

Feedback from Dr Deborah J Verran to the ALRC Issues Paper-Review of Human Tissue Laws 2025

This submission is in response to the ALRC Issues Paper which has been made available for commentary. I will not respond to all the questions which have been raised within the document but will instead focus mainly on the topics for which I have had previous involvement and/or experience with during my professional career.

1) Background-

I was previously employed as a Staff Specialist Transplant Surgeon based at the Royal Prince Alfred in Sydney New South Wales (NSW) from 1995-2018. Of note I also led organ donor surgical retrieval teams during this same period. I was involved in the development of the inaugural 2007 New South Wales (NSW) Donation After Cardiac Death (DCD) Guidelines as well as the development of the subsequent 2015 NSW DCD guidelines. In each case I was the Chair of the relevant committee that was established to facilitate the putting together of each of these guidelines. I have attached a copy of the 2007 NSW DCD Guidelines.

The challenge for the inaugural NSW DCD Guideline Committee was to develop guidelines that would underpin the practice of organ donation from DCD donors within the jurisdiction, ensuring that all aspects of the practice would meet the relevant ethical and legal standards. This committee had representation both from the intensive care (ICU) community as well as from the NSW Ministry of Health. This facilitated the types of conversations which needed to be held around legal and ethical issues as well as how the various stages of the organ donation process might need to be managed. It also became apparent at an early stage that should this practice be deemed to meet the requisite standards, then this would also require that new protocols and processes be developed and implemented.

One of the conversations I clearly remember was how the relevant ALRC definition of death did not contain any guidance as to either the time frames or what additional monitoring technology needed to be used to assist with the declaration death of potential DCD donors in an ICU environment. Mention was made of perhaps there being a need for the law to be changed to something which contained more detail, but this then led to further discussions where other issues were identified. There was a realization that as there was a need for medical practitioners to be able to declare death according to the circulation criterion in other settings, adding in additional detail into the law for something which was specific to the ICU setting purely for the purposes of organ donation could become problematic. It was also perceived that there could then be the potential for there to be confusion in the minds of other non-ICU based medical practitioners as to how best to determine death in other settings, where access to additional monitoring

technology was limited. Plus, there was also the potential for members of the public to then question as to why there was now the requirement for differently worded legislation.

Once it was deemed at the level of the legal branch of the NSW Ministry of Health (MoH), followed by the MoH Ethics Committee, that DCD was permissible under the relevant legislation, albeit with safeguards, the focus of the committee switched to formulating the actual content of the guidelines. The document needed to contain enough in the way of information to enable DCD organ donation to occur in a uniform manner across the jurisdiction with attention being paid to the development and implementation of protocols as well as education of the relevant stakeholders. The relevant content contained within the guidelines also needed to be evidence based, hence a search of the published literature was also performed prior to the final wording of the guidelines being arrived at. Of note as withdrawal of life sustaining treatment (WLST), was already part of clinical practice within the ICU's, what these guidelines then achieved was to establish guidance (sections 3-8), around the practice of WLST for the purposes of DCD organ donation. These 2007 guidelines preceded the development of guidelines from the Australian Organ and Tissue Authority (OTA), as well as the Australian and New Zealand Intensive Care Society (ANZICS).

In September 2012 I took up a part time role with the Australian Organ and Tissue Authority as the Clinical Resource Officer. Part of this role involved undertaking advocacy via social media particularly around organ donation and solid organ transplantation. This proved to be useful particularly when contentious issues were being aired via some of the social media platforms. More on this later.

Fast forward to the mid 2010's when it became apparent within NSW including at the level of the MoH, that the St Vincents Cardiac Transplant service wished to undertake a trial of DCD heart transplantation using normothermic machine preservation as a tool to assess viability of the heart. As this was not possible under the then relevant available NSW DCD guidelines, this required that another working party be established to investigate this. I was the Chair of that working party. Again, there was the requirement to address legal and ethical issues along with undertaking a search of the published literature to gain an understanding around the relevant experience which had been gained to date internationally. The result was that the NSW Guidelines were revised to facilitate retrieval of the heart for the purposes of transplantation with an understanding that one of the important safeguards was the use of normothermic machine preservation to assess the viability of the heart. Of note there was also an increasing understanding by this point in time that the use of the term cardiac death was outmoded and hence the term circulatory death was adopted.

From the time that the 2007 NSW DCD guidelines were finalized, I was also heavily involved in the education of healthcare professionals both in the ICU

as well as the operating room as well as leading organ donor retrieval teams including for DCD donors. Any incidents involving DCD donors within the jurisdiction were rapidly investigated leading to the modification of in-house protocols as required.

Following publication of the 2015 NSW DCD guidelines along with the initial reported experiences with transplantation of DCD hearts within NSW, commentary began to appear around whether this was lawful (please see attached Insight article as well as posts from Twitter/X in the Supplements). I have mentioned this as an example of how individuals including within the medical profession can have different perspectives and how the wording of legislation can be interpreted to have varying meanings by different individuals. However, it also is a reminder as to why it is essential to have legislation which is worded in a manner that there is little room for misinterpretation.

2) Responses to the questions raised in the Issues Paper

I have become aware of the limitations of some of the current legislation in recent years, partly due to having ongoing conversations with individuals who are active in the organ donation and transplant sectors. Some of these individuals have reached out to me to provide background information as to how the early DCD guidelines were developed.

I personally believe that any alteration/amendment to the Human Tissue Laws should encompass the following -

- a) That any alterations/amendments that are made to the relevant laws are based on maintaining the trust of the wider community in the legislative framework that underpins organ and tissue donation. This can be facilitated by having the objective of updating the relevant laws to achieve national consistency, whilst providing greater clarity in some areas along with ensuring that the relevant laws are not a barrier to modern medical practices (Q.3,4).
- b) That the laws continue to uphold the requirements for informed consent, respect for the individual and ethical principles (Q. 4). For example, upholding a registered donors donation decision as per the statement made in the final sentence in point 67 in the Issues Paper may prove to be challenging in practice.
- c) That the role of the Designated Officer be maintained, as it is essential to ensure that there are adequate guard rails in place at the level of the hospitals around organ and tissue donation (Q. 5).
- d) There is a need to harmonize and clarify the relevant jurisdictional legislation that already exists to address the various barriers that have been identified within the issues document with respect to both organ and tissue donation. This includes addressing the issues identified pertaining to antemortem procedures contained in points 73-75 in the Issues Paper.

Thought also needs to be given to how evolving/future medical practices will also be accommodated via any such alterations to these particular laws.

- e) The solicitation of organ donors via media/social media is acceptable if certain principles are followed but where this potentially becomes problematic is when it is being pursued via individuals in the community as per point 91 in the Issues Paper. This is because there is a real risk that the result of public solicitation on the part of individuals will not be equitable. It is important that the trafficking of organs and tissues continues to be illegal under the relevant law, and I agree that it is important that this be addressed further as per point 92 in the Issues Paper.
- f) That there are no unintended consequences that could result from any alterations/amendments to the laws in question. This is an important issue in that it is possible for laws to be misinterpreted, hence thought needs to be given to the potential downsides of any planned alterations to the laws.

I have arrived at comments a) to f) based both on my prior professional experience as well as my understanding of not only the changing milieu of medical practice but also of community expectations. As I was one of the Social Media Ambassadors for the European Society of Transplantation from 2021-2024, I continued to keep an eye on the chatter that occurs via some of the platforms around organ donation.

Plus having also attended some of the recent lectures that were delivered around the time of the Royal Australasian College of Surgeons Meeting in May 2025, it is evident that the management of organ donors particularly DCD donors including during the surgical retrieval process is continuing to evolve internationally. The increasing use of NRP in other countries is now associated with better outcomes for the recipients of the solid organs from the DCD donors where this has been utilized. Hence there is a real need to now facilitate the use of NRP in DCD donors here in Australia. It is important that the relevant legislation not continue to be perceived as a barrier and that transplant recipients across Australia can benefit from the improved outcomes that are being facilitated via NRP.

However, I am also mindful that the consent rates for organ donation per annum here in Australia continue to be at recorded levels which are indicative that not everyone in the wider community is accepting of this (1). The reasons for this are complex many of which are encapsulated in the ANZICS 2021 Statement on Death and Organ Donation, as well as having been the subject of previous reports published via OTA. What is now also particularly evident is that misinformation pertaining to medical treatments continues to be spread via social media channels and if anything has become more of an issue in recent years. This contributes to levels of mistrust in the community to medical

recommendations and is more of an issue for some recommended therapies than others.

Misinformation around organ donation also continues to be spread via social media and can be fueled by media reports of incidents involving organ donors regardless of the location. For example, In the last year one such incident in Kentucky in the United States has acted as a catalyst for ongoing media attention as well as skepticism and misinformation being spread via social media. There are also increasing levels of distrust for government in some quarters as well (2), including here in Australia. To what extent all of this is a factor in the organ donor consent rates here in Australia is not clear, but it is important that this be recognized as being an ongoing issue. Hence this is why I believe that maintaining public trust in the governance of the organ donation system is of critical importance.

The trafficking of people, organs and tissues continues to be an ongoing problem internationally. This is fueled by desperation on the part of the donors as well as the potential transplant recipients with the potential for commercial gains to those who are involved in the dealings between both parties. One does not have to look very far via some social media channels to be able to witness the desperation on the part of individuals who are either seeking a live kidney donor or monetary support to undergo an organ transplant (and not always in the own country of residence). From time to time some of the live donor kidney transplant programs in other countries also promote their contact details with it not always clear as to what the underlying motivation is in all cases. There continues to be a steady stream of news articles around transplant programs being shut down due to their being involved in organ trafficking. Hence the public solicitation of live donors via social media is not a straightforward matter, and if it is to be deemed permissible under the law here in Australia then the appropriate guard rails will need to be put into place (3).

Conclusion,


I believe that the time has come to both harmonize and modernize the human tissue laws and that in doing so to also achieve the aim of ensuring that public trust in the governance framework for organ and tissue donation is maintained. It is essential, however, that any resulting modifications reflect a significant focus on the relevant ethical issues along with an understanding of the values that are currently held in the wider community.

References


- 1) Statistics in Australia, DonateLife Australia (Accessed June 2025)
- 2) A crisis of trust-what the Edelman Trust Barometer tells us about Australian Society, May 2025 (Accessed June 2025) [New data ranks Australians' trust in government](#)
- 3) Meena B, Kute VB, Bhargava B, Mondal R, Agarwal SK. Social Media and Organ Donation: Pros and Cons. Indian Journal of Nephrology 2022; 33(1): 4-11. [Social Media and Organ Donation: Pros and Cons - Indian Journal of Nephrology](#)

Supplement-1

 **Post** Reply 






 **Deborah Verran**   @VerranDeborah  

I am afraid that is totally incorrect, the practice is lawful in NSW ping @theMJA

 **Lesley Russell Wolpe** @LRussellWolpe · Sep 21, 2015

New forms of heart transplant, using hearts that have stopped beating, are illegal, @theMJA article warns smh.com.au/national/~gjqm...

8:11 AM · Sep 21, 2015


 **Deborah Verran**   @VerranDeborah · Sep 21, 2015  



I am afraid that is totally incorrect, the practice is lawful in NSW ping @theMJA [x.com/lrussellwolpe/...](https://x.com/lrussellwolpe/)




1

7

2




 



 **Craig Butt** @CraigDButt · Sep 21, 2015  






@VerranDeborah @theMJA @LRussellWolpe Does NSW have a different definition of circulatory death under the tissue act?

2

1




 



 **Deborah Verran**   @VerranDeborah · Sep 21, 2015  




@CraigDButt @theMJA @LRussellWolpe p.1 @NSWHealth GL2014_008 refers to section 33 of the HTA. NB = irreversible cessation of circulation

2

1



 **Craig Butt** @CraigDButt  

@VerranDeborah @theMJA @LRussellWolpe @NSWHealth what's your interpretation on section 33, particularly the use of "irreversible"?

3:20 PM · Sep 21, 2015

Supplement – 2 MJA InSight 2015

Authored by

CHARLOTTE MITCHELL

Issue 36 / 21 September 2015

AN *MJA* article saying heart transplantation after circulatory death does not conform to statute law has been rejected by transplant experts, who say it could fuel public distrust of the organ donation process. [\(1\)](#)

Professor Peter Macdonald, medical director of the St Vincent's Hospital Heart and Lung Transplant Unit in Sydney, told *MJA InSight* that while the nuances of relevant legislation varied by jurisdiction, "there are no legal barriers to using hearts removed from DCD [donation after circulatory death] donors for transplantation — provided death of the patient is declared consistent with the law".

He said that of all the DCD heart retrievals carried out so far in Australia, the clinical procedures followed in the diagnosis of death and the start of retrieval surgery were exactly the same as those used in the procurement of any other organ from DCD donors.

The authors of the "Ethics and law" article published in the *MJA*, Associate Professor James Tibbals, deputy director of intensive care at the Royal Children's Hospital, Melbourne, and Dr Neera Bhatia, a lecturer at the Deakin University School of Law, wrote that the "source of the problem of heart transplantation after circulatory death is the medical interpretation of the legal definition of circulatory death".

They wrote that the law in all Australian jurisdictions defined death as either "irreversible cessation of all functions of the brain" (brain death) or as "irreversible cessation of circulation of blood in the body" (circulatory death), although circulatory death was not defined in Western Australian legislation. However, the term irreversible or how to determine irreversibility were not defined.

"The fact that a transplanted heart can function and sustain life in a recipient must mean that the circulation of the donor is never ceased irreversibly and therefore that the donor of the heart is never dead until his or her heart is removed", they said.

As a result, the dead donor rule, "which would arguably be violated in heart transplantation after circulatory death, needs societal, legal and medical debate followed by revision or abandonment". The authors wrote that otherwise Australia's improving organ donation program was at risk of adverse publicity and damage if doctors or hospitals were perceived as procuring organs from patients who were not legally dead.

They proposed that the requirement for irreversibility in the definition of circulatory death be omitted and be redefined as "a cessation of circulatory function with cessation of higher brain function".

Professor Macdonald said he was concerned that the authors had used the words "circulation" and "heart" interchangeably throughout the article.

“The legal definition is circulatory death, not cardiac death. The term 'cardiac death' is incorrect both medically and legally”, he told *MJA InSight*.

“This misinterpretation of the law — replacing the legal definition of circulatory death with the term cardiac death — has been perpetuated in multiple publications including the previous NSW guideline and the current national guideline cited by the authors.”

Professor Macdonald said the need to correct this misinterpretation was one reason that the NSW Organ Donation after Circulatory Death Guidelines were revised in 2014. [\(2\)](#)

He also refuted the authors' claim that the removal of the heart, and its successful transplantation into another person, meant that the donor could not have been dead.

“In the deceased DCD donor, the heart is no different from the lungs, liver and kidneys – all these organs have ceased to function after death.”

Professor Jeremy Chapman, renal physician at Westmead Hospital and editor-in-chief of Transplantation, agreed, telling *MJA InSight* that it was misguided to assume that DCD patients only died because their hearts were removed.

“You can put [the donated] heart on a rig and it can recuperate its function and be transplanted into another person and work, but this has nothing to do with the [donor] patient”, Professor Chapman said.

“Ultimately, if I had a major head injury, and my family withdrew therapy and I ceased breathing after the ventilator was switched off, and my heart stops, then I am dead”, he said.

Associate Professor Kumud Dhital, cardiothoracic and transplant surgeon and director of the Sydney Heart Valve Bank at St Vincent's Hospital, told *MJA InSight* he was concerned that the article was “giving emotive, pre-eminence to one organ over the others” and that there was misunderstanding and mixing of medical terminology.

Professor Dhital said he believed the authors had failed to convey the important message they set out to accomplish: “To call for an academic and legal convergence and standardisation to aid clinicians in translating the wishes of the donor and their relatives, and saving the precarious life of another individual on a transplant wait list without victimisation”, he said.

He hoped that the article would not negatively affect the general public's perception of organ donation.

1. [MJA 2015; 203: 268–270.e1](#)
2. [Organ donation after circulatory death: NSW guidelines](#)

Organ Donation after Cardiac Death: NSW Guidelines

Document Number GL2007_012

Publication date 19-Jun-2007

Functional Sub group Clinical/ Patient Services - Human Tissue
Clinical/ Patient Services - Critical care

Summary This Guideline should be read in conjunction with PD2005_406 Consent to Medical Treatment - Patient Information, PD2005_341 Human Tissue - Use/Retention including Organ Donation, Post-Mortem Examination and Coronial Matters, and PD2005_057 Guidelines for end-of-life care and decision-making.

This Guideline describes the requirements and process for organ donation after cardiac death (DCD) in NSW. This approach to organ donation entails procurement of organs after the donors death where death is certified according to irreversible cessation of circulation of blood to the body (rather than according to brain death criteria) The guideline outlines the applicable setting for DCD in NSW, donor selection criteria, donor management (including decision-making and consent processes, surgical requirements, criteria for declaration of death, and care of the donor and family leading up to, and after the donor's death), subsequent organ allocation, and the relevant ethical and legal considerations applicable to this organ donation practice in NSW.

Author Branch Research Ethics and Public Health Training

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Affiliated Health Organisations, Affiliated Health Organisations - Declared, Public Hospitals

Audience All staff, in particular health professionals in ICU, operating theatres and emergency departments

Distributed to Public Health System, Dental Schools and Clinics, Divisions of General Practice, Government Medical Officers, Health Professional Associations and Related Organisations, NSW Ambulance Service, NSW Department of Health, Public Hospitals, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

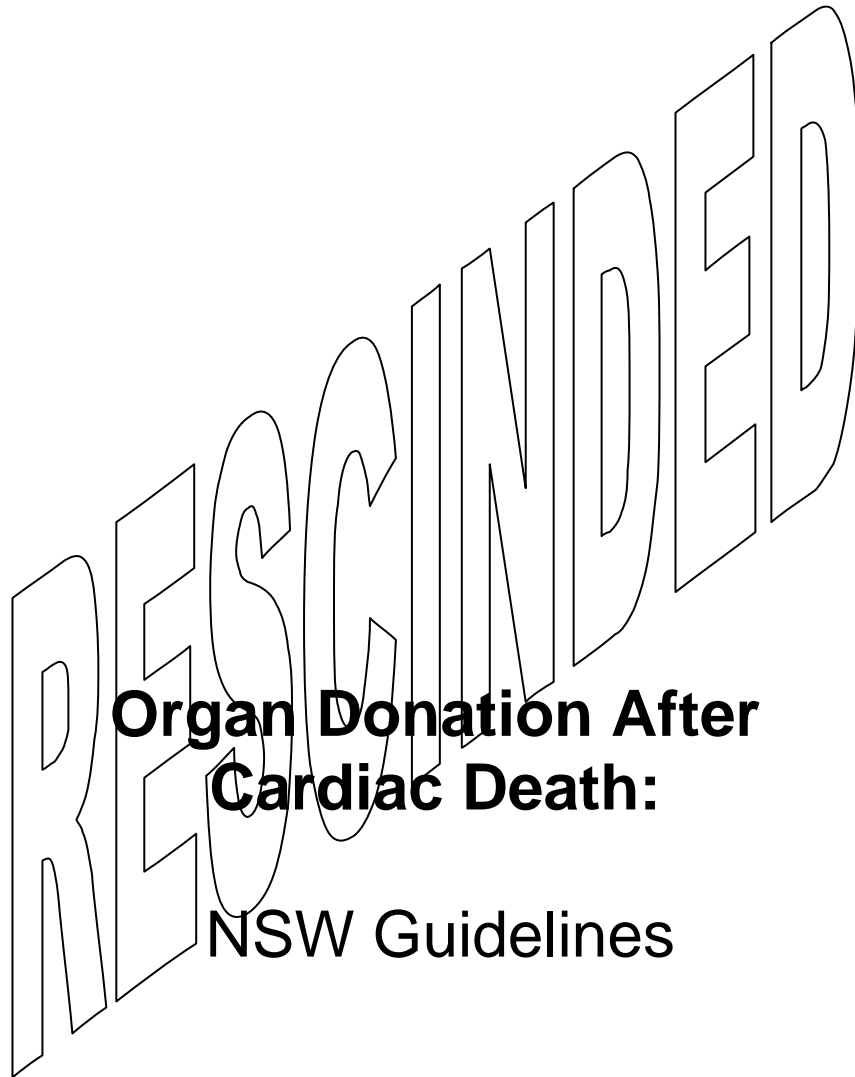
Review date 19-Jun-2012

Director-General

Policy Manual Not applicable

File No. 04/3586-2

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**Organ Donation After
Cardiac Death:**

NSW Guidelines

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(i) PREAMBLE

In 2004, the LifeGift Organ Donation Network NSW/ACT requested the support of the NSW Transplant Advisory Committee (TAC) to establish a working party to examine non-heart-beating organ donation, now termed Donation after Cardiac Death (DCD). The LifeGift Organ Donation Network NSW/ACT *Donation after Cardiac Death Working Party* was established under the auspice of the NSW TAC, and with terms of reference that included drafting guidelines to encompass the donation process from these deceased donors. These guidelines underwent state and national stakeholder consultation in 2006, and have been developed jointly by NSW Health and the TAC.

The aim of developing these guidelines is to provide increased donation opportunities for people who wish to be organ donors after their death, but whose illness or injury means that they do not meet the brain death criteria. DCD allows such individuals to still be donors after their death. As such, DCD also provides a means of potentially increasing the availability of deceased donor organs in NSW.

DCD requires a sensitive approach from all health professionals involved in caring for the potential donor and their family. These guidelines affirm that quality end of life care for a potential organ donor, as with any individual whose treatment is being withdrawn, is the absolute priority and must not be compromised by the donation process.

NSW Health recommends that institutions in NSW intending to implement DCD develop specific local protocols for the facilitation and management of DCD in their relevant services, particularly ICU, the Emergency Department and Operating Theatres. The protocols should be developed with reference to, and in accordance with, these NSW Health guidelines. Assistance from LifeGift Organ Donation Network NSW/ACT and the transplant teams should be sought, as required.

(ii) INTRODUCTION

Organ donation after cardiac death (DCD) is a practice that involves organ procurement after a person has died where that person's death has been declared according to traditional criteria related to permanent cessation of heartbeat and circulation ('cardiac death'). Typically this scenario involves an initial decision where the patient's treating team and family agree that continued use of 'life-sustaining treatment' would be non-beneficial or contrary to the person's wishes and should be withdrawn. Where it is known that that person would wish to be an organ donor, a decision is negotiated with the family that organ donation may proceed upon that person's death. (See Appendix III)

This organ donation scenario differs from the more common current scenario where 'brain death' is the basis for proceeding with organ donation. In the latter, once death has been declared on neurological criteria, ventilation and circulation are artificially maintained in order to optimise blood flow to the organs until the moment of organ procurement. (See Appendix III)

In NSW, there is statutory support, through the Human Tissue Act 1983, for procurement of organs and tissue after death. The Human Tissue Act recognises that death may be declared on the basis of either permanent cessation of neurological function, or permanent cessation of circulation. For patients that die in the Intensive Care Unit, most do so following a decision, made in consultation with the family, to withdraw life-sustaining treatment. Death in those circumstances, and including where DCD is planned, is declared on the basis of cessation of circulation.

All of the initial experience with the transplantation of deceased donor organs was with organs from donors after cardiac death. This early experience with kidneys^{1,2,3} and livers^{4,5} from DCD donors is documented in the literature. The first successful heart transplant performed by Barnard in 1967 was with an allograft from a DCD donor.⁶

In most countries, once brain death legislation was in place, the majority of deceased donor procurement occurred in donors after brain death. In Japan however, virtually all deceased donor organ procurement continued using DCD donors. Meanwhile, a small number of transplant centres continued to pursue the procurement and transplantation of kidneys from DCD donors.^{7,8} From one of these centres came the now widely used Maastricht categories of DCD donors.⁸

There is now a resurgence of interest and experience in DCD, particularly in parts of Europe and North America as a source of not only kidneys,^{9,10,11} but also other organs, including livers,^{12,13} lungs¹⁴ and pancreata.¹⁵ As transplantation is now an established treatment for end-stage organ disease, and as the supply of organs does not currently meet demand, there is an interest in exploring all avenues, within acceptable boundaries, for providing organs. This is reinforced as patient outcomes continue to improve following transplantation, and community expectations about access to transplant therapies increase.

With this renewed interest has come the requirement to ensure that organ procurement from DCD donors meets all current legal, ethical, clinical and societal standards required by oversight organisations. The United Network of Organ Sharing has consolidated all of the relevant information pertaining to the United States into the UNOS Donation After Cardiac Death Manual.¹⁵ Within the United Kingdom, the British Transplantation Society now has guidelines in place.¹⁶

SECTION 1

DONOR CATEGORIES

The 'Maastricht'⁸ categories for non-heart-beating donation, now termed 'donation after cardiac death' (DCD), have been developed as a way to categorise potential donors on a clinical basis and are widely accepted internationally.^{17, 18}

Category 1: Dead on scene (out of hospital) - Unknown warm ischaemic time: 'Uncontrolled'

Category 2: Unsuccessful resuscitation - Known warm ischaemic time: 'Uncontrolled'

Category 3: Waiting cardiac death after planned treatment withdrawal - Known and limited warm ischaemic time: 'Controlled'

Category 4: Cardiac arrest after confirmation of brain death but before planned organ procurement - Known and potentially limited warm ischaemic time: 'Uncontrolled'

Of these, only **category 3 donors** and **category 4** are permitted in NSW. Organ donation in category 4 is a rare occurrence. These guidelines predominantly focus on category 3 donations.

Donor categories: consent provisions in NSW

Category 1 and 2 donors are precluded because in order for the donated organs to be viable, it would be necessary to perform various procedures upon the donor that are for the benefit of a potential recipient, rather than the donor. Such procedures could only be performed with the prior or current consent of the donor that would not be known or available in these kinds of emergency situations. Provision of medical interventions, without the specific consent of the person, is not permissible under common law unless these interventions are being used to save that person's life, prevent serious damage to their health, or alleviate significant pain or suffering.¹⁹

This precludes medical interventions applied for the benefit of future organ recipients, such as those necessary to maintain circulation and organ perfusion in category 1 & 2 donors (CPR, cannulation etc), and use of pre-mortem procedures or drugs in order to optimise organ function in category 3 & 4 donors (see section 2.6).

Consent to pre-mortem interventions by substitute decision-makers, such as the 'person responsible', is not permitted under the *Guardianship Act 1987 (NSW)*, as the Act requires that those providing substitute consent do so only for treatments that 'promote or maintain the health and well-being' of the person involved.¹⁹ Nor would providing consent to such pre-mortem interventions be within the power of the Senior Available Next-of-Kin, under the *Human Tissue Act 1983*, as their consent has no authority until the person's death.²⁰

Implied donor consent to such procedures is theoretically applicable, but such consent can only be presumed when the person has consented to organ donation while alive, in the context of adequate awareness of procedures involved in DCD. This understanding about DCD does not presently exist in the community.

Donor Selection Criteria

The following donor selection criteria are proposed:

1. The donor falls within Maastricht category 3 or 4.
2. Age: more than 5 years and less than/equal to 65 years. Preclusion of children less than 5 years relates to difficulty in this age group in establishing irreversibility of cessation of circulation and cardiac output within the short time frame required to proceed with DCD.
3. Catastrophic, irreversible cardiorespiratory or neurological injury, not fulfilling brain death criteria, where withdrawal of life sustaining treatment is considered appropriate and following which rapid progression to death is anticipated.
4. Expectation that death is likely to occur within 60 minutes once the patient is removed from the ventilator and other supportive measures. Multi-organ retrieval is possible, although retrieval of the liver in this setting usually requires that the patient decease within 30 minutes.
5. No history of malignant melanoma, metastatic malignancy, or non-curable malignancy. Some early stage malignancies that have undergone successful treatment may be considered.
6. No active HIV infection, or risk behaviours for HIV in the last 12 months.
7. No untreated bacterial, viral or fungal infection. Treatment for any suspected sepsis should be provided for at least 24 hours before suitability for donation is considered.
8. Patient identity is known.

SECTION 2

DONOR MANAGEMENT IN THE ICU/OPERATING THEATRE

1. Identification of donors

- (a) The decision to withdraw 'life-sustaining' measures, such as mechanical ventilation and/or inotropes and vasopressors should be made prior to, and independent of, any consideration of DCD. (See NSW Health *Guidelines for end of life care and decision-making* (GL2005_057) that address the process for decision-making in treatment withdrawal).
- (b) Either the family or the treating team may raise organ donation, including DCD, as a potential possible post-mortem outcome. (See 4a. and b.)

2. Referral of potential donors

- (a) All potential DCD donors should be referred to the Organ Donor Coordinator for evaluation of suitability for donation and audit. This is in line with current practice for organ donation.
- (b) Where the death of the patient is reportable to the Coroner, the investigating Police, forensic pathologist and State Coroner should be contacted *pre-mortem* by the organ donor coordinator to seek advice as to the appropriateness for post-mortem organ donation, seek the Coroner's consent, and to arrange the logistics of post-mortem notification and confirmation of donation approval. This differs from usual procedure only in that coronial advice is usually sought after death has been certified based on the brain function criterion.
- (c) Potential tissue donation should be referred to the Tissue Bank as per the routine process.

3. Preliminary evaluation of donor suitability

- (a) DCD is not appropriate if, in the judgement of the treating Intensivist, it is anticipated that a patient is likely to survive after withdrawal of life-sustaining treatment for significantly longer than 60 minutes (or 30 minutes where liver donation is planned). It is recognised that accurately predicting the timing of death can be difficult, and that there will be occasions where a patient's dying process takes longer than anticipated.
- (b) Use of predictive algorithms²¹ to assess the likelihood of the patient dying within the 60-minute period should be at the discretion of treating Intensivist/s.
- (c) The 60-minute time limit is primarily aimed at ensuring a respectful approach to managing the patient's death where the possibility of organ donation might complicate an unexpectedly prolonged dying process. A prolonged dying process may also result in hypoperfusion to organs, thus jeopardising their effectiveness for transplantation.

4. Decision-making and consent

- (a) Discussion with the family regarding potential DCD should be separate from, and following the discussion and decision related to withdrawal of life-sustaining treatment (See 1b). Uncoupling the treatment withdrawal discussion from the organ donation discussion is important for bereaved families and helps minimise any potential or perception of conflict of interest on the part of any persons involved in the care of the patient or the patient's family.

The use of a separate health professional (that is, a 'separate requester') to discuss DCD (eg. another Intensivist or donor coordinator), other than the individual who conducted the discussion about treatment withdrawal, may be appropriate in some circumstances. This is unlikely to be necessary where the family themselves have raised the possibility of organ donation. This may be appropriate however, where there is a potential conflict of interest, for example where the treating Intensivist is likely to care for both the donor and recipient, or where other factors complicate the relationship between the treating team and family.

The treating Intensivist should consider the need for a separate requester on a case-by-case basis, if there is any doubt about whether DCD may generate concerns about conflict of interest.

Local institutional DCD protocols should provide further direction in this matter, as appropriate.

- (b) Where consensus with the patient's family about the appropriateness of treatment withdrawal cannot be reached, or conflict resolved, then consideration of the patient as a potential DCD donor is not appropriate.
- (c) A multidisciplinary team approach to managing end-of-life decisions with families should occur, as per the NSW Health *Guidelines for End-of-Life Care & Decision-Making*.²²
- (d) Other attending medical specialists should be informed where DCD is being considered.
- (e) Clear documentation of any discussions with the family regarding withdrawal of life-sustaining treatment and DCD is essential.
- (f) Following discussion about potential organ donation, and if there is agreement to proceed with donation after the patient has died, appropriate consent must be obtained. If the donor has previously given written consent to donation, for example through a donor registry²³ or other accepted means, the Designated Officer for the hospital may authorise donation in accordance with the *Human Tissue Act 1983*. This authorisation may be provided before death but becomes effective only after death has been certified. As is routinely practised for organ donation, the senior next-of-kin will also sign the authority for organs and tissues to be removed. If the donor has not previously given written consent to

donation, the senior available next-of-kin must provide written consent to the donation, effective upon the person's death, after which the Designated Officer may authorise donation in accordance with the *Human Tissue Act 1983*,²⁹ as detailed above.

- (g) If the death falls within the Coroner's jurisdiction (adult or child), then the matter must be referred to the Coroner for advice as to the appropriateness of potential donation (See 2b). Donation in this context cannot proceed without the Coroner's consent.

5. Comprehensive evaluation of the donor

- (a) The attending donor coordinator will complete the TSANZ/ATCA confidential donor referral form to enable risk assessment and assessment of individual organ suitability for transplantation.
- (b) The donor coordinator will contact the medical consultant on call for LifeGift Organ Donation Network NSW/ACT to discuss donor suitability.
- (c) The donor coordinator will then refer clinical and risk assessment information to the appropriate abdominal and thoracic transplant teams for determination of medical suitability for donation, and potential recipients for solid organ transplantation.
- (d) Pre-mortem bloods are required to allow time for testing of viral serology, and to allow matching of a potential recipient to the donor organ/s. The donation of other solid organs for transplantation, i.e. lungs and livers will not be feasible without these bloods being taken in the pre-mortem period. Blood may be taken from the donor in the pre-mortem period for serology and tissue typing only if 1) the donor has previously consented in writing to organ donation, or 2) if he or she has previously made comments supportive of being an organ donor or, when the matter was discussed, has not expressed an objection to it. The patient's wishes regarding donation may be known through discussion with the potential donor's family or others close to him or her. Thus pre-mortem blood may be taken for serology and tissue typing because the donor's implied consent to 'routine' donation practices, such as taking of blood samples, can be presumed.

Where the person's wishes regarding donation are unknown, pre-mortem blood for serology and tissue typing for the purposes of donation may not be taken, and donation may not proceed.

- (e) The donor coordinator will relay potential donor information to Tissue Typing ARCBS for cross matching. Cross-match and serology results will be conveyed to transplant teams as available.

6. Withdrawal of life-sustaining treatment

- (a) Responsibility for all end-of-life care should remain with the patient's treating team.
- (b) The location for withdrawal of life support for DCD may vary, and may include the ICU, the pre-operative holding area, or the operating theatre itself. When determining the optimal location for treatment withdrawal in individual cases, the following should be considered:
 - Family preference among the possible locations;
 - Treatment withdrawal in the ICU strengthens the separation of those managing the patient's treatment withdrawal from any influence of the procurement team in the Operating Theatre;
 - Treatment withdrawal in the ICU obviates the need for transfer of the patient back to a location for continued care should the patient not die in the 60 minute time period;
 - Treatment withdrawal in the operating theatre or pre-operative holding area minimises the 'warm ischaemia time' prior to organ procurement because there is no transit time from ICU;
 - Capacity of Operating Theatres to commit theatre time should treatment withdrawal occur there; and
 - The type of organs being donated. Procurement of livers requires minimal warm ischaemic time, as the liver is more sensitive to the effects of warm ischaemia than kidneys or lungs'.
- (c) It is appropriate to allow the family to remain present while life-sustaining treatment is withdrawn and until the person's death if the family so wishes, regardless of the location of treatment withdrawal.
- (d) The family should be made fully aware prior to withdrawal of life-sustaining treatment that, in the event of death not occurring within the 60 minute period, DCD cannot proceed, but that the patient will be given continued care in a prearranged location until death does occur. This continued end of life care, aimed at optimal comfort and dignity, is preferably provided in the ICU, but may need to be provided in another appropriate location, especially if the person's dying becomes very prolonged.
- (e) The family should be informed that they will need to leave the bedside by the end of the 5-minute stand-down period. If they are unable to do so, the organ donation will not proceed.
- (f) Following the withdrawal of life-sustaining treatment, ECG and arterial blood pressure monitoring should continue as these will assist in establishing death (defined as irreversible cessation of circulation).
- (g) Any pain or distressing symptoms following withdrawal of life-sustaining treatment may be managed with analgesia and sedation, as they would be in any other instances of treatment withdrawal. Analgesia and sedation should be

provided by whatever route is necessary for relief, in proportion with clinical need, and with the primary goal of relieving pain or other distressing symptoms.²²

The family should be informed that any drugs given following treatment withdrawal are to keep the patient comfortable, and do not form any part of the donation process.

- (h) Use of drugs (such as Heparin or Phentolamine) in the period after withdrawal of life-sustaining treatment but *before* the donor's death (pre-mortem), in order to optimise organ function for the benefit of the recipient, is not legally permitted in NSW. (See Section 1)
- (i) *Pre-mortem* insertion of femoral cannulae to enable rapid cooling of the organs after death is similarly not legally permitted in NSW. Insertion of cannulae *after* the person's death is however, permitted. This may be most appropriate where treatment withdrawal is occurring in the ICU and efforts to minimise warm ischaemic time become essential.

7. Declaration of Death

- (a) Consistent with the NSW *Human Tissue Act 1983*, death is declared when the attending Intensivist, or other designated doctor determines that there is irreversible cessation of circulation of blood in the person's body.
- (b) Under non-donation conditions, clinical examination alone is generally sufficient to determine cessation of circulatory function, and death is confirmed by clinical examination revealing the absence of responsiveness, heart sounds, pulse and respiratory effort. However, the urgent time constraints of DCD require additional definitive proof of cessation of circulation by use of monitoring and/or confirmatory tests. Thus, ECG, intra-arterial monitoring or rarely, Doppler examination, should be utilised to facilitate the determination and subsequent certification of death to ensure that the 'stand down' period is appropriately adhered to, and to assure the family and staff that the patient is dead.
- (c) It is recommended that the death is not be certified by a member of the organ retrieval or transplant team.
- (d) Following declaration of death, a 5-minute stand down period before organ procurement can proceed is considered mandatory. This stand-down period duration is consistent with the recommendations of the Institute of Medicine report¹⁸, and the British Transplantation Society Guidelines on DCD.¹⁶
- (e) All significant time-points, including the time of death, stand-down period and commencement of organ procurement must be accurately documented in the patient notes and formal DCD data sheet (sample at Appendix IV).

8. Counselling

- (a) Counselling support should be offered to the family as required in accordance with usual hospital procedures. Following DCD, the family should be offered bereavement aftercare via the Next Step Programme, as facilitated by LifeGift Organ Donation Network NSW/ACT.
- (b) Families should be offered the opportunity of viewing the patient's body after donation, consistent with routine practice.
- (c) Staff members should be offered counselling support as required.

RESCINDED

SECTION 3

SURGICAL PROCESS FOR DONATION AFTER CARDIAC DEATH

All potential DCD donors will be referred to LifeGift Organ Donation Network NSW/ACT for consideration of organ retrieval, and their suitability for either renal retrieval or multi-organ retrieval.

It should be noted that the nature of the surgical process is dependent on whether renal only retrieval versus multi-organ retrieval is to be performed.¹⁶

A. Renal only retrieval

Withdrawal of life-sustaining treatment and the subsequent declaration of death can occur either in the intensive care unit or the operating room, according to local policy (see Section 2. points 6 and 7).

Femoral cannulae may only be inserted after the person's death in NSW. The aim of femoral cannula placement is to allow immediate commencement of preservation solution after declaration of death. This is in order to shorten warm ischaemic time. Renal procurement will occur only if death is declared less than 60 minutes after withdrawal of life sustaining treatment.

No single preservation fluid has been shown in the literature to be superior for preservation of kidneys from DCD donors. Consideration should be given to low viscosity solutions versus University of Wisconsin solution.^{7,9,16,24} Consideration should also be given to adding heparin to the preservation solution.^{7,9,16,24} Research into the use of other additives with preservation solutions for DCD donors is ongoing. There is some preliminary evidence that streptokinase may be useful in the setting of renal procurement.²⁵

Once in the operating room the renal procurement is performed as for a standard renal procurement.

B. Multi-organ retrieval

Withdrawal of life-sustaining treatment and subsequent declaration of death should occur in the operating room where liver and/or lung procurement is planned.^{12,16,26}

Liver procurement cannot occur if death occurs after 30 minutes following withdrawal of life-sustaining treatment. Renal, lung or pancreas procurement cannot occur if death occurs more than 60 minutes after withdrawal of life-sustaining treatment.

For multi-organ procurement, a laparotomy is performed in tandem with a sternotomy.¹² The aim is to cannulate the aorta and, if necessary, the pulmonary artery to initiate preservation solutions as required. The thoracic aorta is cross-clamped and the right atrium vented. Heparin is added to the preservation solution.

Topical cooling of the thoracic and abdominal viscera with saline slush is also performed, as required.¹³

Once organ flushing with preservation solution has occurred, the surgical procedure continues as for a standard multi-organ procurement, or as a renal only procurement depending on the circumstances.

C. Assessment of organs from DCD donors

Assessment of the quality of organs from DCD donors should be the same as for the assessment of organs from brain dead donors. This includes an assessment of the adequacy of perfusion with the preservation solution along with identification of other abnormalities. Liberal use of biopsy should also be made.^{24 27}

RESCINDED

SECTION 4

ALLOCATION OF ORGANS

Consideration should be given to the fact that all organs retrieved from DCD donors will have been subjected to varying periods of warm ischaemia. On this basis, such organs should be considered 'extended criteria' organs, or in less than optimal condition.

A. Kidneys

Currently within NSW and ACT, all kidneys procured from deceased organ donors are allocated to recipients based on the NSW matching scheme.²⁷ National or interstate kidney allocation for deceased donor kidneys is also performed according to the National Kidney Matching Scheme.

Although there is limited experience with DCD kidneys in NSW in recent years, it should be noted that there is some evidence from international transplant centres supporting a policy of limiting cold ischaemic time to less than 20 hours with DCD kidneys.^{9,10} Limiting cold ischaemic time is also a recommendation of the current Caring for Australians with Renal Impairment (CARI) guidelines.²⁸

The only current national guidelines (CARI) with respect to DCD kidneys²⁸ do not make firm recommendations with respect to allocation. The National Renal Transplant Advisory Committee at this time has agreed that DCD kidneys should not be sent interstate.

Recommendations:

- Allocation should occur within NSW and ACT based on the current NSW matching scheme only.
- Allocation of DCD kidneys should occur based on NSW local allocation policy.
- Transplant centres should aim to limit the cold ischaemia time of such kidneys once allocated.
- Transplant centres should consider the potential information needs of their patients on the waiting list regarding DCD. Information provided to a potential recipient of a DCD organ when obtaining their consent to transplantation should include whether a 'extended criteria' organ is being offered and the potential implications.

B. Other Solid Organs

Currently within NSW, all extra-renal organs from DCD donors are allocated to recipients based on transplant units' policies. This allocation takes into consideration the assessed quality of the donor organ versus the clinical status of the recipient.

Recommendations:

- Allocation of extra renal DCD organs should preferably occur within NSW, based on current local practice, in order to minimise cold ischaemic time.
- Extra-renal organs obtained through DCD should be considered as 'extended criteria' organs, and this should be factored into allocation to recipients.
- Transplant centres should consider the potential information needs of their patients on the waiting list regarding DCD. Information provided to a potential recipient of a DCD organ when obtaining their consent to transplantation should include whether a 'extended criteria' organ is being offered and the potential implications.

RESCINDED

APPENDIX I

GLOSSARY

Brain death

Death defined by irreversible cessation of all function of the person's brain.²⁹

Cardiac death

Death defined by irreversible cessation of circulation of blood in the person's body.²⁹

Cold ischaemic time

The period following cooling of the organs until perfusion to the transplanted organ/s is re-established in the recipient.

Extended criteria organs

Organs procured from donors that incur warm ischaemia (necessarily organs from DCD) or organs from donors who, while meeting suitability criteria, are subject to the effects of donor co-morbidity or age. Previously called 'marginal' organs.

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 defacto), friend, or 'person responsible' according to any express wish of the patient.²²

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.

Stand down time

The period following declaration of death during which organ procurement must not proceed which is used to establish that the circulation has irreversibly ceased to function.

Warm ischaemic time

The period of time following cessation of circulation and blood flow to the organs until the time those organs are removed from the body and cooled.

APPENDIX II

EDUCATION PLAN

Prior to the re-introduction of expanded use of DCD in NSW, some general introductory information about the process should be integrated into education services already provided through the LifeGift Organ Donation Network NSW/ACT.

Upon introduction of a NSW DCD program, a range of organisations currently involved in organ donation education will undertake activities such as:

- Information about DCD should be delivered to the community at large through avenues such as presentations to community groups and promotions like Australian Organ Donor Awareness Week.
- General information should be provided to a diverse range of health and allied health professionals. It should continue to be linked into the educational services provided by the LifeGift to;
 1. Postgraduate Intensive Care, Emergency Department and Operating Theatre nursing education.
 2. Graduate nurses through professional organisations, such as the Emergency Nurses Association, Australasian Transplant Coordinators Association, Australian College of Critical Care Nurses, and Australian College of Operating Room Nurses.
 3. Undergraduate medical education.
 4. Transplant physicians and surgeons (postgraduate specialty) through the Royal Australasian College of Physicians (RACP), Royal Australasian College of Surgeons (RACS) and the Transplantation Society Of Australia and New Zealand (TSANZ).
 5. Critical Care and Perioperative Nursing, Medical and Allied Health staff through the Australasian Donor Awareness Program ADAPT.
 6. Postgraduate Intensive Care, Emergency and Anaesthetic medical education.
- More detailed information needs to be provided to the relevant groups in institutions that may be directly involved in the DCD process, for example ICU, emergency department or operating theatres. Organ Donor coordinators should provide this so that the information provided is up to date, accurate and relevant to the target audience being addressed.
- Specific detailed information about DCD should be addressed to;
 1. Organ Donation Coordinators, particularly the legal and logistical requirements of the DCD process.
 2. Nursing and Medical staff working in Critical Care Areas including the Emergency Dept, Operating Theatres and Intensive Care Units.
 3. Social Work and Pastoral Care Staff providing support to families through the process.

4. Intensivists, Transplant Surgeons, Renal and other Transplant Physicians through professional organisations such as the Renal Special Interest Group, the State Liaison Group, TSANZ and ANZICS.
5. Patients with organ failure / impairment being admitted to the deceased donor transplant waiting lists.

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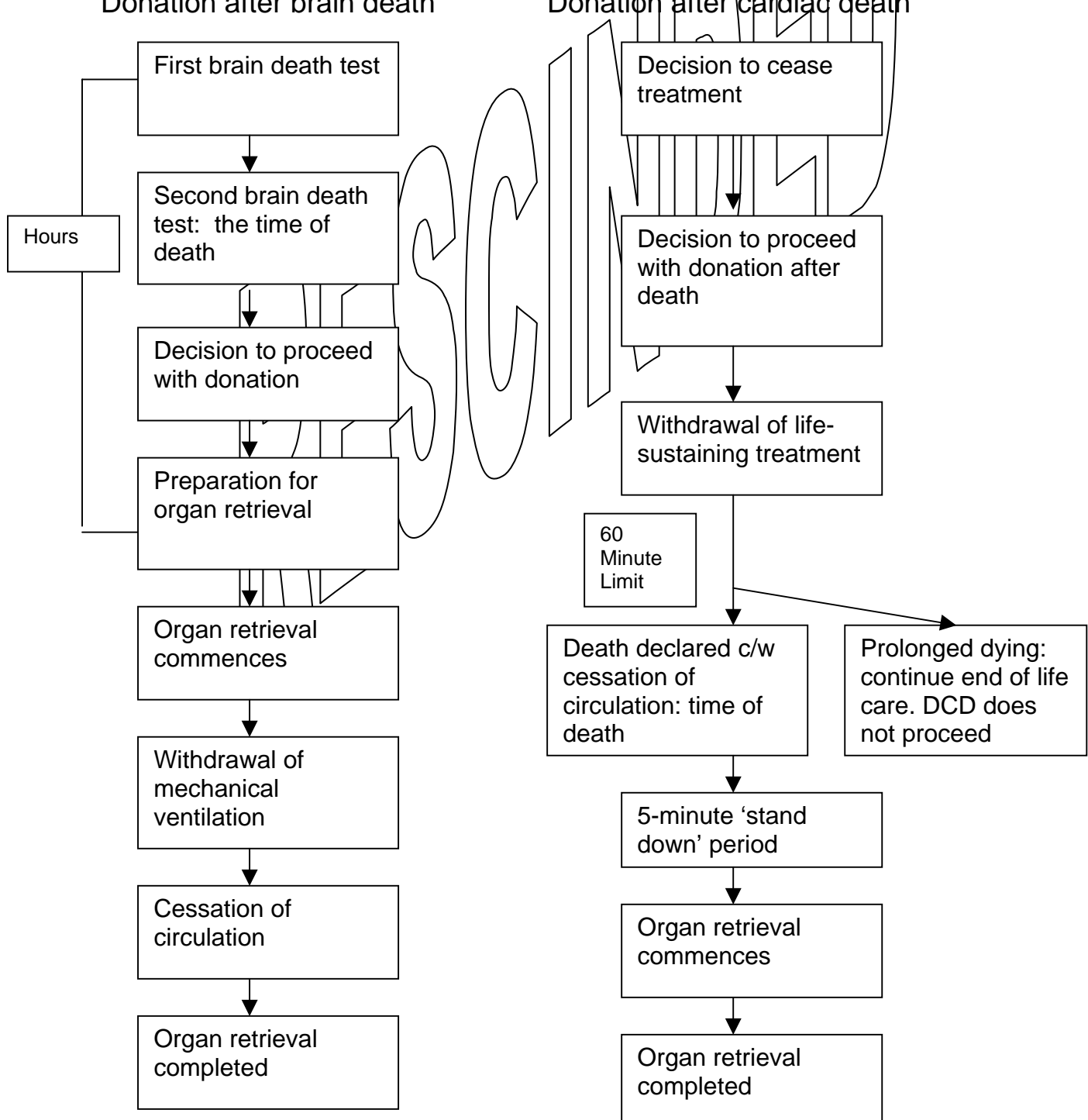
APPENDIX III

OVERVIEW:

DONATION AFTER BRAIN DEATH COMPARED TO DONATION AFTER CARDIAC DEATH

Donation after brain death

Donation after cardiac death



APPENDIX IV

DONOR RECORD FORM (PROFORMA)

DONOR HOSPITAL

Date:/...../..... hrs

Donor Coordinator:

Death certified by:

Results	Adm	Term	ABG	
Date/Time				
Urea			pH	
Creat			PO2	
AST			PCO2	
ALT			HC03	
GGT			BE	
ALP			FiO2	
T Bili				

2. Cannulation and Perfusion

Cannulation time

Cannula site

Insitu Perfusion Commence time

MRN:

DOB:

Donor number.....

1. Withdrawal

Extubation time

SBP < 70mmhg time

Time of death time

3. Operating room

OT start time

X-clamp time

Liver on ice time

Lungs on ice time

Kidneys on ice time

OT finish time

Medication Administered	Dose	Date/time

Team 1

Surgeon:

Asst:

Team 2

Surgeon.....

Asst:.....

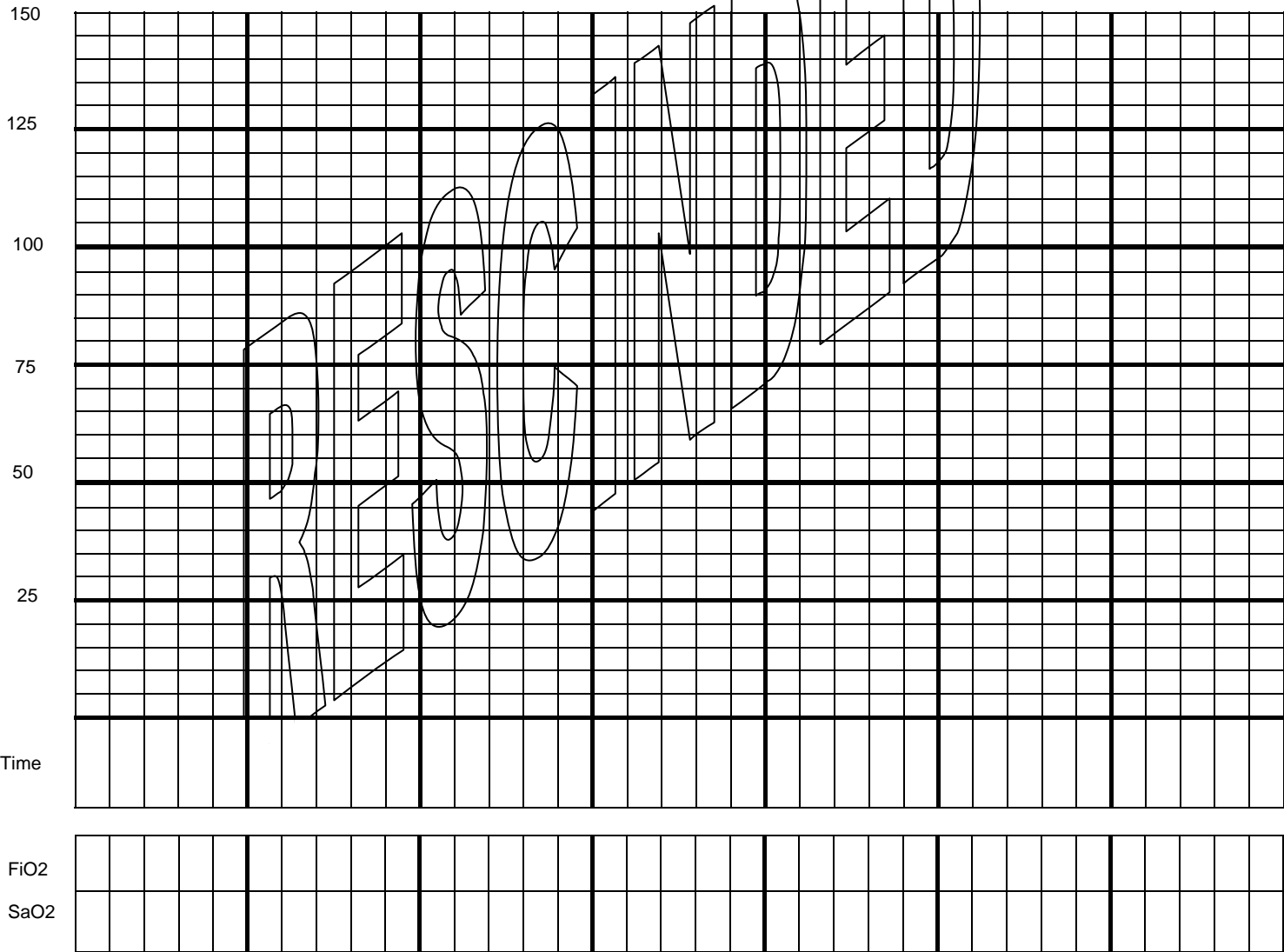
Title: Organ Donation After Cardiac Death: NSW Guidelines

Perfusion: Perfusion:.....

Hospital: Hospital:.....

MONITORING (circle)

ECG Pulse Oximeter NIBP Art Line



Perfusion Fluid (& Additives)	Volume	In-flow access	Date/time started	Date/time ceased

APPENDIX V

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