

**REVIEW OF THE REGULATION OF HUMAN TISSUE AND TISSUE-BASED THERAPIES: PAPER TWO: CONSENT FRAMEWORK FOR ORGAN/TISSUE DONATION FROM DECEASED PEOPLE**

**Proposal**

1. This paper seeks agreement to a consent framework for organ/tissue donation from deceased people for inclusion in new Human Tissue legislation.

**Executive Summary**

2. This is the second in a suite of three papers which seek agreement to a new regulatory framework for human tissue and tissue-based therapies, including agreement to:
  - repeal the Human Tissue Act 1964 and replace it with new Human Tissue legislation; and
  - regulate tissue-based therapeutic products under the trans-Tasman Joint Agency.
3. This paper:
  - proposes that new legislation adopt a consistent approach to consent across the therapeutic use of tissue (transplantation) and non-therapeutic uses of tissue from deceased people (eg., education and research)
  - outlines concerns around organ donation
  - outlines work currently underway to maximise donor rates
  - sets out the benefits and risks of three options for who can give consent to organ/tissue donation.
4. The first option is the status quo. The second option emphasises the role of the individual in making decisions about organ/tissue donation and proposes the establishment of a national consent register. The third option places greater emphasis on the role of the family in decisions about organ/tissue donation and proposes changes to the current Land Transport New Zealand driver licence register. There are substantial differences in the financial implications arising from each of the two options for change.
5. There was a range of views expressed during consultation about who could give consent to organ/tissue donation. I expect the consent framework to be the focus of intense scrutiny by organ donation advocates and health professionals. This was the most contentious issue during the public consultation process.

6. New Zealand's organ donor rate was a key concern raised throughout the Human Tissue Review. Many people believed that everyone who died could be an organ donor. However, only around 100 of the people who die in New Zealand each year are potential donors (ie. those with organs suitable for donation)<sup>1</sup> and around 40 of those become deceased organ donors.<sup>2</sup> The number is small because, in order to be a donor, a person must have been declared brain dead in an intensive care unit (ICU) and their organs maintained with a ventilator. There is, therefore, limited potential for a register to increase donation rates. Given the small pool of donors, the potential for increased donor rates stemming from a change in the consent framework is limited.
7. The purpose of the proposed amendments to the consent framework is primarily to formalise and clarify informed consent requirements, including the role that individuals and families play in the consent process. Intensive care and transplant specialists, donor co-ordinators, the New Zealand Kidney Society, and Ministry of Health officials are of the view that organ donation is best encouraged through initiatives to improve organ donation services, processes and public awareness about organ donation e.g. the establishment of Organ Donation New Zealand (ODNZ) and welfare assistance for live donors.

## **Background**

### **Linkage with Health Committee considerations**

8. In November 2003 the Health Select Committee reported on the petition of Andy Tookey and 1,169 others, which requested that the House take action to address the organ donation shortage in New Zealand. The Committee recommended that a dedicated national organ donor register be set up to replace the current system. The Government did not support this recommendation but requested that the Health Select Committee examine the likely effectiveness and cost of such a register and report back.
9. The Health Committee tabled its report on a national organ donor register in October 2004 and recommended that work on a donor register proceed independently of the Human Tissue Review [CAB Min (04) 40/1 refers]. The Government response advised that work on a national organ donor register should remain as part of the Human Tissue Review, as this will result in a register that is consistent with and appropriate to policy in this area. The options for recording donor wishes or consent are detailed in paragraphs 16 to 45 of this paper.

### **Organ Donation Rates**

10. Both in New Zealand and internationally, there are many more people who would benefit from organ transplants than are currently on the transplant waiting list. Even if organs were retrieved from every potential deceased donor, the supply of organs (especially kidneys) would still fall well short of the demand for them.

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<sup>1</sup> Streat et al 2002.

<sup>2</sup> ANZDTA 27<sup>th</sup> Report, 2004, p94

11. New Zealand's consent rate for donation (between 40–60% of those asked to donate<sup>3</sup>) is comparable with most countries, with the exception of Spain which reports consent rates of around 80 percent.<sup>4</sup> In 2004, the Australian donation rate was 11 per million population compared to New Zealand's rate of 10 per million population.<sup>5</sup>
12. The Australian and New Zealand Intensive Care Specialists Association (ANZICS) submission on the Human Tissue Review states that the large international differences in the rates of donors largely stems from significant differences in the rates of discussion about organ donation with families. Improvements in these processes is likely to have an impact on organ donation rates. Other factors also influence rates of donation such as Intensive Care Unit capacity<sup>6</sup>, reducing the road toll<sup>7</sup> and increasing survival rates from trauma.
13. Work is being done outside legislation to support coherent policy initiatives and process improvements aimed at maximising organ donor rates including, the establishment of ODNZ to provide advice on organ donation services, processes (including improving clinical practice around identifying donors and discussions with families about donation), education of health professionals and the government decision to provide welfare assistance to live donors.

## Comment

14. The following paragraphs set out proposals for a consent framework under proposed new Human Tissue legislation.

## Consent Framework For Use Of Organs/Tissue From Deceased People

15. Consent is a fundamental and complex part of the Human Tissue Review. This section details:
  - A. Who can give consent
  - B. What will require consent
  - C. Requirements for recording consent (i.e., formally recorded or not)
16. It is proposed that the consent framework for human tissue cover consent in relation to the retrieval, use, retention and disposal of tissue taken from **deceased** people in New Zealand. The Code of Health and Disability Services Consumers' Rights 1996 already provides a set of rights in relation to informed consent for living people receiving health and disability support services, including live organ donation, or participating in teaching or research in a health care setting. The proposed legislative framework is consistent with the Code where possible. The Health and Disability Commissioner Act 1994 includes a definition of informed consent. I am

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<sup>3</sup> ANZICS submission on Human Tissue Review

<sup>4</sup> Streat et al 2002

<sup>5</sup> Australia and New Zealand Organ Donor Registry 2005 Report, p2

<sup>6</sup> New Zealand has 45 ICU beds per million population, as opposed to 384 per million in France and 148 per million in Spain.

<sup>7</sup> Nearly one fifth of the 40 cadaveric organ donors in New Zealand in 2004 died as a result of road accidents, ANZOD Report 2004, p8.

proposing that the definition of informed consent in new Human Tissue legislation be broadly consistent with the definition in the Health and Disability Commissioner Act.

17. I am proposing a consistent consent framework across the non-therapeutic and therapeutic uses of tissue, particularly as tissue retrieval may occur for both purposes at the same time. Those involved in the consultation process supported the need for consistency across the various uses of tissue.

**A. Options for who can give consent and mechanism for recording consent/wishes**

18. This section details the status quo with respect to **who can give consent** to the donation of organs/tissue from a deceased person and outlines two potential options for change. It also outlines the potential mechanisms for recording the consent or wishes of the deceased. These options are summarised in **Table One**. The development of the options has been informed by feedback from the public consultation process, evidence from literature, international experience, cost/benefit implications, legal implications, feasibility of implementation and other policy/regulatory developments.

*Table One: Options for who can give consent and mechanism for recording consent/wishes*

Consent framework	Deceased's wishes known	Deceased wishes unknown	Register
<p><b>Option One: Status quo (current law and practice)</b>            Under the Human Tissue Act 1964, if a deceased person recorded their wish to donate then the person lawfully in possession of body may remove organs or tissue.            If the wishes are not known, organs or tissues may be removed if there is no objection from the family.              Current practice is that the family will be asked to consent to donation whether the wishes are known or unknown.</p>	In practice – subject to family's consent	Subject to family's consent	Land Transport Safety NZ indicative register
<p><b>Option Two: Consent of the deceased to be the primary consent</b>            The deceased's recorded wishes to be a donor must be the primary consent.</p>	Deceased's consent is the primary consent (family veto in extreme situations) or a person nominated by the deceased to give consent on their behalf (could be executor of their will) or as expressed in the deceased's will.	Subject to family's consent	Full consent register
<p><b>Option Three: Deceased's wishes important consideration</b>            Discussion about donation with family must give important consideration to the deceased's wishes, where known.</p>	Deceased's wishes followed, subject to family's consent. Wishes may be recorded on the Land Transport NZ register or in the deceased's will.	Subject to family's consent	Improved Land Transport Safety NZ indicative register



***Option one: Status quo (current legislation and current practice)***

19. Under the Human Tissue Act 1964 (the Act) a person may, before their death, record their wish to be a donor. If a person has requested that his/her body or body parts be used after death for therapeutic purposes or medical education or research, the person lawfully in possession of the body may authorise the removal of organs or tissue if they have no reason to believe that the request was withdrawn. If a person has not recorded their wishes, the Act allows the person lawfully in possession of the body to authorise the use of organs or tissue if “having made such reasonable inquiry as may be practicable” he/she has no reason to believe that the surviving partner or any surviving relative of the deceased objects to the body being used for these purposes.<sup>8</sup>
20. However, current practice is that a potential donor’s family will always be asked to agree to their deceased family member’s organs being donated whether that person indicated their willingness to be a donor during their life or not. Intensive care specialists report that the deceased’s wishes, where known, are an important part of the discussion with the family.
21. I do not support retaining the status quo because the consent framework lacks clarity and has been the subject of varying interpretations. As a result, an inconsistency exists between the law and current practice.
22. Retention of the status quo was supported by health professionals who are involved in organ donation but was opposed by many individuals and advocacy groups. Those who supported this option argued that the current system works well and is practical. Those who opposed this option thought that the system was inconsistent with the concept of informed consent, caused division and would not solve the organ shortage problem.

***Current Land Transport New Zealand register for recording donor status***

23. Currently all licensed drivers in New Zealand are required to indicate whether or not they would be willing to donate organs in the event of their death. This information is stored on the national Driver Licence Register, which is maintained by Land Transport New Zealand and is accessible by donation professionals at all times. The Land Transport New Zealand register is indicative and does not record consent to donation.
24. One of the key advantages of the Land Transport New Zealand register is the existing association between driver licensing and organ donation in New Zealand. Another is that the licensing process provides a uniquely powerful way of finding out the donor wishes of a very large percentage (89.5 percent) of the adult population at least once every ten years.

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<sup>8</sup> Under section 2(2) of the Act, the following persons are deemed to be persons lawfully in possession of bodies: a person in charge of any hospital care institution (as defined in the Health and Disability Services (Safety) Act 2001; a person in charge of any hospital within the meaning of the Mental Health (Compulsory Assessment and Treatment Act 1992; and the superintendent of any penal institution, in respect of bodies lying in those institutions

25. However, some ICU staff never access the information on the register due to concerns about the validity of the data, which may be up to 10 years out of date, while others report that they routinely use the register to check donor wishes in cases where donation is possible. There were 40 deceased organ donors in New Zealand in 2003, but the Land Transport New Zealand register was checked in only ten of the 40 cases.
26. Such an inconsistent approach to recorded wishes is not in line with many New Zealanders' expectations. Consultation revealed that people expected the register to be accessed routinely, and wanted their wishes to be given appropriate weight after their death. The Health Select Committee has also expressed concerns with the current Land Transport New Zealand register.

***Option two: requirement for deceased's consent to be the primary consent to organ/tissue donation***

27. This option requires that if a person has recorded that they wish to be an organ or tissue donor, this wish must be followed if they die in the right circumstances and are suitable to be a donor. This option would also require that where a person had stated they did not wish to be a donor, this wish is followed.
28. Generally there was a high level of support for this option in consultation because it was seen to be consistent with many people's expectations around individual autonomy and respect for the wishes of the deceased person. Support seemed to be influenced by a concern that families routinely override the known wish to donate of deceased people and that this had a major impact on organ donation rates. However, the Ministry understands that cases where the family overrides a known wish are rare.
29. There was opposition to this option from health professionals involved in organ donation largely because of concern about reducing the role of the family in the consent process and the potentially negative impact this approach may have on the organ donor programme. This option was also inconsistent with the views of most Māori and Pacific peoples who participated in consultation. For Māori, the expectation of the immediate family, in terms of cultural practices or tikanga is that they will be involved in decisions about the deceased's body and tissues.
30. The key advantages and disadvantages of this option as follows:

*Advantages*

- There was considerable support for this option from a broad range of people in consultation.
- It is consistent with a health consumer's right to informed consent as expressed in the Code of Health and Disability Services Consumers' Rights.

### *Disadvantages*

- There are practical difficulties in recording the deceased's consent and in ensuring that consent was informed. This would require a dedicated consent register and an on-going public education campaign for the entire population. The advantages and disadvantages of a register are outlined in paragraph 35 below.
31. If this option is the preferred option, I recommend that new legislation follow a similar approach to that of the United Kingdom (UK). The new UK Human Tissue Act 2004 requires that primary consent be that of the individual given before he/she dies. If he/she consented to the carrying out of a post mortem, transplantation, education or research use of organs or tissue, that consent will be sufficient to make the activity lawful. This individual could also nominate someone to consent on his or her behalf. In the absence of either of these, the decision would fall to the immediate family. However, I propose that the 'person with lawful responsibility for the tissue' (defined in paragraph 58) may not proceed with organ/tissue donation if it appears that this would cause extreme distress to the immediate family.
32. I am proposing that the 'person with lawful responsibility for the body' must have taken "reasonable steps" or "made reasonable efforts" (or words to this effect) to determine whether consent had been given prior to removing tissue. It is expected that this would include checking the organ donor consent register and also checking with the deceased's immediate family to determine whether the person had changed that decision prior to his or her death.

### *Establishment of a new register to record individual's informed consent to give effect to option two*

33. Under this option, a national organ donor consent register would be established, on which a 'yes' or 'no' to donation would be entered. A 'yes' on the consent register would allow donation to proceed regardless of the family's opinion. Similarly a 'no' to donation would not allow donation to proceed regardless of the family's opinion.
34. In consultation there was some public support for the creation of a consent register. Although many of those who supported a consent register (and a framework of requiring wishes to be followed) recognised that donation should not proceed if it would cause the family significant distress.
35. Any consent register would need to be run by the health system as Land Transport New Zealand does not have the expertise or resources to be able to ensure that consent to donation is properly informed.
36. The key advantages and disadvantages of a consent register are as follows:

### *Advantages*

- A consent register may address the concern about the public perception that the Land Transport New Zealand register records consent and not just indicative wishes.
- It provides a focus for public education activities.

## Disadvantages

- It is difficult to justify a costly consent register (refer table two) that targets all New Zealanders given the small number of potential donors. There are only around 100 potential deceased donors in New Zealand each year (ie. those with organs suitable for donation)<sup>9</sup> and around 40 of those become cadaveric organ donors.<sup>10</sup> There is, therefore, limited potential for a register to increase donation rates.
- There is a risk that donor rates may drop in the short term as numbers on the register are likely to be low initially and families may assume that the absence of an entry on the register means that their family member did not wish to donate.
- There is no evidence from international literature that this type of register improves the rate of donation. Australia, which introduced a national consent register in 2000, has seen donor numbers fluctuate over recent years.<sup>11</sup> In other countries where consent registers have been in place for at least ten years, numbers have fluctuated both before and after the introduction of a register with no impact on donor rates.
- Although it would be allowed in law, donation professionals are likely to continue to consider it unreasonable to retrieve organs without family consent. This is consistent with practice (if not law) in most other jurisdictions, including those with presumed consent frameworks (like Spain). Establishing a consent register would therefore create a misleading impression.
- As the Land Transport New Zealand register's 2.9 million recorded wishes cannot be taken as informed consent and a consent register would have to start from zero. In other countries where registers have been established it has proved difficult to populate the register.<sup>12</sup>

## Estimated Costs of a dedicated consent register

37. Provision already exists on the National Health Index/Medical Warning System (NHI/MWS) register for the recording of donor wishes. It is similar to the Australian register in that it allows for donors to specify which organs/tissue they want to donate.<sup>13</sup> If your preferred option is to establish a donor consent register, I recommend that the NHI/MWS systems be used to record donor consent.

<sup>9</sup> Streat et al 2002.

<sup>10</sup> ANZDTA 27<sup>th</sup> Report, 2004, p94

<sup>11</sup> Australian donor rates per annum

Year	1998	1999	2000*	2001	2002	2003
Number of donors	196	164	196	185	206	179

<sup>12</sup> In the UK it has taken 10 years to get 25 percent of the adult population on the register (only records 'yes'), in Australia they have 25 percent of the adult population on their current register.

<sup>13</sup> This system was set up to allow DHBs to upload wishes from the Land Transport New Zealand database. DHBs showed little enthusiasm for the idea and only one upload occurred, more than five years ago. The NHI/MWS information is very out-of-date and is never checked by intensivists.

*Funding Options for establishment and ongoing operation of a national organ donor consent register*

38. There are three funding options for the establishment and ongoing running of a national organ donor consent register depending on the scope of the register and the scope of publicity and promotion of the register. Tables two and three below set out the options in terms of low, medium and high cost. All costs are GST exclusive.
39. The costs provided are indicative and a full business case would need to be prepared if more precise estimates are to be provided.
40. *[This paragraph has been deleted on the grounds that it relates to matters which are the subject of Budget 2006 discussions].*
41. A stand alone consent register within Land Transport New Zealand is not recommended because of the difficulty of ensuring the data is up-to-date and because Land Transport New Zealand does not have the expertise or resources to be able to ensure that consent to donation is properly informed.
42. *[This paragraph has been deleted on the grounds that it relates to matters which are the subject of Budget 2006 discussions].*
43. *[This paragraph has been deleted on the grounds that it relates to matters which are the subject of Budget 2006 discussions].*

Table Two: Funding options for establishing and promoting an Organ Donor Consent register (one-off costs) to give effect to option two

*[This table has been deleted on the grounds that it relates to matters which are the subject of Budget 2006 discussions].*

Table Three: Ongoing costs of running and promoting the register (per annum)

*[This table has been deleted on the grounds that it relates to matters which are the subject of Budget 2006 discussions].*

*Comparison with other registers*

44. Officials have compared the cost of establishing an organ donor consent register with other existing registers<sup>14</sup>. Table three below provides an approximate comparison of set up and operational costs for the proposed Organ Donor Register with other national registers. While each of the national registers is unique in their uses, development, and implementation, they do provide a reasonable approximate comparison. The estimated costs of establishing and operating an organ donor consent register compare favourably with the costs of other registers, and in particular the Australian National Consent Register, which provides the most direct comparison.

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<sup>14</sup> National Immunisation Register; the Australian Organ Donor Consent Register; the proposed National Outpatient Collection; the recently developed Ministry of Education National Student Index (NSI); and the donor information keeping register established under the Human Assisted Reproductive Technology Act 2004.

Table Four: Development and implementation costs of national registers/retrievals

*[This table has been deleted on the grounds that it relates to matters which are the subject of Budget 2006 discussions].*

***Option three: Requirement for deceased's wishes to be an important consideration, immediate family makes final decision***

45. Under this option, the discussion about tissue donation with the family **must** give important consideration to the wishes of the deceased person, where these are known. However, the decision to donate would stay with the immediate family (paragraph 54 defines 'immediate family'). While this option was not specifically consulted on, it is close to what currently happens in practice. The New Zealand Kidney Foundation and Auckland Kidney Society, support this approach.
46. This option means that in the rare situation where the family has a fundamental opposition to following the known wishes of the deceased, the wishes of the family would prevail. Whilst expected to be a rare event, if the known wishes of the deceased were opposed to donation a family could consent to donation. Similarly, if the known wishes are in favour of donation a family could decide not to donate.
47. The key advantages and disadvantages of a requirement for the wishes of the deceased to be an important consideration is as follows:

*Advantages*

- Balances the expectation that a deceased individual's stated wishes will be taken into account with the reality that the family will be present and will expect to be involved in the donation process (having been involved in decision-making about the now-deceased up to this point).
- Recognises that a family overriding the known wishes of the deceased is a rare event in any case. It is expected that families who override the known wishes of the deceased will have strong and sincere views on donation.
- Recognises that there are different cultural perspectives in New Zealand on the role of the family in making such decisions.

*Disadvantages*

- Does not meet the expectations of a large number of those who participated in the public consultation process.
  - The ability for the family to override the wishes of the deceased may generate adverse publicity.
48. If this option is pursued, I expect this principle would be put into practice by, amongst other things, offering the information about a deceased's donor status on the Land Transport New Zealand register to the family, explaining its shortcomings. However, in the absence of any changes to the current register, this policy could result in a decline in organ donor rates because of the high level of "no" answers currently recorded on the register (approximately 58 percent). If this option is the preferred option, I

recommend changes to the Land Transport New Zealand register. These changes are discussed in the next section.

*Minor changes to the Land Transport New Zealand register to give effect to option three*

49. The proposed changes, and the issues they are intended to address, are as follows:
- An 'undecided' option should be added. The most likely scenario is that this will reduce the numbers of 'yes' answers as well as the number of 'no' answers.
  - The information on organ donation sent out with driver licensing forms should be reviewed and updated, with a view both to increasing donation professionals' confidence in the decisions recorded on the register, and to stimulating family discussions on organ donation.<sup>15</sup>
  - More information on organ donation and the Land Transport New Zealand register should be available through PHOs and other appropriate organisations.
50. I anticipate that, over time, the modifications will increase health professionals' and the public's confidence in the accuracy of the information recorded on the register.
51. The key advantages and disadvantages of modifying the Land Transport NZ register are as follows:

*Advantages*

- Cost effective. Of the two options for change, this approach is by far the least costly as it builds on an existing system.
- Familiarity. There is an existing association between driver licensing and organ donation in New Zealand.
- Access. The driver licensing process provides a uniquely powerful way of finding out the donor wishes of a very large percentage (89.5 percent) of the adult population at least once every ten years. Moving donor recording away from Land Transport New Zealand is likely to result in fewer recorded wishes.

*Disadvantages*

- It is not possible to include non-drivers (10.5 percent of the adult population) on the register.<sup>16</sup>
- While licence holders can change their entry on the register at any time, at no cost to the licence holder, by contacting Land Transport New Zealand, there is no practical means of assuring that a wish (that can be up to ten years old) is still accurate.

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<sup>15</sup> Organ Donation New Zealand, the body which will replace the National Donor Co-ordinators' Office, will consider how best to educate New Zealanders about the issues around organ donation.

<sup>16</sup> Land Transport New Zealand has no authority or funding to collect information on anyone who does not have a licence.

*Costs of modifications to the Land Transport New Zealand register to give effect to option three*

52. The estimated cost for adding an 'undecided' option is \$90,000 –\$190,000 (GST exclusive) for Land Transport New Zealand<sup>17</sup>. There may also need to be some adjustments to the Police after-hours enquiries system if they are still expected to handle such enquiries.
53. The estimated cost of distributing information about organ donation via other agencies, such as PHOs, retail pharmacies, DHBs, private hospitals, Public Trust Offices and the Automobile Association, is approximately \$0.3 million per annum (cost of producing and distributing information).

### **Definition Of Immediate Family**

54. In order to give effect to the proposed consent framework for the therapeutic and non-therapeutic use of tissue, a definition of family is required. The definition needs to recognise the complexity of contemporary families, Māori whānau, hapu and iwi relationships, and the relationships within other cultures such as Pacific peoples.
55. It is proposed that the new Human Tissue legislation include the following definition of '**immediate family**':

Immediate family, in relation to a dead person, -

- (a) means members of the dead person's family, whānau, or other culturally recognised family group who –
    - i. were in a close relationship with the person; or
    - ii. in accordance with the customs or traditions of the community of which the person was part, had responsibility for, [or an interest in] the person's welfare, and best interests; and
  - (b) to avoid doubt, includes a person whose relationship to the dead person was, or was through, that of spouse, de facto partner (whether the partner and dead person were of the same sex or different sexes), or civil union partner, child or step-child, brother or step-brother, sister or step-sister, parent or step-parent or guardian, or grandparent.
56. This definition of immediate family matches the definition in the Coroner's Bill<sup>18</sup> with one amendment. I am proposing that (ii) be amended by deleting the words "or an interest in" (see brackets above). This could be interpreted very broadly (i.e. could capture almost anyone) and I consider that it is inappropriate in the context of the proposed human tissue legislation and the consent framework for the retrieval, use, retention, and return or disposal of tissue from deceased people.

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<sup>17</sup> This includes the estimated IT costs of adding an 'undecided' option and amending licence application forms to include an 'undecided' option and fielding additional phone call queries about donor status

<sup>18</sup> The Coroners Bill is currently before the Justice and Electoral Committee and submissions closed on 1 April 2005. The definition of immediate family is based on recommendations of the Law Commission, which were made following public consultation.

57. A number of submitters supported the proposed definition of immediate family in principle. There was some support for either a particular person being nominated for consent purposes or listing a hierarchy of those who are able to give consent. However, on balance I consider that a broad definition is most appropriate given the variety of family structures in New Zealand, and therefore the difficulty in formalising a hierarchy in legislation.

### **Person with lawful responsibility for the body**

58. While acknowledging the importance of having someone with responsibility for a deceased body while it is in a hospital or other institution, a number of submitters to the Human Tissue Review expressed concern with the use of the word “possession” in the context of the use of tissue from deceased people and supported the use of an alternative word such as “responsibility”, “custody”, “care”, or “control”. It is proposed that the new legislation include reference to **‘the person with lawful responsibility for the tissue’**. This recognises that there are times when it is helpful for some people to have limited responsibilities/authority in relation to the control of a body/tissue for particular purposes. Under the existing Human Tissue Act, the common law rule providing the executor of the will with the right of custody over the deceased’s body takes precedence over the persons deemed under the Act to be in possession of the body.<sup>19</sup> It is intended that this would be retained in new legislation.
59. It is proposed that the person with ‘lawful responsibility for the tissue’ would be the Chief Executive, or equivalent, of the particular institution (District Health Board (DHB), funeral home, school of anatomy etc), with the ability for this responsibility to be delegated as appropriate. For example, the Chief Executive of a DHB could delegate this responsibility to the hospital manager, clinical director, a person in an organisation contracted by the DHB, or other person, as appropriate. Within DHBs, any delegation would need to be reflected in a DHB’s delegation policy under the New Zealand Public Health and Disability Act 2000 and approved by the Minister (Schedule 3, clause 39). There was general support from submitters for such a provision provided the role and responsibilities of this person were made explicit in the legislation. Māori in particular were supportive of delegation as this could be to someone with specific cultural skills in this area.
60. The new legislation would set out the role of the “person with lawful responsibility for the body” as follows:
- to ensure that consent requirements as set out in the legislation are met
  - to facilitate discussion about tissue donation with the immediate family of the deceased, particularly if the family is unable to agree on whether donation should take place.
  - to ensure the appropriate management of bodies/tissue/organs while they are in their care i.e. ensuring that the institution is in compliance with any standards approved under the legislation.

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<sup>19</sup> Section 2(2) Human Tissues Act 1964.

### ***Consent: Children***

61. I propose that prior to the retrieval, use, retention and return/disposal of tissue from a deceased child (under the age of 16 years), consent would be required from a person with guardianship of the deceased child having made reasonable attempts to consult with all other guardians of the child, consistent with the Care of Children Act 2004. When a child dies and there is no guardian then someone who is 'immediate family' as defined in paragraph 55 may give consent to the removal, retention, use and disposal/return of the child's body, organ/s or tissue.

#### **B. What will require consent**

62. I recommend that the removal, retention and use of any human tissue from a deceased person will require informed consent. This was generally supported during public consultation. Consent will need to include information on: retrieval/retrieval; all proposed uses (including education, research, commercial use, export); retention; and return/disposal.

#### ***Exceptions to the consent framework***

63. I propose that the consent framework established in legislation will not cover the retrieval, use, retention or disposal of tissue where this covered by the Coroners Act 1988 or where it is undertaken for criminal justice purposes, including for the purposes of crime prevention, or criminal investigation or prosecution. conduct of a prosecution.

This will allow law enforcement officers to gather and retain evidence in order to solve crimes and I envisage would be used to take samples from a suspect who died shortly after allegedly committing an offence, for example, in a car crash after leaving the scene of a crime.

#### ***Secondary Use***

64. Where consent was obtained for one purpose but someone wants to use tissue for another purpose for which consent was not obtained I am proposing that consent to the secondary use be obtained, subject to exceptions (refer paragraph 64). This was generally supported during consultation.

#### ***Secondary principle – exceptions to requirement for informed consent***

65. I am proposing that the legislative framework for tissue include a secondary principle that recognises certain limited circumstances where the public good associated with the use of tissue should outweigh informed consent requirements; but that safeguards need to be in place for this to happen. The safeguards proposed are based on the recent amendments to Right 7(10) of the Code of Health and Disability Consumers' Rights. Right 7(10) provides exceptions to the current informed consent provisions for the storage, preservation or use of bodily substances or body parts obtained in the course of a health care procedure, for research that has received the approval of an

ethics committee or for professionally recognised quality assurance programmes, external audit or evaluation activities that are aimed at improving the quality of services [CAB Min (03) 40/8 refers]<sup>20</sup>.

66. Feedback from the consultation process was divided on whether a secondary principle should be included in the new legislative framework for human tissue. The key reason for supporting the inclusion of a secondary principle was to ensure safety and further knowledge and treatment options through audit, research, and education. The key reasons cited in submissions that were opposed to, or cautious about, the inclusion of a secondary principle were: an overarching belief that the principle of informed consent should be paramount and exceptions are unacceptable; cultural, family or religious views, and in particular inconsistency with tikanga; and difficulty in defining the “public good”.

#### ***Limits on the return and disposal of tissue***

67. I am proposing that the new legislation place limits on the return or disposal of body parts and bodily samples, consistent with those in the Coroner’s Bill. The ‘person with lawful responsibility’ (refer paragraphs 58– 60) would be able to dispose of retained tissue without consent if the return of the tissue would present a danger to public health or safety or where all reasonable attempts had been made, but failed, to ascertain the views of the immediate family on whether the tissue should be returned.

#### ***Existing holdings of tissue and existing anatomical specimens***

68. I propose that the consent provisions will not cover existing holdings of tissue or existing anatomical specimens, that is, those that were retrieved from a human body prior to the legislation coming into force. This would include, for example, tissue held by museums, schools of anatomy, and medical schools.

#### ***Privacy issues regarding accessing health information on potential eye donors***

69. During the consultation on the Human Tissue Review the New Zealand Eye Bank raised a concern about its ability to access health information about potential deceased donors to determine donor suitability prior to initiating the consent process. I propose that the consent framework allows hospitals to provide the New Zealand Eye Bank with notification of the death of a patient and access to relevant health information, to determine the medical suitability of potential eye donors. I consider that it is in the public interest that hospitals provide information that could identify whether a deceased person who is a patient at the hospital would be suitable as a eye donor. Provision of this information allows the Eye Bank to ascertain whether it is appropriate to initiate the consent process for eye donation.

### **C. Requirements for Recording Consent**

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<sup>20</sup> The Health (National Cervical Screening Programme) Amendment Act 2004 also allows the use of cervical smears for evaluation purposes in certain cases without the specific consent of the women involved.

70. I consider that there is a need for different requirements for the recording of consent for different tissues taken from deceased people or procedures. That is, the recording of consent for whole bodies donated for anatomical examination should be more comprehensive than the recording of consent for taking blood samples. This view was generally supported in the consultation process. I am therefore proposing the following requirements for recording consent:

### ***Anatomical examination and public display***

Formally recorded consent will be required from both the individual and their immediate family, that is, consent must be given in writing or orally in the presence of two witnesses.

The current legislation allows the body of a deceased person to be used for anatomical examination if a lack of objection can be established. The current Act does not address public display of whole bodies or body parts. However, the feedback from consultation was that it is not appropriate to use the body of a deceased person for anatomical examination if their wishes were unknown because of the intrusive and prolonged nature of the process. Schools of anatomy say that this will not impact on their work because they currently receive more bequests than they need and currently require consent from both the individual and their family. This is also consistent with current practice.

### ***Organs and body parts***

Formally recorded consent will be required from the individual or their family, that is, consent must be given in writing or orally in the presence of two witnesses.

### ***Samples taken for microscopic or similar analysis***

Consent will be required but does not need to be formally recorded.

## **Consultation**

71. Details of the public consultation process undertaken by the Ministry of Health are provided in Paper One of this suite of three papers.
72. The following government agencies have been consulted on this paper: Ministry of Justice; Ministry of Research Science and Technology; Ministry of Transport; Land Transport New Zealand; Police; Te Puni Kokiri; Ministry of Pacific Island Affairs; Treasury; Ministry of Social Development, Ministry of Culture and Heritage; New Zealand Defence Force, Office of Disability Issues, Ministry of Women's Affairs; Ministry of Consumer Affairs, Department of Prime Minister and Cabinet, Ministry of Consumer Affairs, Health and Disability Commissioner; Office of the Privacy Commissioner.

The key concerns raised by other agencies are:

***Option one: Status Quo: No change to current system of recording organ donor wishes on the LTNZ driver licence register***

The Ministry of Transport and Land Transport New Zealand support the status quo because option two and option three require significant and costly changes to Land Transport New Zealand's IT systems and operational processes for no direct benefit to licence holders, or improvements to licensing processes.

***Option two: Wishes of the deceased to be primary consent and national consent register***

The Health and Disability Commissioner supports this option because it is consistent with the principle of informed consent.

The Ministry of Justice supports a framework that gives primary recognition to the deceased's consent to organ/tissue donation but doubts whether a new stand-alone register is cost effective if the new Act, and practice continues to rely heavily on the input of other family members.

***Option three: Wishes of the deceased an imported consideration, family decides and modifications to the Land Transport NZ register***

Treasury supports this option because it is the least costly option and it is anticipated that relatively small gains would be achieved under the more costly alternative.

## **Financial Implications**

*Paragraphs 73 to 75 relate to the financial implications arising from the establishment of an organ donor consent register and have been removed on the grounds they relate to matters which are the subject of Budget 2006 discussions].*

## **Improvements in the Land Transport New Zealand intent register**

76. The estimated cost of improvements to the existing Land Transport New Zealand indicative register to give effect to option three are \$90,000 – \$190,000 (GST exclusive). This would be a cost to Vote Transport. There would also be additional costs to Vote Health of around \$0.3 million per annum for production and distribution of information about organ donation via other agencies such as PHOs, retail pharmacies, DHBs, private hospitals, Public Trust Offices, and the Automobile Association.
77. Currently, driver licences are issued on a cost-recovery basis, with licensing fees covering all associated costs. Land Transport New Zealand advise that they would not be able to absorb the cost of modifying the register within their existing budget and they would either require new funding from government or the cost would have to be passed on via licensing fees.

## **Funding Options**

78. I propose that the Ministry of Health, having consulted with Treasury, the Ministry of Transport, and Land Transport New Zealand, reports back to the

Cabinet Committee on Government Expenditure and Administration as soon as possible with:

**Either**

- a fully scoped and costed business model for the establishment, promotion and ongoing operation of a national organ donor consent register and with options for funding the register (the Ministry estimates that this exercise will take three to six months to complete), if 'wishes to be followed' is the preferred option for consent (option two)

**Or**

- a fully scoped and costed business model for amendments to the Land Transport New Zealand driver licence register if wishes to be an important consideration is the preferred option for consent (option three).

79. *[This paragraph has been deleted on the grounds that it relates to matters which are the subject of Budget 2006 discussions].*

## **Legislative Implications**

80. This paper proposes to repeal the Human Tissue Act 1964 and replace it with new legislation. Legislative change is necessary because increasingly issues are raised that either fall outside the scope of the current legislation or are subject to legal interpretation.

81. New Human Tissue legislation will:

- not limit the jurisdiction of the Code of Health and Disability Services Consumers' Rights 1996
- not limit the jurisdiction of the Coroners Act (the Coroners Bill 1988) is currently before the Justice and Electoral Committee).

## **Human Rights/Bill Of Rights**

82. Overall the proposals contained in this Cabinet paper appear to be consistent with the New Zealand Bill of Rights Act 1990, and the Human Rights Act 1993. A final view as to whether proposals will be consistent with the Bill of Rights Act will be possible once the legislation has been drafted.

## **Gender Equity**

83. There are no specific gender equity issues associated with these proposals.

## **Disability Perspective**

84. There do not appear to be any specific disability-related issues to note at this stage.

## **Publicity**

85. I recommend that the suite of Cabinet papers relating to a new regulatory framework for human tissue and tissue-based therapies and the Regulatory Impact Statement/Business Compliance Cost Statement be published on the Ministry of Health website. I also recommend that a copy of each of the three papers be forwarded to the Health Select Committee.

## Recommendations

86. It is recommended that you:

### Background

- 1 **Note** that the key objectives of the consent framework for tissue donation are to:
  - clarify the consent process for the public and clinicians
  - to promote good clinical practice and processes (e.g. includes consideration of individuals views and promotes national consistency)
  - to the extent possible, balance the expectations of New Zealanders regarding who can give consent for organ donation, recognising that there is a diversity of views amongst New Zealanders on this issue
  - address the need for public confidence in the consent process for tissue retention following non-coronial post-mortem examinations (e.g. Greenlane heart register).
- 2 **Note** that the policy proposals in this paper have been developed following an extensive public consultation process, further discussions with those involved in the human tissue sector and additional hui.

### Consent framework for tissue donation

- 3 **Agree** that the consent framework cover consent in relation to the retrieval, use, retention and disposal of tissue from deceased people only.
  - 4 **Note** that the Code of Health and Disability Services Consumers' Rights 1996 already provides a set of rights in relation to informed consent for living people receiving health and disability support services, including live organ donation, or participating in teaching or research in a health care setting.
  - 5 **Agree** that the consent framework established in new Human Tissue legislation will be consistent across all uses of tissue, including therapeutic uses (transplantation) and non-therapeutic uses (e.g. education and research).
  - 6 **Agree** that the definition of informed consent be broadly consistent with the definition in the Health and Disability Commissioner Act.
- A. Who gives consent to tissue/organ donation and the mechanism for recording consent**
- 7 **Note** that public views expressed during public consultation on the Human Tissue Review were divided on whether the families' wishes or the deceased's

wishes on organ donation, if known, should prevail, with strong support for both options.

***Option one: status quo***

- 8 **Note** that the status quo is that organ donation can proceed if the person with possession of the body can establish a lack of objection to donation.
- 9 **Agree** that the status quo is not the preferred option for who can give consent because it does not meet the key objectives of a consent framework.
- 10 **Agree** to one of the following two options for who can give consent to the use of tissue (including whole organs):

**EITHER**

***Option two***

10.1 **Agree** that:

- 10.1.1 The primary consent to organ donation would be that of the individual if formally recorded before he/she dies
- 10.1.2 The individual could also nominate someone to consent to donation on his/her behalf.
- 10.1.3 In the absence of either of 10.1.1 or 10.1.2, the decision will fall to the immediate family.
- 10.1.4 A national organ donor consent register be established to record the consent or objection of an individual to organ/tissue donation.

**OR**

***Option three***

10.2 **Agree** that:

- 10.2.1 The wishes of the deceased, where known, must be an important consideration in any discussion about donation but that the immediate family would make the final decision about donation.
- 10.2.2 Minor changes are made to the Land Transport New Zealand register to include an undecided option and additional publicity around organ donation.

***Definition of immediate family***

- 11 **Note** that in order to give effect to the proposed consent framework, a definition of family is required. The definition needs to recognise the complexity of contemporary families, Māori whānau, hapu and iwi relationships, and the relationships within other cultures such as Pacific peoples.

12 **Agree** that the legislation include a definition of 'immediate family' as follows:

Immediate family, in relation to a dead person, -

- (a) means members of the dead person's family, whānau, or other culturally recognised family group who –
  - i were in a close relationship with the person; or had
  - ii. in accordance with the customs or traditions of the community of which the person was part, responsibility for the person's welfare and best interests; and
- (b) to avoid doubt, includes a person whose relationship to the dead person was, or was through, that of spouse, civil union partner, de facto partner (whether the partner and dead person were of the same sex or different sexes), civil union partner, child or step-child, brother or step-brother, sister or step-sister, parent or step-parent or guardian, or grandparent.

***Person with lawful responsibility for the body***

13 **Agree** that a person be given lawful responsibility for the tissue and that this person should be the Chief Executive or equivalent of the particular institution where the body/tissue is collected or retained (such as, DHB, funeral home, school of anatomy) with the ability to delegate that responsibility as appropriate.

14 **Agree** that the role of the person with lawful responsibility for the body is to:

14.1 ensure that consent requirements as set out in the legislation are met.

14.2 facilitate discussion about tissue donation with the immediate family of the deceased, particularly in cases where the family is unable to agree on whether or not donation should take place.

14.3 ensure the appropriate management of tissue while it is in that person's care i.e. ensuring that the institution is in compliance with any standards approved under the legislation.

***Consent: Children***

15 **Agree** that prior to the retrieval, use, retention and return/disposal of tissue from a deceased child (under the age of 16 years), consent would be required from a person with guardianship of the deceased child having made reasonable attempts to consult with all other guardians of the child, consistent with the Care of Children Act 2004. When a child dies and there is no guardian then someone who is 'immediate family' may give consent to the retrieval, retention, use and disposal/return of the child's body, organ/s or tissue.

**B. What will require consent**

16 **Agree** that consent be required for the retrieval, use, retention, and disposal of all human tissue where human tissue covers whole bodies through to blood,

cell lines derived from tissue, genetic material, stillborn children, and foetal tissue (refer Paper One).

### ***Exceptions***

- 17 **Agree** that the consent framework established in legislation will not cover the retrieval, use, retention or disposal of tissue where this is covered by the Coroners Act or where it is undertaken for where it is undertaken for criminal justice purposes, including for the purposes of crime prevention, or criminal investigation or prosecution.

### ***Secondary Use***

- 18 **Agree** that where consent was obtained for one purpose but someone wants to use the tissue for another purpose, consent to the secondary use of the tissue must be obtained, subject to exceptions (refer recommendation 20).
- 19 **Agree** that a person does not commit an offence if he/she reasonably believed that the necessary level of consent was in place.

### ***Secondary Principle***

- 20 **Agree** to the inclusion of a secondary principle that recognises certain limited circumstances where the public good associated with the use of human tissue should outweigh the informed consent requirements and that these exceptions are as follows:
- 20.1 research that has received the approval of an ethics committee
- 20.2 professionally recognised quality assurance programmes; or external audit or evaluation activities that are aimed at improving the quality of services.

### ***Limits on the return or disposal of tissue***

- 21 **Agree** that the 'person with lawful responsibility for the body' will be able to dispose of retained tissue without consent if the return of the tissue would present a danger to public health or safety or where all reasonable attempts had been made, but failed, to ascertain the views of the 'immediate family' on whether tissue should be returned.

### ***Existing holdings of tissue***

- 22 **Agree** that the consent provisions will not cover existing holdings of tissue or existing anatomical specimens, that is, tissue retrieved and retained prior to new legislation coming into force.

### ***Accessing health information on potential eye donors***

- 23 **Agree** that the consent framework include provision for hospitals to provide information to the New Zealand Eye Bank with notification of the death of a patient and also access to relevant health information, to determine the medical suitability of potential eye donors.

### C. Requirements for recording consent

- 24 **Agree** that the legislation include the following requirements for recording consent:

#### ***Anatomical examination and public display***

Formally recorded consent, that is, in writing or orally in the presence of two witnesses, from both the individual and their immediate family

#### ***Organs and body parts***

Formally recorded consent, that is, in writing or orally in the presence of two witnesses

#### ***Samples taken for microscopic or similar analysis***

Consent must be given but does not need to be formally recorded.

### Legislative Implications

- 25 **Note** that the above proposals will require the repeal of the Human Tissue Act 1964 and the drafting of a new Human Tissue Bill (“the Bill”).
- 26 **Note** that the proposals contained in this paper will not limit:
- 26.1 the jurisdiction of the Code of Health and Disability Services Consumers’ Rights 1996
  - 26.2 the jurisdiction of the Coroners Act 1988 (A new Coroners Bill is currently before Parliament).
- 27 **Agree** that the new Human Tissue legislation will repeal Part 3A of the Health Act 1956, which covers trading and collection of blood and controlled human substances.
- 28 **Agree** that the legislative changes will be binding on the Crown.
- 29 **Invite** the Minister of Health (Hon Annette King) to issue drafting instructions to Parliamentary Counsel Office to give effect to Cabinet’s decisions on those of the above recommendations to be effected through the new Human Tissue Act.
- 30 **Note** that the Human Tissue Bill has priority four on the Government’s legislative programme.

### Publicity

- 31 **Agree** that this paper along with the other two papers in the suite of papers relating to a new regulatory framework for human tissue and tissue-based therapies be publicly released on the Ministry of Health’s website.

Hon Annette King  
**Minister of Health**