

PROTOCOL

Organ and Tissue Donation and Procurement after Circulatory (Cardiac) Death

**The Royal Children's Hospital,
Melbourne (2014)**

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Preface

This protocol needs to be read in conjunction with RCH’s policy on the death of a child; to ensure that patients who have died are treated with respect and dignity.

This protocol also aims to ensure that if the family of a dying child wishes to consider organ and/or tissue donation, both the family and RCH staff involved in the care of the child, are informed about and supported through the process of donation.

In Victoria, legislative law permits the procurement of tissue and organs after death under the *Human Tissue Act* 1982. Section 41 of Act defines death as either irreversible cessation of circulation of blood in the body or irreversible cessation of all function of the brain of the person.

This document deals exclusively with organ and tissue donation and procurement after the cessation of circulation of blood in the body of the donor, which is referred to as “donation after circulatory or cardiac death” (DCD). This term is synonymous with the term “non-beating heart organ donation” (NBHD).

This document does not deal with organ and tissue donation and procurement after irreversible cessation of all function of the brain of the person, which is referred to as “donation after brain death”.

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SECTION ONE: Background Information

1 Practical, logistic, ethical and legal principles

Processes and procedures associated with DCD are in accordance with the *Human Tissue Act* (Vic) 1982, National Protocol for Donation after Cardiac Death (July 2010), current NHMRC guidelines *Organ and Tissue Donation after Death, for Transplantation: Guidelines for Ethical Practice for Health Professionals* (2007) and *Making a decision about Organ and Tissue Donation after Death* (2007).

This Policy should be read in conjunction with the national Protocol for Donation after cardiac death (Australian Government Organ and Tissue Authority) which contains a checklist and forms for recording times of events (Appendix A). It is available at:

http://www.donatelife.gov.au/Media/docs/DCD%20Protocol_September%202010-0e4e2c3d-2ef5-4dff-b7ef-af63d0bf6a8a-0.pdf

Contacts: If DCD is a possibility, notify Dr Ben Gelbart (RCH page 6811) or Dr Jim Tibballs (RCH page 5221) or Dr Johnny Millar (RCH page 4796) or Nurse Karen Sullivan (RCH page 0001000857). Tissue donation: Lion's Eye Donation <www.eyedonation.org.au> (Phone 03 9929 8708); Donor Tissue Bank:

<www.vifm.org/forensics/donor-tissue-bank-of-victoria/about-tissue-donation> (Phone 03 9684 4444)

DCD will only be considered where the decision to withdraw active treatment has been made and agreed to by treating medical or surgical teams and the infants or child's parents or guardian. Decisions regarding withdrawal of treatment should occur independently of any consideration of organ and tissue donation. Appropriate end-of-life care for the patient remains the overriding priority at all times.

The child and parents will be treated with respect, dignity and honesty throughout the process. Parents will be afforded adequate time to assimilate information and reach decisions.

If the parents or guardian wishes to proceed with DCD, they will be asked to give written consent. They may withdraw consent at any time without explanation.

Before organ and tissue procurement can proceed:

- (i) Medical suitability for organ donation must be determined
- (ii) The parents or guardian must provide informed consent for procurement
- (iii) Death must be determined on the basis of irreversible cessation of the circulation
- (iv) The Hospital Designated Officer must give authorization for procurement to proceed
- (v) The Coroner must also give authorization for procurement in reportable cases

An entry should be made in the patient's medical record of discussions about donation and procurement with the parents or guardian, regardless of whether or not consent is given and regardless of whether procurement ultimately proceeds.

Members of the PICU or other RCH clinical staff who have an ethical, religious or personal objection to any part of the process for planned organ procurement after cardiac death are exempted from involvement in the process and will be supported in their decision.

A decision to withdraw life-sustaining treatment and the reasons for this decision must be documented separately in the patient medical record by the Managing Intensivist and Bed-Card

Consultant. A senior physician (usually a neurologist) or surgeon must also document the prognosis of the child.

Withdrawal of life-sustaining treatment will be conducted according to the usual medical practice.

Timing and conduct of withdrawal of active treatment should be in accordance with the family's wishes, as far as is possible.

Time to set up for DCD may take many hours. Blood samples will be taken for assessing suitability of organs and for tissue typing.

The DCD endeavour will be abandoned if death does not occur within 90 minutes of withdrawal of treatment but the patient can still be a tissue/eye donor after death (Maximum warm ischaemic times: liver and pancreas 30 minutes; kidneys 60 minutes; lungs 90 minutes). Organs may be deemed medically unsuitable during the DCD process.

The body must be transported from PICU to the Operating Theatre as soon as possible after expiration of the 5 minute stand-down period after declaration of death (5 minutes after irreversible cessation of circulation).

A death certificate or Coroner's deposition must be completed. Organ procurement cannot otherwise proceed.

In a Coroner's case, an "Application for Coroner's authorisation for retrieval of Human Organs and tissues" and an RCH Statement of Identification (to be completed by a family member) should be forwarded to the Coroner before withdrawal of treatment (The Coroner is aware that death may not occur and organ procurement not proceed). If identification is not completed before or after death of the child at RCH, a family member will be required to attend the Coroner's court later for this purpose.

2 Departments and personnel Responsible

RCH Paediatric Intensive Care Unit staff

RCH Specialist teams

RCH Operating Theatre staff

RCH Dept of Anaesthesia

RCH Designated Officer

RCH Organ & Tissue Donation Nurse

DonateLife in Victoria

SECTION TWO: Management of the Potential DCD Donor in the Paediatric Intensive Care Unit

1 Eligible Patients

Any PICU in-patient, or patient referred to PICU, in whom active treatment is to be withdrawn after discussion and agreement between the medical or surgical teams and the parents or guardians should be *considered* for DCD. The decision to withdraw life-sustaining treatment must be made *prior* to and independently of consideration of DCD.

1.1 Documentation

A senior consultant from an appropriate specialist service (usually a consultant neurologist) will be asked to assess the patient and to document their opinion of the patient's prognosis in the medical record.

The Managing Intensivist and Bed-card consultant must separately document the following in the patient medical record:

- (i) Reasons for withdrawal of life-sustaining treatment.
- (ii) That life sustaining treatment will be withdrawn.
- (iii) That the child's parents or guardian understand and agree.
(Timing and conduct of withdrawal of active treatment should be in accordance with the family's wishes, as far as is possible)

1.2 Conditions of eligibility

The following baseline Criteria for Eligibility must be met prior to considering further patient selection criteria for DCD:

- (i) Death is expected within 90 minutes of withdrawal of active treatment ^a
- (ii) Patients brain dead for whom consent has already been given for organ procurement, who either deteriorate and are likely to suffer cardiac arrest (Maastricht Category IV) or the family request to be with their child when their heart stops. In this circumstance procurement of organs can occur provided that this DCD guideline is followed and that all of the necessary infrastructure and personnel are available
- (iii) Absence of any contraindication (below)

^a 90 minutes is the usual maximum interval between withdrawal of treatment and death after which procurement may be undertaken. The procurement of specific organs within this time will depend on which organs are to be procured (according to parental decision, transplantation requirement and organ suitability) and according to the lapse of time until cardiac death after withdrawal of treatment. In some circumstances, this time can be prolonged beyond 90 minutes, particularly if the onset of warm ischaemic time after withdrawal of treatment is delayed.

1.3 Absolute contraindications to organ and tissue procurement

These include (TSANZ 2010):

- (i) Any history of malignant melanoma;
- (ii) Any history of metastatic malignancy;
- (iii) Other non-curable malignancy (curable malignancy such as localised small kidney tumours, localised prostate cancer, colon cancer more than 5 years previously and other cancers known to have been fully eradicated may be considered after careful risk/benefit analysis);
- (iv) Active human immunodeficiency virus (HIV) infection; or
- (v) Uncontrolled infection (donor sepsis)

Consultation with a DonateLife Organ Donor Coordinator is recommended prior to discussion with family of patients with hepatitis B or hepatitis C as they may be eligible organ donors following a risk/benefit analysis for potential recipients. The Transplant Services will decide which patients and which organs might be medically suitable.

1.4 Other Contraindications

Other considerations which would preclude a patient donating organs after death include:

- (i) Location in any other part of the hospital than PICU or NICU at the time of withdrawal of therapy; or
- (ii) Cardiac arrest occurring before consent for procurement after cardiac death is obtained; or
- (iii) Death is likely to take longer than 90 minutes after withdrawal of treatment; or
- (iv) Unlikelihood of patient survival for a period of 12-18 hours from the time of initial assessment for eligibility, as this is the likely time required to organise organ procurement. If survival for this period is unlikely, organ procurement will not be undertaken. However, in some circumstances, the DonateLife coordinator may be able to facilitate organ procurement within 4-6 hours in cases of physiological instability.

2 Protocol

2.1 Principles

The following principles will be observed:

- (i) A separation of roles between those involved in the care of the child and family and those involved in organ and tissue procurement;
- (ii) Health care professionals who make the initial approach to the parents or guardian about organ and tissue donation have sufficient experience and/or have undertaken specific training in the task;
- (iii) The RCH Hospital Designated Officer ensures that all steps in the process are followed before giving authority for procurement to proceed, and should have training and adequate authority to perform the role. The role will not be delegated to a person without sufficient training or responsibility;
- (iv) The confidentiality of both donors and recipients is maintained; and
- (v) Records of the process are kept with due regard to confidentiality and privacy.

2.2 Application of protocol

The protocol will apply to patients who:

- (1) Are subject to withdrawal of active treatment (as agreed by the Managing Intensivist, the bedcard unit, and the child's parent or guardian) where death is expected to occur within 90 minutes^a *and*
- (2) Meet the criteria for eligibility for DCD *and*
- (3) Are to be considered for donation because (one of the following):
 - (i) the child's parents or guardian ask if organ/ tissue donation can occur;
 - (ii) the patient is registered on the Australian Organ Donor Register as wishing to donate organs and/or tissues (≥ 18 years old only) or as having an intention to donate organs or tissues (16-17year olds only), *or*
 - (iii) withdrawal of active treatment has been discussed with and agreed to by the parents or guardians of a child who meets criteria 2.1(1) and 2.1(2) above.

2.3 Discussions of donation and procurement

All discussions with parents or guardian will be guided by the following ethical principles

- Adequate time will be given for information and privacy given to make a free and comprehending response to the request for procurement, including the opportunity to consult people outside the hospital.
- All relevant information will be offered. Information will not be withheld because of its potential to cause distress or influence the decisions of parents/guardian.
- Discussions will be handled with care, honesty and sensitivity while recognizing the difficulties for parents/guardian.
- As much time as required will be available for parents/guardian to explore outstanding questions.

There will be two sets of discussions regarding organ donation and procurement. The first, preliminary discussion may take place at the parent's request, or will be initiated by the treating clinicians (the treating Physician and the Managing Intensivist). The purpose of the preliminary discussion is to ascertain the child's suitability to donate (if raised by the family) or the parents' or guardian's willingness to consider donation (if raised by the Managing Intensivist).

A second, more detailed discussion or series of discussions will follow if the patient satisfies the above criteria for donor eligibility and if the parents or guardian are willing to consider donation. These discussions will involve a DonateLife Organ Donor Coordinator and the Designated Intensivist who will not be involved in withdrawal of treatment and in the child's care at the time of death. The purpose of these discussions is to provide the parents or guardian with detailed information about DCD so that they can give informed consent for organ procurement.

The **preliminary discussion** with the family regarding DCD may occur at one of two time points:

- (i) In some cases this will be raised by the parents or guardians during the discussion regarding withdrawal of active treatment. If this happens, the treating clinicians will acknowledge the family's interest and indicate that specific discussions about organ donation will only follow the primary decision to withdraw treatment.
- (ii) If the subject is not raised by the parents or guardians during early discussions about withdrawal of active treatment the subject of donation may be raised by the PICU Managing Intensivist during a separate discussion. This will only occur *after* a decision to withdraw active treatment has been made and documented. At this stage it will be appropriate to ask the parents

or guardians of patients over the age of 16 years if they know whether the patient is registered on the Australian Organ Donor Registry.

It is important that the discussion regarding the decision and reasons for withdrawal are documented in the patient's medical record by the Managing Intensivist and the Physician or Surgeon of the bedcard unit.

An opinion from a senior consultant from an appropriate specialist service (usually a Neurologist) regarding prognosis will also be documented in the patient's medical record.

The result of subsequent discussions regarding the parents' or guardian's willingness to consider donation will be documented separately.

After discussions with the parents or guardian about withdrawal of treatment are complete, the Designated Intensivist will then check if the patient is registered on the Australian Organ Donor Register (if aged ≥ 16 years).

A DonateLife Organ Donor Coordinator will then attend RCH and, together with the Designated Intensivist, will discuss the process of organ donation and procurement after cardiac death in detail with the parents or guardian. These discussions will include all aspects of the process, including consent and the procedures involved. The DonateLife Organ Donor Coordinator and Designated Intensivist will make time to answer questions and provide information about the potential donation and should be of the view that the parents or guardian understand the process before consenting to organ/tissue donation.

There should be particular discussion of but not limited to the following points:

- a) The child may be determined not be medically suitable as an organ/tissue donor. If this is the case then organ/tissue donation cannot proceed.
- b) The child will need to be certified dead within 90 minutes ^a of withdrawal of life-sustaining treatment for organ procurement to proceed.
- c) The difficulty of predicting the duration of time it will take for the child to die after withdrawal of treatment. Although the treating teams may expect death to occur within 90 minutes ^a it may take longer. If the child does not die within 90 minutes, organ procurement will be abandoned (procurement of tissue may still be possible).
- d) If death occurs more than 90 minutes ^a after withdrawal of life-sustaining treatment, end-of-life care will continue in PICU. When the child dies, death will be certified according to usual medical criteria.
- e) Withdrawal of therapy will take place in the Paediatric Intensive Care Unit but organ procurement will be performed in the Operating Theatre.
- f) The process of withdrawing life-sustaining treatment and management of any distress or pain.
- g) The process of certifying cardiac death.
- h) The intention of giving no medication or treatment for the purpose of resuscitation.
- i) The abandonment of the procurement process if auto-resuscitation occurs.
- j) The child's family will be afforded a limited time (5 minutes – the stand-down period) with the deceased after death has been declared. After expiration of this time their child's body will be transported quickly to the Operating Theatre.
- k) The child will receive no medications or interventions before death (ante mortem interventions) or during the stand-down period that are aimed at improving viability of organs to be procured.
- l) The possibility that the child's condition may progress to brain death in which case other organs including the heart may be procurable but the projected time of procurement may be revised. Under this DCD protocol, procurement of the heart for transplantation to function as a pump to maintain the circulation in a recipient is not possible because it would violate the "dead donor rule" and would not conform

to the current definition of death according to the Human Tissue Act 1982 (Vic)(Section 41a). However, heart valves may be procured under this DCD protocol.

- m) The parents or guardian may withdraw their consent for organ procurement at any time without explanation.
- n) At surgery, organs / tissues may be found to be medically unsuitable for donation. If this is the case organ / tissue procurement for transplantation will not proceed.

2.4 Procedures following Consent from Parents or Guardian

No blood tests related to organ / tissue donation will be taken prior to the parents' or guardian's agreement to proceed with organ / tissue donation.

If the child's parents or guardian agrees to organ procurement, a DonateLife Organ Donor Coordinator will discuss the medical suitability of specific organ procurement with appropriate transplant physician(s) or surgeon(s). In the case of unsuitability, the child's parents or guardian will be informed and organ procurement will not proceed.

Blood may be taken for tissue typing and other tests after the parents or guardian have given their preliminary consent for organ/tissue procurement to the PICU Designated Officer.

2.5 Role of the RCH Designated Officer

The RCH Designated Officer has no role until organ/tissue donation has been consented and procurement has been organized. (see Section 3, part 2.6)

2.6 Role of the Coroner

If the patient's death must be reported to the Coroner, the potential of organ/tissue procurement after cardiac death has occurred must be discussed with the Coroner, before withdrawal of treatment. A formal "Application for Coroner's Authorisation for retrieval of Human Organs and Tissues" must be faxed (03 9682 1206) or emailed to <iio@coronerscourt.vic.gov.au> prior to withdrawal of treatment (even though the patient may not die). Organ procurement in a Coroner's Case cannot proceed without authorisation of the Coroner (section 27, Human Tissue Act 1982) which may be given before or after death. If this is given orally it must be (eventually) confirmed in writing.

2.7 Withdrawal of Treatment

Treatment will be withdrawn in the Paediatric Intensive Care Unit. End-of-life care will remain the sole concern and responsibility of the Managing Intensivist. Medications may be administered to control pain, discomfort, suffering and anxiety according to usual practice but not with the intention of hastening death. Pulse oximetry and arterial line blood pressure monitoring will continue after withdrawal of treatment.

2.8 Determination of Death

Death will be declared 5 minutes after all the following features are present:

- (i) Immobility, and
- (ii) Apnoea, and
- (iii) Absent skin perfusion, and
- (iv) Absence of pulsatility on an intra-arterial blood pressure monitoring.

At this time the patient will be declared dead by the Managing Intensivist (or a senior medical member of the Paediatric Intensive Care Unit clinical team not involved in the organ procurement).

Following the declaration of death there may be a 5 minute stand-down period where the family can, if they desire, remain with the deceased before transport of the body to the operating theatre for removal of organs/tissues. No procedures or interventions may be performed during the stand-down period.

If the patient does not die within 90 minutes ^a of withdrawal of treatment, end-of-life care will continue uninterrupted in the Paediatric Intensive Care Unit. It should be noted that the period of 90 minutes is a guide and that organs may be procured after this time if, for example, the onset of the warm ischaemic time (WIT) is delayed after withdrawal of treatment and that WIT is still acceptably short from the point of view of procuring viable organs, especially kidneys. In this case, close communication between the PICU and organ procurement teams is essential to determine if a further period of waiting is appropriate. In the event of abandonment or prolongation of the procedure, the parents or guardian should be informed.

2.9 Management of Donor after Death

The body will be transported to a prepared Operating Theatre (bypassing the anaesthetic induction room) by the paediatric intensive care team immediately after the stand-down time has elapsed. The route to theatre should be cleared and protected in advance. All invasive procedures in the Operating Theatre will be performed by the transplant team. If lung procurement is planned, a transplant anaesthetist from the Alfred Hospital will intubate the trachea to protect the lungs from aspiration of stomach contents and to provide insufflation of oxygen to prevent atelectasis. This will be done while the body is still on the PICU bed before transferral to the operating table. Ventilation will be avoided unless required by the thoracic or abdominal surgeon. Preservative fluid for the lungs will be given through an aortic cannula.

Drugs may be administered by the anaesthetist according to their requirements, but it is noted that since the circulation and respiration have ceased, drugs delivered by any route will not be delivered to target tissues.

SECTION THREE: Management of Patient in the Paediatric Intensive Care Unit (PICU) and Operating Theatre (OT)

1 Process

In the setting of the time-critical nature of organ procurement following patient death, timely and accurate communication between the Paediatric Intensive Care Unit and the Operating Theatre staff is vital.

- 1.1 Operating Theatre staff, including surgical teams, who will conduct the organ/tissue procurement, will be notified of a potential organ donor as soon as possible after informed consent for organ/tissue procurement has been given by parents or guardian.
- 1.2 Operating Theatre staff will be notified of proposed time of withdrawal of life-sustaining treatment as soon as possible.
- 1.3 Operating Theatre staff will be called in after hours if necessary. Operating Theatre staff will prepare theatre for the organ/tissue procurement operation.

If withdrawal of treatment occurs within working hours an elective list will be deferred. The emergency Operating Theatre will be utilised if a time critical/urgent case is not pending. If withdrawal of treatment occurs out of hours, the case will be managed as a time critical case.
- 1.4 Withdrawal of treatment from the patient will occur in the Paediatric Intensive Care Unit. The body will be transferred to the Operating Theatre immediately after declaration of death (5 minutes after cessation of circulation) and after elapse of any elective stand-down period (up to 5-minutes). The Operating theatre staff will be advised when treatment is withdrawn, when circulation has ceased, when death has been declared and when any (elective) stand-down time has elapsed. .
- 1.5 The body will be transported by the Paediatric Intensive Care Unit staff directly to a prepared Operating Room, bypassing the anaesthetic induction room.
- 1.6 The body must be identified and parental/guardian consent for specific organ procurement verified.
- 1.7 Authorization from the RCH Designated Officer and additional authorization from the Coroner (if the case is reportable) must be verified.
- 1.8 Surgery will be performed for procurement of organs or tissues.
- 1.9 After organ procurement, Operating Theatre staff will prepare the body for transport. The body will be taken either to the Paediatric Intensive Care Unit if the family wish to spend more time with their deceased child or to the mortuary if they do not.
- 2.0 The Paediatric Intensive Care Unit Social Worker and Chaplain will be available to spend time with the family during, and after the time that the deceased child is in the Operating Theatre.

2 Role descriptions for individual staff

2.1 Managing Intensivist

The Managing Intensivist is the usual rostered Intensivist whose role is to continue to provide care for the child and family in all matters not related to actual organ procurement.

In approximate temporal order, the Managing Intensivist should:

- Make decisions in conjunction with the bed-card consultant and the child's parents regarding withdrawal of life-sustaining active treatment.
- Obtain the opinion of a consultant neurologist or other senior physician or surgeon regarding prognosis.
- If withdrawal of life-sustaining treatment is decided, make enquiries to determine if the child would be a suitable organ donor according to the baseline criteria in the DCD protocol.
- If appropriate, introduce the subject of organ donation as an option after cardiac death to the parents if they have not already requested or enquired about organ donation.
- If the parents are preliminarily agreeable to organ donation: Recruit an independent consultant Intensivist to act as the Designated Intensivist who in conjunction with the DonateLife Organ Donor Coordinator will conduct detailed discussion with the parents to gain informed consent.
- Attend a pre-withdrawal of treatment planning meeting(s).
- Withdraw life-sustaining treatment in PICU at a time suitable to the Parents, Operating Theatre, Surgical team and DonateLife Organ Donor Coordinator.
- Provide care for the child and parents during and after the withdrawal process
- Determine when circulation has ceased irreversibly according to the DCD protocol (record time).
- Determine when death has occurred according to the DCD protocol – 5 minutes after irreversible cessation of circulation (record time).
- Complete the Death Certificate or Coroner's Deposition as appropriate.
- Determine expiration of additional stand-down time (up to 5 minutes) if desired by parents.
- Hand-over body to Designated Intensivist.
- Remember to inform Bed-card unit and other healthcare personnel
- Attend a debriefing meeting.
- Provide or arrange long-term follow-up for the parents after their child's organ donation

2.2 Designated Intensivist

The Designated Intensivist is the PICU Intensivist responsible for providing family with adequate information and seeking informed consent from the child's parents and for facilitating organisation and performance of organ procurement.

This person should not be involved in the decision or discussions about withdrawal of life-sustaining treatment although they may have been involved in day-to-day clinical management of the patient previously.

In approximate temporal order, the Designated Intensivist should:

- Accept the referral from the Managing Intensivist.
- Review the child's medical records.
- Contact the DonateLife Organ Donation Agency to request an organ donor Coordinator to assist and to determine if the child is a suitable and needed donor (24hr pager 9347 0408).
- Inform RCH staff (PICU doctors and nurses) and the RCH Organ & Tissue Donation Nurse of a preliminary plan to procure organs.
- Discuss organ donation and the RCH process of DCD organ procurement in detail with the child's parents/family.

- In collaboration with the DonateLife Organ Donor Coordinator, obtain informed consent from the child's parents/guardian ensuring that they are provided with adequate time and that they ask and are provided with adequate answers to questions and information about organ donation and the process of organ procurement which should include but is not restricted to:
 - Their right to withdraw consent at any time without explanation
 - The process of withdrawal of life-sustaining treatment
 - Management of dying
 - Diagnosis of cardiac death
 - Withholding of any resuscitation attempts
 - Stand-down time and its implications
 - Abandonment of the process if death does not occur within 90 minutes of withdrawal of life-sustaining treatment
 - Transportation of the body to the Operating Theatre
 - Transportation of the body to PICU or the mortuary as they desire after organ procurement
 - Possibility that patient may progress to brain death which would allow more organs to be procured but which may increase the time before donation
 - Possibility (remote) of auto-resuscitation and consequent abandonment of organ procurement
 - Signature on a body identification form if a Coroner's case
- Document in medical records that the parents/guardian have given or declined consent.
- Attend a pre-withdrawal of treatment planning meeting(s).
- Assist in facilitating planning transportation to the Operating Theatre.
- Assist in the transportation of the patient to the Operating Theatre after death has been certified and a stand-down time has been certified by the Managing Intensivist.
- Advise the parents/guardian that organ donation is abandoned if death has not occurred within 90 minutes after withdrawal of life-sustaining treatment.
- Attend a debriefing meeting.

2.3 Bedside PICU Nurse(s)

The Bedside Nurse with the Managing Intensivist is responsible for ensuring that care of the child and family is maintained before organ donation and with the Designated Intensivist during and after organ donation.

Awareness of the specifically different roles of the Managing & Designated Intensivist (and their medical staff) is important.

The Bedside Nurse will be required to:

- Ensure the family are supported through the clinical discussions surrounding withdrawal of treatment and separately of organ donation.
- Refer the family to PICU Social Worker for additional support.
- If DCD is to proceed, commence relevant documentation for the process.
- Ensure that 2 identification bands on separate limbs are attached
- Attend a pre-withdrawal of treatment planning meeting(s).
- Liaise with DonateLife Organ Donor Coordinator to facilitate blood sampling for serology & tissue typing.
- Identify the family wishes surrounding the creation of memorabilia & support the family in obtaining these.
- If patient is stable enough offer family the choice to cuddle and bathe etc their child out of the cot/bed.
- Clarify with the family if they wish to view their child's body following the organ procurement surgery.
- In a Coroner's case ensure that a Statement of Body Identification is available, to be filled out and signed by a family member after death.

- Maintain continuous monitoring of arterial blood pressure and SpO₂ until after declaration of death.
- Ensure that the central monitor is recording patient observations (particularly blood pressure) & place patient monitor on standby.
- Enlist the help of ward support to keep route to the Operating theatre clear – tell them that passage needs to be kept clear for next “... period of time”.
- Assist the Managing Intensivist in the process of withdrawing life-sustaining treatment and subsequent alleviation of pain, distress or suffering as required.
- Disconnect all unnecessary infusions and monitoring from patient and/or bed. Place any required lines/infusions on the bed.
- Ensure patient is covered or that bedding is immediately available for transporting the body.
- Decrease the risk of passive aspiration by leaving the nasogastric tube *in situ* and by aspirating it and leaving it on free drainage.
- Ensure all documentation is up-to-date.
- If the patient’s family have consented to eye and/or tissue donation, and the patient does not progress to organ donation, ensure that there is clear documentation in the medical record regarding contacting Eye or Tissue bank when the patient does die.
- Assist in transporting the body to the Operating Theatre.
- In the event that the child does not die within 90 minutes after withdrawal of life-sustaining treatment, continue to facilitate end-of-life care as per PICU practice.
- Facilitate family viewing when organ procurement surgery is complete, including retrieval of the body from the operating theatre
- Attend a debriefing meeting.

2.4 Operating Theatre staff

Time is critical for the management of the patient who will donate organs after cardiac death due to the harmful effects of warm ischaemia on transplanted organ viability.

The Donateline Organ Donor Coordinator will liaise closely with the Operating Theatre team and the procurement surgeons on all aspects of the potential organ procurement.

The Operating Theatre and all staff involved in the organ procurement must be ready at the time of planned withdrawal of life-sustaining treatment. (Withdrawal of treatment should not be started until the Operating Theatre staff is ready since the circulation may cease immediately after withdrawal of treatment).

Tracheal intubation by an anaesthetic team is required if lung procurement has been planned.

The anaesthetist may administer any drugs considered necessary irrespective of declaration of death by the Managing Intensivist although it is not the intention to give external cardiac compression and mechanical ventilation of the lungs for the purpose of resuscitation.

Organ procurement surgery will commence after a Death Certificate or a Coroner’s deposition has been sighted.

The Operating Theatre staff should:

- Attend a pre-withdrawal of treatment planning meeting (see attached notes on Pre-withdrawal of Life-sustaining treatment meeting) to become aware of the time planned for withdrawal of treatment and so be able to ensure that the receiving Operating Theatre is set up ready to receive the body (bypassing the anaesthetic induction room) without delay as soon as possible after death has been declared and a stand-down period has expired in PICU.
- Be recognised as the point of contact for the Donateline Organ Donor Coordinator who will give notification that withdrawal of treatment has occurred, that the patient has been declared dead and that the body is being transported by the PICU staff to the Operating Theatre after expiration of a stand-down period.

- On arrival of the body in the Operating theatre, assist in:
 - i) Identifying the body
 - ii) Verify that parental consent has been given for specific organ procurement (The routine full “time out” procedure for ensuring correct surgical procedure will not apply).
 - iii) Verify that the Hospital Designated Officer has authorised organ procurement.
 - iv) Verify that the Coroner has authorised organ procurement if the case is reportable
- Assist in transferring the body of the patient immediately from the PICU bed to the operating table.
- At the end of organ procurement, ensure permission has been sought from the Coroner to remove lines, drains etc and to wash the body.
- Clarify with the Donatelife Organ Donor Coordinator if the family wish to view the body following surgery and liaise with PICU to return the body to PICU or to the Mortuary.
- Attend a debriefing meeting.

2.5 Anaesthetist, Anaesthetic Technician

The usual involvement for a theatre case is anticipated in DCD cases.

The body will be transported from PICU directly into the Operating Theatre (bypassing the anaesthetic induction room) by the PICU Designated Intensivist and Bedside Nurse(s) after death has been declared and a stand-down period has expired.

The usual “Time Out” process will not operate EXCEPT that the identity of the body and parental/guardian consent for specific organ procurement and tissue Identity of the body must be confirmed.

The anaesthetist and anaesthetic technician should:

- Attend a pre-withdrawal of treatment planning meeting(s)
- Assist in transferring the body to the operating theatre table.
- Assist in performance of tracheal intubation if the lungs are to be procured (Bronchoscopy and insufflation of the lungs may be required). Intubation would be performed while the body is still on the PICU bed before transferral to the operating table.
- Administer any drug judged to be necessary by the anaesthetist although it is not the intention to perform any treatment such as drug administration, external cardiac compression or mechanical ventilation of the lungs for the purpose of resuscitation.
- Assist the procurement surgical team as needed.
- Liaise with the PICU team at the completion of organ procurement and transport the body back to PICU or to the Mortuary as required.
- Attend a debriefing meeting.

2.6 Hospital Designated Officer

The Hospital Designated Officer is not involved in the management of the patient or procurement of organs.

The specific roles of the Hospital Designated Officer are to:

- Ensure that consent has been obtained from parents/guardian and when relevant that authorisation from the Coroner has been obtained.
- Ensure that the legal requirement to establish irreversible cessation of the circulation prior to organ procurement (sections 41 & 26, Human Tissue Act (Vic) 1988) have been fulfilled.
- Authorise organ procurement after death has been declared (section 26, Human Tissue Act (Vic) 1988).

The Hospital Designated Officer will be contacted initially by the DonateLife Organ Donor Coordinator and will be informed that organ procurement is being planned after withdrawal of life-sustaining treatment from a child in the PICU at a specified time.

Thereafter, after the planned withdrawal of treatment, it is essential that the Hospital Designated Officer be contactable by the DonateLife Organ Donor Coordinator immediately and for a period up to 90 minutes. The Organ Donor Coordinator will be urgently seeking permission to proceed to immediate organ procurement if death has occurred within 90 minutes after withdrawal of treatment or to be informed that organ procurement has been abandoned if death has not occurred within 90 minutes or if organ procurement has been cancelled for any other reason. The Hospital Designated Officer can give authority for organ/tissue removal in writing or by telephone.

SECTION FOUR: Clarification of Issues Particular to the RCH Setting

1 Consent Process

Discussions about organ/tissue donation involving the Designated Intensivist, a DonateLife Organ Donor Coordinator and the child's parents or guardian will occur only after the decision to withdraw active treatment has been recorded in the medical notes. The parents' or guardian's agreement to consider organ/tissue donation will then be documented in the medical notes.

Informed consent must be given in accordance with the Victorian *Human Tissue Act* 1982, and is obtained together by the Designated Intensivist and the DonateLife Organ Donor Coordinator. The consent forms for organ donation available in the Intensive Care Unit, and on The RCH intranet Clinical Practice Guidelines can be used for donation after cardiac death as well as after brain death. The parents' or guardian's consent for procurement will also be recorded in the medical notes. Consent for organ/tissue procurement must be given before withdrawal of treatment occurs if DCD is to proceed.

The parents or guardian can withdraw their consent and stop the process of organ/tissue donation at any time for whatever or no reason. Appropriate end-of-life care for their child will continue.

1.1 Authority from RCH Designated Officer

General guidelines about the role of the Hospital Designated Officer are detailed in Section 3, subsection 2.6. RCH Designated Officers will have received specific training from DonateLife regarding their role and responsibilities. Specific details related to DCD are detailed below.

The Hospital Designated Officer will be alerted to the possibility of a procurement taking place by the intensive care staff once the parents or guardian have agreed to consider organ/tissue procurement. They will be kept informed of the likely time of withdrawal of active treatment as arrangements progress. The Hospital Designated Officer must ensure their availability for the entire (maximum 90 minute) period following withdrawal of treatment. Their authority to proceed with organ/tissue removal surgery must be obtained after declaration of death. The DonateLife Organ Donor Coordinator will contact the RCH Designated Officer.

1.2. Consent from the Coroner

General guidelines about the role of the Coroner are detailed elsewhere (see RCH guideline entitled "Coroner's Cases - Reporting Requirements"). Specific details related to DCD discussed in Section 2.2.4 are detailed below.

If a death is reportable to the Coroner, organ/tissue procurement cannot proceed without the Coroner's authorisation. Discussion of such cases with the Coroner must occur after the parents or guardian have agreed to proceed with organ/tissue donation but before withdrawal of active treatment. This is the responsibility of the Managing Intensivist.

The Coroner may give verbal consent to proceed before death but is required (eventually) to provide written consent (Human Tissue Act 1982, s27(5)).

2 Pre-withdrawal of life-sustaining treatment planning meeting

A meeting is imperative in DCD cases to ensure a smooth and rapid transition from the withdrawal of treatment, declaration of death, expiration of stand-down time, transport to the Operating Theatre, transferral to the operating table and the procurement of organs. Due to the effects of warm ischaemia on the outcomes of organ transplantation it is vital that the warm-ischaemic time is minimised.

It is also important to ensure all members of staff are supported throughout this process.

Ideally this meeting, to be organised by the DonateLife Organ Coordinator and Designated Intensivist, should occur no later than 30 minutes prior to the planned withdrawal of life-sustaining treatment and should be attended by:

- Designated Intensivist
- DonateLife Organ Donor Coordinator
- Managing Intensivist
- PICU bedside nurse(s)
- PICU AUM
- Anaesthetist(s) and anaesthetic technician
- Scrub, scout and in-charge nurses of the Operating Theatre
- Organ procurement surgeons and perfusionist
- RCH Organ & Tissue Donation Nurse

Ensure sufficient time is allowed for setting up Operating Theatre equipment either prior to or following the meeting to minimise delays to planned time of withdrawal of life-sustaining treatment (Operating Theatre and staff must be ready at the time of planned withdrawal of treatment).

Specific subjects to be covered in meeting:

- Introductions of teams/staff involved in case and identification of their role(s)
- Description of the clinical scenario
- Specification of a time for planned withdrawal of life-sustaining treatment
- Estimate of survival after withdrawal of treatment
- Names of parents/guardian providing consent
- Review of consent paperwork
- Location of patient identification bands (minimum of 2)
- Period required for declaration of death after cessation of circulation and the stand-down period
- Organs/tissues planned for donation and individual warm ischaemic times applicable to each
- Whether tissue/eye/cornea donation if consented will occur in the theatre or the mortuary
- Process on arrival of the body in the Operating Theatre of confirming identity of the body and confirming consent for specific organ procurement
- Transportation of the body to the Operating Theatre
- Transferral of the body to the Operating Theatre table
- Procedure for re-intubation +/- bronchoscopy if this to occur
- Surgical preparation and commencement of incisions
- All other concerns

Before break-up of the meeting, the Designated Intensivist and the Donatelife Organ Donor Coordinator must:

- Verify the person and means of contact in the Operating Theatre
- Ensure all staff are aware of their roles
- Encourage organ procurement surgeons to discuss the procurement process with the scrub nurse after this meeting but prior to withdrawal of treatment

3 Protocol Development

This guideline was developed by the PICU medical consultants with reference to senior clinical staff within PICU and RCH as well as Donatelife in Victoria. The document has been approved by

the RCH Clinical Ethics Committee and reviewed by Legal Counsel.

GLOSSARY

Autoresuscitation: Spontaneous re-onset of breathing activity or circulation after declaration of death.

Bedcard unit: All patients admitted to RCH PICU are admitted under the care of both a Paediatric Intensivist and consultant Physician or Surgeon. The 'Bedcard Unit' is the unit of the admitting specialist team.

Child: For the purpose of the *Human Tissue Act* 1982 a child is a person who has not attained 18 years of age and is not married. (This includes newborns and infants)

Coroner: If the death of a potential organ or tissue donor is a death which is reportable to the Coroner (*Coroner's Act* 2008), the consent of the Coroner must be obtained before the Hospital Designated Officer can authorise the removal of tissue from a body. The Coroner is permitted to give this consent either before or after the death has occurred.

DCD: (Organ and/or tissue) Donation after Circulatory (Cardiac) Death.

Death: Section 41 of the *Human Tissue Act* (Vic) 1982 provides that for the purposes of the law in Victoria, a person has died when there has occurred –

- (a) irreversible cessation of circulation of blood in the body of the person; or
- (b) irreversible cessation of all function of the brain of the person.

Deceased donor: A person who gives organs and/or tissues after death for the purpose of transplantation into another person.

(RCH) Designated Officer: A medical practitioner appointed by the RCH CEO under section 4 of the *Human Tissue Act* 1982 who is responsible for authorising in writing the removal of organs/tissue from a patient. At RCH the on-call Designated Officer can be contacted via switchboard.

Designated Intensivist: An RCH Intensivist who has not been directly involved in the decision or discussions with family about withdrawal of treatment (though may have previously been involved in the care of the patient). The Designated Intensivist and a DonateLife Organ Donor Coordinator have a detailed discussion with the patient's parents or guardian after a patient has been identified as a potential organ donor.

Donatelife™ in Victoria: The agency responsible for co-ordinating organ and tissue donation and procurement in Victoria.

Donatelife Organ Donor Coordinator: A person whose role is to facilitate the organ and tissue procurement process by acting as the liaison between the hospital, parents or guardian of the patient and transplant services. The Donatelife Organ Donor Coordinator can be contacted via a 24 hour paging service on 03 9347 0408 if any RCH staff member has questions about a potential organ donor but in the first instance RCH personnel should be contacted.

Guardian: A person appointed by a Court to have legal jurisdiction over a child.

Irreversible cessation of the circulation: The circulation has ceased and the possibility of auto-resuscitation is remote. In the context of DCD, a decision is made by the child's parents or guardian, or by the patient, in conjunction with the Managing Intensivist that resuscitative measures will not be taken in an attempt to restore the circulation after cessation has occurred.

Maastricht Categories: An international meeting on organ donation after cessation of the circulation was held in Maastricht in 1995. There are now five categories of potential donors:

- | | |
|-------------|-----------------------------|
| Category I | Dead on arrival at hospital |
| Category II | Unsuccessful resuscitation |

Category III	Awaiting cardiac arrest following withdrawal of treatment in ICU
Category IV	Cardiac arrest after brain stem death
(Category V	Unexpected cardiac arrest of an inpatient – added 2003)

DCD at RCH will be considered only in category III or IV patients.

Managing Intensivist: The on-service Intensivist involved in day-to-day care and decision making who will co-ordinate discussions regarding end-of-life care and be responsible for the delivery of such care but will not be involved in organ procurement.

Organ Procurement after Circulatory (Cardiac) Death: The process of surgical procurement of organ(s) or tissue after irreversible cessation of the circulation of blood in the body.

RCH Senior Nurse of Organ & Tissue Donation: A nurse whose role is to facilitate donation and procurement of organs and tissues at RCH.

Stand-down period: An elective 5-minute period following declaration of death by the Managing Intensivist for the family to spend time with their dead child. No interventions will be undertaken on the deceased during this time.

Tissue: Unless specified the term Tissue is used in this policy in a general sense to refer to both tissue and organs which can be removed for transplantation.

Warm ischaemic Time: The duration of ischaemia of organs after blood supply has reduced or ceased. In this context, the duration of hypotension and absence of circulation after withdrawal of treatment.

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Synopsis of RCH Organ Donation and Procurement Protocol after Circulatory (Cardiac) Death

