

Part A: Introducing the Review

The Ministry of Health is reviewing the use of human tissue for therapeutic and non-therapeutic purposes. This discussion document is part of the Review and will inform the development of new legislation, standards and frameworks for practice.

Currently the regulatory framework for human tissue spans a number of acts and regulations. It is considered to be out of date, and it is not comprehensive. Increasingly, issues are being raised which fall either outside the scope of current arrangements, or into areas that are subject to varying interpretation. These types of problems are being driven by technological developments and scientific research. The rights and expectations of the public have also become more sophisticated since legislation such as the Human Tissue Act 1964 was passed.

The Review, and this document, are focused on how the current regulations governing the use of human tissue can be updated, and made more comprehensive and streamlined. The Review may signal issues for service delivery and practice, but its primary focus at this stage is the regulatory environment.

In presenting this document the Ministry acknowledges work undertaken overseas that has been very valuable. In particular, work by the Department of Health and the NHS Department of the Welsh Assembly (2002) on the non-therapeutic uses of human tissue, and work by the Australian Therapeutic Goods Administration (2003) on a safety regime for the therapeutic uses of human tissue. The Ministry is also very grateful to those who have shared their initial thoughts on the issues in this document through meetings and discussions.

A1 Goals of the Review

The use of human tissue in research, the study of anatomy and treatment is fundamental to achieving better health and disability support outcomes for individual New Zealanders and population groups. Using human tissue is also intensely personal and raises fundamental questions about how individuals and groups view their bodies, life and death. A new regulatory framework needs to recognise and balance these issues. The Ministry wishes to design a regime that recognises the very personal nature of human tissue and protects the beliefs and sensitivities that surround its use, while allowing the advancement of research and technology that can improve health and disability support outcomes.

The goal of the Review is to develop a new regulatory framework for human tissue that:

- appropriately promotes the cultural and spiritual needs of New Zealanders and the public good associated with the use of human tissue for therapeutic and non-therapeutic purposes
- addresses the safety of tissue for therapeutic and non-therapeutic use

- is flexible to respond to advances in technology that cannot be predicted at this stage
- as far as practicable streamlines the legislation relating to human tissue
- is comprehensive and easily understood by New Zealanders.

A2 Scope of the Review

A2.1 What is human tissue?

For the purposes of the Review, 'tissue' is defined as including:

- a whole human body
- parts of a human body, such as the brain, an arm or leg, or the torso
- bone
- whole organs such as the heart, lungs, kidneys or liver
- parts of organs, such as heart valves
- other tissue, such as corneas, skin or tendons
- tissue specimens
- foetal material
- cellular material²
- cell lines, and other tissue that is grown or cultured.

Tissue may be living or dead, and may have been manipulated or altered. The Review also discusses xenotransplantation – the transplantation of live animal tissue into humans for therapeutic purposes. The use of animal tissue only arises in relation to xenotransplantation.

The definition of tissue excludes:

- donated blood and blood products as defined in the Health Act 1956 (see Appendix 5)
- human sperm and eggs (gametes) and human embryos (up to 14 days development) that are outside the human body
- X-rays or other images of tissue
- secreted substances, such as breast milk
- animal tissue (except as described in the section on xenotransplantation).

² This includes material derived from embryos (such as stem cells) that is proposed for uses other than human reproduction.

We are seeking your views

1. As you go through this document and consider the many issues within it, please consider the above definition of tissue and let the Ministry know if you think the definition should be changed and why.

A2.2 What does the Review cover?

The Review and this document cover issues related to the:

- collection, use, retention, storage and disposal of human tissue for non-therapeutic purposes
- management, oversight and monitoring of the use of tissue for non-therapeutic purposes
- existing privacy arrangements for genetic information (able to be derived from human tissue)
- safety of tissue-based therapeutic products, including whole organs for transplantation, stored and banked tissue, and other tissue-based therapeutic products
- legislative arrangements for organ and tissue donation
- regulation of the importation and exportation of human tissue
- sale and purchase of tissues.

A2.3 What does the Review not cover?

The Review does not cover a number of issues that are currently (or soon will be) regulated under other legislation. The Review is, however, examining how other legislation works in order to ensure consistency and to learn lessons from successfully operating systems.

The Review does not cover:

- the creation and use of human reproductive tissues and cells (ie, in-vitro embryos and gametes); these are covered by the Supplementary Order Paper to the Human Assisted Reproductive Technology Bill, although the human tissue review does include the collection and use of foetal tissue and the use of embryonic cells and cell lines for non-reproductive purposes (the interface between this Review and the proposed reproductive technology legislation is explained in section B2.5)
- the coronial system and the conduct of coronial post-mortem examinations, which are covered by the Coroners Act 1988 and where the Ministry of Justice is leading a review³

³ In August 2000 the Law Commission reported on its review of coroners. In order to address the recommendations of the Commission, the Ministry of Justice is leading a review of the Coroners Act 1988.

- human tissue collected as part of a forensic investigation of a crime, which is covered by the Criminal Investigations (Blood Samples) Act 1995 and the Criminal Investigations (Bodily Samples) Amendment Act 2003
- the genetic modification of human cells and tissues, which is regulated by the Hazardous Substances and New Organisms Act 1996.

The Review is also not covering service or resource allocation issues associated with organ and tissue donation for transplantation. The Ministry is considering these issues in a separate process, which involves the National Donor Co-ordination Office and District Health Boards. The regulatory framework for organ and tissue donation is discussed in section C4.

A2.3.1 Donated blood and blood products

The Review will not revisit the regime regulating the therapeutic use of donated blood and blood-related products, which operates under the Health Act 1956 (see Appendix 5). This regime was thoroughly reviewed in 1998 and is considered to be operating well. However, blood-related examples may be used in this document to illustrate some of the issues. There is also the potential to bring the regime from the Health Act into a new framework for tissue-based therapies, as the Health Act itself is currently under review.⁴

A3 Cultural and religious perspectives

Different cultures, social groups and genders have different world views. A world view will guide an individual's or group's interactions with others and the environment. A world view may be based on religious beliefs, economic beliefs, political beliefs or other tenets. New Zealand is a culturally and socially diverse country and different groups in our society may have different responses to the issues raised in this document.

The use of tissue for therapeutic and non-therapeutic purposes, and the regulation of these activities, may be of specific interest to different cultural and religious groups for which tissue may have symbolic significance. It is worth noting, however, that while concerns may be based in a particular cultural or religious belief, they may be shared by the population more generally. The discussion in sections B4 and B5 regarding informed consent is particularly relevant in this regard, as is section B6, which discusses an approach to tissue management, and D1, which refers to respect for tissue.

Through the consultation process the Ministry is interested in hearing different perspectives on the issues in this document. As a result of feedback from consultation, an important consideration for the new regulatory framework will be what issues are best addressed through legislation, and what issues are best addressed through standards or guides to practice.

⁴ Readers interested in the review of the Health Act, which proposes a new Public Health Bill, should visit the Ministry of Health website (www.moh.govt.nz) for further information.

A3.1 Māori issues

The Ministry is aware that Māori may have a particular interest in tissue concerns and recognises the importance of working to ensure Māori are given the opportunity to experience the same health status as non-Māori. One way to improve health outcomes for Māori is to ensure that policy and practice allow the expression of Māori values as well as those of other cultures.

In terms of the development of a new regulatory framework for human tissue, this points to a role for Māori in contributing to the development of the new legislative framework, and Māori participation in the consultation process is encouraged.

The Ministry has held initial discussions with an informal reference group of Māori health and policy professionals about the issues that may arise in the human tissue area for Māori. A key part of that discussion was the need to ensure that assumptions should not be made about the views that Māori may hold about tissue concerns. For example, it impacts negatively on health outcomes for all New Zealanders if it is simply assumed that Māori will not be comfortable about a technology such as organ transplantation. If organ transplantation is not discussed with Māori as a treatment option, conversations about organ and tissue donation may not arise within Māori communities, thus having a broader impact on society.

The need for an understanding of, and good processes to support, Māori approaches to deceased persons and tissue in general were also highlighted. This includes, for example, the respectful management of tūpāpaku (deceased persons) and recognition of the roles of family and whānau at the time of death.

A3.2 Pacific peoples

Pacific peoples are a significant cultural group in New Zealand and the views they have about the issues raised in this document are welcomed. The Ministry does not want to make assumptions about the views that Pacific people may have about tissue-related matters. It is aware, however, that the following issues may arise for some Pacific people. (This material is drawn from consultation undertaken with Pacific people regarding the management of blood samples, and the concepts may extend to tissue more generally.)

- Blood is a treasure, should be treated with respect, and should not be misused or wasted.
- Blood contains genealogy and important family traits.
- Blood, for Pacific people with a Christian perspective, can be seen as a 'symbol of hope'. Thus when a person gives their blood they do so in the hope that it would be useful and could contribute to improving health (Koloto and Associates Ltd 2003).

Other concepts that may be expressed by Pacific people include:

- a preference that the body of a deceased person remain intact
- a preference that a deceased person be buried rather than cremated
- the importance of treating the body of a deceased person with dignity and respect (Department of Health 1987b).

It is important to note that these concepts do not mean that Pacific people do not approve of, or do not wish to access, tissue-based technologies. Rather, they highlight the importance of good communication with Pacific people about these issues. For example, an American programme that used face-to-face dialogue, culturally appropriate communicators, and culturally appropriate messages made a significant impact on how minority groups responded to initiatives to increase the rate of organ donation (Callender et al 1997).

A3.3 Religious groups

New Zealand is a multi-faith country, and the Ministry is conscious that any religious beliefs a person holds may affect their reactions to some of the issues raised in this document. It is not possible to summarise all the different religious perspectives that may be brought to bear on tissue matters, and the Ministry does not purport to be an authority on these matters. In order to inform your reading of this document, the Ministry has looked to a conference held in the United Kingdom in 2000, which brought together the leaders of many faiths to discuss organ and tissue donation and transplantation. The conference, Organ Donation and Transplantation: The Multi-faith Perspective Conference, noted that:

- there is a strong consensus in favour of organ donation from the major faiths
- the notion of helping another person through giving of oneself is central to many faiths
- it is important not to assume that a person will hold a particular view about organ donation because of their faith or cultural group
- there are many myths and misconceptions that surround organ donation, and these may be exacerbated by institutional procedures and cultural barriers
- being able to sell or purchase organs for donation may be unacceptable
- there is a significant challenge in communicating with the public in this area and people need clear and accurate information; religious leaders have a central role in sharing information with their communities
- treating people with dignity is paramount – be they potential donors of tissue or potential recipients (Proceedings 2000).