GL2016_008 Management of the Adult Brain Dead Potential Organ and Tissue Donor. In the paediatric setting, refer to NSW Organ and Tissue Donation Service Guideline, Paediatric resource reference.
• Continue general nursing care and infection control principles
• All changes in patient's condition and care must be reported to the DSN and communicated to the DSC.

4.8 Operating Theatre
• Theatre RN to check-in patient as per Operating Theatre Policy the following documents:
  o Consent and Authority for the Removal of Tissue after Death
4.9 Care of the deceased

- Operating theatre staff and the DSN will perform last offices and care for the deceased.
- Care should be taken to ensure that the donor's appearance will be suitable for viewing by the family:
  - Family viewing to take place at prearranged location
  - Social Work support to be available for the family.
  - Aboriginal Health Care worker/Aboriginal Hospital Liaison Officer to provide culturally appropriate support at this time when there is Aboriginal or Torres Strait Islander patient and/or family involvement
  - Transfer the deceased to the Mortuary, as per local policy
  - Discharge patient on iPM after organ retrieval surgery has finished.
    (Time and date of death entered is when second brain death test was completed)

4.10 Care of the family

- Attention should be given to any special needs of the donor family
- A lock of hair and hand prints may be offered to the family
- Relatives are offered the opportunity to view the body of their loved one after organ and tissue donation surgery with Social Work support, the DSN and or DSC
- Each donor family is followed up by the Family Support Coordinator for bereavement and aftercare.

4.11 Privacy Issues

- Neither a medical practitioner who performs a transplant operation nor any employee of the hospital may disclose information which could lead to the identity of the donor or recipient of transplanted tissue (whether living or deceased), becoming publicly known
• The designated officer must not disclose information or publish any record that makes publicly known the identity of the donor or the recipient unless one of the following exceptions applies:
  o Information may be disclosed with the consent of the person (other than a child), to whom the information relates (It is highly undesirable for any information to be disclosed which could enable the identity of the donor to become known to the recipient).
• Information may also be disclosed:
  o In connection with the administration or execution of the Act
  o In connection with bona fide medical research
  o For the purposes of any legal proceedings or reporting of such proceedings
  o With other lawful excuse.

4.12 Media Enquiries
Are to be handled through SESHLHD Communications Officers:
• TSH/STG – via switchboard 9113 1111
• POWH – via switchboard 9382 2222

5. DOCUMENTATION
• Authorisation to Delegate Responsibilities of the Next-of-Kin (if applicable, SMR 020.031)
• Consent and Authority for Removal of Tissue after Death (SMR 020.030)
• Clinical Notes
• Cremation Certificate
• Criteria for Diagnosing Brain Death (SMR 010.517)
• Report of Death of a Patient to the Coroner (if applicable)
• Medical Certificate Cause of Death
• Report of Death Associated with Anaesthesia/Sedation (if applicable)
• Preoperative Checklist

6. AUDIT
Not required

7. REFERENCES


9. NSW Ministry of Health Guideline - GL2016_008 Management of the Adult Brain Dead Potential Organ and Tissue Donor

10. NSW Ministry of Health Policy - PD2010_054 Coroners Cases and the Coroners Act 2009

11. NSW Ministry of Health Policy - PD2013_001 Deceased Organ and Tissue Donation - Consent and Other Procedural Requirements

12. NSW Organ and Tissue Donation Service Guideline, Paediatric resource reference.

13. St George/Sutherland Hospitals And Health Services (SGSHHS ) Clinical Business Rule CLIN079 - Preoperative/procedure management of an adult

8. REVISION AND APPROVAL HISTORY

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