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1. Introduction

The Human Tissue Act 1983 (the Act) sets out the law governing the use of human tissue in NSW. Human tissue can be removed for use for therapeutic, medical or scientific purposes only. The Act regulates the following:

- The donation, retrieval and use of human tissues, such as solid organs (e.g. heart, liver, lungs, kidneys and pancreas) and tissue (e.g. eyes, bones, tendons and heart valves) for transplantation from both living and deceased donors
- Blood donations
- Post-mortem examinations.

In 2012, following the release of the discussion paper Increasing Organ Donation in NSW (the previous discussion paper), a number of amendments relating to tissue donation were made to the Human Tissue Act in the Human Tissue Legislation Amendment Act 2012 (the Amending Act). These amendments were one part of a plan to strength existing strategies to raise awareness about organ donation and increase organ donation in NSW.

The Amending Act made the following amendments to the Human Tissue Act:

- Amendments to sections 23 and 24 to allow, when there is no written consent to organ donation, consideration to be given to most recent views of the deceased person with respect to organ donation (rather than the previous test of whether the person had, at any time in their lifetime, expressed an objection to organ donation)\(^2\). Previously, if there was no written consent and the deceased had at any time in their lifetime expressed an objection to donation, tissue could not be removed from the deceased.
- Amendments to section 27 to allow, once the relevant consents and authorities to removal of tissue have been obtained, a non-medical practitioner appointed by the Secretary to remove cardiovascular tissue (other than the whole of the heart for the purpose of a heart transplant).
- The inclusion of a new section, s27A, to allow the Secretary to make guidelines relating to the removal of tissue after death, including with respect to recording reasons for not proceeding with organ donation where the deceased person had given their consent but the family had objected.

The Amending Act also amended Schedule 1 of the Human Tissue Act to require the Minister to review the Act to determine whether the amendments in the Amending Act have been effective in achieving an increase in the rate of tissue donation in the State. The clause requires the review to be undertaken 5 years after commencement of the Amending Act, with a report tabled in Parliament 12 months after the commencement of the review.

This discussion paper has been prepared for the purpose of the review to seek feedback regarding the effect of the amendments and whether they have been effective in achieving an increase in the


\(^2\) The Amending Act made similar amendments to the Anatomy Act in respect of donation of a body for anatomical purposes.
rate of organ donation in NSW. In addition, the discussion paper more broadly looks at a range of contemporary issues relating to the Act.

We welcome the views of stakeholders regarding the impact of the Amending Act, and other related tissue and organ donation issues presented in the discussion paper

2. Background to the 2012 amendments

Ensuring access to organ donation and transplantation is an important part of the provision of quality healthcare in NSW. The NSW government is committed to putting the patient first, which includes ensuring that the wishes of patients about organ donation are respected and, as far as possible, upheld.

From 2007 to 2010 there were sustained increases in the NSW and national rates of organ donation and transplantation. In 2010, 87 people donated their organs and the rate of donors per million population was 12.5. However, in 2011 NSW experienced a decline in both of these numbers. In 2011, there were 77 solid organ donors in NSW and rate of donors per million population was 11, one of the lowest of any Australian jurisdiction.

Figure 1: NSW Solid Organ* Donors 2007-2011

Any decrease in organ donation, however small, can cause devastating consequences for individuals, and their families, who require a transplant in order to lead full and healthy lives. The relatively low rate of organ donation in NSW during this period motivated the release of a discussion paper Increasing Organ Donation in NSW (the previous discussion paper) in 2011. The previous discussion paper outlined the key elements of the National Reform Agenda package to maximise organ donation, how organs are made available in our health system and factors influencing organ donation.

3 Second Reading of the Human Tissue Legislation Amendment Bill - Minister for Health, and Minister for Medical Research, 5 March 2012 page 52 Hansard
The previous discussion paper looked at the reasons for the decrease and canvassed strategies aimed at increasing the rates of organ donation and transplant rate in NSW. In 2012, 88 people donated their organs in NSW and the rate of donors per million population was 12.4.

The discussion provided the public with ideas that can make a difference in NSW and sought feedback on a range of issues including:

• Whether New South Wales should move to a single national register by closing the Roads and Maritime Services Register.
• Whether to switch to an "opt-out" model of presumed consent to organ donation.
• The promotion of advance care directives as a means to indicate consent to organ donation.
• Trialling new models for assisting families to consider donor consent such as doctors initiating donor requests, designated requestors and dual advocacy.
• Whether to revoke the practice of allowing family members to refuse organ donation in circumstances where the deceased person has consented to it.
• Strategies to better support and raise awareness among Aboriginal and culturally and linguistically diverse community members; and
• Strategies to further enhance the living donor program such as better promotion of financial support options.

Seventy six submissions were received in response to the previous Discussion Paper. The majority of submissions were from individuals. Based on the feedback from the community and key stakeholder groups to the previous discussion paper, the NSW government developed the policy document Increasing Organ Donation in NSW: Government Plan 2012 (the Plan). The aim of the policy is to increase organ donation and transplantation rates through maintaining and strengthening existing Commonwealth strategies, along with implementing new approaches for NSW.

The Plan included the following initiatives:

• Transferring existing donors from the NSW Roads and Maritime Services Register to the national Australian Organ Donation Register.
• Increasing community education and awareness campaigns to encourage people to have discussions with their families about organ donation.
• Employing specialists in hospitals to help families through the difficult decisions about consenting to organ donation.
• Providing guidelines to doctors which help them uphold a person’s desire to become an organ donor.
• Promoting living donation programs.

To meet the Plan’s objectives a number of amendments were made in 2012:

• Amendments to sections 23 and 24 of the Human Tissue Act to allow consideration to be given to most recent views of the deceased person with respect to organ donation (rather than the previous test of whether the person had, at any time in their lifetime, expressed an objection to organ donation).
• Amendments to section 27 to allow, once the relevant consents and authorities to removal of tissue have been obtained, a non-medical practitioner appointed by the Secretary to remove cardiovascular tissue (other than the whole of the heart for the purpose of a heart transplant).

• The inclusion of a new section s27A, to allow the Secretary to make guidelines relating to the removal of tissue after death, including with respect to recording reasons for not proceeding with organ donation where the deceased person had given their consent but the family had objected. This provision aimed at ensuring that clinicians involved in organ donation can adequately document the reasons organ donation did not proceed. Such documentation is intended to support analysis of the reasons for family refusal and assists in developing awareness campaigns that focus on addressing the concerns that lead to family refusal.


The policy directive provides guidance on protocols and procedures that must be in place in health facilities to support organ donation including:

- the identification of potential donors.
- the determination of death.
- the scope and format of consent (including the specific requirements of the Human Tissue Act 1983 as to who may consent).
- authorisation.
- obtaining Coronial authorisation for donation to proceed when relevant.
- donor maintenance.

The policy also establishes the documentation required when a family objects contrary to the consent of the potential donor. The documentation is labelled as Attachment 3 to the policy directive and is titled ‘Documenting family objection to organ/tissue donation contrary to the known wishes of the donor form’.

3. Rates of organ and tissue donation in NSW
Since the introduction of the Increasing Organ Donation in NSW: Government Plan 2012 and the Amending Act, NSW has increased its donor rates (Figure 2).

In 2011 there were 77 deceased organ donors (11 donors per million population) and in 2017, there were 135 deceased organ donors (17.7 donors per million population).
The 2017 organ and tissue donation and transplantation data show that previous growth has been sustained nationally and in NSW, with small net increases. Living kidney donation in NSW remains strong and NSW tissue donation has significantly increased.

NSW had 2,248 unique tissue donations in 2017, the highest number of any jurisdiction. 2,139 of these donations were from living musculoskeletal tissue donors where femoral head donation following hip replacement surgery allowed 6,509 musculoskeletal grafts to be transplanted to 4,688 recipients. In relation to eyes, 380 eye tissue donors meant 952 eye tissue grafts (corneal tissue and sclera unit tissue) were implanted in NSW.

The NSW Ministry of Health is of the view that the improved rates of organ and tissue donation in NSW is the result of a range of factors including:

- the changes in the Amending Act,
- the ongoing partnership with the Commonwealth in raising awareness,
- implementation of new models for hospital placement of specialist clinicians,
- supporting clinicians to have conversations with donor families, and
- trialling a new model for approaching families for consent.

**Issues for consideration**

1. Have the amendments to sections 23, 24 and 27A assisted in increasing the rates of organ donation?
2. Are there any other strategies that should be considered to assist in raising awareness and improving the organ donation rates in NSW?
4. Impact of families decisions in organ and tissue donation

In NSW, consent to organ and tissue donation does not always translate to actual donation rates. There may be cases in which donation is considered inappropriate for clinical or other reasons, regardless of the donor's decision. Each case should be considered on its merits.

For prudential and compassionate reasons, current practice is for clinicians or transplant coordinators to always seek agreement for organ and tissue donation from family members, even if the deceased had while alive consented to organ and tissue donation. In most cases, families support donation where they know their loved ones wishes to become a donor.

It should be noted that the Act makes no provision for families to override prior patient consent for organ and tissue donation. However, if there is dissent amongst the family to proceeding with donation, the benefits of carrying out the donation should be weighed against the distress and resentment that may result if donation proceeds in the face of strong objection from some family members.

Therefore the discussions with the family about obtaining their support for organ/tissue donation require complex and sensitive communication, regardless of whether the donor's decisions are known.

If a deceased person had given their consent to the removal of organ and/or tissue but a health practitioner determines that the removal of an organ and/or tissue should not proceed due to the strong and sustained family objection, then the relevant health practitioner must document the reasons for not proceeding.

Section 27A of the Act allows guidelines to be made relating to the removal of organ and tissue after death, including with respect to recording reasons for not proceeding with organ and tissue donation where the deceased person had given their consent but the family had objected. As noted above, the Ministry of Health published a policy directive in 2013 on this issue, PD2013_001 Deceased Organ and Tissue Donation - Consent and Other Procedural Requirements. The policy directive has a form titled ‘Documenting family objection to organ donation contrary to known wishes of the donor’ that was developed to assist requesting health professionals meet their obligations under this policy. The form should be completed and signed by the requesting clinician and then signed by the Designated Officer, where the decision is not to proceed with donation.

Section 27A and the policy are aimed at ensuring that clinicians involved in organ and tissue donation can adequately document the reasons it did not proceed. Such documentation supports analysis of the reasons for family refusal and will assist in developing awareness campaigns that focus on addressing the concerns that lead to family refusal.

<table>
<thead>
<tr>
<th>Year</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Overrides of 'Yes'</td>
<td>19</td>
<td>16</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>Family Overrides of 'No'</td>
<td>2</td>
<td>9</td>
<td>11</td>
<td>10</td>
</tr>
</tbody>
</table>
The table above shows that since the introduction of s27A to the Act in 2012 and the implementation of the policy more families have respected the wishes of the deceased to become an organ donor.

Table 1 also shows that with the introduction of amendments to s23 and 24 of the Act, more families are able to consent to donation where they have evidence to show that the deceased (who had previously said no to donation) had more recently changed their mind.

### Issues for consideration

3) Does s27A appropriately assist with improving communications with family members when a family objects to organ donation despite the deceased consenting while alive?

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### 5. Organ trafficking

In recent years there has been growing community concern around trading in human tissue and reports of so-called ‘transplant tourism’, where NSW recipients travel to other jurisdictions to obtain tissue for transplants that may have been sourced outside legal channels.

People can travel overseas to receive an organ transplant in a range of ways. For example, a dual citizen may travel to their home country and be placed on their waiting list for an organ. On the other hand, a person can travel overseas to buy an organ for transplant. Generally this would be illegal in the overseas country, although some countries, such as Iran, do allow certain commercial arrangements in relation to organ transplantation.

NSW, along with all other States and Territories, requires organs and tissue to be donated voluntarily. As such, section 32 of the Act makes it an offence (with a maximum penalty of 40 penalty units or 6 months imprisonment or both) for a person in NSW to enter into a commercial contract or arrangement for the sale or supply of tissue from a person either living or deceased or for the conduct of a post-mortem examination, subject to a number of exemptions.

The exemptions to s32 include the sale of tissue that has been reprocessed for therapeutic purposes; reimbursement of expenses; or contracts or arrangements the Minister considers desirable (for example, the Minister allows donor and recipient pairs to exchange kidneys through the Australian Kidney Exchange Programme).

While s32 is contained in NSW legislation, it can have extraterritorial effect if there is a geographical nexus between the offence and NSW. Section 10C of the Crimes Act 1900 provides that a geographical nexus exists where one or more of the elements of the offences occurs in NSW or the offence occurs outside of NSW but takes effect in NSW. Relying on s10C of the Crimes Act to prosecute a person who enters into a commercial arrangement can have practical limitations, as with all cases of prosecuting offences that occur outside of NSW.

The Commonwealth *Criminal Code* also contains offences relating of organ trafficking, which may occur after or in the course of entry into or exit from Australia, as well as the offence of domestic organ trafficking. The removal of a person’s organ is prohibited under the legislation if it would be
contrary to the law of the State or Territory where it is, or is to be, carried out, or if it is undertaken without consent and it would not meet a medical or therapeutic need of the victim. The maximum penalty for the offence of organ trafficking is imprisonment for 12 years, while aggravated organ trafficking carries a maximum penalty of imprisonment for 25 years.

This review provides an opportunity to canvass views on whether additional provisions should be included in the Act to respond to growing concerns about NSW residents travelling overseas to buy organs. While legislation is one means to respond to this issue, it is noted that one of the ways to combat potentially unlawful transplant tourism is to focus on increasing organ donation rates in NSW, to ensure local access to organ and tissue transplantation. The NSW government policy document *Increasing Organ Donation in NSW: Government Plan 2012* focuses on increasing organ donation and transplantation rates through maintaining and strengthening existing Commonwealth strategies, along with implementing new initiatives in NSW.

### Issues for consideration

4) Are additional measures required to respond to NSW residents travelling overseas to buy organs?

### 6. Coroner’s consent to organ donation after circulatory death

Optimising the process of organ donation after circulatory death (DCD) has been identified as an important area of focus for NSW. Modifying legislation around the timing of coroner’s consent to DCD organ donation may facilitate an increase in the number of people receiving organ transplants from DCD donors.

In NSW, under section 25 of the Act, the coroner may give consent for organ donation for coronial cases (deaths that will be referred to the coroner for review or investigations). However, the coroner does not have jurisdiction, and cannot consent, until a person has died. There is a limited timeframe for donation to occur following circulatory death (DCD) and therefore a short time period to seek authorisation for the donation from the coroner.

While there are processes in place to ensure that the coroner can consider the issue of donation urgently after death, there are risks that the current process means that by the time the Coroner provides their consent to the donation, the organs will no longer be viable. Requiring the coroner’s consent after death, is out of step with some other states in Australia, which have legislative provisions to allow the coroner to give consent in advance in cases of DCD.

Organs from DCD donors make a significant contribution to transplant rates in NSW. Between 2012 and 2017 169 donors have donated after circulatory death and DCD presently accounts for 25 % of donors in NSW.

### Legislation in other jurisdictions

Table 2 outlines the relevant human tissue (or equivalent) legislative provisions concerning coronial consent of Australian jurisdictions other than NSW.
In all States and Territories other than NSW a coroner may give a direction on the removal of tissue from the body of a potential donor either before or after the death of that person. The provisions allow coroners in other jurisdictions in Australia the option to make a decision on donation in advance of the death of a potential DCD donor. Making that determination in advance of the death of a DCD donor minimises the time to retrieval, a factor that impacts on the number and function of organs able to be retrieved and transplanted.

NSW is the only jurisdiction in Australia where the relevant legislation does not allow a coroner to consider their decision regarding the removal of tissue before or after death.

The Human Tissue Act and related legislation could be amended to address procedures around obtaining authorisation from a coroner in cases of DCD, in order to minimise delay and increase rates of organ retrieval in coronial cases.

### Table 2: Coronial consent to the removal of tissue in jurisdictions other than NSW

<table>
<thead>
<tr>
<th>State/Territory</th>
<th>Legislative provision</th>
<th>Coroners consent prior to death (Y/N)</th>
<th>Specific provisions: A coroner...</th>
</tr>
</thead>
<tbody>
<tr>
<td>WA</td>
<td>Human Tissue and Transplant Act 1982 s23 Coroner’s consent to removal of tissue required in some cases</td>
<td>Y</td>
<td>S23(2)...may give a direction either before or after the death of a person that his consent to the removal of tissue from the body of the person after the death of the person is not required</td>
</tr>
<tr>
<td>ACT</td>
<td>Transplantation And Anatomy Act 1978 – s29 Consent by coroner—pt 3</td>
<td>Y</td>
<td>s29 (4)...may give a direction, either before or after the death of a person to whom this section applies, that a coroner’s consent to the removal of tissue from the body of the person after the death of the person is not required</td>
</tr>
<tr>
<td>NT</td>
<td>Transplantation And Anatomy Act s20 Consent by coroner</td>
<td>Y</td>
<td>s20(4)...may give a direction either before or after the death of a person to whom this section applies or may apply, that the coroner’s consent to the removal of tissue from the body of the person after the death of the person is not required</td>
</tr>
<tr>
<td>QLD</td>
<td>Transplantation And Anatomy Act 1979 s24 Consent by coroner</td>
<td>Y</td>
<td>s24(4)...may give a direction, either before or after the death of a person to whom this section applies, that his or her consent to the removal of tissue from the body of the person after the death of the person is not required</td>
</tr>
<tr>
<td>SA</td>
<td>Transplantation and Anatomy Act 1983 s23 Consent by State Coroner</td>
<td>Y</td>
<td>S23(3) The State Coroner may give a direction either before or after the death of a person that his or her consent to the removal of tissue from the body of the person after the death of the person is not required and, in that event, subsection (1) does not...</td>
</tr>
</tbody>
</table>
apply to or in relation to the removal of tissue from the body of the person.

<table>
<thead>
<tr>
<th>Country</th>
<th>Act</th>
<th>Consent by Coroner</th>
<th>Section</th>
<th>Provision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tas</td>
<td>Human Tissue Act 1985</td>
<td>Y</td>
<td>S28A(2)</td>
<td>However, before or after the death of an affected deceased person, a coroner may give a direction that his or her consent is not required under this section....</td>
</tr>
<tr>
<td>Vic</td>
<td>Human Tissue Act 1982</td>
<td>Y</td>
<td>S27(3)</td>
<td>... may give a direction either before or after the death of a person that his consent to the removal of tissue from the body of the person after the death of the person is not required</td>
</tr>
</tbody>
</table>

**Issues for consideration**

5) Should the Act be amended to allow the Coroner to give consent prior to death for organ donation (with the consent to only be acted upon after death)?

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### 7. Emerging technologies and the definition of human tissue

The definition of tissue in the Human Tissue Act 1983 states “tissue includes an organ, or part, of a human body and a substance extracted from, or from a part of, the human body”. The Act specifies that a reference to tissue includes blood, ova and semen, and foetal tissue.

The Human Tissue Act 1983 was developed from model legislation proposed by the Australian Law Reform Commission in 1975. Since 1975, growth in biotechnology has expanded the ways in which bodily tissue is able to be used for therapeutic and other purposes. These purposes might not have been contemplated when the original definition was decided. The current legislation also makes no distinction between a solid organ, such as a kidney used for transplant, tissues such as gametes used for reproductive purposes and bodily fluids such as urine used for diagnostic purposes. While these are all considered tissue by definition in the Act, they may not all require the same level of legal or policy oversight.

A number of contemporary international legislative provisions allow authorities to decide whether certain bodily materials or “tissues” should be included or excluded from legislation for regulatory purposes. For example **s53 of English Human Tissue Act 2004** excludes material such as hair and nails from living people. It also has provisions that allow regulators to determine whether certain tissue might be excluded from regulation by the UK Human Tissue Authority.

In NSW gametes are considered tissue under the Human Tissue Act 1983 and the Act regulates their removal after death. However, the donation and removal of gametes from a living person, and the subsequent use of all gametes removed is regulated under the Assisted Reproductive Technology Act 2007. This means that the same tissue is regulated in two distinctly separate ways in NSW. Being able to exclude gametes from the HTA might reduce this complexity.
There is currently no power in the NSW legislation to allow certain bodily materials to be considered for exclusion from the Act. This may result in over or under regulation of future therapies or therapeutic products. It may also lead to inconsistencies in the way tissues or products derived from tissues are treated by different pieces of legislation.

8. Submissions

The NSW Ministry of Health is calling for submission on the issues raised in the Discussion Paper. There is no special form for submissions. Submissions should be in writing and directed to:

Contact for submission:

The Office of the Chief Health Officer
NSW Ministry of Health
Locked Mail Bag 961
North Sydney NSW 2059
Email: organ@doh.health.nsw.gov.au


The closing date for comment is 3 August 2018

Individuals and organisations should be aware that generally submissions made to a Review can be made available under the Government Information (Public Access) Act 2009. The Ministry of Health, in formulating its Report may also circulate submissions for further comment to other interested parties or to publish parts of submissions. If you wish for your submission (or any part of it) to remain confidential (subject to the Government Information (Public Access) Act), this should be stated clearly and marked.