ORGAN DONATION: BRAIN DEATH PATHWAY

PRACTICE GUIDELINE ©

DOCUMENT SUMMARY/KEY POINTS

- Organ donation may only occur after the neonate, infant or child donor has been pronounced dead according to legally recognised criteria (brain death or circulatory death). In this document we will only be discussing the procedure for Organ donation following brain death.
- We recognised that families require time and assistance to come to terms and understand determination of death via neurological criteria. This assistance may be necessary for some staff members caring for the deceased.
- Exceptional end-of-life care must be the focus for ICU staff and this is not altered by the decision of a family to consent to organ donation. The respect and dignity of the deceased and the families' wellbeing will always be our paramount concern.
- A family has the right to withdrawal their consent to the donation process at any time.
- This document provides an operational outline of how organ donation can be facilitated at SCHN.
- Enquiries concerning this Practice Guideline please contact:
    - Medical Specialist (Donation Specialist Medical – "DSM") or Nursing Specialist (Donation Specialist Nursing – "DSN") via switch

Related policies:

Designated Officer - http://webapps.schn.health.nsw.gov.au/epolicy/policy/2906

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 2018	**Review Period:** 3 years
Team Leader:	Donation Specialist Medical (SCHN)	**Area/Dept.:** Intensive Care Unit

READ ACKNOWLEDGEMENT

- Clinical staff working (medical and nursing) in intensive care areas must read and acknowledge they understand the contents of this document.
- Other relevant clinical staff, as identified, should read this document.

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TABLE OF CONTENTS

1 Organ Donation

1.1 Introduction

In accordance with NSW Health Department and ANZICS policy, the Intensive Care Units (ICUs) of the Sydney Children's Hospital Network support the donation of organs after death with informed parental/legal guardian consent.

This document has been created by using as a guide the following documents:

- ANZICS Statement on Brain Death and Organ Donation Guidelines v3.2
- NSW Government: Human Tissue Act 1983 No 164
- NSW Health PD2013_001 Deceased Organ and Tissue Donation- Consent and Other Procedural Requirements
- NSW Health PD2005_341 Human Tissue Use and Retention Including Organ Donation, Post Mortem Examinations and Coronial Matters.

ICU staff are aware and sensitive to the extreme stress and grief felt by parents and other relatives following the declaration of brain death of a child. Accordingly this guideline, and the accompanying procedures, identifies ways to offer organ donation in all potential cases that supports the parents and respects their values and decisions.

Organ donation may ONLY occur after a neonate, infant or child has died, i.e. been lawfully declared dead.

Circumstance where organ donation may be feasible in the ICU setting is:

- when death has been declared on the basis of neurological criteria (i.e. the patient has been declared brain dead), or
- When death has been declared on the basis of circulatory standstill ("acirculation") following (planned) removal of cardiorespiratory support (inotropes and mechanical ventilation).

1.2 Suitable Donors

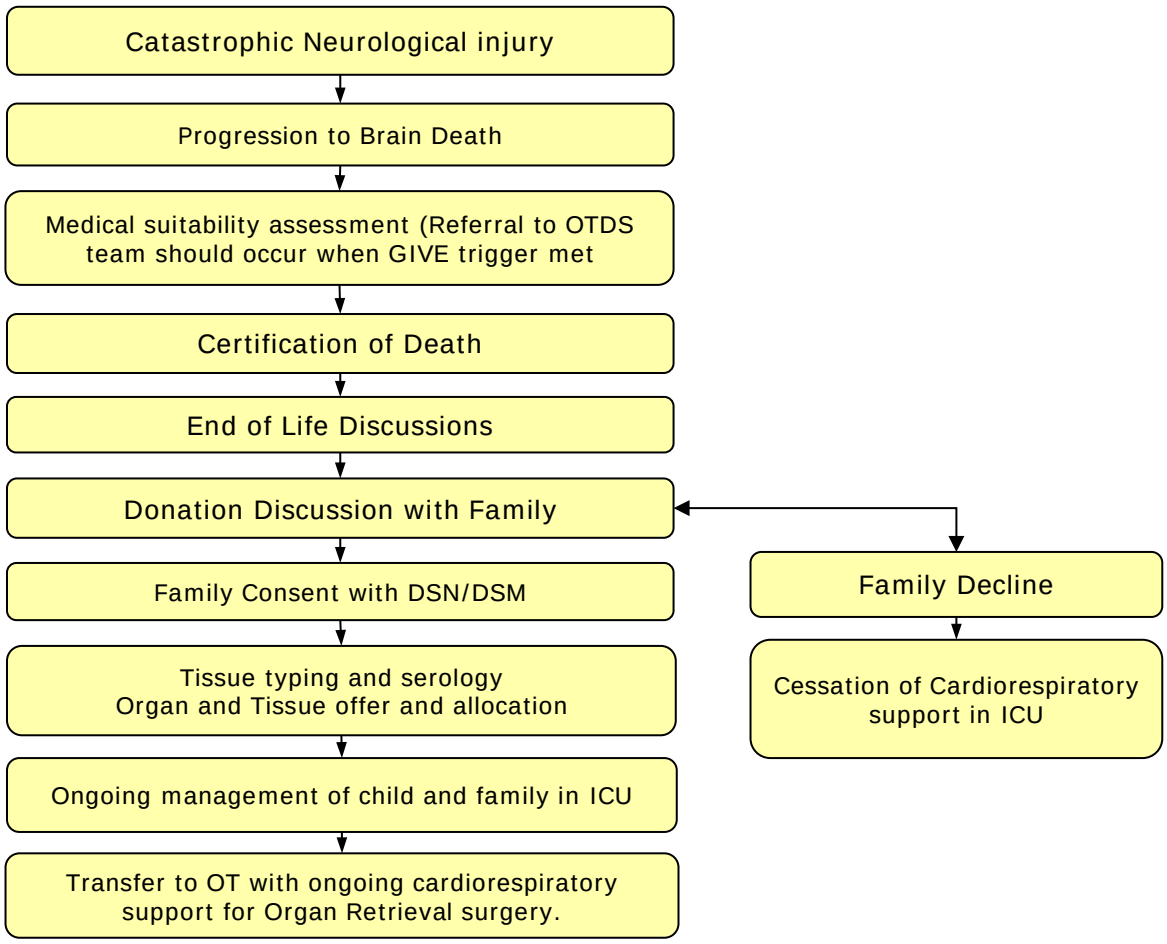
Neonates, infants and children who have been certified and documented as brain dead either through clinical testing or imaging (Determination of Brain Death Policy) are suitable to be considered as potential organ donors.

Once a child meets the clinical **GIVE Trigger** (**G**lasgow Coma Score <5, **I**ntubated, **V**entilated and **E**nd of Life Care) a referral to the NSW Organ and Tissue Donation Service (OTDS) should be made by contacting the Donation Specialist Nurse (DSN) or Donation Specialist Medical (DSM) via switch. Medical suitability is assessed by the OTDS team in conjunction with transplant physicians and not by staff at Sydney Children Hospital Network.

Optimising end-of-life care for the patient and the family should take precedent at all times.

1.3 Pathway to Organ Donation after Brain Death (DBD)

1. Flow Diagram outlining the Brain Death Donation Process



1.4 Family Donation Conversations

After determination of brain death, parents/guardians must be informed of the death of their child. Time should be allowed for the family to process and understand this information and ask questions.

After the family has had time to process and understand the information about the death of their child, a second meeting should be arranged by the intensive care consultant to discuss the possibility of organ and tissue donation. If organ donation is raised earlier by the family, it is at the discretion of the intensivist to continue or defer the organ and tissue donation conversation to a later time.

In cases where donation is being considered, a multidisciplinary meeting should be convened involving the intensivist, the primary medical / surgical team, nursing staff, social worker, pastoral care and other relevant consulting services. The purpose of the meeting is to review any possible conflicts of interest and anticipate any other concerns or issues that should be addressed during the family donation conversation.

Clear documentation in the medical record of any family donation conversations is mandatory.

1.5 Donor Referral and Coordination

The **Donation Specialist Nurse** (DSN) and/or **Donation Specialist Medical** (DSM) are notified when a patient meets the GIVE trigger as described in the NSW Health Policy Directive (PD2013_001) "Deceased Organ and Tissue Donation - Consent and Other Procedural Requirements". This enables the determination of medical suitability for donation. They will be available to meet with the family to provide information regarding the donation process. They can be contacted via the hospital switch board.

The role of the DSN:

- Consult with the ICU team to obtain accurate information regarding the child's current medical status.
- Meet with the family and provide information about organ and tissue donation to support informed decision making.
- Obtain formal documentation of consent (with the Designated Officer present)
- Complete a medical and social history to determine suitability of organs and tissues for donation.
- Refer information via the Electronic Data Referral to the Donor State Coordinator (DSC) who will liaise with the surgical and theatre teams, Transplant coordinators, Forensic pathologist and Coroner.
- Organise donor bloods for serology, tissue typing and HLA testing.
- Ensure all documentation is complete (including determination of death, consent forms ensuring all legal requirements have been met).
- Liaise with ICU staff, Designated Officer, Donor State Coordinator, Coroner (as indicated), theatre staff
- Ensure confidentiality of both donor and recipients.
- Provides ongoing care to the family including information on available support services and feedback on transplant recipient outcomes.
- Support health professional and provide feedback to teams involved with the donation process
- Maintain up to date documentation and data base records.

1.6 Screening

The DSN will require the following information about the potential donor for assessment of medical suitability:

- Name, DOB, Weight, Girth and Height
- Cause of death and current status

- ABO blood group (including A/AB subtypes)
- FBC, EUC, LFT, Calcium, Magnesium, Phosphate, Coagulation Profile, Troponin, Transaminases and microbiology results
- ABG on 100% 02, PEEP 5cm for 30mins prior to gas
- recent chest x-ray and relevant radiology reports
- ECHO and ECG with reports post Certification of Brain Death
- Medications and fluids

Any specific requests from transplant teams will be discussed with the ICU medical team (i.e. need for additional imaging, bronchoscopy).

2 Consent

The process involved in organ donation must be explained to the parents in detail by the DSN/DSM. Interpreters must be used when parents don't speak English well enough to understand or give consent. Consent must be given for each organ and/or tissue to be removed, as well as a post-mortem examination if appropriate.

Parents will be provided with the following information in order to give *informed* consent:

- the possibility that some or even all of the organs may not be suitable for transplantation;
- Anticipated time frames for the donation process (i.e. 18-24 hrs.)
- Tissue donation alone (e.g. corneas, heart valves) can be an alternative to organ donation;
- The family can change their mind at any stage and rescind consent;
- The steps in the process – e.g. going to the operating theatre for 3-5 hours, returning to a single room in the ICU where they can spend time with their child;
- Whether the death will need to be reported to the Coroner and, if it does, the coronial process;
- The fact that organ donation doesn't have any benefits for their child;
- Prior to retrieval surgery, changes to medical treatment strategies (i.e. alterations in FiO_2, fluid bolus) may be required to ensure stability

Time must be given to a family to consider if organ donation is the right decision for them. Bloods for serology and tissue typing at the SEAL laboratory/ARCBS may be collected following verbal consent due to the length of processing time (6 - 8 hours). The DSN will organise the collection and transportation of these bloods.

If the child is <18months of age or has been breast fed in the last 6 months, maternal bloods and a medical/social history will need to be collected for screening.

When the family are ready, parents (or 'senior available next of kin' – see glossary) are requested to sign the Consent Form (SMRO20.030 Consent and Authority for Removal of Tissue after Death) with the DSN/DSM.

The Designated Officer (DO) for the SCHN campuses can be contacted via the switchboard. The Designated Officer must sign and verify consent has been given by the Senior Next of Kin and authorise the organ donation and removal of tissue. The DO may want to be present for the consent and speak to the consenting family. The DSN will ensure the DO is informed as soon as possible.

2.1 Coroners Cases

If the case is Coronial, consent from the Coroner for organ donation will need to be obtained by the Donor State Coordinator. The Coroners Forensic Pathologist is contacted regarding limitations on organ and tissue retrieval.

The medical officer will be required to complete Form A (SMR010.510 Report of Death of a Patient to the Coroner) that can be found in the death pack.

The local police will be contacted and identify the child with the Next of Kin before organ donation when possible. The police identification tag must remain on the child's limb throughout the retrieval surgery process

After the retrieval surgery the Police are contacted to organise the Government Contractor to collect the child's body from the morgue and deliver it to the State Coroner

2.2 Child in the Care of the State

Where a child was in the care of the State immediately prior to their death (i.e. in FACS care/under the care of the Minister for Community Services), consent must be obtained from:

- The Coroner;
- the Principal Care Officer of the designated agency which has full case management responsibility of the child, must "…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. These 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; and persons considered relevant by the PCO". (Deceased Organ and Tissue Donation - Consent and Other Procedural Requirements; PD2013_001)
- the Designated Officer; must ensure that the above has occurred prior to authorising the retrieval of organs

3 Donor Management in ICU

All medical and nursing cares are continued as per ICU to maximise the suitability of organs being considered for transplantation.

1. **Optimisation of respiratory function**:
    - Ventilate to normocarbia
    - Supplemental oxygen to maintain PaO_2 > 80 mm Hg
    - Tidal volume 6-8mL/kg
    - PIP < 35mmHg , Peep 5-10cm H_20
    - Continue suctioning/physiotherapy/repositioning

- Four hourly Arterial blood gas (ABG)

2. Optimisation of cardiovascular function:

- Maintain age-appropriate normotension/titrate inotropes
- Maintain urine output > 1 ml/kg/hr
- Arterial & CVP monitoring when possible

Management of Hypovolemia

- Replace volume to aim for CVP 6-10mmHg and assess fluid balance. Try and avoid hyperchloremia and hypernatremia and using starch-based colloids
- Blood transfusion should aim for Hb >70g/L; unstable donor >90g/L

Management of Vasoplegia

- Noradrenaline is the most commonly administered vasopressor for brain dead donors. If Noradrenaline infusion is greater than 0.2microg/kg/min, low dose vasopressin infusion 0.01-0.05 Units/kg/h. Vasopressin infusion may be considered
- Hydrocortisone, stat dose of 4mg/kg then 1mg/kg 6 hourly administered before organ retrieval may allow reduction of Noradrenaline infusion.

Management of atrial and ventricular tachycardia

- Maintain normal serum electrolytes (optimize K^+, Mg^+, Ca^{2+}). Optimize fluid status, and prevent hyperthermia.
- Standard arrhythmias management should be initiated (i.e. amiodarone, cardioversion)

Management of Bradycardia

- Normally resistant to atropine or glycopyrrolate (due to abnormal vagal response)
- Consider Adrenaline, Isoprenaline or pacing

3. Optimisation of endocrine and metabolic function

- Aim for normal range for all the following:
  Temperature (<37.5°C, >36°C); Electrolytes (Ca^{2+}, Mg^+, K^+,PO_4, Na^+);
  Blood sugar (5-8mmol/L); urine output (1mL/kg/hr)

Hypothermia

The inability to generate heat by shivering or conserve it by vasoconstriction increases the risk of a brain dead donor to become hypothermic. It is easier to prevent hypothermia than to reverse hypothermia. The effects of hypothermia include an increased risk of arrhythmias, coagulopathy and infection

Management: Ensure that temperature is maintained >36.0°C by the use of warming blankets, humidification devices and fluid warmers for large fluid volumes.

Diabetes Insipidus (DI)

Brain dead donors commonly develop DI (80-90%) due to lack of ADH hormone secretion from the posterior pituitary gland. Results in polyuria, hypernatremia and hypovolemia. Deficiency in DDAVP can lead to a systemic vasodilatation induced by the loss of sympathetic activity. The use of vasopressin infusion is therefore preferred in brain-dead donors with vasopressor requirements.

Management: (as per local guideline) Start either Vasopressin (arginine vasopressin) infusion or DDAVP (desmopressin, 1-desamino-8-D-arginine vasopressin) early in DI.As soon as urine output is >4mL/kg/hr and with rising plasma sodium start treatment for DI. Send paired urine and plasma electrolytes and osmolality to make a diagnosis but DO NOT delay treatment. Vasopressin infusion can be used up to a maximum of 0.06 Units/kg/h and DDAVP is IV bolus dose every 2-6 hours or as required.

Fluid replacement for DI as per local unit policy replacement of urinary losses and insensible losses + maintenance fluids. Large urinary volume loss should be replaced with intravenous low-sodium content fluids (i.e. 5% dextrose or sterile water)

Hypernatremia

As a consequence of DI or intracranial hypertension serum sodium can be significantly elevated (>155mmol/L). Hypernatremia (serum sodium >155 mmol/L) in the donor has been associated with worse outcomes for liver and renal transplant recipients.

Management: Remove all sources of sodium in intravenous solutions. If DI is contributing to hypernatremia, follow DI management guideline.

Hyperglycaemia

This may be pre-existing or as a consequence of high volumes of 5% dextrose solution.
Management: Insulin as per the unit policy should be administered to achieve plasma glucose levels 5-8mmol/L

Hormonal therapy

Lack of agreement exists regarding the benefits of hormonal replacement therapy following brain death. Animal and human data suggests that the loss of the hypothalamic/pituitary axis can impact on the haemodynamic stability in the brain dead donor. Randomized controlled trials (RCT) have not demonstrated any beneficial effect with the administration of thyroid hormone or steroids to the potential organ donor. It is therefore advised that hormonal replacement therapy be used in hemodynamically unstable patients (Low age appropriate MAP in the presence of a CVP >12 mmHg and noradrenaline infusion > 0.2 micrograms/kg/min) or in patients that have an evidence of cardiac dysfunction on ECHO.

Management: T3 infusion at 0.05-0.2microg/kg/h without a bolus injection. Repeat cardiac echo should be performed 4 hours after the administration of T3

Changes in the child's condition or management should be discussed with the DSN/DSM

4 Post-donation care

At the completion of surgery the family have the option of seeing their child. This can be negotiated and viewing arrangements in the ICU/mortuary viewing room arranged with staff and social workers.

4.1 Family follow up

1. The unit social worker will have telephone follow-up with the bereaved family at least once during the first week following the child's death. The family will be contacted by the

DSN 48 hours after the child's death, to outline the outcome of the donation process and provide feedback and support to the family.

2. Parents are offered an opportunity to re-visit the ICU approximately six weeks after the death of their child to meet with the intensive care consultant or Co-Consultant most involved emotionally with the family, together with the Social Worker. The DSN/DSM is also invited to this meeting.
3. Telephone follow-up, with the offer of further meetings or counselling, should be continued for at least twelve months.
4. Parents of children who are organ donors are provided with support through NSW Organ & Tissue Donation Network NSW .This program includes regular contact and information regarding donation outcomes, counselling services, support groups and anonymous exchange of letters.

4.2 Patient privacy

It is important to maintain the privacy of the transplant recipients and donor families. The identity of recipients and donors **MUST NOT** be relayed to the family. It is an offence in Australia to disclose information regarding the donor or recipient under The Human Tissue Act 1983 Section 37(2) and 37(3). The DSN and staff at OTDS will provide families with appropriate information about the transplant recipient outcomes.

4.3 Staff Support

The staff involved in the donation process will receive information about the outcomes of the donation from the DSN. Letters will be sent to all areas involved in the donation process. The DSN will arrange a case review at an appropriate date and time following each donation. This will provide feedback to all staff involved in the donation process and provide an opportunity to identify process issues that may be improved upon for future donations.

5 Glossary

Acirculation

A state of no blood flow throughout the body; although there may be residual electrical activity, the heart muscle does not contract (c.f. 'asystole' where there is no electrical (ECG) activity or contraction of the heart muscle).

Brain death

Death defined by irreversible cessation of all function of the person's brain

Designated Officer (DO)

The role of the Designated Officer is to authorise:

1. the removal of tissue from a body for transplant or other therapeutic, medical or scientific purposes;
2. the performance of non-coronial post mortem examination;
3. the release of a body for anatomical examination

The Designated Officer has discretionary authority not simply administrative authority. The role may require decision-making, conflict resolution, and high level communication and negotiation skills.

The Public Health Organisation Board of Governing Authority must appoint a Designated Officer in any hospital where post mortems, donation of tissue etc. are carried out.

The appointment of several Designated Officers may be necessary to ensure that one is available when required, particularly after hours.

Source: NSW Human Tissue Act 1983 No.164 (includes amendments up to Act 2003 No. 45 and NSW Health Circular 2004/1).

Donation Specialist Nurse (DSN)

A Clinical Nurse Consultant who is a member of the Organ and Tissue Donation Service

Donation Specialist Medic (DSM)

Specialised doctor trained in the management of potential organ and tissue donors who is a member of the Organ and Tissue Donation Service.

Family

Recognising the collaborative nature of end-of-life decision-making, the term 'family' is used to refer to a person or persons who have a close, ongoing, personal relationship with the patient, whom the patient may have expressed a desire to be involved in treatment decisions, and who have indicated a preparedness to be involved in such decisions. This may or may not include biological family. However, it may include relatives, partner (including same sex and de facto), friend, or 'person responsible' according to any express wish of the patient.

GIVE Trigger

The GIVE Trigger tool is a national government initiative to identify patient who may be considered for organ or tissue donation. The GIVE tool identifies intubated and ventilated patients who have started to have end of life conversations. . If a child meets the GIVE Trigger the treating team should notify the DSN/DSM for a referral to the NSW Organ and Tissue Donation Service for assessment of medical suitability.

Intensive Care Unit (ICU)

Includes Paediatric Intensive Care Unit (PICU) and Neonatal Intensive Care Units (NICU)

Intensivist

Refers to Paediatric Intensive Care physicians

Life-sustaining treatment

Life-sustaining treatment is any medical intervention, technology, procedure or medication that is administered to forestall the moment of death, whether or not the treatment is intended to ameliorate life-threatening diseases or biological processes.

These treatments may include, but are not limited to, artificial airways, mechanical ventilation, artificial hydration and nutrition, cardiopulmonary resuscitation, or drugs to support circulatory function.

Organ and Tissue Donation Service (OTDS)

State service that is responsible for the coordination and management of potential organ and tissue donors.

Senior available next of kin (SANOK)

1. In relation to a child who is living means: (i) a parent of the child, or (ii) if no parent is available-a person who is a guardian of the child, and
2. In relation to a deceased child is: (i) a parent of the child, (ii) where a parent of the child is not available - a brother or sister of the child, being a brother or sister who has attained the age of 18 years, or (iii) where no parent or sibling is available - a person who was a guardian of the child immediately before the death of the child.

6. References and Further Reading

1. NSW Health, Policy Directive 2013_001, Deceased Organ and Tissue Donation -Consent and other Procedural requirements http://www.health.nsw.gov.au/policies/PD/2013_001.html
2. NSW Health, Policy Directive 2016_001, Donation, Use and Retention of tissues from living persons http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2016_001.pdf
3. NSW Health, Guidelines for End-of-Life Care and Decision Making, 2005. http://www0.health.nsw.gov.au/policies/gl/2005/pdf/GL2005_057.pdf
4. NSW Health, Policy Directive 2013_002, Designated officer Policy and Procedures http://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2013_002.pdf
5. Transplantation Society of Australia and New Zealand (TSANZ), Organ transplantation from Deceased Donors: Consensus statement on Eligibility Criteria and Allocation Protocols V 1.1 (2017) https://www.tsanz.com.au/organallocationguidelines/documents/ClinicalGuidelinesV1.1May2017.pdf
6. Human Tissue Act 1983 (NSW): www.legislation.nsw.gov.au/inforcepdf/1983-164
7. Human Tissue Amendment (Children in Care of State) Act No 164 (2008) (Date of commencement-13.2.2009) http://www.austlii.edu.au/au/legis/nsw/consol_act/
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9. National Health and Medical Research Council (2007) Organ and Tissue Donation After Death for Transplantation: Guidelines for Ethical Practice for Health Professionals. http://www.nhmrc.gov.au/publications/synopses/files/e75.pdf .
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11. SESIAHS Policy on Organ and Tissue Donation after Brain Death (2007)/ Organ Donation (Deceased Infant or Child) 2007.