Review of the Regulation of Human Tissue and Tissue-based Therapies
Discussion document
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Executive Summary

The regulatory framework for human tissue spans a number of acts and regulations. This creates confusion, and there are gaps in the framework.

New and emerging technologies, changes in societal attitudes, and ethical, cultural and spiritual issues arising out of the use of human tissue have led the Ministry of Health to review the regulation of human tissue and tissue-based therapies. The goal of the Review of the Regulation of Human Tissue and Tissue-based Therapies is to put a new regulatory framework in place 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 enough 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.

One of the important issues in developing the framework is ensuring an appropriate balance between the cultural and spiritual needs of New Zealanders, and the public good associated with access to tissue for therapeutic benefit and non-therapeutic uses such as education or research.

The purpose of this document is to set out the key policy issues that require consideration in developing a new regulatory framework. Following consultation on this document, the Ministry of Health will be providing advice to the Minister of Health and the Government on a proposed approach to governing the human tissue area. It is likely that both legislative and non-legislative changes will be recommended. It is expected that new legislation will be in place by June 2005, when provisions in the Medicines Act regarding xenotransplantation will expire.

Notwithstanding the need to decide on the detail of the policy issues, it is proposed that the regulatory regime could comprise:

- a new Human Tissue Act
- amendments to therapeutic products regulation
- use of the provisions of the Health and Disability Services (Safety) Act
- use of the provisions of the Health Act 1956 relating to ‘controlled human substances’
- other regulations, guidelines or codes of practice.
A new Human Tissue Act

It is proposed that a new Human Tissue Act be developed to regulate the collection and use of tissue from deceased persons for therapeutic and non-therapeutic purposes. In particular, it is proposed that the new Human Tissue Act include:

- a requirement that tissue from deceased persons be treated with dignity and respect, including respect for cultural sensitivity
- consent requirements for non-coronial post-mortem examinations and anatomical examinations
- consent requirements for the collection of tissue for research and education, including when tissue is to be collected at the time of a non-coronial post-mortem examination
- provisions for the collection of tissue for therapeutic purposes (organ and tissue donation)
- definitions of who is able to give consent for tissue use on behalf of a deceased person
- provisions regarding the sale and purchase of tissue
- provisions that allow new tissue-based technologies to be controlled while they are assessed for acceptability and safety.

Amendments to therapeutic products regulation\(^1\)

It is proposed that a comprehensive regime be put in place to ensure the safety of tissue-based therapeutic products. The proposed regime could add a new part to therapeutic products regulation and develop standards as described below under the Health and Disability Services (Safety) Act. It is envisioned that, in time, the regime for the safety of tissue-based therapeutic products could come under the jurisdiction of the Joint Therapeutic Products Agency.

The amendments would include:

- a definition of tissue-based therapeutic products based on an assessment of the risk associated with a particular product
- a definition of the activities to be regulated
- a definition of the people to be regulated.

\(^1\) Work is under way to replace the Medicines Act 1981, to implement the joint therapeutic products regulatory scheme and to regulate New Zealand-specific aspects of medicines regulation. The specific vehicle for tissue-based therapeutic products will be considered at a later date.
Standards under the Health and Disability Services (Safety) Act 2001

The Health and Disability Services (Safety) Act provides a framework for setting safety standards in the health and disability sector. When this Act was developed it was anticipated that tissue-based services would be regulated in the future, and the Act has made provision for standards to be developed for this purpose. This document suggests that formal standards could be developed for:

• tissue banking
• whole organ retrieval and transplantation.

These standards would draw on voluntary codes and standards that have been developed by those involved in these services.

This document also proposes that a more comprehensive form of oversight for non-therapeutic use of tissue be developed. A considerable body of information exists in this area, but it is scattered and in some cases its status is unclear. Some is becoming out of date. One option is for a tissue management standard to be developed and monitored under the Health and Disability Services (Safety) Act. This would require an amendment to this Act and the development of a standard. Your feedback on this proposal is welcomed, as are other suggestions for achieving the objective of comprehensive oversight without imposing unnecessary costs on to the health and disability sector.

Health Act 1956

As part of the overall framework for the safety of tissue-based therapies, this document suggests that it may be appropriate to use the provisions in the Health Act 1956 to recognise particular entities as being authorised to collect controlled human substances. The Health Act could also be used to prevent trade in controlled human substances.

Other regulations, codes, or guidelines

To complete the framework for human tissue, this document has asked for your comments on a number of other regulations, codes or guidelines.

• Health (Retention of Health Information) Regulations 1996 – following changes to the relevant regulation-making powers, this document seeks your initial comment on the issues to be addressed in requiring specimens to be retained in the same way as other health information.

• Health Information Privacy Code – in response to the increasing focus on genetic information, this document seeks your comment on the coverage of the Health Information Privacy Code in relation to genetic information, and specimens in particular.
• Import and export of tissue – it is suggested that the import and export of tissue could be covered by a code of practice.
• Your comment is also sought on whether or not more detailed guidance is needed to assist ethical decision-making about the use of foetal tissue for non-therapeutic purposes.

How this document is organised
This document covers a considerable number of complex and interrelated issues. It is divided into the following parts:
• Part A: Introducing the Review
• Part B: Non-therapeutic use of tissue
• Part C: Therapeutic use of tissue
• Part D: Common concerns for all uses of tissue
• Part E: Looking toward a regulatory framework.

The distinction between therapeutic and non-therapeutic tissue is whether the tissue itself is to be used as a therapeutic product or treatment. For example, organ donation is discussed in the section on therapeutic uses, while tissue donated for research is discussed in the non-therapeutic uses section.

How to have your say
This discussion document is being widely distributed among health service providers, university departments, researchers, consumer groups, government agencies, and other organisations and individuals with an interest in the regulation of human tissue. Further copies of this document are available from the Ministry of Health, and from the Ministry’s website (www.moh.govt.nz).

The Ministry welcomes submissions on the issues raised in this document. The closing date for submissions is Friday 4 June 2004.

Submissions may be made easily through the Ministry of Health’s website. All the questions in this document and an electronic template for your responses can be found at: www.moh.govt.nz.

Or send your postal submission to:
The Human Tissue Review
Sector Policy Directorate
Ministry of Health
PO Box 5013
WELLINGTON.
During April and May consultation workshops to discuss the issues in this document will be held in Auckland, Wellington, Christchurch and Dunedin. Hui will also be held. If you are interested in attending, please let the Ministry know by completing and returning the enclosed sheet. For any other queries you can email the Ministry at humantissue@moh.govt.nz, or telephone 04 496 2244.

All submissions received will be considered and analysed before policy advice is developed for the Minister of Health.

This document covers many issues and your views are welcomed on any of the issues raised. However, if you are specifically interested in only a few areas, please focus your comments on these. It would help the analysis of submissions if your comments were referenced to either the specific questions raised throughout this document or to the relevant section of this document. To assist you in making a submission, the questions raised throughout the document are summarised at the end.

If you are making a submission on behalf of an organisation, please describe the organisation and its interest in relation to the regulation of human tissue, identify your position within the organisation, and indicate the extent of any consultation or discussion you have undertaken within your organisation. If you are making a submission individually, please indicate the reason for your interest in the regulation of human tissue (eg, as a consumer of health or disability support services, researcher or health practitioner).

Please note that all correspondence and submissions may be the subject of a request under the Official Information Act 1982. If there is any part of your correspondence that you consider could properly be withheld under that Act, please include comment to that effect and give reasons why you would want it withheld. The justifications for withholding information under the Official Information Act 1982 are contained in Appendix 1.
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 material
• 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 review\(^3\)

\(^3\) 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 extent 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).
Part B: Non-Therapeutic Use of Tissue

This Part of the discussion document is concerned with the use of human tissue for non-therapeutic purposes. These purposes and the current regulatory framework are described, and the key problems are identified. Sections B4 to B10 then discuss issues to be covered by a new regulatory framework.

B1 Non-therapeutic uses of human tissue

Human tissue has a number of non-therapeutic uses. It is crucial to many aspects of diagnosis and treatment, population health programmes, illness prevention, and extending our understanding of the human body and its functions.

The main non-therapeutic uses of tissue are as follows.

B1.1 Diagnosis and other uses as part of health care

Tissue is used as part of the care of individual health care consumers, or may result from such care. For example, a small tissue sample (a biopsy) may be taken for testing to assist a health practitioner with diagnosis; or tissue, such as placenta or an appendix, may result from childbirth or a surgical procedure. The proposals in this document are not generally concerned with tissue obtained during a health care procedure except where this tissue may be used for another non-therapeutic purpose (eg, tissue resulting from surgery that is donated and subsequently used in research or education). This situation is discussed in later sections.

B1.2 Anatomical examination

Whole bodies of deceased persons that have been bequeathed with consent are dissected and examined by health practitioners during their education (eg, medical students or physiotherapy students). This allows a detailed examination of the structure of the human body and how the components relate to each other.

B1.3 Education and training

Tissue from living or deceased persons is used for education and teaching. For example, health practitioners may study preserved specimens before undertaking a complex procedure on a patient, or may study microscope slides of tissue as part of in-service training within hospitals (particularly in teaching diagnosis skills). Tissue samples may also be used as part of other teaching programmes or courses to enhance the quality of care for New Zealanders.
B1.4 Research

Our understanding of the human body, its ailments and potential treatments is expanding rapidly, and human tissue is vital for such research. The research uses for human tissue are many and varied. For example, the Human Brain Bank in Auckland uses donated tissue to research the causes and potential ways of treating neuro-degenerative diseases of the brain (eg, Alzheimer’s, Parkinson’s and Huntington’s disease), and the Otago School of Dentistry is studying tissue samples to determine if there is a link between oral cancer and the yeast that causes oral thrush. Research over the years using human tissue has also vastly increased our understanding of, and ability to treat or minimise the impact of, heart disease, cancer, HIV/AIDS and many other diseases.

B1.5 Determining the cause of death, or gathering more information about an illness, through a post-mortem examination

The majority of post-mortem examinations are now undertaken under the authority of the coroner when required under the Coroners Act 1988, such as when the cause of death is otherwise unable to be ascertained (coronial post-mortems and the Coroners Act are under review by the Ministry of Justice). However, a non-coronial or hospital post-mortem may be requested by the family of the deceased or by the physician to provide further information about the cause of death of a person.

B1.6 Clinical audit

A clinical audit for quality assurance purposes may include examination of preserved tissue, such as specimens stored on microscope slides. This type of audit would usually be undertaken on existing tissue collections (such as those used for clinical purposes, described above).

Note that the above categories of non-therapeutic tissue use do not stand alone. Tissue collected for anatomical examination may be preserved and used subsequently for education or research. Tissue collected for clinical purposes may be valuable for researchers, and a post-mortem examination provides a practical time to collect tissue, with consent, for other purposes.
B2 Current regulation of tissue for non-therapeutic use

The regulation of non-therapeutic tissue use spans a range of acts and regulations. These are listed below and then described. Much of the current regulatory framework is currently being amended or reviewed.

- Human Tissue Act 1964 – governs the collection of tissue from deceased persons for anatomical examination, education, and research. It also provides for non-coronial post-mortem examinations, schools of anatomy and inspectors of anatomy.
- Code of Health and Disability Services Consumers’ Rights 1996 – sets out the rights of consumers of health and disability support services and the responsibilities of providers.
- Operational Standard for Ethics Committees 2002 – provides the operating procedures for health and disability ethics committees.
- Supplementary Order Paper to the Human Assisted Reproductive Technology Bill 1996 – proposes a framework for the regulation of assisted human reproductive procedures and research. Certain unacceptable activities will be prohibited, and all applications to undertake human reproductive research and non-established procedures will require ethical approval.
- Health (National Cervical Screening Programme) Amendment Act 2004 that has recently amended the Health Act 1956 to give effect to some of the recommendations of the Gisborne Cervical Screening Inquiry.
- Health Information Privacy Code 1994 – provides protection for health information relating to identifiable individuals.

Health practitioners are also regulated and practise under professional codes and can be subject to disciplinary proceedings. Employers, such as District Health Boards, also have codes of confidentiality and good practice as part of their terms of employment.

B2.1 Human Tissue Act 1964

The Human Tissue Act is contained in Appendix 2. The Act is concerned with the bodies of deceased persons (excluding stillborn children) and their use in medical education, research, post-mortem examination and anatomical examination. The Act is particularly focused on anatomical examination and schools of anatomy.

[The Act also provides the legislative base for the collection of tissue from deceased persons for therapeutic uses; namely, organ and tissue donation. Issues relevant to organ and tissue donation are discussed in Part C of this document.]
For all uses of tissue covered by the Act, the Act requires decency to be observed. This requires any person performing an examination or removing any part of a body under the Act to do so in a way that avoids unnecessary mutilation of the body and in an orderly, quiet and decent manner.6

B2.1.1 Requirements for tissue collection and use

The Act sets out the requirements to be met before:

- tissue can be removed from the body of a deceased person for medical education or research
- a hospital may conduct a post-mortem examination
- the body of a deceased person may be released to a school of anatomy.

With regard to obtaining consent, or, as it is phrased in the Human Tissue Act, establishing a ‘lack of objection’, the Act distinguishes between when the wishes of the deceased person are known and when they are not known. Table B1 provides a summary of the consent provisions in the Act. In each of these cases, the person lawfully in possession of the body of the deceased must be sure that an inquest or coronial post-mortem is not required before the body can be used for any of the purposes in the Act.

The person lawfully in possession of the body may be:

- the person in charge of the hospital where the deceased person is lying (a hospital is defined in the Health and Disability Services [Safety] Act 2001 and the Mental Health [Compulsory Assessment and Treatment] Act 1992)
- the superintendent of any penal institution where the deceased inmate is lying.7

In ascertaining the views of the persons listed in Table B1, the person lawfully in possession of the body is required to make ‘such reasonable inquiry as may be practicable’ to inform their decisions. In guidance issued in 1987, this phrase is described by the Department of Health (1987a) as requiring (in the context of organ donation), in most instances, that the matter be discussed with any one relative who has been in close contact with the deceased person. The relative should be asked their views, the views of the deceased and also if there is any reason to believe that any other relative would be likely to object.

The guidance further notes that there is no need to establish a lack of objection from all relatives or to make inquiries that are unreasonable or impractical. For example, if a donor’s relatives were found to be young children, inaccessible or seriously ill, it would be impractical to ask them (Department of Health 1987a).

Section B2.1.3 describes the Human Tissue Act in practice.

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7 Superintendents have been replaced with chief executives or general managers in most institutions.
<table>
<thead>
<tr>
<th>Role</th>
<th>Anatomical examination</th>
<th>Education or research</th>
<th>Non-coronal post-mortem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person lawfully in possession of the body</td>
<td>May allow this use provided there is no known objection from the deceased, surviving partner, or any surviving relative.</td>
<td>May allow this use provided there is no known objection from the deceased, surviving partner, or any surviving relative.</td>
<td>May allow this use provided there is no known objection from the deceased, surviving partner, or any surviving relative.</td>
</tr>
<tr>
<td>Deceased person</td>
<td>May request or object to the use.</td>
<td>May request or object to the use. In requesting this use, the person may specify the terms of the request (e.g., body parts to be used and for what purpose).</td>
<td>May object to this use.</td>
</tr>
<tr>
<td>Surviving partner</td>
<td>Must agree with the request of the deceased.</td>
<td>May object to a request by the person lawfully in possession to use the body for this purpose.</td>
<td>May object to this use.</td>
</tr>
<tr>
<td></td>
<td>May object to a request by the person lawfully in possession to use the body for this purpose.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surviving near relative</td>
<td>If there is no surviving partner, must agree to a request of the deceased that their body be used for this purpose.</td>
<td>Not mentioned in relation to education.</td>
<td>Not mentioned in relation to post-mortem.</td>
</tr>
<tr>
<td>Any surviving relative</td>
<td>The same right as a surviving partner to object to a request by the person lawfully in possession to use the body for this purpose.</td>
<td>The same right as a surviving partner to object to a request by the person lawfully in possession to use the body for this purpose.</td>
<td>May object to this use.</td>
</tr>
</tbody>
</table>
The Act sets some requirements for the management of tissue and provides some coverage of monitoring and oversight matters. These requirements are focused on tissue that has been donated for anatomical examination and schools of anatomy. In particular the Act provides that:

- schools of anatomy may be established on the authority of the Governor-General by order in council
- anatomical examination may only take place at a school of anatomy by a medical practitioner licensed by the Minister of Health, unless permission is given by an inspector of anatomy and school authorities for a body, or body parts, to be moved to another place for the purpose of teaching anatomy
- schools of anatomy must keep specific records about the bodies of deceased persons that have been bequeathed to the school
- inspectors of anatomy are appointed to oversee the practices of schools of anatomy
- inspectors of anatomy are to provide regular reports about bodies of deceased persons that have been bequeathed to the school
- inspectors of anatomy may give permission for any part of a body donated for anatomical examination to be retained indefinitely for further study
- all human remains resulting from anatomical examination are to be buried or cremated in accordance with the written instructions of an inspector, who will take into consideration any wishes that the deceased or their relatives have expressed.
**B2.1.3 The Human Tissue Act in practice**

There are a number of points to note concerning the operation of the Human Tissue Act in practice.

- Schools of anatomy do not accept bodies of deceased persons for anatomical examination without the consent of both the deceased and their family. Box B1 following describes the process used by schools for accepting bequeathed bodies.

- The ability, under the Act, for unclaimed bodies to be released for anatomical examination, education or research is not used in current practice in New Zealand. These provisions reflect historical circumstances when the bodies of persons that died without known relatives or sufficient resources for burial could be released for anatomical study. Unclaimed bodies have not been used in New Zealand since the 1950s.\(^8\)

- Schools of anatomy are very appreciative of the donations of tissue they receive and currently receive sufficient bequests to fulfil teaching requirements.

- Schools of anatomy and inspectors of anatomy have developed good working relationships and report that the current provisions for managing and overseeing the processes regarding anatomical examination are working well.

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**Box B1: Bequests to schools of anatomy**

The schools of anatomy at the universities of Auckland and Otago accept 30 to 45 bodies each annually and they both have similar processes for accepting bequests. The schools provide information about the process to individuals, family, solicitors, health practitioners, hospital staff, and organisations such as the Public Trust. After considering the information, those wishing to make a bequest are asked for a letter or completed form confirming their wish. Schools encourage people to discuss their wishes with close relatives and ascertain whether anyone is likely to object to their wish.

Public support for the bequest of bodies is good and the schools are able to meet their need for tissue from the geographic region around the school. Those wishing to bequeath their body are asked to inform their family and friends of the arrangements they would like if a school is unable to accept their bequest.

After the person’s death, the family, health practitioner or undertaker informs the school. The licensed anatomist then checks the school's records. If the school does not have a record of the bequest, there are two options:

i) an open discussion is held with the family to confirm that it was the wish of the deceased to bequest their body and to ensure that the family are all in agreement that the bequest should proceed; or

ii) it is automatically declined – it is very important that a body is only accepted with the collective agreement of the whole family. A bequest will not be accepted if it is likely to cause any disharmony within a family.

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\(^8\) For a fuller discussion of this history, see Jones 1994.
Following further discussion with family to ensure that everyone is comfortable with the process and understands what will happen, the body is moved to the school and embalmed. The school then writes to the family expressing their appreciation and gratitude for the bequest.

Bodies bequeathed to the schools are used for a variety of teaching and research purposes by medical and dental students, allied health science students, and academic staff. Most are used for anatomical examination. They may also be prepared by members of the technical staff as prosections. With the permission of the inspector, some tissue is preserved and kept using a technique known as plastination. Plastinated tissue keeps almost indefinitely and is extremely valuable for both teaching and research purposes.

Once the examination is complete, the school requests the permission of the inspector of anatomy to cremate the remains. If a family wishes, the person’s ashes will be returned to them – under these circumstances no tissue is retained (excluding microscopic samples and tissue for which explicit consent has been gained from the family). Some families do not wish to have the ashes returned to them. If this is the case, the school ensures that the person’s ashes are disposed of in a dignified manner – usually they are scattered in the memorial rose gardens at the crematorium. In Auckland an annual service of thanksgiving is held in the University’s chapel.

The schools meet all the costs associated with the process, including the return of the ashes to the relatives where this has been requested.

B2.2 Code of Health and Disability Services Consumers’ Rights 1996

The Code of Health and Disability Services Consumers’ Rights (the Code) is contained in Appendix 3.

The Code is in regulations made under the Health and Disability Commissioner Act 1994. It provides a set of rights for people receiving health and disability support services and only applies to living people. The rights that are most relevant to tissue used for non-therapeutic purposes are described below.

- Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. For example, a person must agree, after being given sufficient information, to give a sample of tissue such as a biopsy or blood test; or to have a surgical procedure such as the amputation of a limb.

- Consumers of health and disability support services must be fully informed of any proposed participation in teaching or research (including being informed about whether the research requires and has received ethical approval). Consent to participate in research as part of a health care procedure must be informed and in writing.

9 Right 7(1).
10 Right 6(1)(d).
11 Right 7(6).
• Every consumer may use an ‘advance directive’ in accordance with the common law. An advance directive is a written or oral instruction where a consumer makes a choice about a possible future health care procedure that is intended to be put into effect if the person is unable to make that choice at the time due to incompetence.

• Right 9 extends all the other rights in the Code to occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.

• Any body parts or bodily substances removed or obtained in the course of a health care procedure may be stored, preserved or utilised only with the informed consent of the consumer. This right is currently subject to some amendment (see section B2.2.1 for further discussion).

These rights mean that consumers of health and disability support services need to agree to the collection of tissue at the time of a health care procedure – whether that tissue is to be used for their health care, or is being collected for teaching or research. The Code also gives consumers the right to decide if any tissue that results from a health care procedure can be used for other purposes; for example, a person who has had surgery to amputate a leg can give informed consent for the amputated leg to be used for research into varicose vein formation. The Code also requires consumers to be given sufficient information to make an informed decision.

B2.2.1 Amendment to Right 7(10)

Right 7(10) of the Code provides that ‘any body parts or bodily substances removed or obtained in the course of a health care procedure may be stored, preserved or utilised only with the informed consent of the consumer’. That is, consent needs to be gained for the initial collection of tissue for health care purposes and for the subsequent storage and use of the tissue. Separate from this Review, the Government has decided to amend Right 7(10) as there are times when it is in the greater public interest to allow certain research and audit activities to be undertaken without specific informed consent. However, safeguards must be in place to ensure that this ability is only used when appropriate.

In 1999 the then Health and Disability Commissioner undertook a review of the Code, which included extensive consultation with consumers and the health and disability sector. As part of the Commissioner’s review, some researchers, pathologists and ethics committees proposed that Right 7(10) be amended to allow ethics committees to review specific research proposals to see whether the public interest should allow exceptions from compliance with the informed consent requirements in the Code. The current Health and Disability Commissioner accepted this proposal.

12 Right 7(5).
13 Right 7(10).
14 Section 21 of the Health and Disability Commissioner Act 1994 requires reviews of the Code by the Commissioner.
The underlying concern is that it is not always reasonably practical to fulfil the consent requirements of Right 7(10), and in some cases this may hinder valuable public health research and audit activities for quality improvement processes. For example, a researcher may propose to use specific body parts or bodily substances for a purpose that was not envisaged, or indeed possible to envisage, at the time the samples were collected from the consumers, and it may not be practicable, or possible, to locate the consumers to seek new consent, particularly given the highly mobile nature of the New Zealand population, the number of samples that may be involved, and the time that may have elapsed since consent was initially obtained.

A similar exception is contained in Rule 11(2)(c)(iii) of the Health Information Privacy Code, which enables information to be disclosed without an individual’s authorisation, where it is not desirable or not practicable to obtain individual authorisation, and the information is to be used for research purposes (which have been approved by an ethics committee), and the information will not be published in an identifiable form.

Right 7(10) of the Code is to be changed to the following:

Any bodily substances or body parts removed or obtained in the course of a health care procedure may not be stored, preserved or used other than:

(a) with the informed consent of the consumer; or
(b) for the purpose of research that has received the approval of an ethics committee; or
(c) for the purpose of a professionally recognised quality assurance programme or an external audit or evaluation of services that is undertaken to assure or improve the quality of services.

For each research proposal reviewed, ethics committees will need to weigh up the public interest in allowing for an exception from the informed consent provisions of the Code against the very strong ethical principle of protecting individual autonomy. This is a strong protection for health and disability consumers.

It is expected that this change will be contained in the Code by mid-2004.

**B2.3 Operational Standard for Ethics Committees**

Ethics committees have an important role in governing the use of tissue from both live and deceased persons. They have two key roles:

- scrutinising health and disability support research proposals
- scrutinising proposals for innovative practice (an innovative practice involves the provision of a clinical intervention that is untested, unproven or not in common use).

They are an important check to ensure that the expansion of scientific knowledge and the development of new treatment and technologies take place in a safe and ethical manner.
The Operational Standard for Ethics Committees (Ministry of Health 2002) guides the operation of Health and Disability Services Ethics Committees and accredited Institutional Ethics Committees. It also recognises the role and functions of the National Advisory Committee on Health and Disability Support Services Ethics (NEAC), the National Ethics Committee on Assisted Human Reproduction (NECAHR), and the Health Research Council Ethics Committee (HRCEC). A description of the different ethics committees and their roles is contained in Appendix 4.

The objectives of ethics committees covered by the Operational Standard are to:

- safeguard the rights and interests of participants in research and innovative practice, and consumers of health and disability services
- protect Māori cultural interests, promote the wellbeing of Māori and ensure mechanisms for Māori participation in ethical review
- foster awareness of ethical principles and practices within service providers, researchers and the wider community
- consider any ethical matters relevant to health and disability services
- promote excellence in research for the wellbeing of society
- give due consideration to both local and national community views and perspectives in ethical review
- assure the public that the above are being done.

In reviewing a research or innovative practice proposal, an ethics committee uses the principles given in Table B2, many of which are underpinned by legal provisions such as the New Zealand Bill of Rights Act 1990, the Code, the Mental Health (Compulsory Assessment and Treatment) Act 1992 and the Protection of Personal and Property Rights Act 1988.

### Table B2: Principles of ethical review

<table>
<thead>
<tr>
<th>Main principles</th>
<th>Additional issues for Māori</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect for persons</td>
<td>Respect for Māori collectives – whānau, hapū, and iwi</td>
</tr>
<tr>
<td>Informed consent</td>
<td>Gaining consent of collectives</td>
</tr>
<tr>
<td>Privacy and confidentiality</td>
<td>Collective ownership of information</td>
</tr>
<tr>
<td>Validity of research proposal</td>
<td>Kaupapa Māori and Māori-focused methodologies</td>
</tr>
<tr>
<td>Minimisation of harm</td>
<td>Minimising harm to te taha whānau (family and community), te taha hinengaro (emotional wellbeing and state of mind), te taha wairua (spirit), te taha tinana (the body or physical self)</td>
</tr>
<tr>
<td>Justice</td>
<td></td>
</tr>
<tr>
<td>Cultural and social responsibility</td>
<td>Cultural diversity</td>
</tr>
<tr>
<td>Compensation for research participants</td>
<td>Koha</td>
</tr>
</tbody>
</table>

15 If the legislative proposals in section B2.5 are passed, NECAHR will be replaced by a ministerial advisory committee on assisted reproductive procedures and human reproductive research, and a designated ethics committee. These committees will consider policy matters and individual applications, respectively.
All proposed health and disability research investigations that involve human participants must be submitted to an ethics committee for review. In particular, ethics committees are required to review proposals that seek to further scientific or professional knowledge by means of laboratory analysis of human blood, tissues, etc of living people, cadavers or discarded body tissues.

Currently, the Operational Standard for Ethics Committees states that ‘Research involving research participants or the use of human tissue or bodily substances or innovative practice may not proceed without first obtaining consent from the individual or the individual’s legal representative’. It continues: ‘Consent should be obtained before human tissue or bodily substances may be used for any purpose other than that for which consent was originally given.’ These provisions will need to be updated and further guidance developed in light of the proposed amendment to Right 7(10) of the Code described in section B2.2.1.

B2.3.1 National Application Form for Ethical Approval of a Research Project

All research applications seeking ethical approval must be submitted on the National Application Form for Ethical Approval of a Research Project. The HRCEC develops this form and reviews it periodically. In terms of human tissue, the form requires detailed information about:

- tissue collection – who will undertake the procedure, the type of tissue, and the number and volume of samples
- tissue use – who will have access to tissue samples, whether samples will go out of New Zealand and for what purpose
- tissue storage and disposal – the means of storage and labelling, the length of storage and method of disposal, and whether data or other information will be stored for use in a later study
- genetics issues, including:
  - whether the research involves analyses of DNA or clinical genetics, and if so, how samples are to be collected and stored, whether they will be transported out of New Zealand, and who will have access to them; if samples are to be collected from Māori, a separate analysis of these issues is required for those samples
  - information about the ability for the sample or data to be withdrawn by the participant
  - whether it will be possible to link information from DNA analysis to other health information about the participant, and how privacy is to be assured
  - whether a clinical geneticist will be involved in the study, and if provision has been made for genetic counselling to be available to participants if required.

Proposals for innovative practice are also required to be submitted for review by an ethics committee. However, these proposals fall outside the scope of the non-therapeutic use of human tissue. Innovative practice is defined in the Operational Standard as practice that involves the provision of a clinical intervention (diagnostic, therapeutic or prophylactic), be it a therapeutic drug, medical device or clinical procedure, that is untested, unproven or not in common use and therefore poses its own unique set of characteristics and issues.
B2.3.2 Current work on the systems for ethical review in New Zealand

The systems for ethical review in New Zealand are currently being examined by the National Ethics Advisory Committee (NEAC). NEAC is established under section 16 of the New Zealand Public Health and Disability Act 2000. Its statutory functions are to:

- provide advice to the Minister of Health on ethical issues of national significance in respect of any health and disability matters (including research and health services)
- determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services.

As a first priority, the Minister of Health has asked NEAC to provide advice on four matters arising from the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region. These matters are to:

- develop guidelines on conducting observational studies in an ethical manner and establish parameters for the ethical review of observational studies (including guidance regarding weighing up the harms and benefits of this type of health research)
- consider the application of second opinion and appeals processes and recommend their appropriate use for ethics committees
- review the current processes for the ethical review of national and multi-centre research
- review the operation of ethics committees and the impact their decisions are having on independently funded evaluation exercises and on medical research generally in New Zealand.

These four matters combine to form a broad review of the current processes for ethical review of health and disability research in New Zealand. NEAC provided advice on these matters to the Minister of Health in December 2003, and NEAC’s advice is under consideration by the Minister.

B2.4 Hazardous Substances and New Organisms Act 1996

The Hazardous Substances and New Organisms Act is primarily concerned with protecting the environment and the health and safety of people and communities. This Act has recently been amended so that the genetic modification of human cells and tissues has been brought within its coverage.

Human cells are defined as:

‘Human cells’ –

(a) means human cells, human cell lines, or human tissues that are being grown or maintained outside the human body; and

(b) includes human reproductive cells or human embryonic cells that are being grown or maintained outside the human body.
The effect of this change is that any proposal to genetically modify human cells and tissues, or import genetically modified human cells and tissues, will require approval under the Hazardous Substances and New Organisms Act. This will include a risk assessment process that will assess the potential for adverse environmental, health and economic effects.

It is important to note that the Hazardous Substances and New Organisms Act applies to the genetic modification of human cells outside the human body (i.e., in test tubes). If these cells were then to be used for other purposes (e.g., clinical trials in humans), additional processes will apply. In the case of clinical trials, the approval processes under the Medicines Act 1981 will apply.\(^\text{17}\)

### B2.5 Supplementary Order Paper to the Human Assisted Reproductive Technology Bill

The Health Select Committee is currently considering a Supplementary Order Paper to the Human Assisted Reproductive Technology Bill 1996 (HART SOP). The Committee is due to report back on the Bill in April 2004. It is important to note that the proposals in the HART SOP may be subject to change as a result of the select committee process.

The objectives of the proposals in the HART SOP are to:

- prohibit unacceptable assisted reproductive procedures (e.g., human cloning for reproductive purposes), commercial surrogacy and the commercial supply of embryos or human gametes; this includes making unlawful the importation of reproductive tissues, or embryos that have been subject to an unacceptable practice
- provide a framework for regulating and guiding the performance of assisted reproductive procedures and the conduct of human reproductive research
- ensure that the performance of non-established assisted reproductive procedures and all human reproductive research can only be conducted with the continuing approval of an ethics committee
- establish a comprehensive information-keeping regime to enable people conceived using donated gametes to access information about their genetic origins and to enable donors and offspring to access information about each other.

The main interaction between this proposed legislation and a new human tissue regulatory framework is the use of embryos for the collection of stem cells, and the subsequent use of embryonic stem cells and cell lines. Embryonic stem cells have the potential to be valuable in research and health treatments, although some people have ethical concerns about the collection of embryonic stem cells because the collection means that the embryo is prevented from developing into a human being.

\(^{17}\) Work is under way to replace the Medicines Act to implement the joint therapeutic products regulatory scheme and to regulate New Zealand-specific aspects of medicines. The process for the approval of clinical trials will be carried into the new regulatory environment for therapeutic products.
Under the proposals in the HART SOP, a ministerial advisory committee would be established. This committee would be required to consider and undertake public consultation and develop advice on the creation and use of embryos for research purposes, which is likely to require consideration of whether the destruction of embryos to collect embryonic stem cells is acceptable in New Zealand. This is a very complex issue that needs careful consideration.

If it is decided that embryonic stem cells can be collected in New Zealand, individual applications to use or create embryos for this purpose will require ethical approval under the HART legislation.

If the embryonic stem cells and cell lines are to be used:

- for reproductive research, the approval processes under the proposed HART legislation would apply
- for any process that involved genetic modification of the cells outside the human body, the Hazardous Substances and New Organisms Act described in section B2.4 will apply
- for therapeutic purposes in humans (including clinical trials), the processes in the Medicines Act will apply18
- for other research purposes, this document seeks your views about whether additional requirements are required (stem cells and cell lines are discussed further in section B8.2).

### B2.6 Health (National Cervical Screening Programme) Amendment Act 2004

The Health (National Cervical Screening Programme) Amendment Act has recently been passed and responds to some of the recommendations of the Gisborne cervical screening. The Act amends the Health Act 1956.

Most relevant to this Review is the amendment to the regulation-making powers in section 121A of the Health Act 1956. The amendment allows the regulations made under the Health Act that require health information to be kept, to be extended to specimens. Currently, the Health (Retention of Health Information) Regulations 1996 only apply to traditional types of health information, such as doctors’ notes. The Regulations set out the minimum periods for which health information must be retained, the safeguards to be taken by holders of health information, and the procedures to be followed before health information may be destroyed. The amendment to the Health Act allows these regulation-making powers to be extended to specimens collected as part of the delivery of health care.

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18 Work is under way to replace the Medicines Act, to implement the joint therapeutic products regulatory scheme and to regulate New Zealand-specific aspects of medicines regulation. The approval process for clinical trials will be carried into the new regulatory environment for therapeutic products.
Now that the Health (National Cervical Screening Programme) Amendment Act is passed regulations can be made to require specimens taken from an individual as part of clinical care to be retained in the same way that other health information is retained, thus providing a complete record of a person’s health history.

Giving effect to this regulation-making power is discussed further in section B10.

B2.7 Health Information Privacy Code 1994
The Health Information Privacy Code is established under the Privacy Act 1993 and governs the collection, storage, security, access, correction and retention of health information. It is concerned with protecting the privacy of individuals and the highly personal information that is required for health care.

In terms of the review of human tissue, the question arising more frequently is whether genetic information, obtainable from human tissue, requires more protection than that currently provided by the Health Information Privacy Code.

Privacy and genetic information issues are discussed further in Section B9.

B2.8 Coroners Act 1988
Following a report by the Law Commission (2000), the Ministry of Justice is undertaking a review of the Coroners Act 1988. The review is centred on both the structure of the coronial system and the processes used within that system. The review of processes has aimed to strike a balance between the cultural and spiritual needs of families and the public good associated with understanding the causes and circumstances of death in an accurate and timely way. Some of the issues raised in the review of the Coroners Act are pertinent to the review of human tissue and are raised in later sections of this document.

B3 What are the issues, gaps and problems?
The central concern is that currently New Zealand lacks an overall framework for dealing with tissue for non-therapeutic uses. The legislation described in the previous section provides a patchwork of coverage, but it is not comprehensive, consistent, or organised in an easily understandable way. Aspects of the legislation are also out of date and need to reflect modern practices and structures.

Particular problems are:
- the place of informed consent – informed consent is a central part of the health and disability sector in New Zealand, but currently the legislation is unclear about informed consent in a number of areas, including:
  - the test of ‘lack of objection’ instead of ‘informed consent’ for the use of tissue from deceased persons
the need for informed consent for the collection of tissue at a post-mortem examination

the role of family members in giving consent for tissue use after a person has died

inconsistent requirements for tissue management and monitoring depending on the use of the tissue and the donor of the tissue

whether current provisions provide the protection of genetic information that New Zealanders expect

the lack of coverage of some types of tissue (eg, stillborn children)

out-of-date terminology and definitions.

The current legislation and regulations also fail to provide recognition of Māori and other cultural perspectives.

The next section proposes a new approach to non-therapeutic tissue regulation, which recognises the special nature of tissue, is aligned with current good practice, and as far as possible streamlines regulation across the different non-therapeutic uses of tissue. It is proposed that informed consent be the guiding principle for use of tissue for non-therapeutic purposes, while recognising that there may be times when the benefits from tissue use may outweigh this principle. Your views on the proposed approach are sought throughout the section.

There are also gaps in the current framework regarding the acceptability of the sale and purchase of human tissue, the import and export of human tissue, and how new and challenging uses of tissue can be formally addressed on an ongoing basis. These issues are covered in ‘Part D: Common concerns for all uses of tissue’, because they relate to both therapeutic and non-therapeutic uses of tissue.

The central issues that will need to be included in a new framework for regulating the non-therapeutic uses of human tissue are:

- informed consent
- tissue management, oversight and monitoring
- definitions
- special types of tissue
- privacy and genetic information
- amending the regulations made under the Health Act 1956.

Before moving to these issues in detail, section B4 discusses post-mortem examinations. Post-mortem examinations, both in New Zealand and overseas, have been the subject of some controversy, and the sad events where tissue from post-mortem examinations has been retained without consent (such as at Greenlane Hospital) have illustrated the need for a clear legislative framework in this area.
A note about non-coronial post-mortem examinations

A non-coronial, or hospital, post-mortem examination is conducted to provide further information about the cause of death of a person. Obtaining this information can benefit the family of the deceased person and the public, and can provide an overall improvement in health care delivery.

The number of hospital post-mortems being undertaken has been declining steadily for some time. This trend is of concern to many health practitioners and policy makers focused on quality improvement and clinical audit, as evidence suggests that the causes of death recorded without the benefit of a post-mortem are subject to error (Royal College of Pathologists of Australasia 2002, Rutty et al 2001).

The Royal College of Pathologists (2002) identifies the following benefits of conducting a non-coronial post-mortem examination:

- identifying the presence or absence of pathologies and providing family with the best information about the cause of death
- identifying diseases with genetic components, enabling accurate health care information to be given to family
- providing information about the cause of death and pathology for clinical audit (ensuring that the illness is being correctly diagnosed and treated)
- contributing to the knowledge about poorly understood diseases
- contributing to the evaluation of medical therapies and surgical techniques
- providing an accurate cause of death, which contributes to improved mortality statistics that inform public policy
- contributing to medical research and education.

In order to achieve these types of benefits, the value of a post-mortem examination needs to be recognised and the public must be confident that such an examination will be undertaken with the utmost sense of decency and respect.

The Human Tissue Act governs agreement to a non-coronial post-mortem examination being conducted. That Act is silent, however, on the process or any requirements to be met before tissue may be collected and retained from the post-mortem examination. In the past, consent to a non-coronial post-mortem was assumed to also be consent to the collection and retention of tissue. This assumption is clearly at odds with the expectations New Zealanders have of the health and disability sector.

Section B5 discusses consent and agreement to a post-mortem being conducted. This section (B4) discusses the collection and retention of tissue once consent to undertake a post-mortem examination has been addressed.
B4.1 Why is it necessary to retain tissue from a post-mortem examination?

It may be desirable to retain tissue from a hospital post-mortem examination for two reasons:

- to undertake more detailed examination about the death as part of the post-mortem examination
- to undertake other research or education.

Determining the cause of death through the pathological study of the tissue of the deceased person can be a complex process, which requires tissue to be retained after the body of the deceased person has been released to the family, whānau or funeral director.

Common reasons for needing to retain tissue, particularly organs, are that the:

- organ is small and all of it is required for examination
- tissue shows signs of a complex abnormality and a more comprehensive examination is required – possibly by another specialist doctor
- tissue needs to be prepared in a special manner before certain types of examination and testing can be undertaken, and this takes time.

These reasons for retaining tissue relate to the conduct of the post-mortem and obtaining a full picture of the causes of death.

Tissue may also be desired to be retained at post-mortem for other reasons – usually to further education or research into the condition from which the person has died.

B4.2 New provisions for tissue retention at non-coronial post-mortem examinations

The Ministry considers that the two reasons for collecting and retaining tissue from a hospital post-mortem examination should be treated differently in the new regulatory framework for human tissue. It is proposed that the new regulatory framework should make it clear that:

- consent to conduct a non-coronial post-mortem examination explicitly includes consent to retain tissue, *where that tissue is to be retained for the purposes of the post-mortem examination only*; in this situation, the person giving consent for the post-mortem examination should be given information about the tissue to be retained, the reason for its retention and the length of time it will be retained for
- if it is proposed that tissue be retained for any reason other than for the purposes of the post-mortem (such as ongoing research or education), separate and specific consent is required.

These proposals are consistent with the approach to tissue retention proposed as part of the review of the Coroners Act.
We are seeking your views

2. Do you agree that the new regulatory framework should make it clear that:
   a) consent to conduct a non-coronial post-mortem examination explicitly includes consent to retain tissue, where that tissue is to be retained for the purposes of the post-mortem only; and that the person giving consent for the post-mortem examination should be given information about the tissue to be retained, the reason for its retention and the length of time for which it will be retained?
   b) if it is proposed that tissue be retained for any reason other than for the purposes of the post-mortem (such as ongoing research or education), that separate and specific consent is required for this purpose?

Please explain any changes you would make and why.

B5 Informed consent

Informed consent is a central part of the New Zealand health and disability sector. Seeking informed consent is an important way in which the people interacting with the health and disability support sector are shown respect and dignity. It is based on the principle of self-determination, such that mature people should be able to decide how their life unfolds (van Diest and Savulescu 2002). The principle of informed consent is very important to the use of human tissue for non-therapeutic purposes, but also creates particular challenges when dealing with tissue from deceased persons, and when there are other situations where it seems it is not desirable or practical always to obtain informed consent.

Box B2: What is informed consent?

Informed consent is the ability to make choices about one’s life based on sufficient information and consideration. It consists of the following components.

- Adequate information is provided to enable an informed judgement to be made.
- The information provided is presented in a way that will enable it to be understood.
- The consent is voluntary (i.e., it is free from manipulation, coercion, inducement or any other undue influence) (Ministry of Health 2002).

B5.1 General principles: striking the right balance

New Zealand has developed a strong culture of informed consent, and this is reflected in the Health and Disability Services Consumers’ Code of Rights and ethics committee processes (described in sections B2.2 and B2.3). While the test of ‘lack of objection’ is used in the Act, in practice the Human Tissue Act also uses informed consent for the collection and use of tissue for non-therapeutic purposes, in recognition of the fact that there are significant gaps in the Human Tissue Act regarding post-mortem examinations.
New Zealanders also recognise that there may be specific circumstances where important public health research would be prevented because obtaining informed consent is not practicable (eg, problems of sample bias, or donors cannot be traced).

The amendment to Right 7(10) of the Code (discussed in section B2.2.1) illustrates the protection for consumers that can be put in place through ethics committees providing rigorous scrutiny of research applications that do not propose seeking informed consent. When ethics committees look at these types of applications they will be considering very carefully whether:

- the proposed outcome of the research justifies not seeking informed consent
- the type of research to be conducted means it is better not to seek informed consent.

For example, a study that links pathological diagnoses of cancer made many years ago with the Cancer Registry and mortality data could be conducted to improve our understanding of the spread of cancer and how it can be prevented. The specimens in this type of study would need to be linked to identifying information so that the pathological diagnoses could be checked with current diagnostic criteria, the Cancer Registry and mortality data. It may not be practical to obtain informed consent to use such specimens – many years may have passed since the samples were taken and lots of these people will have moved, and some will have passed away. It would also be very expensive to try to locate everybody. But there is real benefit to the health of New Zealanders from knowing more about the spread of cancer and ways to prevent it.

In the above example, an ethics committee would examine the proposal and consider both the practicality of obtaining informed consent (can it realistically be done) and the desirability of doing so (cancer is a sensitive issue). The committee would also consider whether using the specimens could cause any harm and whether there are particular cultural considerations that need to be taken into account. The researchers would also be bound by the Health Information Privacy Code, which protects information about identifiable individuals.

After weighing up all these factors an ethics committee would then decide if the research project should be allowed to go ahead or not. Ethics committees would consider all such applications on a case-by-case basis.

The need to strike this balance arises in other contexts, and the Ministry proposes that an approach similar to that used in the amended Right 7(10) should be taken. That is, the principle of informed consent should be foremost in the new legislative framework, but, as a secondary principle, the framework should allow the public good associated with the use of tissue to outweigh informed consent in some situations. In these situations, individuals and their families should be protected by some type of safeguard (such as ethics committees in the example above).
We are seeking your views

3. Do you think the new legislative framework should have informed consent as its foremost principle?

4. If so, should a secondary principle recognise that in certain circumstances, the public good associated with the use of tissue will outweigh informed consent provided that safeguards are in place?

   Please explain your reasons for agreeing or disagreeing.

One specific situation where the Ministry considers that it may not be necessary to seek specific informed consent is when tissue or human samples (eg, blood or urine) are used in laboratory quality control procedures. For example, a small sample of tissue may be used to check that particular dyes that show the presence or absence of microorganisms are working properly. This is an important part of maintaining the quality of health care services.

A safeguard that could be applied in this situation is that people are informed, before a tissue sample is taken, that this use could be made of the sample, and that it would be anonymised before it was used for this purpose. This would mean that the person testing or calibrating equipment would not know who the tissue sample belonged to. It is also useful to note that health practitioners and other employees of health care institutions are required to abide by confidentiality agreements as part of their terms of employment or other professional codes.

We are seeking your views

5. Do you agree that it is acceptable for tissue samples to be used for the purposes of laboratory quality control, so long as the person giving the sample is told beforehand that their tissue may be used for this purpose and the sample is made anonymous? If you disagree, please explain why.

B5.2 Seeking consent in different circumstances

This section discusses seeking consent to tissue collection and use in a range of circumstances. The proposals aim to apply the principle that informed consent should be the foremost consideration while recognising that there are certain circumstances where the public good associated with the use of tissue will outweigh the need for informed consent. In these situations safeguards need to be in place.

The proposals in this section raise two issues that are discussed in later sections:

• From whom should consent be sought (see section D2)?
• How should consent be recorded (see section B5.4)?
B5.2.1 Consent: living people

The Code applies to living people and clearly sets out the rights of consumers of health and disability support services to make an informed choice and give informed consent. Under the Code, the person using health and disability support services, or a person entitled to give consent on behalf of that individual, gives consent.

A person may give consent through, for example, a power of attorney or an advance directive.

The Code also provides for situations where a consumer is not competent to make an informed choice and give informed consent, and there is no one else entitled to make this decision. In terms of the collection of tissue for non-therapeutic purposes, including health care, teaching and research, Right 7(4) and Right 9 interact to mean that if a person is not competent to make a decision:

a) the provider may collect and use tissue where it is in the best interests of the consumer; and
b) reasonable steps have been taken to ascertain the views of the consumer; and
c) if the consumers views have been ascertained the provider must assess if the provision of services is consistent with the informed choice the consumer would make if they were competent; or
d) if it is not possible to ascertain the views of the consumer, the provider must take into account the views of other suitable persons who are interested in the welfare of the consumer and who are available to provide such advice.

In practice, it is unlikely that these provisions would allow for the collection and use of tissue for education or research unless this was explicitly recorded by the individual when they were competent.

The Ministry and the Health and Disability Commissioner consider that these provisions are working well and no changes are proposed.

B5.2.2 Consent: deceased persons

The provisions presently in the Human Tissue Act for the collection of tissue from deceased persons for non-therapeutic purposes are lacking in a number of respects and do not reflect current practice. This section considers how a new system for consent with regard to deceased persons could be designed.

Any new regulatory provisions will need to cover:
- deceased people whose wishes are unknown
- deceased people whose wishes are known.

This section also considers whether different levels of consent should be required for different uses of tissue from deceased persons.

Firstly, it is useful to address definitional issues.
‘Lack of objection’ or ‘informed consent’

The Human Tissue Act requires the person lawfully in possession of the body to establish that there is no objection to the use of tissue from a deceased person. The Ministry considers that the test of ‘lack of objection’ should be updated to reflect ‘informed consent’, as described in Box B2.

We are seeking your views

6. Do you agree that the concept of ‘informed consent’ is preferable to ‘lack of objection’ and that this should be included in the new regulatory framework? If not, please explain your reasons.

When the wishes of the deceased are unknown

If a person dies without indicating what their wishes are regarding a hospital post-mortem examination, anatomical examination, education or research being undertaken using tissue from their body, the Human Tissue Act allows the person lawfully in possession of their body to authorise these uses of tissue provided their partner or family do not object.

In updating the regulatory framework there are a number of issues that need considering, including:

- whether the current ability for unclaimed bodies of deceased persons to be used for non-therapeutic purposes should be retained
- in what circumstances it is acceptable for appropriate people to give consent for tissue from a deceased person whose wishes are unknown to be used for non-therapeutic purposes
- what should happen when tissue collected during the life of a person is proposed to be used after that person’s death for a different purpose.

These issues are addressed in turn.

While not used in practice, the Human Tissue Act allows for unclaimed bodies of deceased persons to be used for anatomical examination, education or research under the authority of the person in lawful possession of the body. These provisions reflect the time before the mid-1900s when the bodies of those who had died without known relatives or money for burial were the primary source of tissue for anatomical examination. These people usually died in hospital, the poorhouse or mental health institutions.19

The Ministry considers that the new legislation should remove this provision, making the new legislation consistent with current practice by schools of anatomy and the principle of informed consent.

19 For a fuller discussion of this history, see Jones (1994).
We are seeking your views

7. Are there any reasons why the provision in the Human Tissue Act allowing the use of unclaimed bodies for non-therapeutic purposes should be retained?

8. If the provision were removed, do you foresee any problems being created for the practice of anatomical examination, education or research? If so, do you have suggestions for how these could be addressed?

The next issue to consider is, whether, and in what circumstances, it is acceptable for consent to be given for tissue from a deceased person whose wishes are unknown to be used for non-therapeutic purposes. The Ministry considers it to be useful to distinguish anatomical examination from other non-therapeutic uses.

- Anatomical examination – for reasons previously explained, schools of anatomy do not accept bequests of bodies if the wishes of the deceased person are unknown. The Ministry supports this approach and proposes that the new regulatory framework reflect this practice as a requirement.

- Other non-therapeutic purposes – depending on the reasons for a person’s death, and any illnesses they had, there can be real benefit to families, health professionals, researchers and the health and disability system as a whole in knowing more about the tissue of the deceased person (see, for example, the reasons for undertaking a post-mortem examination listed in section B4). Further knowledge may be gained as part of a detailed post-mortem examination or other research or education activities.

The Ministry considers that it is appropriate for tissue from deceased persons whose wishes are unknown to be used for non-therapeutic purposes (excluding anatomical examination) provided that appropriate consent has been obtained from a person able to give consent on behalf of the deceased person. The persons who may be able to give such consent are discussed in section D2. There are two reasons for the Ministry holding this view:

- As compared with anatomical examination, the use of tissue for other non-therapeutic purposes may not have been considered by an individual before their death. It is likely, therefore, that their wishes will be unknown.

- Following public concern about the retention of tissue at post-mortem without consent, it was revealed that many people would have given consent for the tissue of their loved ones to be retained and used for research and education if they had been asked, and that some people may have desired that this benefit was derived from the sad death of their loved one.
We are seeking your views

9. Do you agree that it is not appropriate for the body of a deceased person to be use for anatomical examination if the views of the deceased person about this use are not known? Please explain any comments.

10. Do you agree that the new legislative framework should allow tissue from deceased persons to be used for non-therapeutic purposes (other than anatomical examination) with appropriate informed consent? If not, please explain your reasons.

The third issue in this area is what should happen when tissue is collected during the life of a person (when the provisions of the Code would apply), but it is proposed to be used after that person has died and specific consent for this use has not been obtained. Examples of potential uses are to assist with the genetic testing of a relative, or to undertake a research project that was not anticipated at the time the tissue was collected.

This is an area where it is not possible to obtain informed consent and the secondary principle could apply. That is, the use of the tissue could be permitted provided that appropriate safeguards are in place.

These situations could be managed by requiring another form of approval. Possible mechanisms are as follows.

- If the proposed use is a one-off event for clinical purposes, consent could be sought from another family member.
- If the proposed use is a research project, or audit, the provisions should be consistent with the recent amendment to Right 7(10) of the Code. This approach would mean that tissue could not be used unless the research had been approved by an ethics committee, or the tissue was to be used for a professionally recognised quality assurance programme (an external audit or evaluation of services undertaken to assure or improve the quality of services).

We are seeking your views

11. When tissue has been collected during the life of a person and is wanted for uses after that person’s death for a reason where the wishes of the deceased person are not known, should the new legislation allow these uses with appropriate safeguards? If so, are the following suggested safeguards appropriate.

   a) If the proposed use is a one-off event for clinical purposes, consent could be sought from another family member.

   b) If the proposed use is a research project, or audit, the tissue could not be used unless the research had been approved by an ethics committee, or the tissue was to be used for a professionally recognised quality assurance programme, an external audit or evaluation of services that was undertaken to assure or improve the quality of services.

Please describe any other ideas you have.
When the wishes of the deceased person are known

Some people have clearly recorded or discussed their preferences about any use of their body, or body parts after their death. There are three situations that can arise when a person has clearly recorded or expressed their wishes.

- They have recorded an objection to their body being used after their death for non-therapeutic purposes: in this situation, the person’s wishes are easily, and appropriately, followed. This is the current law in the Human Tissue Act and the Ministry supports continuing this position.

- They have recorded a desire that their body be used after their death and their family is aware of and in agreement with their wishes: in this situation it is also relatively straightforward to follow through with the deceased person’s wishes.

- They have recorded a desire that their body be used after their death and their family is in disagreement with their wishes. This third situation is somewhat more complex; that is, what should happen when it is known that a person wished for their body to be used for non-therapeutic purposes, but at the time of their death their family does not want this to happen. This situation does not occur frequently as most people want to follow through with the wishes of their loved one, but it does arise at times.

Schools of anatomy can not accept bequeathed bodies from deceased persons if a family member objects. While it would be possible to design the law to require that the wishes of the deceased to donate their body for non-therapeutic purposes be followed, the Ministry considers that it is preferable to allow flexibility for a deceased person’s family and the relevant health professionals to resolve these issues. Currently schools of anatomy and researchers work carefully and sensitively with families to resolve these issues at a very difficult time. Sometimes it is decided to follow the wishes of the deceased, and sometimes it is decided that this is too distressing for the family and the wishes are not followed. This case-by-case approach seems to work well.

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We are seeking your views

12. Do you agree that, where a person is known to object to their body being used after their death for non-therapeutic purposes, this objection should be respected and their body should not be able to be used for these purposes, as is currently in the Human Tissue Act 1964? If you disagree please explain your reasons.

13. Do you think that the new legislation should allow families to have the final say over the donation of tissue from their deceased loved one for non-therapeutic purposes? If not, please explain why you think the wishes of the deceased should be required to be followed and if there should be any exceptions to this requirement.

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B5.3 Consent for children

Guidance on obtaining consent for health care procedures for children is provided in the document Consent in Child and Youth Health: Information for practitioners (Ministry of Health 1998). The key concern for the Review is consent for the non-therapeutic use of tissue from children who have died.
Much of the concern in New Zealand and overseas about the retention of tissue without consent from a post-mortem examination has related to tissue from children who had died. Many parents were understandably very upset that consent had not been sought, and many noted that if consent had been sought it would have been given.

It is important that the new legislative framework is clear about the need to obtain consent for the use of tissue from children for non-therapeutic purposes.

Until a child is 18 years old their parents or guardians are responsible for them. However, the legal age of consent in New Zealand is 16 years. This raises a question as to what should happen for a child aged between 16 and 18 years. To address this difficulty the Care of Children Bill proposes that competence as opposed to chronological age be used as a guide to the decisions children and young people are able to make. The Ministry supports this policy and proposes that:

- consent to obtain tissue from a deceased child should be obtained from the parents or persons responsible for the day-to-day care of the child (it would be preferable to obtain consent from both parents, although precisely who is involved will depend on the nature of the family relationships)
- if a child or young person is legally competent, and their wishes in relation to the non-therapeutic uses of their tissue are known, then the same procedures as with adults should apply (as described in section B5.2.2).

In some cases it may be argued that the mother has a greater need than the father to know the cause of death of a newly born child, a stillbirth or miscarriage. In these types of situations the information to be gained from a post-mortem examination may allow the mother to assess the risk to herself of future pregnancies. The Ministry is seeking your views about whether, in this situation, the wishes of the mother should prevail.

We are seeking your views

14. Do you agree that consent from the parents or guardians should always be gained for tissue from a deceased child to be used for non-therapeutic purposes? If you don’t agree, please explain why.

15. If a child or young person is legally competent, and their wishes in relation to the non-therapeutic uses of their tissue are known, then should the same procedures as with adults apply? If you don’t agree, please explain why.

16. Should both parents have an equal say in what happens to the body of their deceased child, or are there circumstances where the mother’s wishes should prevail?

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Children under 16 with sufficient understanding of the issues may be able to give consent under the principle of Gillick competence established in Gillick v West Norfolk Area and Wisbech Area Health Authority [1985] 3 All ER 402.
B5.4 Recording consent

Currently the provisions for recording consent vary.

- In the Code (which applies to living people), consent may be oral for any procedure, except those that involve participation in research, participation in an experimental procedure, a general anaesthetic, or a significant risk of adverse effects. In these circumstances consent must be given in writing.
- Under the Human Tissue Act (which relates to deceased persons), people may have expressed their wishes in writing or orally. If a person has expressed their wishes orally, it must have been in the presence of at least two witnesses.

While written consent to any procedure makes it clearer what an individual wants, the Code recognises that this is not practical for every situation and that oral consent for more routine procedures is sufficient.

When dealing with consent issues for deceased persons it can be argued that consent should always be in writing. This may not be practical, however, as a person with the capacity to give consent may only be contactable by telephone or email. The person may be unwilling to travel, or physically unable to give consent in writing. In these types of situations the views of the person able to give consent may be clearly understood, but risk being disregarded because they are not recorded in writing.

We are seeking your views

17. Are there situations in which consent for non-therapeutic uses of human tissue may be given other than in writing? If so, should any safeguards or special procedures apply? Are there alternative forms of consent that may be acceptable?

B6 Tissue management, oversight and monitoring

The current regulatory framework does not provide comprehensive coverage of tissue management requirements, or oversight and monitoring issues. Section B2.1.2 describes the coverage of these issues in the Human Tissue Act for tissue used for anatomical examination. While the provisions for anatomical examination are working well, they do not extend to tissue that has been obtained for other purposes, and there are gaps in the coverage (e.g., tissue transport). Simply extending the provisions to other tissue use, or collections outside schools of anatomy, may not work well.

B6.1 A framework for tissue management

Tissue is held in different places, including universities, District Health Boards and some private hospitals. In thinking about designing a new framework for tissue management, consideration needs to be given to these different settings. Consideration also needs to be given to the level at which different issues are addressed: some may be best covered by legislation (such as informed consent for collection, as previously discussed) and others may be best addressed by codes of practice or standards. Legislation may require a code or standard to be developed.
Issues that may be suitable for coverage in a tissue management framework that is not included in legislation include, among others:

- protocols for managing tissue that are consistent with cultural practices
- the types of records that should be kept about tissue (this will include some of the matters currently covered by the Human Tissue Act, such as recording the names of deceased persons, the time their body was transferred to the school of anatomy, and any parts that have been retained for further study; record keeping requirements will also need to contain processes for unlinking and anonymising samples)
- safety procedures to ensure that people handling tissue for non-therapeutic purposes are protected from pathogens that may be present in the tissue
- those persons who should be allowed to undertake certain procedures (eg, currently only a licensed anatomist may practise anatomy)
- identification of a nominated ‘person responsible’ for a tissue collection
- the status and management of historical tissue collections, where it is unknown whether consent has been obtained for the tissue to be retained
- appropriate ways to transport tissue
- appropriate ways to store tissue
- appropriate processes for the return or respectful disposal of tissue, including recognising that at times not all tissue will be able to be returned as some may be destroyed as part of testing processes, or may represent a health hazard if it is infectious
- communication with families at difficult times
- consent requirements and (potentially) standard consent forms.

Agencies in the health and disability sector already have a lot of information on these types of issues, which could be used to inform an overall tissue management framework, including:

- detailed guidelines developed by the Auckland District Health Board Body Parts, Tissues and Substances Review Panel (Auckland District Health Board 2002)
- the Auckland District Health Board’s *Tikanga: Recommended best practice policy* (Auckland District Health Board undated)
- guidance on ethical processes for human specimen collection, storage, use and disposal developed for the Department of Health (Human Specimen Ethical Guidelines Committee 1992)
- guidance, developed by Te Puni Kōkiri (1999a, 1999b), for both service providers and Māori for the removal, retention, return and disposal of body parts and organs
- Health Research Council (2002) ethical guidelines for researchers using human tissue
- best practice models for anatomical examination developed by schools of anatomy.
Some of these documents are becoming dated, however, and others may be affected by the new regulatory regime currently being designed. Given these factors and the fact that the status of existing material is not always clear, there is merit in considering developing a single framework that provides a consistent and comprehensive approach to tissue management across the different non-therapeutic uses.

A consistent approach to tissue management would not necessarily take the form of a single standard for all agencies. There may be issues that are better considered separately, and there may be aspects of such a standard that would not apply to some agencies or some types of tissue – the coverage of microscopic samples would need to be considered, for example. The level of detail that such a framework prescribed also needs consideration.

The development of an overarching framework for the management of tissue for non-therapeutic use involves a significant amount of work, and the Ministry is interested in your views on this proposal.

**We are seeking your views**

18. Do you think that an overarching standard or code for tissue management that can be applied flexibly to different agencies is appropriate? Please explain why or why not.

19. Please tell us your suggestions for what should, or should not, be covered by such a framework and why.

20. Please tell us if you think there are agencies for which, or specific occasions when, there should be exemptions from the requirements of such a framework.

**B6.2 Oversight and monitoring**

Currently the formal oversight and monitoring of non-therapeutic tissue in the Human Tissue Act is confined to the inspectorate regime for schools of anatomy (see section B2.1.2). The Code also provides for complaints to be made to the Health and Disability Commissioner if a consumer considers that their rights under the Code have been breached. While many health practitioners, researchers and professional bodies are actively addressing the appropriate use of tissue, some form of ongoing oversight and monitoring may be necessary to align public policy with public concerns.

An important consideration in any oversight and monitoring regime is to ensure that the regime is commensurate with the risks posed and does not place unnecessary costs or burdens on to agencies managing tissue, or on to the health and disability sector in general. On the other hand, any regime must be robust and meet the expectations of New Zealanders that tissue-related matters are well managed.

One potential way to provide oversight and monitoring is through a system of standard setting, audit and certification. This system is used to ensure the safety and quality of health and disability support services under the Health and Disability Services (Safety) Act and may provide a model for the non-therapeutic tissue area.
The Health and Disability Services (Safety) Act works as shown in Table B3.

**Table B3:** Framework for services safety under the Health and Disability Services (Safety) Act 2001

<table>
<thead>
<tr>
<th>Process</th>
<th>Requirements to be met</th>
<th>Sign-off</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service to be covered (eg, hospital, rest homes)</td>
<td>A service not yet anticipated by the Act may be added so long as acceptable standards have been developed or will be developed within 12 months and providers have at least 12 months to comply with the standard.</td>
<td>Governor-General</td>
</tr>
<tr>
<td>Standard (has the status of regulation)</td>
<td>This must be independently developed in consultation with the sector, and consultation must have been considered, and be in the public interest in terms of safety and compliance costs.</td>
<td>Minister of Health</td>
</tr>
<tr>
<td>Audit and certification</td>
<td>Designated audit agencies must be independent and approved.</td>
<td>Director-General of Health</td>
</tr>
</tbody>
</table>

If this type of model were considered appropriate, one question that needs to be resolved is whether the Police should continue to be involved in monitoring and audit processes. Currently the two inspectors of anatomy are senior members of the New Zealand Police and have developed good working relationships with the schools of anatomy. The Police are independent of the health and disability sector and have a standing in the community that can provide the public with reassurance that the schools of anatomy are following good processes. However, if the proposals in this document were carried forward, the scope of monitoring and audit to be undertaken would be wider than the current ambit of the inspectors and is likely to require more specialist knowledge.

**We are seeking your views**

21. Please share your ideas on possible approaches to monitoring tissue management practices that allow for robust monitoring to take place without imposing unnecessary compliance costs on the health and disability support sector.

22. Do you think that a system based on standards, audit and certification could work in New Zealand? Please tell us why or why not, and share any other ideas you have.

23. Do you think that the New Zealand Police should continue to be involved in the monitoring and audit of non-therapeutic tissue use? What type of role should the Police fulfil?

So far this document has considered two fundamental aspects of a new legislative framework for the non-therapeutic use of human tissue: informed consent for tissue use and tissue management practices. We now consider a number of other matters that need to be addressed as part of the new framework.

21 Consultation is required with consumers, representatives of affected providers and a number of providers, funders and consumers.
B7 Definitions

As part of the overall improvement of the framework for human tissue use, the Ministry believes there are particular terms that need to be considered and updated to reflect contemporary structures and practices. This section covers the following terms:

- ‘body’
- ‘lawful possession of a body’.

B7.1 Body

A body is defined in the Human Tissue Act as ‘a dead human body, but does not include the body of a stillborn child’. The legislative coverage of stillborn children and foetuses is discussed in section B8.1.

The Ministry considers that the definition of a body in legislation could be more respectfully worded, and suggests the following terms may be preferable:

- ‘tūpāpaku, or body of a deceased person’
- ‘tūpāpaku, or deceased human being’.

We are seeking your views

24. Please share any suggestions you have for terms that respectfully describe a ‘body’. Are either of the following terms acceptable:

a) tūpāpaku, or body of a deceased person?

b) tūpāpaku, or deceased human being?

B7.2 Lawful possession of a body for non-therapeutic purposes

It has long been considered as a matter of common law\(^\text{22}\) that there is no property in the body of a deceased person. That is, no one is able to ‘own’ the body of a deceased person, and determining what happens to a human body after death cannot be decided on the basis of anyone owning the dead body.

The Human Tissue Act recognises, however, that there are times when it is helpful for some people to have limited rights to the possession of a body for particular purposes. The Human Tissue Act recognises the person in charge of a hospital or the superintendent of a penal institution as the ‘person lawfully in possession of a body’ for the purposes of the Act. That is, the person is able to be in possession of those bodies that are to be used for research, anatomical examination or education – not all the people that may die in the institution.

\(^{22}\) The common law is the body of law that has been built up through the decisions of the Courts.
Having this type of central point of authority is intended to ensure that institutions, such as hospitals, can maintain overall control of the collection and retention of tissue occurring under their auspices. Recent revelations both in New Zealand and overseas have demonstrated what can happen when tissue is collected and retained by individual clinicians or departments without such a system of centralised control.

There are two issues to consider.

- Can the phrase ‘lawful possession’ be improved to reflect the fact that there is no property in a human body, but that at times people have control over the bodies of others, need to provide care for others and have guardianship responsibilities. For example, it is important to many Māori that the tūpāpaku is not left alone and is cared for appropriately.

  Alternative terms that may be appropriate are:
  - the person with lawful control over the body
  - the person with lawful responsibility for the body
  - the person with custody or care or control of the body.

- Is it appropriate to assign a single person as being in possession of a body simply on the basis of that person being the ‘person in charge’ of an institution.

  The management structure of most modern hospitals can include, for example, the board of the District Health Board, the chief executive, the hospital manager and the clinical director. Under such a structure it is unclear who would be ‘the person in charge’ for the purposes of the Act.

  There are three options for resolving this ambiguity.

  a) Legislation could prescribe a particular position within a hospital as the person lawfully in possession (eg, the institution’s chief executive or medical director). Prescribing a particular position could help to remove the ambiguity of the ‘person in charge’, although some District Health Board chief executives are responsible for more than one hospital.

  b) Legislation could require institutions to appoint, or nominate for appointment, a particular person from time to time.

  c) A third alternative is for legislation to prescribe a particular person, to be the person in possession, with the ability for this responsibility to be delegated as appropriate. For example, the chief executive of a District Health Board could be prescribed as the person in possession, and the chief executive may then delegate this responsibility to the hospital manager, clinical director or other person, as appropriate. Under the New Zealand Public Health and Disability Act, this delegation would need to be included in a District Health Board’s Delegation Policy, which is approved by the Minister of Health.\(^{23}\)

\(^{23}\) New Zealand Public Health and Disability Act 2000, schedule 3, clause 39.
We are seeking your views

25. Please tell us your ideas for a phrase that may be preferable to ‘the person lawfully in possession of the body’. Are the phrases ‘the person with lawful control of the body’, ‘the person with lawful responsibility for the body’ or ‘the person with custody or care or control of the body’ appropriate?

26. Please tell us your ideas for removing the ambiguity created by the term ‘the person in charge (of an institution)’. In the case of hospitals, which of the following three options do you prefer for the new legislation:

a) a particular position within a hospital designated as the person lawfully in possession (eg, the institution’s chief executive or medical director)?

b) a requirement that institutions appoint or nominate for appointment a particular person from time to time?

c) a particular position within the District Health Board, likely to be the chief executive, with the ability for this responsibility to be delegated as appropriate?

Please share any other suggestions you have.

B8 Special types of tissue

This section discusses and seeks your views about some specific types of tissue that may need special provisions in the new legislative framework:

- stillborn children and foetal tissue
- stem cells (excluding haematopoietic stem cells covered by the Health Act (see Appendix 5).

B8.1 Stillborn children and foetal tissue

The use of tissue from stillborn children or foetuses raises particular issues. In part this is due to the distress and sensitivity that usually surrounds the premature loss of a child, or the decision to terminate a pregnancy. Because of the sensitive and personal nature of tissue from stillborn children and foetuses it is important that the legislative framework provides clear guidance.

Currently, stillborn children and foetuses are excluded from the Human Tissue Act through the definition in the Act of a ‘body’. The Code may cover stillborn children and foetuses through the mother, but this is not clear. Ethics committee guidance also makes reference to the use of foetal tissue in research.

24 Application of the Code of Rights to the removal and retention of body parts from abortuses and stillborns. Unpublished correspondence to the Health and Disability Commissioner.
The use of tissue from a stillborn child, or foetus following the termination of a pregnancy, is objectionable to some people. Other people consider that the benefits to be gained from education or research outweigh other considerations, provided that consent is gained for the tissue use.

The Ministry considers that it would be wise to include stillborn children and foetuses in the new regulatory regime. This would make it clear that requirements to use tissue from stillborn children and foetuses, such as the need to obtain consent, apply.

B8.1.1 Ethical concerns

The use of foetal tissue for non-therapeutic purposes, predominantly research, raises particular ethical concerns, such as ensuring there is no inducement provided to the mother to have an abortion.

Overseas jurisdictions have specific information to guide ethical decision-making in this area. For example, the United Kingdom draws on the Polkinghorne Guidelines (Polkinghorne 1989). New Zealand ethics committees do not have detailed New Zealand-specific guidance to draw upon. The Operational Standard and advice from the Health Research Council (2002), however, steer their decision-making, and approval of a research application would be dependent on factors such as:

- obtaining informed consent from the mother
- recognition and management of cultural issues
- a clear separation between the decision to terminate a pregnancy and the decision to allow the use of foetal tissue for research – in particular the decision to terminate a pregnancy should be taken before consent is sought to use foetal tissue
- no inducement such as payment, koha, gifts or otherwise being offered to the mother, or those who may influence her decision, to either terminate a pregnancy or allow the use of foetal tissue
- ethics committee guidelines are clear that it is unacceptable to provide payment, koha or gifts that are an undue inducement to participate in research.

Other non-therapeutic uses of tissue from stillborn children and foetuses (beyond research) could be managed through the consent processes already described and the tissue management standard suggested in section B6.

We are seeking your views

27. Do you think that stillborn children and foetuses should be brought within the coverage of the new regulatory framework? If not, please explain why.

28. Currently, New Zealand does not have separate guidance for ethics committees and researchers to follow when dealing with research using stillborn children and foetal tissue. Do you think guidance in addition to the general guidelines detailed above is needed? Please explain your response.
B8.2 Stem cells and cell lines

B8.2.1 Tissues and cells in research

This section is concerned with the use of cells and tissue (particularly stem cells) for research purposes. This research, including that on stem cells, is likely to include the development of cell lines. Table B4 sets out the current controls on the collection and use of cells and tissues for research. The controls cover ethical, environmental (genetic modification) and health safety issues.

The question for this Review is whether the current regulation of the collection and use of cells and tissue for research is sufficient, or if additional controls are required for particular cells or tissues. If additional controls are desired, then the purpose of those controls and the types of cells or tissues to which they should apply need to be clearly described.

Stem cells are cells that have the ability to continuously divide and develop into different kinds of tissues. Because of this property they are of great interest to researchers and have considerable potential for future health treatments. It is anticipated that researchers will be able to trigger stem cells to transform into specific cells types – blood, skin and neural cells, for example. These cells could then be used to repair diseased or damaged tissue and may be able to treat diseases such as cancers, spinal cord injury, heart disease and neurological disease. Research using stem cells is a relatively new area.

Stem cells can be obtained from a number of different sources, including:

- early embryos (around five to six days old), eg embryos created for IVF treatment but not required for that purpose could be used with the informed consent of the relevant parties.
- foetuses (from pregnancy terminations – see also the discussion in section B8.1)
- umbilical cord blood
- other tissues from humans (often called adult stem cells).

Currently in New Zealand, Auckland University is undertaking research that uses stem cells obtained from adults (with informed consent). There is no research in New Zealand that uses embryonic stem cells.

Cell lines are cells grown in culture and have been derived from tissue that has been processed to extract a certain type of cell. This cell is then grown in the laboratory to form an ongoing cell line. Many types of cell lines are in existence and this technique allows for the ongoing study of both healthy and diseased tissues. Cell lines can be established from many types of cells, including stem cells.
Embryonic stem cells

As described above, stem cells are found in embryos and the special properties of embryonic stem cells mean that these cells may offer considerable opportunities for health treatments. The use of embryonic stem cells is a controversial issue, however, as the collection of stem cells from embryos means that the embryo is not able to develop into a human being.

The collection of embryonic stem cells is a complex and challenging issue internationally for policy makers, researchers and ethicists. In New Zealand it is proposed, under the Supplementary Order Paper to the Human Assisted Reproductive Technology Bill (see section B2.5), that a ministerial advisory committee be established to consider and consult on a number of issues, including the use of gametes and embryos for research purposes. This will undoubtedly include consideration of issues related to embryonic stem cell collection in New Zealand. If the decision is made to allow for the collection of embryonic stem cells, guidelines and/or regulations will be developed for this purpose. In addition, any research application that involves the collection of embryonic stem cells would require the approval of an ethics committee established under the Human Assisted Reproductive Technology legislation, as well as being subject to the controls in Table B4.

There is also the potential to use imported embryonic stem cell lines, in which case the matters raised in section D5 regarding the import and export of tissue will be important.
### Table B4: Framework governing the collection and use of tissues and cells for research in New Zealand

<table>
<thead>
<tr>
<th>Body/mechanism</th>
<th>Role</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regional ethics committees (not established in legislation, but the requirements to submit proposals for ethical review are derived from a variety of sources)</td>
<td>Decide on individual research applications to obtain and use cells and tissues.</td>
<td>Must follow the Operational Standard for Ethics Committees, and ensure the health and safety of any human participants in research or clinical trials.</td>
</tr>
<tr>
<td>Code of Health and Disability Services Consumers’ Rights 1996</td>
<td>Provides a set of rights for people receiving health and disability support services, including when it is proposed that the consumer participate in teaching or research.</td>
<td>Health practitioners who are likely to be responsible for tissue collection must, among other things, ensure that the consumer has given informed consent and received sufficient information to guide their decisions (see section B2.2 for a fuller discussion).</td>
</tr>
<tr>
<td>Mechanisms under the Hazardous Substances and New Organisms Act 1996</td>
<td>To assess the potential for adverse environmental, health and economic effects of genetic modification of human cells and tissues.</td>
<td>A research proposal to genetically modify human cells would need to be approved under the Hazardous Substances and New Organisms Act 1996 before it could proceed.</td>
</tr>
<tr>
<td>Health Research Council committees: Standing Committee on Therapeutic Trials (SCOTT) and the Gene Technology Advisory Committee (GTAC) (committees of the Health Research Council to fulfil the requirements of the Medicines Act 1981)</td>
<td>Under s30 of the Medicines Act, the Director-General of Health may permit the use of medicines that have not received marketing consent, to be used in clinical trials for the purpose of obtaining clinical and scientific information on advice from a health research committee.</td>
<td>Under proposals in this discussion paper, the use of human cells or cells lines as a therapeutic product would first have to go through clinical trials. Applications to undertake clinical trials would be scrutinised by SCOTT and/or GTAC. Based on this advice and ethical considerations, trials may be approved by the Director-General of Health.</td>
</tr>
</tbody>
</table>

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25 Appendix 4 contains a description of the ethics committees referred to in this table, and section B2.3 describes ethical review processes.

26 Sources include the Code of Health and Disability Services Consumers’ Rights, international declarations such as the Declaration of Helsinki, approval requirements of funding organisations, and the Injury Prevention, Rehabilitation and Compensation Act 2001. (See B2.3).

27 Work is under way to replace the Medicines Act, to implement the joint therapeutic products regulatory scheme and to regulate New Zealand specific aspects of medicines regulation. The approval processes for clinical trials will be carried forward into this new environment for therapeutic products regulation.
We are seeking your views

29. Are the current processes outlined in Table B4 for reviewing the ethical and safety dimensions of research applications using cells and tissues (specifically stem cells) sufficient, or should such research be subject to any additional review processes before it can proceed? If so, please explain your reasons.

30. What should the main purpose of any additional processes be?

B8.2.2 Established cell lines (including stem cell lines)

Cell lines are lines of single cells that have been grown in the laboratory from human tissue samples. They have been processed and reproduced in a culture medium. Most human tissues can be grown in this way, and this allows ongoing research of both healthy and diseased tissues to be undertaken.

These cell-line cultures can survive for many years – potentially well after the death of the original donor. They are important tools for both medical diagnosis and research. The cell lines are almost always unable to be linked to the original donor of the tissue.

There are thousands of cell lines in existence, and many are sold by providers of laboratory supplies and imported. Some lines are also established in New Zealand. The use of established cell lines, predominantly for research, is currently not regulated and is generally not subject to ethics committee review. The question for this review is whether there are any circumstances when these cell lines should be subject to ethical review, and if so what the purpose of such a review would be.

In considering this question it is important to note that:

- the collection of the original human tissue sample will be subject to consent requirements (see sections B4 and B5 for a discussion of informed consent requirements)
- ethical review processes are concerned with protecting human participants (see section B2.3 for a discussion of ethical review issues)
- cell lines are almost always anonymous
- reviewing projects that propose to use cell lines would consume a considerable amount of ethics committee resource
- a code of practice for importing human tissue is proposed in section D5.

On balance, the Ministry does not consider that ethical review of projects using established cell lines is warranted as routine, but is interested in your views.

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28 These types of sales are different from those discussed in section D4, as the remuneration relates to the process of work and skill that has allowed the cell line to develop and be maintained – it does not relate to the donation of the original tissue.
We are seeking your views

31. Do you think there are any circumstances in which established cell lines should be subject to ethical review, and if so what would the purpose of such a review be?

B9 Privacy and genetic information

This section discusses genetic information, which is obtainable from human tissue, and the current protections for genetic information under the Health Information Privacy Code 1994. The question that has arisen in this Review is whether this coverage is sufficient, or whether changes to the Health Information Privacy Code should be investigated.

B9.1 Why is genetic information different?

Genetic testing is increasingly being used in the provision of health care to obtain genetic information for the purposes of:

- improving the diagnosis of diseases
- providing individuals with information about whether they have a higher risk of developing certain diseases
- contributing to the development of new therapeutic interventions to treat genetic disorders.

The United Kingdom Human Genetics Commission identified the following reasons for distinguishing between genetic information and other types of health information (Human Genetics Commission 2000).

1) Genetic information is uniquely identifying information. Only an identical twin will have exactly the same genotype as someone else.

2) Genetic information can be obtained from a very small amount of material and does not require lengthy observation or history-taking. It may also be possible to obtain a sample without the knowledge or consent of the person affected – such as from a sample obtained in the past for another purpose, or from cells shed unknowingly (eg, hair follicles).

3) Genetic information may be used to predict some rare inherited disorders that develop later in life and to predict what may be passed by a parent to children. This prediction may be made even before the birth of the person in question.
4) The predictive possibilities may be of interest to people other than the owner of the tissue sample tested (e.g., insurance companies or employers, who might wish to take them into account in their dealings with the subject). In many (though not all) cases, genetic information is not only information about the individual person, but about his or her biological relations. Genetic information about one family member may have significant implications for other members of the family, including information about susceptibility to disease and issues of family genetic relationships. (In other cases, of course, genetic information may have no implications for other family members. This will be the case where a mutation has occurred in an individual’s cells leading to disease such as cancer.)

5) Genetic information has a potential commercial value and methods of obtaining it may be the subject of patents. In addition, there are complex issues as to ownership interests in human DNA.

6) Collections of genetic information combined with individual medical and life-style information provide an important research resource for understanding individual susceptibilities to disease and its treatment. Increasingly, drug treatments may be targeted to sub-sets of the population identified, in part, by genetic information.

7) Genetic information may be collected for a variety of very different purposes (disease prediction, determining family relationships, etc). However, once this information is collected, it can be used for a quite different purpose from that for which the provider of the information originally gave consent.

B9.2 Protections for genetic information

Although the majority of the human genetic structure is identical from one individual to another, it is the variations in our genetic structure that give rise to each individual’s particular physical characteristics. We may also have shared family characteristics that are passed from one generation to the next. Such characteristics range from the colour of our hair or eyes, to our susceptibility or resistance to different diseases. Information about the more or less unique genetic variations that contribute to making us who we are is very personal.

There are many advantages to knowing each person’s genetic structure and how those characteristics are shared within families. Knowing that members of a particular family are more likely to suffer from a particular medical condition can help people take precautions with regard to their own health. Knowledge of a person’s particular genetic makeup may enable medicines to be specifically tailored to that individual in the future. This would enable more effective medication with reduced or eliminated side-effects.

Genetic information can be obtained from a variety of sources. Such information can range from general information gathered through the study of a family’s medical history, to the observation of a person’s external physical characteristics, to the analysis of blood and tissue samples containing DNA.
Concerns have been raised about the possibility of uncontrolled access to and use of genetic information, given the relative ease with which genetic material can be obtained. A commonly acknowledged concern is that access to such information could potentially lead to discrimination by insurance companies and employers. It is also of concern to some people that parts of their unique genetic makeup may be used for purposes other than that for which the original consent was given, without their knowledge or consent. Māori and Pacific peoples may have specific concerns about genetic information and implications for whakapapa or genealogy.

B9.2.1 The Health Information Privacy Code

The Health Information Privacy Code (HIPC) is established under the Privacy Act. The principles in the Privacy Act apply to all ‘personal information’ collected or held by agencies. Personal information is information about identifiable living persons. The HIPC applies to ‘health information’, which is a subset of personal information. The HIPC also applies to health information about deceased persons that was obtained after 1993/94, but only with respect to the disclosure of that information.

The HIPC defines health information as information about an identifiable individual, which includes information:

- about the health of that individual, including his or her medical history
- about any disabilities that individual has, or has had
- about any health services or disability services that are being provided, or have been provided, to that individual
- provided by an individual in connection with the donation of any body part or any bodily substance of that individual, or derived from the testing or examination of any body part or any bodily substance of that individual
- about that individual which is collected before or in the course of, and incidental to, the provision of any health service or disability service to the individual.

The HIPC applies specific rules to agencies in the health sector which hold the types of information described above to ensure the protection of individual privacy. The HIPC also recognises that there is public benefit in allowing access to some information for particular purposes, and allows the use of anonymised health information with appropriate safeguards.

In terms of tissue, the HIPC covers any information given in association with body parts or bodily substances, or derived from them.

Potential gaps in the HIPC in relation to genetic information may therefore be:

- coverage for the actual tissue sample from which genetic information may be gathered
- whether it is appropriate, or even possible, for genetic information to be anonymised and used for other purposes.
If the HIPC were to be amended to specifically address genetic information, some of the issues that will need to be addressed are:

- whether it is possible to anonymise genetic information and how this should be done
- whether a distinction should be made between a portion of genetic information about a person, and the complete set of genetic information about a person
- how consent to collect, access, use and/or dispose of genetic information should be obtained and recorded
- whether there are times when consent would not be needed to use genetic information, and if so, what safeguards would be needed for this to happen
- whether individuals should be able to own genetic information derived from the analysis of their tissue
- whether there are any circumstances in which genetic information should be disclosed to other family members
- whether family members, or any individual who has not authorised the genetic testing of their tissue, should have the right not to know the outcome of such testing, and whether there are any circumstances in which this right could be breached. For example if a general consent to the use of tissue in research had been given and subsequent analysis shows the likelihood of a genetic condition that may be treatable.

**We are seeking your views**

32. The implications of access to genetic information are complex and affect people beyond the individual who is the source of the information. We are seeking your thoughts on whether the coverage of the Health Information Privacy Code should be extended to specifically address genetic issues. If so, please tell us your views on any or all of the issues listed above.

**B10 Retention of specimens as health information under the Health Act 1956**

As part of the Government’s response to the recommendations of the Gisborne Cervical Screening Inquiry (Duffy et al 2001), the Health (National Cervical Screening Programme) Amendment Act has recently been passed by Parliament. The Act makes a number of changes to the legislative provisions for screening programmes. Most relevant to this review are the changes to the regulation-making powers in the Health Act 1956.

Section 121A of the Health Act allows regulations to be made to govern the retention of health information. The Act extends this regulation-making power to cover specimens, as well as more traditional types of health information such as doctors’ notes.
The Act allows changes to be made to the Health (Retention of Health Information) Regulations 1996 to ensure the appropriate coverage of specimens.

The change was made in response to the Gisborne Cervical Screening Inquiry, which considered that cervical screening slides and blocks should be retained to allow robust quality assurance and audit programmes to be conducted. The regulation-making power is broader than just cervical screening specimens and recognises that there is broader benefit in a full health record being retained.

This discussion document is seeking your initial views on the matters to be resolved in extending the Health (Retention of Health Information) Regulations to include specimens.

B10.1 Health (Retention of Health Information) Regulations 1996
Currently the Health (Retention of Health Information) Regulations 1996 (the Retention Regulations) require providers of health or disability services to retain health information about identifiable individuals for a minimum period of 10 years from the last time the person received a health or disability service. Information must be retained whether or not:

- the provider holding the information is the person that most recently provided a service
- the information existed before 1996, when the Retention Regulations came into effect
- the information includes material that existed before the beginning of the 10-year period.

Health information may be transferred between providers (eg, if a person moves and wants their new general practitioner to have their previous record), or may be given to the individual concerned.

It is useful to note that the Health Information Privacy Code and the Code of Health and Disability Services Consumers' Rights cover issues of access to health information and privacy.

B10.1.1 Issues for the retention of specimens
The Retention Regulations can now be extended to require the retention of specimens. The Ministry has identified the following issues as needing to be resolved before the regulations are extended.
The definition of a ‘specimen’ to be covered by the regulations

The proposed amendment to the Health Act defines a specimen as ‘a bodily sample or tissue sample taken from a person’, but for the purposes of the Retention Regulations this broad definition may need to be refined. For example, cervical smear slides would need to be retained, but all blood samples, or urine samples taken during a person’s lifetime, may not need to be retained. Neither may the tissue from which a specimen for a microscope slide has been obtained. Consideration will also need to be given to specimens that are held in specialist databases, such as the Guthrie Card samples held at the National Testing Centre.  

The key consideration in defining the specimens to be retained is the purpose for which the specimens are to be retained. The main purpose is ensuring that a full health record is kept to facilitate clinical management, and quality assurance.

The minimum period or periods for which specimens should be retained

The retention period could be variable depending on the type of specimen involved. This involves examining the minimum 10-year period for other health information and whether this is appropriate for specimens, or whether a different length of time is more appropriate.

Any particular storage conditions that may be required for specimens

For example, there may need to be special facilities that ensure the specimen is able to be used again if required (including whether different arrangements are needed for different types of specimens). There are also likely to be practical space issues to be considered.

Return of specimens

There are implications for specimens of health information being able to be returned to the individual concerned, and whether special requirements will be needed.

Ways that the regulations can be designed to anticipate future developments in technology

For example, in the future it is feasible that records of specimens may be kept electronically (similar to X-rays), meaning that the physical specimen may not need to be retained.

The Ministry is also aware that currently there is a gap in the coverage of the Retention Regulations regarding the management of health information held by a provider that ceases to practice. It would be wise to make changes to the Retention Regulations to cover this circumstance when other changes are being made. This would cover the situation, for example, where a general practitioner resigns, or a laboratory holding specimens goes out of business.

29 The Privacy Commissioner has recently recommended, among other things, that clear guidance on the retention of Guthrie Card specimens be developed. See Privacy Commissioner 2003.
We are seeking your views

33. Following the passage of the Health (National Cervical Screening Programme) Amendment Act, changes are able to be made to the Health (Retention of Health Information) Regulations 1996 to cover the retention of specimens as well as other health information.

The Ministry is proposing that the following changes be made to the regulations:

a) the definition of a ‘specimen’, beyond ‘a bodily sample or tissue sample taken from a person’, should be covered by the regulations (ie, the sorts of specimens the regulations should apply to)
b) the purposes for which different sorts of specimens should be retained
c) the minimum period or periods for which specimens should be retained and any particular period for which particular specimens should be retained
d) particular storage conditions that may be required for specimens (including whether different arrangements are needed for different types of specimens), and the practical issues that arise from any storage requirements
e) the implications for specimens of health information being able to be returned to the individual concerned
f) ways the regulations can be designed to anticipate future developments in technology
g) the management of health information (including specimens) when a provider ceases to practise or be in business.

Are there matters in addition to those listed above that you think need to be considered when changes are made to the regulations? Please explain your suggestions and share your initial thoughts about what should be covered by the regulations in relation to these issues.
Part C: Therapeutic Use of Tissue

So far this document has focused on the use of tissue for non-therapeutic purposes. Part C looks at the issues that need to be covered when tissue is used as a therapeutic product.

The use of human tissue as a therapeutic product has improved the quality of life for many people, including the recipients of organ and tissue transplants. The increasing success of these types of treatments and the potential offered by new techniques mean that it is timely to examine the current regulatory framework for the therapeutic use of human tissue.

In looking at the regulatory framework the following issues are of primary concern:

- Is the proposed use or therapy acceptable to the community, including different cultural groups?
- What systems are needed for the collection of tissue for tissue-based therapies?
- What type of safety and quality control system needs to be in place to make tissue-based therapies as safe as possible?

C1 What are tissue-based therapies?

The following description is drawn from a discussion paper released by the Australian Therapeutic Goods Administration (2003), which summarises the different types of tissue-based therapies.

Tissue-based therapies can be broadly categorised as:

- human tissue and cells, and cellular and tissue-based therapies
- gene and related therapies
- xenotransplantation.

These are discussed in turn below.

C1.1 Cell and tissue therapies

The transplantation of human tissues has been undertaken successfully for some time. The following types of treatments are now well established practice:

- transplantation of kidney, liver, lung and pancreas
- transplantation of heart valves to replace defective heart valves
- transplantation of corneas to restore eyesight
- skin replacement after severe burns
- transplantation of bone.
Recently, technology has advanced and the potential uses of human tissue have expanded considerably. Improvements in biotechnology have led to new ways in which human tissues can be manipulated to provide therapeutic benefits.

The above list details the use of larger amounts of tissue as a therapeutic product, but it is also possible to use cells as therapeutic products or replacements for cells that are defective or deficient in particular conditions.

There is no clear line between tissue therapy and cell therapy. A therapy may make use of living cells that are organised as tissues, or tissues may be purified to extract certain cells, and cell lines developed for therapeutic benefit.

One of the most significant developments in cell therapy is the identification and use of stem cells. Stem cells are found in different human tissues and are capable of developing into different types of cells with particular characteristics. For example, particular stem cells could grow into bone cells or nerve cells, and be used to replace damaged cells. Stem cells have the potential to be used in a range of therapies and treatment, although much research in this area still needs to be undertaken.

Stem cells from blood have been used for several years to treat people with bone marrow diseases. Recent research suggests, however, that there may be great potential for stem cells from different tissues to be used for a broad range of therapies, such as in treating certain degenerative brain conditions.

C1.2 Gene and related therapies

Gene therapy, simply put, is the genetic modification of cells to produce a therapeutic effect. This means that a number of medical conditions caused by genes that do not work normally could be cured or alleviated by gene therapy. Cystic fibrosis may be amenable to gene therapy, for example. Gene therapy is currently the subject of research and is not a therapeutic treatment at this stage.

One definition of gene and related therapies is:

Somatic gene therapy is defined as the insertion of DNA/RNA into the somatic cells\(^{30}\) of humans. The term ‘related therapies’ has been used to allow the inclusion of some vaccines containing genetically modified organisms and novel DNA-based strategies or technologies that might be developed and have the potential to modify the human host genome (Therapeutic Goods Administration 2003).

Gene therapy can involve cells being removed from a patient, modified in the laboratory and put back into the patient, or it can involve the genetic modification of cells while they remain in the body.

\(^{30}\) A somatic cell is any cell other than a sperm or egg cell.
Under current regulation, undertaking such processes would require approval under the Hazardous Substances and New Organisms Act (to perform the genetic modification) and the Medicines Act (see section C2 for a description of this legislation).

It is important to note that the process of gene therapy described in this section is not the same as germ-line genetic modification. Germ-line genetic modification generally means the genetic modification of gametes and embryos which, if implanted and allowed to develop, would mean the altered genes are passed on to subsequent generations. The genetic modification of gametes and embryos for reproductive purposes is likely to be prohibited under new human-assisted reproductive technology legislation.

C1.3 Xenotransplantation

Xenotransplantation is the transplantation of live cells, tissues or organs from another species (such as pigs) into humans. Xenotransplantation also includes any procedure where human fluids are exposed through a filtering system to living non-human cells, tissues or organs. The actual tissue transplanted is called a xenograft.

Xenografts are live tissue from another species, which makes them different from, for example, the pig heart valves that are routinely used in cardiac surgery and which contain no living cells.

Xenotransplantation is currently not undertaken in New Zealand, although in the future there may be the potential to use the following types of xenografts:
- clusters of specialised cells, such as pancreatic islet cells to treat diabetes
- other tissues such as skin
- solid organs such as a kidney or heart.

Xenotransplantation is a complex area, which raises significant issues in terms of acceptability and risk.

The current regulation of xenotransplantation is discussed in section C2.1 and the issue of public acceptability of this technology is discussed in section D3.

C2 Current regulation of tissue for therapeutic use

The use of tissue for therapeutic purposes is regulated through the:
- Medicines Act 1981
- Human Tissue Act 1964
- Code of Health and Disability Services Consumers’ Rights 1996

These are discussed below.
C2.1 Medicines Act 1981

The primary concern of the Medicines Act 1981 is the safety of medicines and medical devices. The Act establishes a system of pre-market approval for medicines, an approval mechanism for clinical trials of medicines, and a licensing scheme for manufacturers and wholesalers of medicines. The Act also provides for post-market controls on medicines and medical devices.

Currently, the safety regime in the Medicines Act applies only to tissue that meets the definition of a medicine or medical device. The Medicines Act does not cover whole human organs and other transplantable tissue that have not been subject to a manufacturing process. The safety provisions of the Medicines Act and proposals to amend them are covered in detail later in this Part.

The Medicines Act also contains important provisions about ‘specified biotechnical procedures’, which includes xenotransplantation. Under part 7A of the Medicines Act no one may undertake xenotransplantation in New Zealand (including clinical trials) without the permission of the Minister of Health. Before permission for xenotransplantation to take place could be given, the Minister must be satisfied that any risk to the health or safety of the public is minimal and will be managed effectively, and that any ethical, cultural and spiritual issues have been adequately addressed. No applications to undertake xenotransplantation have been requested under these provisions. The provisions that limit xenotransplantation are due to expire in June 2005. One of the goals of the Review is to have new legislation in place for xenotransplantation before these provisions expire. This is discussed in section D3.1.

Work is under way to replace the Medicines Act, to implement the joint therapeutic products regulatory scheme and to regulate New Zealand-specific aspects of medicines regulation. The specific vehicle for tissue-based therapies discussed later in this section will be considered at a later date.

C2.2 Human Tissue Act 1964

The Human Tissue Act is contained in Appendix 2. The Act sets out the requirements to be met before tissue may be removed from the body of a deceased person for therapeutic purposes.

With regard to obtaining consent, or, as it is phrased in the Human Tissue Act, establishing a ‘lack of objection’, the Act distinguishes between when the wishes of the deceased person are known and when they are not known. Table C1 provides a summary of the consent provisions in the Act for therapeutic use of tissue. In each of these cases, the person lawfully in possession of the body of the deceased must be sure that an inquest or coronial post-mortem is not required before the body can be used for therapeutic purposes. If a coronial post-mortem is required, consent must be gained from the coroner before organs or tissue can be retrieved for transplantation. If the coroner gives consent, the coronial post-mortem would take place after the retrieval of organs for therapeutic use. About 50 percent of donors also require a coronial post-mortem.
The person lawfully in possession of the body may be:

- the person in charge of the hospital where the deceased person is lying (a hospital is defined in the Health and Disability Services [Safety] Act 2001 and the Mental Health [Compulsory Assessment and Treatment] Act 1992)
- the superintendent of any penal institution where the deceased inmate is lying.\(^{31}\)

A discussion about the appropriateness of this definition, and the concept of ‘lack of objection’, is contained in Part B of this document (see sections B7.2 and B5.2), where it is recommended that the test become one of giving consent and that the concept of the ‘person in possession of the body’ be updated.

In ascertaining the views of the persons listed in Table C1, the person lawfully in possession of the body is required to make ‘such reasonable inquiry as may be practicable’ to inform their decisions. In guidance issued in 1987, the then Department of Health described this phrase as requiring, in most instances, that the matter be discussed with any one relative who has been in close contact with the deceased person. The relative should be asked their views, the views of the deceased, and if there is any reason to believe that any other relative would be likely to object.

The guidance further notes that there is no need to establish a lack of objection from all relatives or to make inquiries that are unreasonable or impractical. For example, if a donor’s relatives were found to be young children, inaccessible, or seriously ill, it would be impractical to ask them.

\(^{31}\) In practice penal institutions are now under the control of chief executives or general managers as opposed to superintendents.
Table C1: Decision authority for the collection of tissue from deceased persons for therapeutic use under the Human Tissue Act 1964

<table>
<thead>
<tr>
<th>Person lawfully in possession of the body</th>
<th>May allow this use if there is no known objection from the deceased, surviving partner, or any surviving relative.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deceased person (the wishes of the deceased may be written, or oral and witnessed by two people)</td>
<td>May request or object to the use. In requesting this use, the person may specify the terms of the request (eg, the body parts to be used, and for what purpose).</td>
</tr>
<tr>
<td>Surviving partner</td>
<td>May object to a request by the person lawfully in possession to use the body for this purpose.</td>
</tr>
<tr>
<td>Surviving near relative</td>
<td>Not mentioned in relation to therapeutic uses (but mentioned in relation to non-therapeutic uses, see section B2.1.1).</td>
</tr>
<tr>
<td>Any surviving relative</td>
<td>Has the same right as a surviving partner to object to a request by the person lawfully in possession to use the body for this purpose.</td>
</tr>
</tbody>
</table>
| Summary | If the deceased has requested this use, then the use may be authorised by the person lawfully in possession. Any terms specified by the deceased must be honoured.  
If the deceased has objected, then the use cannot be authorised.  
If the deceased hasn’t stated an opinion, then the decision rests with the partner and family.  
If there is no known objection from the deceased or relevant family, then the use may be authorised by the person lawfully in possession. |

C2.2.1 Seeking consent for tissue donation in practice

Although not strictly required by the law, in practice, even if a person has stated their wish to be an organ or tissue donor, the whānau or family will always be asked for their agreement to the procedure and much good practice has developed in this area. Some people find this practice unacceptable, however, particularly in light of the gap between the demand for organs and other tissue for donation and the supply. This important issue is discussed further in section C4.

C2.3 Code of Health and Disability Services Consumers’ Rights 1996

The Code of Health and Disability Services Consumers’ Rights (the Code) is contained in Appendix 3. The Code is in regulations established under the Health and Disability Commissioner Act 1994. It applies to living people and provides a set of rights for people receiving health and disability support services. In terms of the therapeutic use of tissue, the Code relates to those situations where:

- a living person is a donor of tissue (eg, live kidney donation)
- a person is the recipient of a tissue-based therapy.
While all of the rights in the Code are relevant, those relating to information and consent are critical in relation to tissue-based therapies. In summary, services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. For example, a person must give their consent, after being given sufficient information, to living tissue or organ donation, or to receiving a tissue-based therapy.

C2.4 Hazardous Substances and New Organisms Act 1996

The Hazardous Substances and New Organisms Act is primarily concerned with protecting the environment and the health and safety of people and communities. This Act has recently been amended so that the genetic modification of human cells and tissues has been brought within its coverage.

Human cells are defined as follows:

‘Human cells’ –

(a) means human cells, human cell lines, or human tissues that are being grown or maintained outside the human body; and

(b) includes human reproductive cells or human embryonic cells that are being grown or maintained outside the human body.

The effect of this change is that any proposal to genetically modify human cells and tissues or import genetically modified human cells and tissues will require approval under the Hazardous Substances and New Organisms Act. This will include a risk assessment process that will assess the potential for adverse environmental, health and economic effects.

It is important to note that the Hazardous Substances and New Organisms Act applies to the genetic modification of human cells outside the human body (ie, in test tubes). If these cells were then to be used for other purposes, such as clinical trials in humans, additional processes will apply. In the case of clinical trials the approval processes under the Medicines Act 1981 will apply.

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32 Right 7(1).
33 Hazardous Substances and New Organisms Act, section 2.
34 Work is under way to replace the Medicines Act, to implement the joint therapeutic products regulatory scheme and to regulate New Zealand-specific aspects of medicines regulation. The approval processes for clinical trials will be carried into the new regulatory environment for therapeutic products.
C3 What are the issues, gaps, or problems?
The Ministry has identified three areas where the current framework for regulating tissue for therapeutic use should be examined:

- whether particular tissue-based therapies are acceptable to New Zealanders, and how therapies that arise in the future can be considered (this is discussed in Part D)
- whether the legislative requirements for organ and tissue donation are the best approach to maximising the organs and tissue available for transplantation while also respecting the wishes and beliefs of the public
- how the safety of tissue-based therapies can be best assured.

C4 Organ and tissue donation
In common with people in other countries, there are more New Zealanders who could benefit from an organ or tissue transplant than there are organs or tissue available for transplantation. The projected increase in the proportion of older people in the population and trends that show an increasing number of people with conditions such as diabetes indicate that the gap between demand and supply is likely to widen.

The Ministry is approaching the issue of organ and tissue donation in two ways, by:

- examining the legislative provisions through this Review, which involves examining the current provisions of the Human Tissue Act that deal with consent and the issue of sale and purchase of organs and tissue
- examining service-level issues relating to organ donation in conjunction with the National Donor Co-ordination Office and District Health Boards, which includes service funding issues, the role of the National Donor Co-ordination Office, the training of health practitioners, and public education.

While it may be possible to make improvements to the current legislative framework for organ and tissue donation, the Ministry considers that changes to practice will have the most impact on rates of donation.

C4.1 Organ and tissue donation in New Zealand
In New Zealand the following organs or tissue may be transplanted:

- heart or heart valves
- pancreas
- lungs
- eyes (corneas, sclera)
- liver
- bone
- kidneys
- skin.
At any one time there are around 350 people on the waiting list for organ transplants, and of these, about 300 are waiting for a kidney transplant. Increased waiting times for patients on transplant waiting lists are associated with increased periods of hospitalisation prior to transplantation, increased morbidity at the time of transplantation, longer rehabilitation following transplantation and, sadly for some, death while waiting for a suitable transplant to become available.

Organs and tissues can be donated following death in the following circumstances.

- **Organ donation** – those who have suffered severe and irreversible brain damage, most commonly following a brain haemorrhage or trauma, will be admitted to an intensive care unit, will be on artificial ventilation, and brain death will be certified. After brain death has been confirmed the family will be offered the option of organ donation.

- **Tissue donation** – in Auckland, the donor tissue co-ordinators, employed by the University of Auckland, contact the families of those requiring a coroner’s autopsy to offer the option of tissue donation.

- **Eye donation** – eye donation can be facilitated in a number of circumstances. It can take place in a hospital ward mortuary or funeral home.

The acceptable age and medical criteria for potential donors have been increasing for several years in an attempt to increase donor rates. However, the numbers of organs and tissues available for transplantation in New Zealand has remained relatively unchanged over the past 10 years.

New Zealand has one of the lowest organ donor rates in the world when measured by donors per million population (dpmp). New Zealand’s rate of organ donation dpmp for 2002 was 9.6, slightly lower than Australia’s rate of 10.4 and well below Italy’s rate of 18.1 (Herbertt and Russ 2003). This measure is influenced by people’s willingness to donate, as well as factors such as the number of intensive care beds available in each country.

- The number of cadaveric kidneys retrieved for transplantation in the past 10 years has remained unchanged (69 in 2002). Organs are allocated to patients of a compatible blood group and tissue type. Live kidney transplant rates have increased as a result of the low cadaveric kidney donation rate (48 in 2002).

- The number of livers retrieved has increased since the New Zealand Liver Unit has been established due, at least in part, to improved logistics (ie, New Zealand donor co-ordinators will travel within New Zealand to examine livers that may be marginal. This doesn’t happen in Australia due to the Australians’ increased travel costs). Organs are allocated to patients of a compatible blood group.

- The number of hearts and lungs retrieved is often dependent on the types of recipients on the waiting lists. For hearts and lungs the recipient must not only be of a compatible blood group, but of similar body weight to the donor.
The majority of hospitals in New Zealand that have an intensive care unit or can otherwise support ventilated patients are involved with organ donation. Some patients will have been transferred to a tertiary centre for treatment, whereupon organ donation becomes an option.

Tissue donation, such as eye donation, can take place in a more flexible range of circumstances. Donation can take place several hours after a person has died and the use of technology such as ventilators is not necessary. This means that a person who dies in the community may be able to be a tissue donor where they may not be able to be an organ donor.

C4.2 Increasing the organ and tissue donor rate in New Zealand

Organ and tissue donors are largely deceased persons, so there is, therefore, a natural limit to the number of potential donors. Welcome reductions in road traffic deaths and other tragic events have further reduced the number of potential donors. It has been estimated that even with very proactive strategies to recruit donors there will still be a significant gap between the demand for organs and tissue and the supply (Jessamine 2001).

Other factors that influence New Zealand’s donor rate are:

- the number of intensive care beds available and whether people are able to be cared for in an intensive care unit
- whether health practitioners identify potential donors and seek consent to organ and tissue donation
- whether people are willing to donate organs or tissue
- whether the surviving relatives consent to donation.

While there are natural limits to the number of organ and tissue donors in New Zealand, the Ministry considers that there is the ability to increase the current donor rates. The Ministry is also very conscious of the highly personal and sensitive nature of organ and tissue donation, and that in seeking to improve the rate of donation, care must be taken to respect the wishes of individuals and families.

These objectives seem to be best balanced by taking an approach that aims to ensure that everyone who is suitable to be an organ donor is offered – or their family/whânau is offered – the opportunity to be a donor. This aim should then result in all organs and tissue that are able to be donated being donated and transplanted.

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35 A limited amount of live organ donation occurs in New Zealand. This is discussed in section C4.8.
C4.3 The role of legislation

The Human Tissue Act 1964 sets out who is able to make decisions regarding the use of organs and tissue for therapeutic purposes after a person’s death. The provisions are detailed in section C2.2 and Appendix 2, and are summarised as follows.

• A person may, before their death, record their wish to be an organ or tissue donor and they may specify the particular organs or tissue to be used. If this request is made, the person lawfully in possession of the body may authorise the removal of organs or tissue. This is subject to the person lawfully in possession having no reason to believe that the request was withdrawn.

• If a person has not recorded their wishes, the law allows the person lawfully in possession of the body to authorise the use of organs or tissue so long as they have made sure that there is no objection to this from the surviving partner or any surviving relative. In effect this means that the decision rests with the surviving partner or relatives if the deceased person hasn’t recorded their wishes.

It is important to note that, in practice, families will always be asked for their consent to organ or tissue donation. Each family is recognised as being unique, is placed under no pressure to make a decision, and is encouraged to take the time they need to make a decision that is right for them. Even if it is known that a deceased person wished to be an organ donor, organ donation will only take place with the agreement of the family. The practice of allowing the family the final say over donation, even when the wishes of the deceased person are known, is contentious for some people.

C4.3.1 What are the problems with the current law?

A recent report (Chen et al 2003) analysing both New Zealand law and the laws of other countries set out the following issues with New Zealand’s current law.

• Even though the Human Tissue Act was amended in 1989 to allow for a central computer system to be established recording organ donors, the number of organ donors in New Zealand remains low.

• A person’s request to be an organ donor under section 3 of the Act is not required by the law to be mandatory upon that person’s death. If that was the intention of the legislation, that is not how the Act is worded and the person lawfully in charge of the body is under no legal obligation to carry out the request of the deceased.

• Even if a person has indicated a preference to become a donor, at the time of their death the family will always be asked for their agreement. This appears to be contrary to the intent of the legislation, which does not require the permission of the donor’s relatives where the donor’s wishes are known.

• Practically, the most likely way a person will record their wish to be a donor is on their driver’s licence. About 43 percent of licence-holders have indicated they wish to be donors. Recording a wish to be a donor on a driver’s licence does not equal recording one’s wishes under the Human Tissue Act. It does, however, provide an indication of what a person’s wishes were. The driver’s licence application notes that in the event of the licence-holder’s death, family will be asked for their agreement to donate organs even if the licence-holder has ticked the ‘yes’ box.
• The driver’s licence application form does not allow a person to specify what organs or tissue they are comfortable donating. Some people would be happy to donate some organs (e.g., their kidneys) but not others, such as their heart, and may be put off ticking ‘yes’ for this reason.

Public debate about the legislation in New Zealand centres on the ability for the family to override the wishes of the deceased person to donate their tissue for therapeutic purposes. While this does happen in practice when family members find the idea of donating tissue overly distressful, in general people wish to follow through with the wishes of their loved ones.

C4.4 What are the options for changing New Zealand’s law regarding consent to organ and tissue donation?

In addition to the system under our current law, there are four other approaches taken in laws around the world that could be considered for New Zealand. Some of these options could be used in combination with each other.

Important: With each of these options it is very important to note that organ and tissue donation is a secondary consideration to the duty of care and treatment of any individual. A person would only ever be considered as a potential organ or tissue donor once it is clear that a person is likely to become brain dead. The aim of saving life, and the best possible quality of life, remains the first consideration. Section C4.5 discusses brain-death.

Given the gap between the demand and supply of organs and tissue, the central issue in considering these options is which of two competing principles should be paramount, and whether the differences between the non-therapeutic and therapeutic uses of tissue justify different principles applying for these different uses.

In the non-therapeutic part of this document it has been proposed that the wishes of deceased persons should be regarded, but that there are situations where the wishes of the living should be able to take precedence. For example, section B5.2.2 proposes that the law should not require the wishes of the deceased to be followed when a person has requested that their body be used for anatomical examination after their death, if at the time of their death this would cause undue distress to the surviving family. In this situation the wishes of the living are allowed to override the wishes of the deceased.

In the case of organ and tissue donation, it could be decided that the benefit to be gained from increasing the availability of transplantable organs and tissue warrants a different approach. This approach could be thought of as based on the principle of maximising all possible health benefit obtainable from transplantation. If this principle were to take priority, the options that limit the ability for individuals to decide about donation of tissue (such as presumed consent) become more acceptable.
These are fundamental matters concerning how individuals, groups and cultures in New Zealand view their bodies, life and death. The Ministry is not proposing that either principle outlined above take priority in relation to organ and tissue donation. The principles are outlined only to illustrate the dilemma that needs to be resolved. Your views on this dilemma are welcomed.

C4.4.1 Option 1: Presumed consent

This system presumes that everyone is an organ or tissue donor unless they have specifically recorded their objection to being a donor. This system operates in a number of countries that have a higher donor rate than New Zealand, such as France, whose donor rate is 17 per million (Chen et al 2003). The system also operates in a partial fashion in Singapore, whose law states that all mentally competent citizens or permanent residents aged between 21 and 60 who are victims of fatal accidents are presumed to be kidney donors when they die unless they opt out by signing a form.

While it is likely that a presumed consent system would increase New Zealand’s organ and tissue donation rate, it may not be acceptable to New Zealanders for a number of reasons. In particular, the approach:

• appears inconsistent with the culture of individual informed consent in the health and disability sector
• is likely to impact most on people who are poorly educated or unaware of how to opt out of the system if they do not wish to be donors
• may increase the grief for family members at an already difficult time – family members may feel unhappy at the idea of organs or tissue being retrieved from a loved one, but feel unable to prevent this happening
• may be inconsistent with different cultural views.

On the other hand, a presumed consent system may be the most effective way of increasing the number of organs and tissue available for transplantation. It has also been suggested that it has the advantage of not requiring families to make an important decision when they are grieving. Supporters of presumed consent systems also feel that the system is justified because:

• people can always opt out of the system, and this preserves their autonomy to make an informed choice
• it is a cost-effective system as less money needs to be spent on advertising and awareness, and it may also be more efficient to administer as health practitioners do not need to spend time gaining consent from families.
C4.4.2 Option 2: Requiring donor wishes to be followed (requirement for wishes to be followed)

A second option for New Zealand is to change the current law to require that donor wishes be followed. That is, if a person has recorded that they wish to be an organ donor, this wish must be followed if they die in the right circumstances and are suitable to be a donor (eg, they have been assessed as medically suitable to be a donor). Currently, health practitioners, who always seek the consent of the potential donor’s family, do not take this approach.

This option would also require that where a person had stated that they did not wish to be a donor that this wish is followed.

If this option were to work in New Zealand it would need to be supported by both the general public and health practitioners. In particular, the public would need to be confident that they would still receive the best of treatment in intensive care units if they agreed to be an organ or tissue donor. Health practitioners would need to be confident that the public supported the system and would need guidance in providing support to bereaved families.

Other conditions that would be important to having this system work successfully are as follows.

- Informed consent – it would be important, if the wishes of the deceased person were required to be followed, that in making their decision during life the deceased person’s decision was made with informed consent (ie they had been provided with sufficient information, and had not been subject to coercion – see Box B2)

- Currency of view – it would be important to know that the recorded wish of the deceased person was their view at the time of death. Experience with the driver’s licence database is that decisions relating to organ donation do not necessarily remain fixed once they are initially made. When renewing drivers’ licences people change their minds about donation in both directions. An analysis shows that about 3.2 percent of people changed their donor status from ‘yes’ to ‘no’, and about 7 percent changed from ‘no’ to ‘yes’. These changes are significant if the law is changed to require donor wishes to be followed.

Currently there are concerns that the donor rate may fall if this type of approach were taken. This is based on the fact that only about 43 percent of people who hold a driver’s licence have indicated their wish to be a donor, although about 55 percent of families consented to donation in an audit of intensive care units. In the United States, however, the laws regarding following the wishes of the deceased person are stronger, and the United States has a higher donation rate.

36 This analysis was conducted by the Land Transport Safety Authority and included a sample of licence holders.

37 Chen et al 2003, referring to Streat (in preparation).
C4.4.3 Option 3: Requiring New Zealanders to indicate their wishes (requirement to state wishes)

Another option for New Zealand is that people be required to indicate whether they wish to be a donor or not. This system would mean that people would have to make a decision. This option would then be combined with Option 2 above. That is, if people were required to make a decision, it would then be necessary to require that decision to be followed.

New Zealand already has a variation of this system through the requirement that people state their wishes when they obtain a driver’s licence. However, this is not currently associated with a requirement to then follow those wishes. The concerns raised above regarding people changing their wishes have important implications for this option.

C4.4.4 Option 4: Requiring organ and tissue donation to be discussed with all patients entering hospital (requirement to request)

This requirement is part of the Uniform Anatomical Gift Act in the United States and could be an element of a New Zealand system. Such a requirement would mean that organ and tissue donation would have to be discussed with all people who are admitted to hospital. For most people this would mean that they would consider organ and tissue donation and would make a decision to be a donor or not should the situation arise at some time in the future. The acceptability of discussing organ and tissue donation with reasonably, or very, unwell people needs to be considered, however.

For a much smaller group of people this would mean that organ and tissue donation would be discussed with them, they would make a decision, and they may would become a donor during that hospital stay.

This option would not capture all New Zealanders, only those entering a hospital. It should also be noted that most hospital patients that become donors are admitted to hospital in an unconscious state and many young donors will never have been in hospital before. This option could, however, be combined with another option already described.

C4.4.5 Status quo

The current system under the Human Tissue Act is explained in section C4.3. In brief, the system is that a person may indicate their willingness to be a donor during their life and if they die in the appropriate circumstances their family will be asked if they wish to donate organs. The Human Tissue Act allows for organs to be collected from a deceased person based on that persons record of their wishes (which may be written or oral and witnessed by two people), however in practice the grieving family is always asked if they know what the deceased person’s wishes were and for their consent. The ‘flag’ of donor wishes on a driver’s licence is an indication of a person’s wishes only – it does not constitute a record of a person’s wishes under the Human Tissue Act. It is also important to note that almost all organ donors are people who die in an intensive care unit.
C4.4.6 Access to information for tissue donation

The Ministry is also aware that there is concern in the tissue donation sector about the need for a timely assessment of medical suitability to be a tissue donor. It is highly preferable to assess whether a person is suitable to be a donor before donation is discussed with the family of the deceased person. Discussing donation before this assessment can be very distressing for families if donation is not then able to proceed. As tissue donors are often people who have died in the community (or in hospital outside an intensive care unit), information about their health status needs to be accessed from other health providers, such as their general practitioner or a hospital where they have previously been treated.

This has been an issue internationally, particularly for eye donation, and the Ministry is interested in the processes and experiences of the tissue donation sector and others in New Zealand in accessing information about the medical suitability of potential donors, including experience of the operation and interpretation of the Health Information Privacy Code in this regard.

We are seeking your views

34. The new legislative framework could consider five options (with combinations) to consent for organ and tissue donation. Of the options below, please tell us which you think may be better and why. The options are:
   1) presumed consent
   2) requirement for wishes to be followed
   3) requirement to state wishes
   4) requirement to request
   5) status quo.

35. If you think one of the options (other than status quo) would be better for New Zealand, do you think there should be any time when families/whânau should be able to override the wishes of the deceased person? Why or why not? If not, do you have suggestions for managing a situation when the wishes of the deceased person are not the same as those of the family/whânau?

36. The Ministry is interested in the processes and experiences of the tissue donation sector and others in accessing information about the medical suitability of potential donors. Please describe any experiences, difficulties or good practice in this area – including experience of the operation and interpretation of the Health Information Privacy Code.

C4.5 Defining death and determining brain-death

The Human Tissue Act refers to ‘death’ and a ‘deceased person’, but it does not provide a definition of these terms or a way of establishing that a person has died. This section seeks your views on whether a definition of death, and a process for establishing death, should be included in new legislation.
Organ donors are usually people who have suffered brain-death. Ventilators (breathing machines) and other medical processes are used to maintain the bodily systems of the brain-dead person until organ retrieval can take place. The use of ventilators and other systems means that organs are kept in good condition for transplantation, but it is not possible to use traditional tests, such as a lack of heart beat, to determine that a person has died.

In these situations, doctors use brain-death tests to determine that a person has died and that it is only machines, such as a ventilator, that are keeping the person’s bodily systems working. The Australian and New Zealand Intensive Care Society’s (1998) Recommendations Concerning Brain Death and Organ Donation use the definition of death contained in most Australian state laws:

a person is dead when there is irreversible cessation of circulation of blood in the body of the person, or irreversible cessation of all function of the brain of the person.

The Recommendations also contain detailed guidance about how brain-death tests should be done. The Recommendations are used in New Zealand and are contained in the Guidelines for Organ and Tissue Donation issued by the National Transplant Donor Co-Ordination Office (1998). For organ donation, two sets of brain-death tests are done by two different doctors at two different times. After the second doctor completes the second test, brain-death can be certified, and this is the time of death that is recorded on the person’s death certificate.

The process for determining brain-death has been thoroughly considered by experts in this area and the Ministry does not propose to review it here. The Ministry is also not aware that there is any non-compliance with the recommended practice for determining brain-death. The Ministry is, however, interested in your views on whether the new regulatory framework should require compliance with this type of guidance.

We are seeking your views

37. Do you think that the new regulatory framework should contain a definition of ‘death’? Please explain what you think the advantages or disadvantages of including this definition would be.

38. If you think a definition should be included, is the following a suitable definition? If not, please suggest any changes you would make.

‘A person is dead when there is irreversible cessation of circulation of blood in the body of the person, or irreversible cessation of all function of the brain of the person.’

39. Do you think that the new regulatory framework should require compliance with the current guidelines for establishing brain-death? Why or why not?
C4.6 Different types of deceased donors

Most deceased persons who donate organs or tissue for transplantation will have had their bodily systems maintained by ventilators and other processes until the organs or tissue are retrieved. This is called ‘heartbeating donation’. When transplantation began in the 1960s, organs and tissue were retrieved from ‘non-heartbeating donors’. That is, the deceased person was not maintained by medical processes and death was determined by the absence of a heart beat or breathing. Non-heartbeating donation diminished as the development of technology allowed donation from heartbeating donors.

As transplantation medicine has advanced and the gap between the demand for, and supply of, organs has widened it is timely to consider whether the regulatory framework can be improved to support non-heartbeating donation. As there are limitations to the people that will be able to be heartbeating donors (see section C4.2), changes to the regulatory framework may also allow more people to fulfil their wish to be a donor.

C4.6.1 How does non-heartbeating donation work?

A non-heartbeating donor is a person who is declared dead on the basis that breathing and heart beat have ceased. For example, the donor may have suffered a non-recoverable brain injury and has died after the family and health practitioners have discussed and made the decision to withdraw life support systems; or the donor may be in the emergency department following a cardiac arrest and resuscitation efforts are unsuccessful.

If a deceased person’s organs are to be in good condition for donation and transplantation it is important that the kidneys, for example, are cooled quickly. This cooling can be performed before the life support machine is withdrawn or before resuscitation is stopped if the family has agreed to donation. The cooling process involves inserting a small tube into the aorta to carry cooling solution to the organs. The detailed processes involved in non-heartbeating donation are sensitive and complex; and currently there is no detailed guidance developed to guide New Zealand practice in this area (Australian and New Zealand Intensive Care Society 1998: 15).

Some of the more complex ethical and practical issues that arise in this area are as follows.

- Is it acceptable to undertake processes to cool the organs of a deceased person, thus preserving the opportunity of donation, while donation is discussed with the family? This difficulty arises when it has not been possible to discuss donation with the family earlier.

- What process should be used for withdrawing life support from a person with a non-recoverable injury who may be a suitable donor? Issues that arise are the clinical evaluation that death is likely to occur and within what time period, the need to ensure that such assessment is thoroughly undertaken and records kept, and that there is a clear separation between the doctor(s) assessing the likelihood of death and the team of people involved in any subsequent transplantation.38

38 In the case of heart beating donation there is currently a clear separation between the doctors involved in assessing brain death and those involved in transplantation.
• Is it acceptable to keep a person who may be able to be a non-heartbeating donor on life-support systems for a longer period to allow arrangements to be made for donation to take place?

These types of issues need to be carefully considered but are beyond the scope of this Review. The issue for the Review is whether the new regulatory framework should make specific provision for non-heartbeating donation to take place, subject to such detailed guidance being developed. Including provisions in the new regulatory framework for non-heartbeating donation provides a degree of ‘future-proofing’ for the framework, and the Ministry considers this may have merit, provided that safeguards are in place. In particular, standards to guide practice should be developed by those expert in this area.39

We are seeking your views

40. Should the new regulatory framework allow for non-heartbeating donation to take place, subject to appropriate standards and guidance being developed in this area? Please explain why you agree or disagree.

41. As well as informed consent, one particular safeguard that needs to be in place is a separation between the health professionals that assess a non-heartbeating donor and those that are involved in transplantation processes. Please describe any other safeguards you think should be considered.

C4.7 Directed donation by deceased donors

Internationally the practice is that organ or tissue donation by deceased donors is an unconditional or anonymous act. That is, a donor is not able to place conditions on the use of their organs or tissue. For example, a donor cannot state that their organs or tissue be given to a person of a particular age, gender, or ethnicity. Direct contact between donor families and recipients is also discouraged (see Box C1).

Donations of organs or tissue are gratefully accepted by the health and disability system and allocated to those who are in the best position to benefit from them. In order to determine who should receive donated organs or tissue, careful matching is undertaken between the donor and the recipient. It is useful to note that ethnicity is a factor in assessing tissue matches as, for example, there is a better clinical match between Māori donors and Māori recipients. This is, however, assessed on clinical grounds only.

Another criterion for determining who receives donated hearts, lungs or livers is how critically ill the recipient is: some people waiting for donated organs to become available are very ill and may die within a short period of time if a suitable organ is not available for transplantation.

Note: the Australian and New Zealand Intensive Care Society (1998) have signalled the need for work in this area
Box C1: Organ and tissue donor co-ordinators

There are organ and tissue donor co-ordinators for whole organs, eyes and other tissues. The co-ordinators provide similar services with regard to information and support for the family, with specific expertise in their particular area. Co-ordinators are often health professionals who work to organise the donation processes. One of their main roles is to provide information and ongoing support for families who have agreed to donation.

After donation and transplantation have taken place, the co-ordinators can:

- provide donor families with general information about the recipient (e.g., age, sex and how successful the transplant operations were); this can happen days or years after the donation took place
- help recipients and their families express their gratitude. Direct contact is not recommended, but an anonymous letter of thanks from the recipient to the family of the donor can be forwarded through the co-ordinator. The donor family is always contacted to see if they wish to receive such a letter or card (National Transplant Donor Co-ordination Office undated, New Zealand National Eye Bank 2003).

We are seeking your views

42. Should the new legislative framework make it clear that donation of organs or tissue from people who have died should only be on the basis that the organs or tissue are an ‘unconditional gift’?

43. Do you think that, if both parties wish to, donor families and recipients should be able to meet? If so, what type of support should be offered for this to happen?

C4.8 Live tissue donation

So far the discussion has focused on the donation of organs and tissue from people who have died. There is also the ability for living people to donate kidneys and parts of the liver for transplantation. The most well-known type of live donation and transplantation is kidney transplantation between relatives.

The National Health and Medical Research Council (1997) identifies two issues that need to be carefully considered in relation to living donors.

- The potential for harm to the donor – undertaking live donation of tissue causes a degree of harm, risk, pain or loss to the donor. This may be relatively short-lived (e.g., when a person donates blood, which is quickly replaced by the donor), or it may be permanent, such as when a person donates a kidney. In the latter case, the person suffers a permanent loss from their body. The donation procedure also requires the donor to suffer a degree of pain; this may be minor as in the case of blood donation, or more significant, as in the case of surgery to obtain a kidney.
• The fact that the donation is to benefit another person who may be known to the donor – this situation raises the difficulty that the donor may feel, as a result of coercion or as a result of the gravity of the situation, that they have little option but to be a donor. The donor may also gain great satisfaction from having been able to assist a family member and witness their improved health.

The key to managing the live donation process is ensuring that good informed consent processes are followed. In New Zealand, the Code covers both live tissue donation and transplantation (see section C2.3 and Appendix 3). The Code provides for informed consent to health care procedures, and these requirements cover both the donor and recipient of tissue. The question for your consideration is whether you believe that the provisions of the Code are sufficient coverage for live organ and tissue donation, or whether special provisions are needed.

We are seeking your views

44. Live organ and tissue donation in New Zealand is regulated through the Code of Health and Disability Services Consumers’ Code of Rights, in particular the requirement to ensure that informed consent is obtained before such procedures (either donation or transplantation) take place. Do you think the new regulatory framework should include any additional provisions? If so, please explain what these should be and why.

C4.9 Safety of whole organs that are transplanted

The section following this (C5) contains a detailed discussion of a proposed regulatory framework for tissue-based therapies. Section C5.2.6 contains a number of proposed exceptions to the framework. One of the proposed exceptions is whole organs for transplantation. While whole organs for transplant may best be exempt from regulation under therapeutic products regulation, ensuring the safety of these transplants is an important part of a comprehensive framework for therapeutic tissue. This section seeks your views about the current arrangements for ensuring the safety of whole organs for transplant and whether there should be changes.

Currently the safety of whole organs for transplant is governed by the Guidelines for Organ and Tissue Donation (National Transplant Donor Co-Ordination Office 1998). The Guidelines cover the following factors related to the safety of whole organs that are transplanted:

• criteria to identify a potential donor, and criteria that exclude a potential donor (eg, untreated bacterial, fungal or viral infections, or HIV)
• blood and other tests that need to be done before a person can be confirmed as a donor, and that are needed to match the donor with a recipient (these tests include blood type, HIV antibodies, Hepatitis B, and Hepatitis C)
• guidance for the clinical management of the donor in the intensive care unit once it is decided that donation will proceed (eg, the management of the ventilator and tests to ensure that oxygen levels are appropriate)
• guidance for the clinical management of the donor just before and during the donation operation (e.g., anaesthetic requirements)
• special process requirements for when several organs are being donated (including special requirements for cornea donors).

The transplanting team also assesses medical suitability of organs before a transplant takes place.

We are seeking your views

45. Do you think the new regulatory framework should formalise safety guidance for whole organ donation? Please explain why or why not.

C5  Safety of tissue-based therapies

As a result of research, significant advances have been made in the ability to use tissue-based therapies to treat a number of ailments and improve the health of people. Just as legislation is needed to ensure that pharmaceuticals are safe to use, the Ministry considers that legislation is needed to ensure that tissue-based therapies are as safe as possible.

Because tissue-based therapies are a relatively recent treatment option the current regulatory framework under the Medicines Act and the Health and Disability Services (Safety) Act does not provide full coverage of these therapies. The Medicines Act only provides coverage of certain tissue-based products if they have been subject to a ‘manufacturing’ process, and the Health and Disability Services (Safety) Act has not been extended to cover services that deliver tissue-based therapies.

The regulation of services delivering tissue-based therapies is discussed next (section C5.1), and the regulation of tissue-based products is discussed in section C5.2.

C5.1 Regulating services and entities that deliver tissue-based services

The Health and Disability Services (Safety) Act provides a framework for setting safety standards in the health and disability sector. It also encourages continuous quality improvement by providers of services. The Act enables standards to be set for particular types of services. Providers are then independently audited against those standards and certified by the Director-General of Health to provide the relevant services. The Act also contains strict provisions for providers who do not meet the required standards. Table C2 illustrates how the Health and Disability Services (Safety) Act works.
Table C2: Framework for services safety under the Health and Disability Services (Safety) Act 2001

<table>
<thead>
<tr>
<th>Process</th>
<th>Requirements to be met</th>
<th>Sign-off</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service to be covered (e.g., hospital, rest homes)</td>
<td>Services not yet anticipated by the Act may be added so long as acceptable standards have been developed or will be developed within 12 months, and providers have at least 12 months to comply with the standard.</td>
<td>Governor-General</td>
</tr>
<tr>
<td>Standard (has the status of regulation)</td>
<td>Standards must be independently developed in consultation with the sector;(^{40}) consultation must have been considered, and be in the public interest in terms of safety and compliance costs.</td>
<td>Minister</td>
</tr>
<tr>
<td>Audit and certification</td>
<td>Designated audit agencies must be independent and approved.</td>
<td>Director-General</td>
</tr>
</tbody>
</table>

The Act recognises that providers may need to change their systems and practices in response to any standards put in place, and allows providers at least 12 months to comply with a new standard.

Services across the sector (e.g., hospital services, residential disability care and rest home services) are regulated under the Act. The Act does not currently apply specifically to services providing tissue-based therapies (e.g., tissue banks). When the Act was developed, however, it was anticipated that these types of services should be regulated in the future and specific provision was made for services that provide tissue-related therapies to be included in the regime.

There are tissue banks in New Zealand for corneas, skin and bone. The Ministry is conscious that, while operating under voluntary codes of practice,\(^{41}\) tissue banks are not formally regulated in New Zealand and that this is unusual internationally and creates risk in the following areas:

- the potential inability for some people to benefit from tissue grafts
- a recipient of a tissue graft could become ill
- difficulty in controlling costs
- the inability to look back through records to respond to an adverse event if one should arise (Compass Group 1999).

The same report notes that these risks could be created by:

- inadequate storage systems
- donor screening and processing
- inefficient use of resources
- factors such as ethical considerations, business continuity and data control
- inadequate systems for tracking donors to recipients.

\(^{40}\) Consultation is required with consumers, representatives of affected providers and a number of providers, funders and consumers.

\(^{41}\) For example, the American Association of Tissue Banks Standards and the New Zealand Eye Bank Quality Manual.
These types of issues could be addressed by bringing tissue-banking services under the Health and Disability Services (Safety) Act. This would mean that a national standard for tissue banking would need to be developed in consultation with the sector. Tissue banks would then be independently audited against the standard and, pending the outcome of the audit, certified to provide tissue-banking services.

There is also the potential to regulate the collection of tissue for therapeutic purposes under the provisions in the Health Act 1956 that regulate blood and controlled human substances. Currently these provisions have only been given effect for blood, blood products and bone marrow. The detailed provisions of the Health Act are contained in Appendix 5. Using the provisions in the Health Act could:

- give particular entities the authority to collect controlled human substances (e.g., corneas or skin)
- prohibit trade in controlled human substances (issues related to the sale and purchase of human tissue are discussed further in section D4).

We are seeking your views

46. Do you think tissue banking services should be regulated under the Health and Disability Services (Safety) Act, noting that this would mean the development of a national standard for tissue banking that was then audited and providers being certified accordingly? Please explain why you agree or disagree.

47. Do you think tissue services should be regulated under the provisions in the Health Act (excluding for the moment the provisions that restrict trade, as these are discussed in a later section)? Please explain why you agree or disagree.

C5.2 Regulating tissue-based therapeutic products

As noted previously, the Medicines Act is currently primarily concerned with medicines and medical devices, and only provides coverage of certain tissue-based therapeutic products. The Ministry proposes that the legislation that regulates medicines and medical devices should be extended to make it clear that it also covers tissue-based therapeutic products. This section discusses how this could work in practice, as tissue-based therapeutic products are different from traditional medicines in a number of important ways.
C5.2.1 What coverage do tissue-based therapeutic products have under current legislation?

The Medicines Act defines a medicine to be:

... any substance or article ... that is manufactured, imported, sold, or supplied wholly or principally:

a) for administering to one or more human beings for a therapeutic purpose; or

b) for use as an ingredient in the preparation of any substance or article that is to be administered to one or more human being for a therapeutic purpose, where it is so used

i. in a pharmacy or hospital or

ii. by a practitioner, or registered midwife, or designated prescriber or in accordance with a standing order or

iii. in the course of any business that consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, or herbal remedies; or

c) for use as a pregnancy test.42

In practice, this definition has been interpreted to apply to manufactured products such as tablets and capsules, and to blood and blood products, but not to tissue-based therapeutic products that have not been subject to a manufacturing process. For example, skin that has been donated by a person for use in transplantation (eg, after serious burns) and is stored in a skin bank until it is required is currently not subject to the Medicines Act because it has not been manufactured.

In practice, therefore, the following tissue-based therapeutic products are currently not subject to the Medicines Act:

• whole organs for transplantation (eg, kidneys, liver, heart and lungs)
• tissue that has not been significantly altered (eg, skin, tendons, ligaments, heart valves, corneas and bone)
• tissue-based therapeutic products that are custom-manufactured for a particular person.

By not having these types of tissue-based therapies covered by legislation, the government has limited ability to:

• control the safety and quality of tissue-based therapeutic products – the key safety concerns are the transmission of disease and poor tissue processing
• withdraw tissue-based therapeutic products from use
• control the use of clinical trials using tissue-based products.

42 Medicines Act 1981, section 3(1).
C5.2.2 What requirements are medicines subject to under the Medicines Act?

For the products covered, the Medicines Act applies a system of pre-market approval of products and licensing of manufacturers. The Act also contains a number of exemptions from these requirements, such as when a clinical trial of a medicine is conducted (although approval of the trial is required), or when a medical practitioner requests that a particular form of a medicine be supplied for the care or treatment of a particular person.

Medsafe, the unit of the Ministry of Health that administers the Medicines Act, gives effect to the Act by:

- ensuring that medicines are assessed and shown to be safe, of high quality, and effective before they are marketed in New Zealand
- monitoring the ongoing safety of medicines once they are on the market, and removing permission to market them in New Zealand if they are proven unsafe at a later time
- licensing and auditing manufacturers, packers and wholesalers of medicines to make sure their premises and practices meet an acceptable standard
- approving clinical trials of medicines in New Zealand (clinical trials are subject to detailed requirements under the Medicines Act, including being independently evaluated by specialist committees of the Health Research Council)
- handling complaints and investigations.

C5.2.3 Tissue-based therapies are different from pharmaceuticals

In designing a regime for the safety of tissue-based therapies, it is useful to note a number of significant differences between pharmaceutical and tissue-based therapies that will need to be accounted for in a new regulatory framework. In contrast to regular pharmaceuticals the following characteristics apply to the safety of tissue-based therapies.

- The product is often a one-off, and therefore more labour intensive to produce. In contrast, pharmaceuticals are produced in large production batches with a high turnover of product.
- The processes for production are less able to be standardised and may be to some degree experimental, whereas pharmaceuticals are produced through highly developed and controlled processes.
- The recipient of the product is often the primary consideration in development, as opposed to pharmaceuticals, which are manufactured for unknown users.
- Products generally have a short shelf-life.
- Those developing and applying the therapy may have limited control over the starting material because it is derived from a human or animal.
- Sterilisation to eliminate pathogens can be more difficult.
Key issues in the use of tissue-based therapies are, therefore:

- the potential for the transmission of infectious disease – an infectious disease may be present in the tissue when it is collected from the donor, or may be caused by contamination during handling or processing
- proving clinical effectiveness and safety – pharmaceuticals must receive approval before they can be marketed to the public. This approval is dependent on proof that the pharmaceutical is both effective and safe. Because many tissue-based therapies are ‘one-off’ products, this type of approach is not practical. It also needs to be recognised that tissue-based products may be offered to people with very serious medical conditions and few other treatment options.

C5.2.4 Designing a new regulatory framework for tissue-based therapeutic products

The New Zealand and Australian governments have agreed to establish a Joint Therapeutic Products Agency. The agency will replace the Australian Therapeutic Goods Administration and New Zealand’s Medsafe from 1 July 2005 (subject to the passage of legislation and ratification of a treaty43), and will regulate therapeutic products such as medicines and medical devices.

Both New Zealand and Australia are undertaking work on the regulation of tissue-based therapies. Once each country has decided on its approach, the Government may decide that the Joint Therapeutic Products Agency should also regulate tissue-based therapeutic products. This is a significant decision to be taken at some time in the future.

Decisions about how New Zealand wants to regulate tissue-based therapeutic products will be made to suit the particular needs of this country. Looking to the future, however, it is useful to examine the approach that Australia is proposing to take to tissue regulation and consider how it may be adapted for New Zealand. Taking this approach means that the two systems will be similar if, in the future, the Government decides that tissue-based therapies should be regulated by the Joint Therapeutic Products Agency.

The following proposal for a regime to regulate tissue-based therapeutic products is, therefore, largely drawn (with amendments as required for the New Zealand context) from a discussion document released by the Australian Therapeutic Goods Administration in 2003 to inform deliberations in Australia.

C5.2.5 What needs to be included in the new legislation?

There are three areas that need to be regulated:

a) issues relating to safety and quality
b) issues relating to promotion and labelling
c) issues relating to the administration of a regulatory system.

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Issues relating to safety and quality

There are two main concerns with regard to the safety and quality of tissue-based therapeutic products: the transmission of disease and the way the tissue is processed.

With any use of human tissue there is some risk of diseases being transmitted. This risk is dependent on factors such as whether the donor and the recipient are the same person (autologous use), the tissue has been stored in a tissue bank, what types and what volume of other tissue are processed by the tissue bank, and the degree to which the tissue has been handled or manipulated in preparation for transplantation.

The regulation applied to minimise the risk of disease transmission should be commensurate with the level of risk posed. For example, the autologous use of tissue within a single surgical procedure presents a low risk of disease transmission, whereas tissue that has been transported or stored with other tissue from a range of donors presents a higher risk.

Some of this type of risk can be managed through requiring tissue banks to comply with a standard of practice, such as that proposed under the Health and Disability Services (Safety) Act (see section C5.1).

Other risks to the safety and quality of the therapeutic product are posed by processing tissue. The level of risk presented by processing tissue will depend on:

- the level of manipulation of the original tissue – this impacts on the potential for transmitting disease and the ability of the tissue to function as desired, although increasing levels of manipulation do not always mean increased risk
- whether the tissue is to be used for its normal biological function (homologous use) – non-homologous use of tissue may involve additional risks compared to homologous use, as it may be more difficult to predict accurately how the tissue will behave, but this may also vary with the type of tissue and the non-homologous use to which it is put
- whether the tissue is combined with non-tissue-based components – tissue-based therapeutic products that are combined with non-tissue-based products need to be considered in terms of the type of components added and the action of the added product
- whether the tissue is to be used for a metabolic function – products with a metabolic function will generally rely on viable cells to provide that function (eg, stem cells or islet cells). This is important for the handling of the product, as these types of cells are easily damaged, which will affect their ability to function after transplantation. Which is to say, minimally manipulated stem cells may carry significantly more risk than highly manipulated tendon tissue (which is non-metabolic).

These issues pose real questions with regard to how a regulatory framework should be designed.
Issues relating to promotion and labelling

The medicines legislation contains strict provisions regarding the packaging and labelling of medicines, including the statement of purpose, what it contains, and storage conditions. Similar issues arise with tissue-based therapeutic products.

Promotion and labelling issues for tissue-based therapeutic products include what the tissue is, how it should be used, and what its effects are. Any promotion of a tissue-based therapeutic product needs to be backed by studies that prove its efficacy and safety.

Issues relating to the administration of a regulatory system

The new regulatory framework needs to be focused on safety and quality. However, it also needs to make sure that it does not place unnecessary restrictions on practice and treatment, and barriers to innovation. In particular the system needs to:

- be able to respond to the development of new tissue-based therapeutic products and to new information about the risks posed by existing products
- allow for exceptional circumstances when a person’s life may be seriously and immediately at risk and the only option is to use tissue that has not completed screening processes
- be focused on improving outcomes and continuous quality improvement and not simply on process issues
- be clear and unambiguous about the coverage of tissue-based therapeutic products and be well integrated with current processes for therapeutic products regulation
- be mindful of the international context of tissue-based therapeutic products and not place unnecessary barriers to New Zealanders accessing tissue-based therapeutic products
- distinguish between medical procedures and manufacturing processes. As noted earlier, there are important differences between tissue-based therapeutic products and pharmaceuticals; there are also current exemptions for health practitioners in certain areas. The place of these types of one-off innovative treatment needs to be considered in the new regulatory framework.

C5.2.6 A new legislative framework for tissue-based therapeutic products

Defining the product to be covered

In an environment where technology and science are developing rapidly it is useful to develop quite a broad definition of tissue to allow for future uses of tissue as a therapeutic product. A broad definition can then be narrowed with specific exemptions. A potential definition (based on material from the United States) is:

Human cells, tissue and cellular and tissue-based products are articles containing or consisting of, or derived from, human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.
If a broad definition, such as that above, is used it will be necessary to provide a number of exceptions. The following are proposed as exceptions:

- blood and blood products – the use of blood is currently regulated through the Health Act and the Medicines Act and the system is working well, and it is proposed that New Zealand follow international practice and continue to regulate blood separately
- secreted or extracted human substances (eg, breast milk)
- products used in the manufacture of tissue-based therapeutic products such as antibiotic solutions – these products would continue to be regulated as medicines
- reproductive cells (ie, in-vitro gametes and embryos), which will be regulated under the proposed human assisted reproductive technology legislation (see section B2.5)
- cells, tissues and organs derived from animals (a proposed approach to xenotransplantation is discussed in section D3.1)
- non-viable tissues, such as heart valves, which are currently regulated as medical devices
- whole human organs for transplantation (see C4.9).

**We are seeking your views**

48. Do you think the definition of human cells, tissue and cellular and tissue-based products adequately describes the ‘subject’ of the proposed new regulatory framework for tissue-based therapeutic products? Please explain any changes you would make.

49. Do you agree that the products listed above should be exempt from the regulatory framework? Please explain your views.

**Defining the activity to be regulated**

Developing an appropriate description of the activity to be regulated is a key part of the new regulatory regime. Currently the Medicines Act uses the term ‘manufacture’ to describe:

any process carried out in the course of making the medicine; but does not include –

a) dissolving or dispersing the medicine in, or diluting or mixing it with, some other substance used as a medium for the purpose of administering the medicine to another person;

b) incorporating the medicine in any animal food.
Consideration has been given to whether the term ‘manufacture’ can appropriately be applied to tissue-based therapeutic products. Other terms that may more accurately reflect the actual processes are ‘handle’ or ‘process’. This discussion has been conducted internationally, and it has been concluded that terms other than ‘manufacture’ are too narrow and that ‘manufacture’ should continue to be used as the umbrella term to capture the actions and organisations that are involved in the preparation of tissue-based therapeutic products.

If the term ‘manufacture’ is used in New Zealand for tissue-based therapeutic products, it may need to be tailored specifically for these products. The definition of manufacture proposed in the United States is ‘any or all steps in the recovery, processing, storage, labelling, packaging or distribution of any human cell or tissue, and the screening or testing on the cell or tissue donor’.

A further issue that needs to be resolved is whether there are any activities that should not be considered as part of the manufacturing process. In the Medicines Act definition of manufacture for medicines, activities such as the dissolving of the medicine in water for administration to a person are excluded. Similarly, it is proposed that the definition of manufacture of tissue-based therapies could exclude the following activity:

- the removal of tissue and its implantation in a single surgical procedure – this may be autologous or non-autologous use.

**We are seeking your views**

50. Do you think the term ‘manufacture’ and the definition proposed for that term is appropriate for tissue-based therapeutic products? If not, please share your suggestions for a better term or definition.

51. Is the proposed exemption from the definition of ‘manufacture’ appropriate? Are there other activities you think should be exempt from the definition? Please explain your suggestions.
Defining the people to be regulated

The third branch of the proposed regulatory framework is defining the people who should be regulated with regard to tissue-based therapeutic products. Currently the Medicines Act provides exemptions from licensing requirements for a number of people.

- An authorised prescriber may manufacture, pack and label medicines that are specially prepared for administration to a patient under that prescriber’s care.44

- Pharmacists working in a hospital or registered retail pharmacy do not need a licence to manufacture, pack, label, sell and supply a medicine to a patient that has requested that medicine (these provisions do not, however, give pharmacists the right to prescribe medicines).45

In deciding whether there should be exemptions from licensing for particular people involved in manufacturing tissue-based therapeutic products, the following factors need to be considered.

- Most ‘manufacture’ of tissue-based therapeutic products occurs in hospital settings that are already subject to safety standards. However, the safety risks associated with the manufacture of tissue-based therapeutic products may be the same regardless of whether the manufacturing occurs in a hospital or in another setting. For this reason it may be inappropriate to exempt medical practitioners and others from the regulatory regime where they are manufacturing tissue-based therapeutic products for the benefit of an individual patient.

- Should the ongoing use of a ‘one-off’ tissue-based therapeutic product be exempt from the regulatory regime on an ongoing basis? That is, at what point is a product no longer a ‘one-off’ manufacture for a specific patient? The issue at the heart of this question is whether the types of tissue-based therapies being developed pose any special risks that should distinguish them from other custom-made medicines or medical devices; and if so, what level of regulation is appropriate? This question is related to definitions of innovative treatment and international moves to license hospitals for all ‘manufacture’.

- How should the distinction be made between supply and manufacture on the one hand, and medical practice on the other? This is a particularly complex issue and we are interested in your views on this.

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44 Medicines Act, section 25.
45 Medicines Act, section 26.
We are seeking your views

52. Your suggestions on potential exemptions from licensing requirements for particular people are sought. Consideration of this issue needs to be in the context of:

a) other exemptions proposed for particular products or manufacturing activities
b) any differences in the risks posed by the processing of tissue in a hospital setting compared to other settings
c) whether exemptions for custom-made products are appropriate
d) how we distinguish between medical practice and supply and manufacture of tissue-based therapeutic products, and the impact of any regulation on clinical decision-making.

A risk-based approach to regulating tissue-based therapeutic products

As described previously, the risk to safety posed by any tissue-based therapeutic product is a complex combination of the type of product, the use proposed for the product, and the degree of manipulation of the product. Table C3 provides a summary of the degree of risk posed by different tissue-based products, which could form the basis of the degree of regulation applied to each type of tissue.

Table C3: Summary of the degree of risk posed by different tissue-based therapeutic products

<table>
<thead>
<tr>
<th>Low risk</th>
<th>Medium risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue that has not been altered at all, or subject only to flushing,</td>
<td>Any tissue that has been banked, including tissue that has been subject to</td>
<td>Tissue that has been manipulated using chemical or genetic processes that</td>
</tr>
<tr>
<td>trimming and cutting</td>
<td>only flushing, trimming or cutting processes (or their equivalent); except</td>
<td>alter the natural properties of the tissue</td>
</tr>
<tr>
<td></td>
<td>where that tissue would fall under ‘high risk’</td>
<td></td>
</tr>
<tr>
<td>Tissue that has been subject to processes equivalent to flushing,</td>
<td></td>
<td>Tissue that, by its action, produces a pharmacological or chemical effect</td>
</tr>
<tr>
<td>trimming or cutting that does not deliberately alter the biological or</td>
<td></td>
<td>in the recipient</td>
</tr>
<tr>
<td>mechanical characteristics of the tissue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tissue that is removed and re-</td>
<td></td>
<td>Tissue manufactured using biological reagents such as monoclonal antibody</td>
</tr>
<tr>
<td>implanted in a single surgical procedure – either autologous or</td>
<td></td>
<td>sequestering, or cell expansion techniques</td>
</tr>
<tr>
<td>non-autologous use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tissue used for a homologous or a metabolic purpose in the person from</td>
<td>Tissue used for either non-homologous use or for a metabolic purpose where</td>
<td></td>
</tr>
<tr>
<td>whom it was obtained, or in a close blood relation of the donor –</td>
<td>the patient is not a close blood relative of the donor</td>
<td></td>
</tr>
<tr>
<td>provided that the tissue is also minimally manipulated and used without</td>
<td></td>
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<tr>
<td>non-tissue components</td>
<td></td>
<td></td>
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</tbody>
</table>
We are seeking your views

53. What do you think of the categorisation of tissue contained in Table C3? Would you assign any activities differently? Please explain your comments.

What level of regulation should apply to the different categories of risk?

The level of regulation applied to tissue-based therapeutic products needs to be commensurate with the level of risk posed and other arrangements that are in place, or are proposed to be put in place. The Ministry proposes that:

- low-risk tissue-based therapeutic products could be exempt from regulation under new therapeutic products regulation – these products are largely covered by safety standards for whole organs discussed in section C4.9
- medium-risk tissue-based therapeutic products could be exempt from regulation under new therapeutic products regulation, but that tissue banks be regulated as described in section C5.1
- high-risk tissue-based therapeutic products be subject to regulation under new therapeutic products regulation.

This would mean that high-risk products would be:

- assessed to ensure they are safe, of high quality, and effective before they are used in New Zealand
- subject to ongoing monitoring once they are in use, and would be removed from use if proven unsafe at a later time.

The process of collection, manufacture, packing and distribution of these products would also be licensed and audited to ensure that acceptable standards were met.

Clinical trials of such products would be subject to the approval processes through the medicines regulator and an ethics committee. The committees currently involved in such approvals are described in Appendix 4.

In giving effect to this type of regulatory system, the medicines regulator would require information about:

- the product, any sub-products and the method by which it has been manufactured
- important steps in manufacture, such as the source and criteria for acceptance of raw materials, the tests applied to raw materials to ensure they are free of infectious diseases, the tests and criteria for acceptance applied to the final product, and other quality control systems
- the uses for the product and how it is to be administered to people
- robust evidence that validates the critical steps in the manufacture, storage, freedom from infectious agents, quality and safety of the product.
The classification of a product as high-, medium- or low-risk would be made by the medicines regulator on an ongoing basis, as is currently the case for pharmaceuticals.

**We are seeking your views**

54. Your comments are sought on the proposed regulatory approach to tissue-based therapeutic products and any concerns you have about how it may impact on the practice of health care.
Part D: Common Concerns for All Uses of Tissue

This document has covered a large number of issues related to both the therapeutic and non-therapeutic uses of human tissue. This Part now turns to issues that are common to both these areas and that need to be addressed to ensure that the new framework for human tissue is comprehensive and meets New Zealand’s needs now and into the future.

The following issues are addressed in this Part:
- treating tissue with respect
- defining who is able to give consent
- future-proofing the legislative framework
- the sale and purchase of human tissue
- the import and export of human tissue.

D1 Respect for tissue

In various contexts throughout this document the concept of treating tissue with respect has arisen. Informed consent requirements, the notion of 'guardianship' as opposed to 'possession', and requirements for guidance to be developed for tissue disposal are all examples of this.

The Human Tissue Act currently contains requirements that the activities allowed under the Act be conducted in an orderly, quiet and decent manner. The Ministry considers that the new tissue framework should continue this concept of respect for tissue, whether tissue originates from a live or deceased donor. The need to treat tissue for non-therapeutic use in a respectful manner could be given effect through the management framework recommended in section B6, and as an underlying principle in legislation that governs the therapeutic use of tissue. The detailed needs of different cultural groups with regard to tissue can then be given effect through these frameworks.

D2 Definitions of who is able to give consent

Section B5.2 discussed a number of issues related to obtaining consent from family members of a deceased person for non-therapeutic uses, and section C4 discussed issues related to therapeutic uses of tissue where consent may be needed from family members. Both of these areas are governed by the Human Tissue Act, which uses the terms ‘surviving partner’, ‘surviving near relative’ and ‘any surviving relative’. These terms do not cover the complexity of contemporary families, Māori whānau, hapū and iwi relationships, and the relationships within other cultures such as Pacific peoples.
Similar issues have arisen in the review of the Coroners Act. After undertaking public consultation, the Law Commission recommended that the Coroners Act be amended in this regard (Law Commission 2000). Based on the Law Commission’s recommendations, one potential definition of immediate family that could be used in the new human tissue legislative framework for the purposes of obtaining consent, is:

a) any person who was the spouse of the deceased including de facto and same-sex partners, or a parent, grandparent, child, brother or sister, or guardian or ward, of the deceased

b) any person whose relationship to the deceased is that of step-child, step-parent, step-brother or step-sister

c) any person who in accordance with the traditions and customs of the community or whānau of which the deceased is a member, had the responsibility for, or an interest in, the welfare of the deceased.

We are seeking your views

55. Do you think the definition of ‘immediate family’ given below is suitable for new legislation for both the therapeutic and non-therapeutic uses of human tissue? Please explain any changes you think should be made. (Please note that this definition is not proposed for use in the risk framework for tissue-based therapeutic products described in section C5.2.6. It is only proposed for times when consent is needed.) The proposed definition is:

a) any person who was the spouse of the deceased including de facto and same-sex partners, or a parent, grandparent, child, brother or sister, or guardian or ward, of the deceased

b) any person whose relationship to the deceased is that of step-child, step-parent, step-brother or step-sister

c) any person who, in accordance with the traditions and customs of the community or whānau of which the deceased is a member, had the responsibility for, or an interest in, the welfare of the deceased.

56. Please tell us how you think the proposed definition of ‘immediate family’ would work in practice.

46 Consideration would have to be given to whether this includes de facto step relationships. This matter is also under consideration as part of the Coroners Act review.
D3 Future-proofing the legislative framework – acceptability and safety

It is important that the new regulatory framework for human tissue is able to respond to developments in science and research that cannot necessarily be predicted at the moment. While providing exciting opportunities for diagnosis and treatment of disease, it is likely that new uses for tissue will arise that will challenge the cultural, spiritual and ethical views of New Zealanders, and our mechanisms for regulating the safety and quality of therapeutic products.

In the past, new activities have been promoted in New Zealand and the government has not had a simple mechanism available to it to limit the activity in the face of public anxiety and public health concerns.

The Ministry believes that it is important that the regulatory framework contains a mechanism that will allow the government to prevent certain activities taking place while the cultural, spiritual, ethical, and safety implications of the activity are assessed. Once these issues have been considered, a decision can be made about whether the activity should take place in New Zealand and whether special provisions are required to govern the activity (eg, special record keeping provisions or safety practices).

This type of approach is contained in other legislation, such as the Misuse of Drugs Act. This Act allows for the relevant Minister to recommend to the Governor-General that a drug or other substance be added, amended or removed from the schedules of the Act that classify controlled drugs. Before the Minister makes such a recommendation, the advice of an expert advisory group must have been given and considered. The Act also requires that the Governor-General’s decision to give effect to the Minister’s recommendation is approved by the House of Representatives.

Depending on exactly how the detail of the legislative framework is developed, this type of provision could be in one act and cover both therapeutic and non-therapeutic issues, or two provisions could be enacted to cover both areas.

If such a mechanism is included in the new legislation there needs to be careful safeguards for its use. Issues that would need to be clarified are:

- the level of authority needed to place an activity on the list
- the level of authority needed to take an activity off the list
- whether the activities on the list should be reviewed periodically, and if so, the time period for such a review
- the criteria that need to be met before an activity is placed on the list or removed from the list.
D3.1 Xenotransplantation

Xenotransplantation is the transplantation of live cells, tissues or organs from another species into humans. The tissue transplanted is called a xenograft (see section C1.3 for a more detailed description).

Internationally, xenotransplantation knowledge has developed to the point where researchers are ready to conduct clinical trials of xenografts in humans. There have been some trials of xenotransplantation, but they are not common. Research is not yet at the stage where xenotransplantation is a treatment option, and the outcome of clinical trials is difficult to predict. The development of xenotransplantation to the point where clinical trials are impending has meant that governments around the world have been considering the ethical, cultural, spiritual and safety considerations of this technology. The technology is also of interest and concern to the World Health Organization.47

In New Zealand, the report of the Royal Commission on Genetic Modification led to an amendment being made to the Medicines Act. Part 7A of the Medicines Act was created by the amendment. Part 7A allows xenotransplantation clinical trials to be considered and approved by the Minister of Health, but places a number of strict criteria that must be met before trials can be approved. No proposals have been put to the Minister of Health for approval under these criteria.

At the time Part 7A was put into the Medicines Act the Government felt that more consideration needed to be given to the ethical, cultural, spiritual and safety considerations of this technology. However, the Government did not want to limit New Zealanders’ access to xenotransplantation if it could be shown that the technology was acceptable, safe, and offered the ability to improve health outcomes for New Zealanders. For this reason Part 7A is set to expire in June 2005.

The issues to be resolved before the Ministry would be comfortable that xenotransplantation is an acceptable technology for New Zealand are complex and need public engagement to resolve. Some of the issues to be discussed are as follows.

- What is the social acceptability of live animal tissue being used in humans (including cultural and spiritual considerations)?

- What are the ethical and safety concerns, particularly in relation to the risk of infection? Xenotransplantation carries a very small risk that a retrovirus, such as HIV, will be introduced to the human population. The ethical dilemma is that while an individual may give informed consent to receive a xenograft, the risk of a retrovirus is borne by both the individual concerned and the population at large. On the other hand, xenotransplantation clinical trials may lead to beneficial health treatments, and these benefits accrue to both the individual and the population.

- What is the clinical evidence, including the management of rejection of xenografts by recipients, and the potential offered by cellular xenografts?

47 World Health Organization Executive Board Provisional Agenda Item EB 113/14 Human organ and tissue transplantation. URL: http://www.who.int/gb/EB_WHA/PDF/EB113/eeb11314.pdf
The Royal Commission on Genetic Modification (2001) also signalled the need for ethical guidelines to be developed for xenotransplantation involving genetic modification.

Until these types of issues have been debated publicly, the Ministry considers that xenotransplantation should be placed in the proposed new section of the legislative framework that prevents new activities taking place until the implications of the technology have been fully considered. Fully assessing xenotransplantation has been challenging internationally and has taken longer than many jurisdictions anticipated.

While the Ministry is concerned about the risks to public health and safety that may be posed by xenotransplantation, it also wishes to access any health benefits offered by this technology. This approach is consistent with the Government’s overall strategy for biotechnology, which seeks to manage the development and introduction of new biotechnologies with a regulatory system that provides robust safeguards and at the same time allows innovation (Minister of Research, Science and Technology 2003).

In order to progress the public debate on xenotransplantation in New Zealand, the Ministry is working with Toi te Taiao – the Bioethics Council and other agencies experienced in biotechnology, public engagement and research to design a way for the public to discuss the issues.

**We are seeking your views**

57. Do you think the inclusion of a section that enables particular activities to be restricted until full consideration can be given to the implications of the activity and any special requirements that might be needed before the activity can be undertaken (such as safety procedures, or record keeping requirements) provides sufficient ‘future-proofing’ of the new legislation? Please explain your response and share any other ideas you have for future-proofing the legislation for new technologies.

58. If you think a section restricting certain activities would be useful, please share your ideas about the following issues:
   a) the level of authority needed to place an activity on the list
   b) the level of authority needed to take an activity off the list
   c) whether the activities on the list should be reviewed periodically, and whether a time period should be set for such a review
   d) any criteria an activity may have to meet before it is placed on the list or removed from the list.

Questions cont. over
59. Pending further work on the public acceptability and safety of xenotransplantation and the development of any special requirements that may be needed if xenotransplantation is to be undertaken in New Zealand, do you agree that xenotransplantation should be included in the proposed new list of prohibited activities? If not, please explain why.

60. Are you interested in being involved in any ongoing discussion of the acceptability of xenotransplantation in New Zealand? Toi te Taiao – the Bioethics Council has agreed to undertake work in this area: may the Ministry give the Bioethics Council your contact address so that you can be sent any material on xenotransplantation?

D4 Sale and purchase of tissue

It has long been considered as a matter of common law that there is no property in the body of a deceased person. That is, no one is able to ‘own’ the body of a deceased person and determining what happens to a human body after death cannot be decided on the basis of anyone owning the dead body.

Current New Zealand law, and proposed law, prohibits the sale and purchase of some human tissue:

- the Health Act 1956 prohibits trade in blood and blood products
- the Supplementary Order Paper to the Human Assisted Reproductive Technology Bill proposes to prohibit the sale and purchase of gametes and embryos.

Other tissue, such as organs for transplantation, cannot be sold or purchased as a matter of common law.

While many people find the idea that human tissue could be sold or purchased an affront to human dignity, others have suggested that enabling the sale and purchase of tissue could help to improve the availability of organs and tissue for transplantation and could allow donors to benefit financially from the development of biotherapies. It should also be noted that tissue can be used for cosmetic purposes (and is used for this purpose in other countries) as well as health or research purposes.

While the sale and purchase of whole organs or tissue for transplantation is fairly easy to understand, the sale and purchase of other types of tissue is a bit more complex. Following are two examples that illustrate this complexity. The examples are followed by some of the arguments for and against the sale and purchase of human tissue.

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48 The common law is the body of law that has been built up through the decisions of the Courts.
Box D1: Examples illustrating the complexity of the issues surrounding the sale and purchase of tissues

Example 1: A company came to New Zealand with the intention of obtaining retinal cells from aborted foetuses to develop a vaccine. They proposed to pay a fairly large amount of money to the clinic doing the abortion, and a nominal amount to the parents of the aborted foetus. The money for the clinic was to be kept in a trust fund and used for research. The retinal cells would be used to develop a vaccine for commercial purposes. The donors (in this case the mother) of the retinal cells would have received no share of the profits from the vaccine developed.

The ethical issues in this situation are challenging and difficult, and the application to the ethics committee to obtain the foetal retinal cells was subsequently withdrawn. Even so, should a company be allowed to take tissue for its own profit? What rights should the donors of the tissue have in regard to those profits?

Example 2: A man, John Moore, who lived in another country, fell ill with hairy cell leukaemia. He went to a top specialist in his area, and had surgery to remove his spleen and other treatments. Over the next seven years the specialist kept asking him to return to the clinic to provide samples of blood, bone marrow, skin and sperm. Moore discovered that the specialist had patented unique chemicals in Moore's blood, and set up a contract with another company for shares worth approximately $3 million. A Swiss pharmaceutical company then paid a reported $15 million for the right to develop the cell line taken from Moore, subsequently named the Mo-cell line.

Moore sued his doctor for theft. The Supreme Court ultimately decided that Moore did not have a property interest in his body. The justices were concerned that giving Moore a property right to his tissue would 'destroy the economic incentive to conduct important medical research'.

The doctor should not have taken Moore’s tissue without informed consent, however, and the Court gave him the right to sue the doctor on this basis. Should the doctor be allowed to profit from Moore’s tissue? What rights should Moore have to gain something from research done with his tissue?

D4.1 Arguments for allowing the sale and purchase of human tissue

- As technology is becoming more sophisticated and techniques improve, the risks to the donor of live organ donation are relatively low.

- Maintaining medical alternatives to organ donation can be expensive (eg, kidney dialysis). If there are people who would donate their organs (either while they are alive or after they die) if a payment were made, and who otherwise would not donate, then payment is justified.

- Even if they were paid for doing so, an organ donor or their family would know they had saved a life and, therefore, the altruistic nature of organ donation would be the same as it is if they hadn't been paid.

- People should have a right to make a decision to sell a body part, as much as they have a right to sell their labour. They should also be able to share any profit made from products that their tissue helped develop.
• The families of donors would be appropriately compensated to pay for funeral expenses or other ways of honouring their loved one.

• Human bodies contain a number of elements that are useful in biomedical research, and payment for these may increase supply.

D4.2 Arguments against allowing the sale and purchase of human tissue

• Paying donors of organs and tissue is likely to exploit people who have little money or other resources.

• It encourages people to take risks, such as the risk of surgery to be a live donor, which they may not otherwise have taken if no payment had been offered.

• People cannot give genuine voluntary informed consent when motivated by the idea of payment for their tissue.

• There should be no property in a body or bodily tissues; that is, the current common law position that no one 'owns' their body or the body of another person should be maintained.

• It is offensive to many cultural and spiritual beliefs to allow the sale or purchase of human tissue.

• Altruism on the part of the donor or their family would be diminished.

• People who cannot pay for the organs or tissue may be the most in need of them.

• Allowing the sale and purchase of human tissue may decrease the rate of donation.

• People are not entitled to share the profit from products their tissue may have contributed to because they do not actively help to develop the materials into a valuable product.

• The commercialisation of biotechnological materials could hamper the free flow of information and materials: negotiations over the transfer and value of property rights for cell lines could reduce the exchange of information among scientists, and transaction costs of negotiation could be prohibitive.

• Transaction costs of any payment system could add significant burdens to the process of developing biotechnological products and processes, and could dwarf the costs of actual payments to the source donors.

• Some tissue samples – probably the majority – would never be developed into cell lines or products and yet would incur significant transaction costs.

• Source donors are likely to allow access to their tissues when it is combined with a medical procedure they are receiving. The total amount of payment for these tissues would therefore be likely to exceed the actual amount required to draw forth the services of an adequate number of donors.

• It would be difficult to negotiate a value for a particular human tissue at the time it is obtained.

• Many of the cell lines used in research are used for purposes other than developing commercial products.
• The safety and quality of donations could be compromised, or could compromise the safety of the donor, encouraging them to take on risks for money.
• Court battles over the ownership of human tissue could be detrimental to academic researchers and the biotechnology industry.

Ethical objections to commercial activities in human biological materials

• Respect for persons – trade in human tissues and cells ought to be limited if the body is considered part of the basic dignity of human beings. To the extent that the body is indivisible from that which makes up personhood, the same respect is due the body as is due persons.
• Beneficence – marketing human tissues and cells might be justified if that would lead only to good results or to a prevalence of good results over bad.
• Justice – would a market setting be equitable to all members of society, including those who are financially disadvantaged?

On balance the Ministry does not think that the sale and purchase of tissue should be allowed in New Zealand, but is interested in what you think. Please note that work is to be undertaken elsewhere on the proposal that welfare assistance be given to live organ donors.

We are seeking your views

61. Do you think the new legislation should prohibit the sale and purchase of all human tissue in New Zealand?
62. If you think some sale and purchase of human tissue should be allowed, please explain what types of tissue this should apply to, for what purpose it should be allowed to be bought or sold, and who should be permitted to sell it.

D5 Import and export of tissue

Tissue may be imported or exported from New Zealand for a number of reasons, including:
• testing for public health surveillance, such as in the New Zealand Health Survey, where samples of blood are sent overseas for nutritional analysis; or when samples of tissue are sent overseas for detailed analysis into the cause of illness or death
• research by overseas organisations or by a combination of New Zealand-based and overseas-based researchers
• teaching of health practitioners and other educational purposes.
These are practices the Ministry considers could be supported by formal guidance. At present, however, the only coverage is provided by:

- the Hazardous Substances and New Organisms Act 1996 (see section B2.4), which requires scrutiny of the importation of any genetically modified human cells

- ethics committee processes – the National Application Form for Ethical Approval of a Research Project requires information about whether tissue samples will go out of New Zealand and for what purpose

- the Supplementary Order Paper to the Human Assisted Reproductive Technology Bill, which proposes prohibitions on the import or export of gametes or embryos derived from a prohibited action.

The Ministry considers that this coverage is inadequate to provide assurance that tissue imported to New Zealand has been collected in an ethical manner (including obtaining informed consent), and has been screened to minimise the risk of infection. It is also insufficient in terms of providing assurance to Māori that tissue exported from New Zealand will be managed in a culturally appropriate manner.

The United Kingdom Department of Health has recently issued a code of practice on the import and export of tissue from Britain (Department of Health 2003), which provides a useful steer on an approach for New Zealand. The following material is largely drawn from the United Kingdom guidance.

The Ministry considers that the new legislative framework could usefully provide guidance on:

- principles to guide import/export – these could include the need to treat human tissue with respect, including ascertaining that tissue was collected with informed consent, the need to assess New Zealand sources of tissue before importation is considered, and the need to keep thorough records of tissue imported or exported

- the reasons for which tissue may be imported/exported (eg, approved health practitioner education programmes, or approved clinical research)

- whether tissue may be imported/exported for public exhibitions – this has been a particular issue overseas, where exhibitions of plastinated tissue have been held with a degree of public controversy

- the characteristics of acceptable sources of tissue to be imported – characteristics could include ethical processes for tissue collection (including informed consent), and information about screening for infectious agents

- the characteristics of acceptable destinations for tissue to be exported – characteristics could include ensuring the destination country has similar controls on the use of tissue as New Zealand, and ensuring that tissue is to be used for ethically approved projects such as research

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49 The *Körperwelten* or ‘The Human Body World’ was an exhibition of about 200 plastinated body parts, including whole bodies, that has been held in a number of countries overseas, including Germany, Japan and England. All the tissue was obtained with consent but was the subject of considerable controversy by health practitioners and the public. The exhibition was visited by over 700,000 people. See Andrews and Nelkin 2001.
• the management practices required to ensure that tissue from Māori is treated in a culturally appropriate manner
• transport and customs requirements
• record-keeping and storage requirements
• disposal or return requirements.

We are seeking your views
63. Do you think the new legislative framework should provide more comprehensive coverage of the import and export of human tissue? If not, please explain why.
64. Are there issues for the import and export of tissue other than those identified above that you think should be covered by the new legislative framework? Please explain your reasons.
Part E: Looking Toward a New Regulatory Framework

This document has covered many complicated and interwoven issues. The final Part provides a summary of the proposed structure of the overall framework. Your comments and responses to the issues in this document will inform the shape of the overall framework, as well as the detail that is developed within it.

E1 A new human tissue act

It is proposed that a new human tissue act be developed to regulate the collection and use of tissue from deceased persons for therapeutic and non-therapeutic purposes. In particular, it is proposed that the new human tissue act include:

- a requirement that tissue from deceased persons be treated with dignity and respect
- consent requirements for non-coronial post-mortem examinations, and anatomical examinations
- consent requirements for the collection of tissue for research and education, including when tissue is to be collected at the time of a non-coronial post-mortem examination
- provisions for the collection of tissue for therapeutic purposes – organ and tissue donation
- definitions of who is able to give consent for tissue use on behalf of a deceased person
- provisions regarding the sale and purchase of tissue
- provisions that allow challenging new tissue-based technologies to be controlled while they are assessed for acceptability and safety.
E2 Amendments to therapeutic products legislation\textsuperscript{50}

It is proposed that a comprehensive regime be put in place to ensure the safety of tissue-based therapeutic products. The proposed regime would add a new part to therapeutic products legislation and potentially develop standards as described below under the Health and Disability Services (Safety) Act. It is envisioned that, in time, the regime for the safety of tissue-based therapeutic products could come under the jurisdiction of the Joint Therapeutic Products Agency.

The amendments to therapeutic products legislation would include:

- a definition of tissue-based therapeutic products based on an assessment of the risk associated with a particular product
- a definition of the activities to be regulated
- a definition of the people to be regulated.

E3 Standards under the Health and Disability Services (Safety) Act 2001

The Health and Disability Services (Safety) Act provides a framework for setting safety standards in the health and disability sector. When this Act was developed it was anticipated that tissue-based services would be regulated in the future and it has made provision for standards to be developed for this purpose. This document proposes that standards could be developed for:

- tissue banking
- whole organ retrieval and transplantation.

This document also proposes that a more comprehensive form of oversight for non-therapeutic use of tissue be developed. One option is that a tissue management standard be developed and monitored under the Health and Disability Services (Safety) Act. This would require an amendment to this Act, and the development of a standard. Your feedback on this proposal is welcomed, as are other suggestions for achieving the objective of comprehensive oversight without imposing unnecessary costs on the health and disability sector.

\textsuperscript{50} Work is under way to replace the Medicines Act 1981, to implement the joint therapeutic products regulatory scheme and to regulate New Zealand-specific aspects of medicines regulation. The specific vehicle for tissue-based therapeutic products will be considered at a later date.
E4 Health Act 1956

As part of the overall framework for the safety of tissue-based therapies, this document suggests that it may be appropriate to use the provisions in the Health Act 1956 to recognise particular entities as being authorised to collect controlled human substances. The Health Act could also be used to prevent trade in controlled human substances.

E5 Other regulations, codes or guidelines

To complete the framework for human tissue, this document has asked for your comments on a number of other regulations, codes or guidelines, including the following.

- Health (Retention of Health Information) Regulations 1996 – following changes to the relevant regulation-making powers, we seek your initial comment on the issues to be addressed in requiring specimens to be retained in the same way as other health information.
- Health Information Privacy Code – in response to the increasing focus on genetic information, we seek your comment about the coverage of the Health Information Privacy Code in relation to genetic information, and specimens in particular.
- Import and export of tissue – it is suggested that the import and export of tissue could be covered by a code of practice.
- Your comment is also sought on whether or not more detailed guidance is needed to assist ethical decision-making about the use of foetal tissue for non-therapeutic purposes.
Glossary

Advance directive – defined in the Code of Health and Disability Services Consumers Rights as:

- a written or oral directive –
  a. By which a consumer makes a choice about a possible future health care procedure; and
  b. That is intended to be effective only when he or she is not competent.

An advance directive is simply the consumer’s advance use of his or her right to make a health care choice, and any unreasonable interference with the consumer’s valid advance refusal of treatment will be a breach of the Code. A signed surgical consent form, an agreement between the doctor and the expectant mother as to what drugs are to be used in an emergency, or even the explicit instructions of a patient to their doctor are all examples of advance directives.

Advance directives that refuse life-saving treatment raise the most difficult issues. Such decisions involve the fundamental right of consumers to refuse medical treatment under the Bill of Rights Act 1990 (section 11) and the statutory obligations on doctors to provide the necessities of life.

The validity of an advance directive will depend on four key issues:
1. whether the consumer was competent to make the particular decision when the decision was made; and
2. whether the consumer made the decision free from undue influence; and
3. whether the consumer was sufficiently informed to make the decision; and
4. whether the consumer intended his or her directive or choice to apply to the present circumstances when the advance directive was made.

A doctor should not provide services in contradiction to an advance directive unless there are reasonable grounds to doubt the validity of the advance directive.

Advance directives can be set up with a doctor or lawyer, who will either design a directive specifically for the consumer’s needs, or use forms that have been developed by the National Policy Council and the New Zealand General Practitioner Association. Although these forms have not been tested in a New Zealand court, they are designed to prevent problems such as a legal challenge based on the competency of the person signing, or allegations of undue influence. These forms are available from the New Zealand Medical Association.

Under the Code, an advance directive can be written or oral, and does not need to be witnessed by a doctor or lawyer.
Autologous – involving one individual as both donor and recipient (as opposed to non-autologous use when the donor and recipient are different people).

Biotechnology – any technological application that uses biological systems, living organisms or derivatives thereof (whether genetically modified or not) to make or modify products or processes for general use.

Cells – the individual units from which tissues of the body are formed. All living organisms are composed of one or more cells.

Dead tissue – tissue that is structurally or mechanically functional but is no longer physiologically or metabolically functional. Without intervention, tissue will cease to be functional two to three hours after removal from a living body or two to three hours after the death of a person.

DNA (deoxyribonucleic acid) – the biochemical substance that genetic material is made of. DNA controls the structure and function of each cell and carries genetic information during reproduction.

Embryo – the early human form from fertilisation to its eighth week of development (ie until it is considered a foetus).

Foetus – the early human form from week eight until birth.

Gamete – the male sperm or the female egg.

Gene – an ordered sequence of nucleotides located in a particular position on a particular chromosome that encodes a specific functional product.

Gene therapy – treatment of a disease caused by malfunction of a gene, by transferring the cells of an organism with the normal gene.

Genome – the total set of genes carried by an individual or cell.

Homologous – corresponding in structure, position or origin (eg, the feathers of a bird and the scales of a fish).

In-vitro – occurring outside the living organism; typically an experiment performed in a test tube or other artificially designed environment.

Plastination or plastinated tissue – the process of plastination results in the fluids of the body or tissue sample being replaced by reactive plastics, such as silicone rubber, epoxy resin or polyester resin. This process preserves the cell structure of the tissue. The specimens are dry and odourless, and hence can be handled with ease.
Post-mortem – the after-death examination of a body. A post-mortem examination involves the visual inspection, careful dissection, weighing and measuring of the body, organs and tissue. A post-mortem is also likely to involve the microscopic, biochemical and genetic examination of tissue taken from organs. A post-mortem examination is undertaken by a pathologist (a doctor who specialises in the diagnosis of disease and the identification of the cause of death).

Prosections – slices of tissue samples.

Somatic cell – any cell other than a sperm or egg cell.

Stem cell – a cell that is able to give rise to a range of specialised cells.

Tissue banks – services storing human tissue intended to be used for therapeutic purposes.

Tissue collections – collections of dead tissue intended to be used for clinical, quality assurance, research and educational purposes. This does not cover living or dead tissue intended for therapeutic purposes.

Tissue samples or blocks (also called paraffin blocks) – during a post-mortem, small pieces of organs may be cut out for more detailed inspection under a microscope. The samples are treated with chemicals and fixed into a paraffin wax block so that they can be handled without getting damaged.

Xenotransplantation – the transplantation of live cells, tissues or organs from another species (eg, pigs) into humans. Xenotransplantation includes any procedure where human fluids are exposed through a perfusion system to living non-human cells, tissues or organs. The actual tissue transplanted is called a xenograft.
Appendix 1: Relevant Provisions of the Official Information Act 1982

9. Other reasons for withholding official information –

(1) Where this section applies, good reason for withholding official information exists, for the purpose of section 5 of this Act, unless, in the circumstances of the particular case, the withholding of that information is outweighed by other considerations which render it desirable, in the public interest, to make that information available.

(2) Subject to sections 6, 7, 10, and 18 of this Act, this section applies if, and only if, the withholding of the information is necessary to –

(a) Protect the privacy of natural persons, including that of deceased natural persons; or

(b) Protect information where the making available of the information –

(i) Would disclose a trade secret; or

(ii) Would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information; or

(ba) Protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information –

(i) Would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied; or

(ii) Would be likely otherwise to damage the public interest; or

(c) Avoid prejudice to measures protecting the health or safety of members of the public; or

(d) Avoid prejudice to the substantial economic interests of New Zealand; or

(e) Avoid prejudice to measures that prevent or mitigate material loss to members of the public; or

(f) Maintain the constitutional conventions for the time being which protect –

(i) The confidentiality of communications by or with the Sovereign or her representative;

(ii) Collective and individual ministerial responsibility;

(iii) The political neutrality of officials;

(iv) The confidentiality of advice tendered by Ministers of the Crown and officials; or
(g) Maintain the effective conduct of public affairs through –
(i) The free and frank expression of opinions by or between or to Ministers of the Crown or members of an organisation or officers and employees of any Department or organisation in the course of their duty; or
(ii) The protection of such Ministers, members of organisations, officers, and employees from improper pressure or harassment; or

(h) Maintain legal professional privilege; or

(i) Enable a Minister of the Crown or any Department or organisation holding the information to carry out, without prejudice or disadvantage, commercial activities; or

(j) Enable a Minister of the Crown or any Department or organisation holding the information to carry on, without prejudice or disadvantage, negotiations (including commercial and industrial negotiations); or

(k) Prevent the disclosure or use of official information for improper gain or improper advantage.
Appendix 2: Human Tissue Act 1964

An Act to consolidate certain enactments of the General Assembly relating to post-mortem examinations, the practice of anatomy, and the removal of human tissue for therapeutic purposes and for purposes of medical education and research.

1 Short title and commencement

(1) This Act may be cited as the Human Tissue Act 1964.

(2) This Act shall come into force on the 1st day of January 1965.

2 Interpretation

(1) In this Act, unless the context otherwise requires, –

anatomical examination means examination of a body or any part of a body for the purpose of the study of the science of anatomy:

body means a dead human body; but does not include the body of a stillborn child:

health computer system means any system of computers and terminals—

(a) Under the control of the Director-General of Health; or

(b) Part of which is under the control of the Director-General of Health:

inspector, in relation to any school of anatomy, means a person appointed under section 8 of this Act to be an Inspector of that school of anatomy:

medical practitioner means a person registered as a medical practitioner under the Medical Practitioners Act 1995:

Minister means the Minister of Health:

practise anatomy means teach the science of anatomy by performing an anatomical examination:

school of anatomy means a school of anatomy established under section 7 of this Act.

(2) Without limiting the rights, powers, or duties of any person entitled under any rule of law to the possession of any body, it is hereby declared that, for the purposes of this Act, the following persons shall be deemed to be persons lawfully in possession of bodies in the cases hereinafter specified, namely:

(a) the person for the time being in charge of any hospital care institution within the meaning of section 58(4) of the Health and Disability Services (Safety) Act 2001, in respect of any body lying in that institution:

(b) The person for the time being in charge of any hospital within the meaning of the Mental Health (Compulsory Assessment and Treatment) Act 1992, in respect of any body lying in the hospital, being the body of a patient:

(c) The Superintendent of any penal institution, in respect of any body lying in the institution, being the body of an inmate.
3 Removal of human tissue for therapeutic purposes, etc.

(1) If any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body or any specified part of his body be used after his death for therapeutic purposes or for purposes of medical education or research, the person lawfully in possession of his body after his death may, unless he has reason to believe that the request was subsequently withdrawn, authorise the removal from the body of any part or, as the case may be, the specified part, for use in accordance with the request.

(1A) Where a record of a request in writing to which subsection (1) of this section applies is held on a health computer system, the person lawfully in possession of the body of the person who made the request may, in reliance on the record, unless that person has reason to believe that the request was subsequently withdrawn, authorise the removal from the body of any part or (as the case may be) the specified part for use in accordance with that request.

(2) Without limiting subsection (1) of this section, it is hereby declared that the person lawfully in possession of the body of a deceased person may authorise the removal of any part from the body for use for the said purposes if, having made such reasonable inquiry as may be practicable, he has no reason to believe –

(a) That the deceased person has expressed an objection to his or her body being so dealt with after death, and had not withdrawn it; or

(b) That the surviving spouse, surviving de facto partner of the same or different sex, or any surviving relative of the deceased person objects to the body being so dealt with.

(3) Subject to subsections (4) and (5) of this section, the removal and use of any part of a body in accordance with an authority given in pursuance of this section shall be lawful.

(4) No such removal shall be effected except by a medical practitioner, who must have satisfied himself by personal examination of the body that life is extinct.

(5) Where a person has reason to believe that an inquest may be required to be held on any body or that a post-mortem examination of any body may be required by the coroner, he shall not, except with the consent of the coroner, –

(a) Give an authority under this section in respect of the body; or

(b) Act on such an authority given by any other person.

(6) No authority shall be given under this section in respect of any body by a person entrusted with the body for the purpose only of its interment or cremation.

(7) Nothing in this section shall be construed as rendering unlawful any dealing with, or with any part of, the body of a deceased person which is lawful apart from this Act.
4 Post-mortem examinations

(1) Nothing in sections 5 to 9 of this Act shall apply to any post-mortem examination directed to be made by a coroner or any other competent legal authority, or to any post-mortem examination carried out for the purpose of establishing or confirming the causes of death or investigating the existence or nature of abnormal conditions or for any of the purposes specified in section 3 of this Act.

(2) No post-mortem examination shall be carried out otherwise than by or in accordance with the instructions of a medical practitioner; and no post-mortem examination, other than one which is directed or requested by a coroner, or any other competent legal authority, shall be carried out without the authority of the person lawfully in possession of the body; and subsections (2), (5), and (6) of section 3 of this Act shall, with the necessary modifications, apply with respect to the giving of that authority.

4A Restrictions on persons holding probationary registration

For the purposes of sections 3 and 4 of this Act, but for no other purpose of this Act, a person who holds probationary registration under the Medical Practitioners Act 1995 shall be subject to the restrictions imposed by section 15 of the last-mentioned Act.

5 Anatomical examinations

(1) If any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body be used after his death for the purposes of anatomical examination, the person lawfully in possession of the body after death may authorise such an examination, and may permit the body to be removed to a school of anatomy accordingly, unless he has reason to believe that the request was subsequently withdrawn, or unless objection to the body being so dealt with is made by –

(a) The surviving spouse or surviving de facto partner (whether of the same or different sex) of the deceased person; or

(b) If there is no surviving spouse or surviving de facto partner (whether of the same or different sex), a person who is the nearest known relative, or one of the nearest known relatives, of the deceased person.

(2) Without limiting subsection (1) of this section, it is hereby declared that the person lawfully in possession of the body of a deceased person may authorise the body to be used for the purposes of anatomical examination, and may permit the body to be removed to a school of anatomy accordingly, if, having made such reasonable inquiry as may be practicable, he has no reason to believe –

(a) That the deceased person had expressed an objection to his or her body being so dealt with after death, and had not withdrawn it; or

(b) That the surviving spouse or any surviving relative of the deceased person objects to the body being so dealt with.
Subsections (5) and (6) of section 3 of this Act shall, with the necessary modifications, apply with respect to the giving of any authority under this section.

6 Removal, burial, and cremation of bodies

(1) Any person empowered by this Act to authorise the use of a body for anatomical examination shall, before causing the body to be removed to a school of anatomy, cause a written notice in duplicate to be sent to the medical practitioner in charge of that school of his intention so to do, and shall, so far as he is able, state in that notice the following particulars:

(a) The name, age, and sex of the deceased person:

(b) The place, date, and cause of death:

(c) The religion of the deceased person.

(2) Every body that is removed for anatomical examination under this Act shall, before it is so removed, be placed in a decent coffin or shell and shall be removed therein.

(3) The medical practitioner in charge of any school of anatomy to which a body is removed for anatomical examination shall, within 24 hours of the time at which the body is received at the school of anatomy, cause to be sent to any Inspector notice in writing of the receipt of the body into the said school of anatomy.

(4) In no case shall any body undergo anatomical examination until after 36 hours have elapsed from the time of death, nor until after 24 hours’ notice has been given to an Inspector of the intention to make the examination.

(5) All human remains resulting from anatomical examination shall be buried or cremated in accordance with the written instructions of an Inspector, who shall take into consideration any wishes that the deceased or his relatives may have expressed:

Provided that, with the permission of an Inspector, any part of the body may be retained indefinitely for further study.

(6) Notwithstanding anything in this Act or in any other enactment, the written instructions of an Inspector shall be sufficient authority for the cremation of any body that has been removed for anatomical examination or of any human remains resulting from such an examination.

(7) In the month of November in each year, the medical practitioner in charge of any school of anatomy shall cause to be sent to an Inspector a return specifying the name of every person whose body has undergone anatomical examination at the school of anatomy during the year and has been disposed of by burial or cremation under this section.
7 Schools of anatomy

(1) The Governor-General in Council may from time to time authorise the establishment of schools of anatomy where the study and practice of anatomy may be carried on in connection with any University or school of medicine, in such place or places and upon such conditions as he thinks fit, and may at any time revoke any such authority.

(2) It shall not be lawful for any person to perform an anatomical examination, or to receive or have in his possession any body for anatomical examination, at any place other than a school of anatomy.

(3) Nothing in this section shall prevent any person, who is licensed under this Act to practise anatomy and who obtains the permission of an Inspector in writing for that purpose and the permission of the governors, teachers, or proper authorities of the school at which he is licensed to practise anatomy, from removing any body or portion of a body to such place as the Inspector deems fit for the purpose of practising anatomy, upon such terms and conditions as the Inspector and authorities of the school, in their uncontrolled discretion, think fit.

8 Inspectors of schools of anatomy

(1) The Minister may from time to time, with the concurrence of the Minister in Charge of Police, appoint one or more members of the Police as an Inspector or Inspectors of any school of anatomy, and may direct in what manner Inspectors shall transact the duties of their office.

(2) Every Inspector shall, unless he sooner dies, continue in office until some other person is appointed in his place.

(3) Every Inspector of a school of anatomy shall make a quarterly return to the Minister of all bodies which, during the preceding quarter, have been removed for anatomical examination to the school, or that may have been removed to any other place under the provisions of section 7 of this Act, distinguishing the sex and, as far as is known at the time, the name and age of each person whose body was so removed as aforesaid.

(4) An Inspector may visit and inspect at any time the school of anatomy for which he is appointed an Inspector.

(5) There shall be payable to an Inspector, out of money appropriated by Parliament for the purpose, such remuneration as is fixed from time to time by the Minister of Finance.

(6) Every Inspector of any school of anatomy who was in office immediately before the commencement of this Act shall continue in office after the commencement of this Act as if he had been appointed by the Minister under this section.
9 Licences to practise anatomy

(1) Subject to the provisions of section 10 of this Act, it shall not be lawful for any person to practise anatomy, or to receive or have in his possession any body for anatomical examination, unless he is licensed under this section to practise anatomy.

(2) The Minister may grant a licence to practise anatomy, subject to such conditions as he sees fit to impose, to any medical practitioner who is employed to teach at a school of anatomy.

(3) Any licence granted under this section shall specify the school of anatomy at which the holder of the licence may practise anatomy.

(4) Any licence granted under this section shall continue in force until it is cancelled or surrendered:
   Provided that any such licence may, if the Minister thinks fit, be granted for any specified period, and in any such case the licence may be renewed from time to time by the Minister, if he thinks fit, for any specified period.

(5) Any licence granted under this section may be cancelled by the Minister at any time by notice in writing to the holder of the licence.

(6) Any licence to practise anatomy that was subsisting immediately before the commencement of this Act shall continue in force after the commencement of this Act as if it had been granted by the Minister under this section.

10 Saving

Nothing in sections 5 to 9, or in section 12, of this Act shall be construed as prohibiting –

(a) Any anatomical examination or the practice of anatomy by any person who is acting under the directions and supervision of a person licensed to practise anatomy and is carrying out the anatomical examination or the practice of anatomy at a school of anatomy or place at which the person so supervising is licensed to practise anatomy; or

(b) The receipt or possession of a body on behalf of a person so licensed.

11 Decency to be observed

Any person performing a post-mortem or anatomical examination or removing any part of a body pursuant to this Act shall do so in a manner that avoids unnecessary mutilation of the body which is being examined or from which any such removal is being effected, and shall conduct the examination or removal in an orderly, quiet, and decent manner.

Compare: 1908 No 116, s35

Status Compendium
12 Offences

Every person commits an offence and is liable on summary conviction to a fine not exceeding $1000, or to imprisonment for a term not exceeding three months, who, –

(a) Not being a medical practitioner, performs any post-mortem examination otherwise than in accordance with the instructions of a medical practitioner; or

(b) Not being licensed under this Act to practise anatomy, practises anatomy, or, otherwise than on behalf of a person so licensed, receives or has in his possession any body for the purpose of anatomical examination; or

(c) Performs an anatomical examination of a body at a place where or at a time when that examination is prohibited by this Act.
Appendix 3: Code of Health and Disability Services Consumers’ Rights

1. Consumers have rights and providers have duties
   1) Every consumer has the rights in this Code.
   2) Every provider is subject to the duties in this Code.
   3) Every provider must take action to –
      a) Inform consumers of their rights; and
      b) Enable consumers to exercise their rights.

2. Rights of consumers and duties of providers
The rights of consumers and the duties of providers under this Code are as follows:

Right 1: Right to be treated with respect
   1) Every consumer has the right to be treated with respect.
   2) Every consumer has the right to have his or her privacy respected.
   3) Every consumer has the right to be provided with services that take into account the needs, values, and beliefs of different cultural, religious, social, and ethnic groups, including the needs, values, and beliefs of Māori.

Right 2: Right to freedom from discrimination, coercion, harassment, and exploitation
Every consumer has the right to be free from discrimination, coercion, harassment, and sexual, financial or other exploitation.

Right 3: Right to dignity and independence
Every consumer has the right to have services provided in a manner that respects the dignity and independence of the individual.

Right 4: Right to services of an appropriate standard
   1) Every consumer has the right to have services provided with reasonable care and skill.
   2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.
   3) Every consumer has the right to have services provided in a manner consistent with his or her needs.
4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer.

5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

Right 5: Right to effective communication

1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.

2) Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively.

Right 6: Right to be fully informed

1) Every consumer has the right to the information that a reasonable consumer, in that consumer’s circumstances, would expect to receive, including –
   a) An explanation of his or her condition; and
   b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
   c) Advice of the estimated time within which the services will be provided; and
   d) Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and
   e) Any other information required by legal, professional, ethical, and other relevant standards; and
   f) The results of tests; and
   g) The results of procedures.

2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer’s circumstances, needs to make an informed choice or give informed consent.

3) Every consumer has the right to honest and accurate answers to questions relating to services, including questions about –
   a) The identity and qualifications of the provider; and
   b) The recommendation of the provider; and
   c) How to obtain an opinion from another provider; and
   d) The results of research.

4) Every consumer has the right to receive, on request, a written summary of information provided.
Right 7: Right to make an informed choice and give informed consent

1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.

3) Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.

4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where –
   a) It is in the best interests of the consumer; and
   b) Reasonable steps have been taken to ascertain the views of the consumer; and
   c) Either, –
      i. If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
      ii. If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

5) Every consumer may use an advance directive in accordance with the common law.

6) Where informed consent to a health care procedure is required, it must be in writing if –
   a) The consumer is to participate in any research; or
   b) The procedure is experimental; or
   c) The consumer will be under general anaesthetic; or
   d) There is a significant risk of adverse effects on the consumer.

7) Every consumer has the right to refuse services and to withdraw consent to services.

8) Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.

9) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.
10) Any body parts or bodily substances removed or obtained in the course of a health care procedure may be stored, preserved, or utilised only with the informed consent of the consumer.

Right 8: Right to support
Every consumer has the right to have one or more support persons of his or her choice present, except where safety may be compromised or another consumer’s rights may be unreasonably infringed.

Right 9: Rights in respect of teaching or research
The rights in this Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.

Right 10: Right to complain
1) Every consumer has the right to complain about a provider in any form appropriate to the consumer.

2) Every consumer may make a complaint to –
   a) The individual or individuals who provided the services complained of; and
   b) Any person authorised to receive complaints about that provider; and
   c) Any other appropriate person, including –
      i. An independent advocate provided under the Health and Disability Commissioner Act 1994; and
      ii. The Health and Disability Commissioner.

3) Every provider must facilitate the fair, simple, speedy, and efficient resolution of complaints.

4) Every provider must inform a consumer about progress on the consumer’s complaint at intervals of not more than one month.

5) Every provider must comply with all the other relevant rights in this Code when dealing with complaints.

6) Every provider, unless an employee of a provider, must have a complaints procedure that ensures that –
   a) The complaint is acknowledged in writing within five working days of receipt, unless it has been resolved to the satisfaction of the consumer within that period; and
   b) The consumer is informed of any relevant internal and external complaints procedures, including the availability of –
      i. Independent advocates provided under the Health and Disability Commissioner Act 1994; and
      ii. The Health and Disability Commissioner; and
c) The consumer’s complaint and the actions of the provider regarding that complaint are documented; and
d) The consumer receives all information held by the provider that is or may be relevant to the complaint.

7) Within 10 working days of giving written acknowledgement of a complaint, the provider must, –
   a) Decide whether the provider –
      i. Accepts that the complaint is justified; or
      ii. Does not accept that the complaint is justified; or
   b) If it decides that more time is needed to investigate the complaint, –
      i. Determine how much additional time is needed; and
      ii. If that additional time is more than 20 working days, inform the consumer of that determination and of the reasons for it.

8) As soon as practicable after a provider decides whether or not it accepts that a complaint is justified, the provider must inform the consumer of –
   a) The reasons for the decision; and
   b) Any actions the provider proposes to take; and
   c) Any appeal procedure the provider has in place.

3. Provider compliance

1) A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code.

2) The onus is on the provider to prove it took reasonable actions.

3) For the purposes of this clause, “the circumstances” means all the relevant circumstances, including the consumer’s clinical circumstances and the provider’s resource constraints.

4. Definitions

In this Code (unless the context otherwise requires),

“Advance directive” means a written or oral directive –

(a) By which a consumer makes a choice about a possible future health care procedure; and

(b) That is intended to be effective only when he or she is not competent:
“Choice” means a decision –
(a) To receive services:
(b) To refuse services:
(c) To withdraw consent to services:

“Consumer” means a health consumer or a disability services consumer; and, for the purposes of rights 5, 6, 7(1), 7(7) to 7(10), and 10, includes a person entitled to give consent on behalf of that consumer:

“Discrimination” means discrimination that is unlawful by virtue of Part II of the Human Rights Act 1993:

“Duties” includes duties and obligations corresponding to the rights in this Code:

“Exploitation” includes any abuse of a position of trust, breach of a fiduciary duty, or exercise of undue influence:

“Optimise the quality of life” means to take a holistic view of the needs of the consumer in order to achieve the best possible outcome in the circumstances:

“Privacy” means all matters of privacy in respect of the consumer, other than matters of privacy that may be the subject of a complaint under Part VII or Part VIII of the Privacy Act 1993 or matters to which Part X of that Act relates:

“Provider” means a health care provider or disability services provider:

“Research” means health research or disability research:

“Rights” includes rights corresponding to the duties in this Code:

“Services” means health services, or disability services, or both; and includes health care procedures:

“Teaching” includes training of providers.

5. Other enactments
Nothing in this Code shall require a provider to act in breach of any duty or obligation imposed by any enactment or prevents a provider doing an act authorised by any enactment.

6. Other rights
An existing right is not overridden or restricted simply because the right is not included in this Code or is included only in part.
Appendix 4: Ethics Committees in New Zealand

The following ethics committees have a role in the health and disability support sector:

- health and disability ethics committees
- Health Research Council Ethics Committee
- National Ethics Advisory Committee
- National Ethics Committee on Assisted Human Reproduction
- Standing Committee on Clinical Trials
- Gene Technology Advisory Committee
- Toi te Taiao: the Bioethics Council.

Following is a short description of the role of each committee.

Health and disability ethics committees

The primary role of a health and disability ethics committee (HDEC) is to provide independent ethical review of innovative practice and health research that will be conducted in their designated region of authority. HDECs may also provide advice on service delivery issues.

In undertaking this role, HDECs will:

i. safeguard the rights, health and wellbeing of consumers and research participants and, in particular, those persons with diminished autonomy

ii. foster an awareness of ethical principles and practices in the health and disability sector and research community

iii. facilitate excellence in health research and innovative practice for the wellbeing of society

iv. give due consideration to local community views

v. ensure that the principles of the Treaty of Waitangi, particularly the principles of participation, partnership, and protection, are incorporated in the proceedings and processes and outcomes of committees

vi. operate in accordance with the Operational Standard for Health and Disability Ethics Committees

vii. operate in accordance with any guidelines issued or approved by the National Advisory Committee for Health and Disability Support Services Ethics.

Accredited ethics review committees at tertiary educational institutions (referred to as institutional ethics committees) and one ethics committee in the private sector also carry out ethical review in accordance with the above principles.
Health Research Council Ethics Committee (HRCEC)

The HRCEC considers and makes recommendations to the Health Research Council (HRC) on ethical issues in relation to health research, especially those emerging through the development of new areas of health research.

In respect of each application submitted to the HRC for a grant for the purposes of health research, the HRCEC is empowered to ensure that an independent ethical assessment of the proposed health research is made either by itself or by a committee approved by the HRCEC.

In relation to ethics committees established by other bodies, the HRCEC has the function of giving advice on:
- the membership of those committees
- the procedures to be adopted, and the standards to be observed, by those committees.

National Ethics Advisory Committee (NEAC)

NEAC was established under the New Zealand Health and Disability Act 2000. NEAC’s functions are to:
- provide advice to the Minister of Health on ethical issues of national significance in respect of any health and disability matters (including research and health services)
- determine nationally consistent ethical standards across the health and disability sector and provide scrutiny for national health research and health services.

National Ethics Committee on Assisted Human Reproduction (NECAHR)

NECAHR was established under the New Zealand Public Health and Disability Act 2000. NECAHR’s functions are to:

i. review assisted human reproductive proposals (including health research and innovative treatment) to determine whether they are ethical and, in particular, to determine whether:
   a. the rights of the people involved will be protected
   b. proper account will be taken of the ethical perspectives of Māori, and other cultural ethnic, religious, and social groups in New Zealand

ii. develop for providers protocols and guidelines relating to the ethical issues involved with aspects of assisted human reproduction

iii. advise the Minister of Health on ethical issues relating to assisted human reproduction

iv. consider any matters relating to assisted human reproduction the Minister of Health from time to time determines.
Standing Committee on Therapeutic Trials

SCOTT is a committee of the Health Research Council (HRC). It is convened to provide recommendations to the Director-General of Health on the scientific validity of applications for clinical trials on new medicines. All clinical trials involving pre-registration medicines need to have the approval of SCOTT to proceed. Section 30 of the Medicines Act 1981 empowers the Director-General of Health on the advice of the HRC to permit the use of medicines that have not received marketing consent to be used in clinical trials for the purpose of obtaining clinical and scientific information.

Gene Technology Advisory Committee

GTAC is a standing committee of the HRC. The function of GTAC is to review, for the purposes of seeking an exemption under section 30 of the Medicines Act 1981 or as required by the HRC, any of the HRC’s committees or an ethics committee’s proposals for clinical trials:

i. that include the introduction of nucleic acids (genetically manipulated or synthesised in the laboratory) or genetically manipulated micro-organisms, viruses or cells into human participants for the purpose of gene therapy or cell marking

ii. in which the introduction of nucleic acids (genetically manipulated or synthesised in the laboratory), or genetically manipulated micro-organisms, viruses or cells is designed to stimulate an immune response against the participant’s own cells, as in the treatment of certain cancers

iii. in which nucleic acids either from or within cells from animal species are transferred into human participants for the purposes of disease treatment (xenotransplantation)

iv. in which human nucleic acids have been introduced into the genome of an animal species, including genetically manipulated micro-organisms, for the purpose of developing products to be used for either disease prevention or treatment in human participants

v. involving vaccines in which nucleic acids (genetically manipulated or synthesised in the laboratory) or genetically manipulated micro-organisms, viruses or cells have been introduced to stimulate an immune response to antigenic determinants of an infectious agent.

Toi te Taiao: the Bioethics Council

The goal of the Bioethics Council is to enhance New Zealand’s understanding of the cultural, ethical and spiritual aspects of biotechnology and ensure that the use of biotechnology has regard for the values held by New Zealanders. The Bioethics Council is a ministerial advisory committee set up to:

• provide independent advice to government on biotechnological issues involving significant cultural, ethical and spiritual dimensions

• promote and participate in public dialogue on cultural, ethical and spiritual aspects of biotechnology, and enable public participation in the Council’s activities

• provide information on the cultural, ethical and spiritual aspects of biotechnology.
Appendix 5: Part 3A of the Health Act 1956

Part 3A – Trading in human blood and controlled human substance

92A Interpretation
In this Part, unless the context otherwise requires, –

Appointed entity means an entity appointed under section 92H:

Blood means human blood; and –

(a) Includes the following:
   (i) A substance derived from blood:
   (ii) A human organ, or human bone marrow, or human tissue, including the placenta, of a kind that is suitable as a source from which to derive a constituent of blood that may be used therapeutically or in the preparation of a substance for therapeutic use:
   (iii) A constituent of an organ, bone marrow, or tissue described in subparagraph (ii):
   (iv) Human haematopoietic stem cells, or a constituent of human haematopoietic stem cells, that may be used therapeutically or in the preparation of a substance for therapeutic use; but

(b) Does not include the following:
   (i) Any substance derived from blood, a human organ, human bone marrow, human tissue, or human haematopoietic stem cells that is intended for use in quality control or as a diagnostic product:
   (ii) Any substance containing a fraction of blood, a human organ, human bone marrow, human tissue, or human haematopoietic stem cells that the Governor-General by Order in Council declares not to be blood for the purposes of this Part:

Controlled human substance –

(a) Means –
   (i) Human bone marrow (other than human bone marrow referred to in paragraph (a)(ii) of the definition of the term “blood” in this section) that may be used therapeutically or in the preparation of a substance for therapeutic use; or
   (ii) A constituent of human bone marrow described in subparagraph (i); or
   (iii) Any other substance of the human body that may be used therapeutically or in the preparation of a substance for therapeutic use and that the Governor-General by Order in Council declares to be included in this definition; but
(b) Does not include –
   (i) A product derived from any controlled human substance that is intended for
       use in quality control or as a diagnostic product; or
   (ii) A substance containing a fraction of any controlled human substance that
       the Governor-General by Order in Council declares not to be a controlled
       human substance for the purposes of this Part.

92B Trading in own blood or controlled human substance prohibited
(1) No person may require or accept financial or other consideration for the blood or
    any controlled human substance of that person.
(2) No person may provide financial or other consideration for the taking of blood or
    any controlled human substance from the body of a person for administration to
    another person.
(3) Every person commits an offence and is liable to a fine not exceeding $1000 who
    contravenes subsection (1).
(4) Every person commits an offence and is liable to imprisonment for a term not
    exceeding six months or a fine not exceeding $5000 who contravenes
    subsection (2).

92C Collection of blood or controlled human substance
(1) No person may take blood or any controlled human substance from the body of a
    person for the purpose of obtaining that blood or that substance for administration
    to another person.
(2) Every person commits an offence and is liable to imprisonment for a term not
    exceeding six months or a fine not exceeding $5000 who contravenes
    subsection (1).
(3) Subsection (1) does not apply to –
    (a) An appointed entity that is authorised to take blood and controlled human
        substances from persons; or
    (b) An employee or agent of an appointed entity who is authorised by the entity
        to take blood or controlled human substances on behalf of the entity, if the
        entity has the power to authorise employees or agents to do so.
(4) For the purposes of subsection (3), an appointed entity is authorised to take blood
    and controlled human substances, and has the power to authorise employees and
    agents of the entity to do so, unless the notice by which the entity is appointed
    provides otherwise.
(5) Every appointed entity described in subsection (3)(a) and every employee or
    agent described in subsection (3)(b) who takes blood or any controlled human
    substance must give due recognition to the fact that the blood or controlled human
    substance has been donated.
92D Charging for administered blood or controlled human substance

(1) No person who administers blood or any controlled human substance to another person may require or accept financial or other consideration for that blood or that substance from the person to whom it is administered.

(2) Every person commits an offence and is liable to imprisonment for a term not exceeding six months or a fine not exceeding $5000 who contravenes subsection (1).

Penalty


92E Exemptions

(1) The Minister may, in his or her discretion and on such terms and conditions (if any) as the Minister thinks fit, by notice in writing, exempt a person or persons or class of persons from compliance with any or all of the provisions of sections 92B(1), 92B(2), and 92D(1), and may in the same manner vary or revoke any such exemption.

(2) Where a notice is given under subsection (1), the Minister must as soon as practicable after giving the notice, publish in the Gazette and present to the House of Representatives a copy of the notice.

92F Unauthorised advertising prohibited

(1) No person may distribute an advertisement relating to the purchase or sale in New Zealand of blood or a controlled human substance.

(2) For the purposes of subsection (1), distribute means –

(a) To publish or otherwise disseminate, by newspaper, magazine, periodical, book, billboard, radio, television, cinematograph film, or any other means whatever; or

(b) To exhibit to public view in any premises or place; or

(c) To deposit in any area, yard, garden, or enclosure comprising part of or appurtenant to any premises.

(3) Every person commits an offence and is liable to imprisonment for a term not exceeding three months or a fine not exceeding $2500 who contravenes subsection (1).
92G Liability of employers, principals, and directors

(1) An act done by a person as the employee (“the employee”) of another person (“the employer”) is for the purposes of an offence against this Part to be treated as done by the employer as well as by the employee, if –
   (a) The employer approved of the act; or
   (b) The employer knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it.

(2) An act done by a person as the agent (“the agent”) of another person (“the principal”) is for the purposes of an offence against this Part to be treated as done by the principal as well as by the agent, if –
   (a) The principal approved of the act; or
   (b) The principal knew that the act was to be done or was being done and failed to take all reasonable steps to prevent it.

(3) Where a body corporate is convicted of an offence against this Part, a director of the body corporate is to be treated as having committed the same offence if –
   (a) The director approved of the act that constituted the offence; or
   (b) The director knew the offence was to be or was being committed and failed to take all reasonable steps to prevent it.

(4) In subsection (3), the term director includes a person who is concerned in the management of a body corporate.

92H Appointed entities to collect and distribute blood and controlled human substances

(1) The Minister may from time to time, by notice in writing, appoint 1 or more entities to be responsible for the performance of such functions in relation to blood and controlled human substances as are specified in the notice.

(2) An appointment under subsection (1) may be subject to such terms and conditions as are specified in the notice appointing the appointee.

(3) The Minister may from time to time, by notice in writing, revoke, vary, or add to—
   (a) Any of the functions for which an appointee is responsible:
   (b) Any of the terms or conditions of the appointment.

(4) The Minister may, at any time, by notice in writing, revoke an appointment made under subsection (1).

(5) A notice given under this section takes effect on the date specified for the purpose in the notice or, if no date is specified for that purpose, on the day after the date on which it is issued.
(6) An appointed entity that performs, in accordance with a notice given under this section, any function in relation to blood or a controlled human substance, is entitled to do anything, or refrain from doing anything, that is necessary or desirable for the purpose of performing that function, unless a notice given under this section provides otherwise.

(7) As soon as practicable after the Minister gives a notice under subsection (1) or subsection (3)(a) or subsection (4), the Minister must—

(a) Publish a copy of it in the Gazette; and

(b) Present a copy of it to the House of Representatives.

92I Exemption from Part 2 of Commerce Act 1986

Nothing in Part 2 of the Commerce Act 1986 applies to—

(a) Any contract, arrangement, understanding, or covenant in relation to blood or controlled human substances that—

(i) At the time it is entered into is, or is of a class that is, approved for the purposes of this section by the Governor-General by Order in Council; or

(ii) Is entered into by a person who (at the time it is entered into) is, or is of a class that is, approved for the purposes of this section by the Governor-General by Order in Council; or

(b) Any act done to give effect to a provision of any contract, arrangement, understanding, or covenant to which paragraph (a) applies.

92J Protection of appointed entities

(1) Section 129 applies to any appointed entity, and to any employee or agent of an appointed entity, who, in pursuance or intended pursuance of a provision in a notice given under section 92H, does any act, or fails or refuses to do any act, in relation to blood or a controlled human substance.

(2) For the purpose of applying section 129 in accordance with subsection (1), a provision in a notice given under section 92H is to be regarded as a provision of this Act.

92K Exemption from Part 2 of Commerce Act 1986

Repealed.

92L Protection of trustees of blood transfusion trust

Repealed.
References


List of Consultation Questions

Part A

1. As you go through this document and consider the many issues within it, please consider the definition of tissue on page 2 and let the Ministry know if you think the definition should be changed and why.

Part B

2. Do you agree that the new regulatory framework should make it clear that:
   a) consent to conduct a non-coronial post-mortem examination explicitly includes consent to retain tissue, where that tissue is to be retained for the purposes of the post-mortem only; and that the person giving consent for the post-mortem examination should be given information about the tissue to be retained, the reason for its retention and the length of time for which it will be retained?
   b) if it is proposed that tissue be retained for any purpose other than for the purposes of the post-mortem (such as ongoing research or education), that separate and specific consent is required for this purpose?

Please explain any changes you would make and why.

3. Do you think that the new legislative framework should have informed consent as its foremost principle?

4. If so, should a secondary principle recognise that in certain circumstances, the public good associated with the use of tissue will outweigh informed consent provided that safeguards are in place?

Please explain your reasons for agreeing or disagreeing.

5. Do you agree that it is acceptable for tissue samples to be used for the purposes of laboratory quality control, so long as the person giving the sample is told beforehand that their tissue may be used for this purpose and the sample is made anonymous? If you disagree, please explain why.

6. Do you agree that the concept of ‘informed consent’ is preferable to ‘lack of objection’ and that this should be included in the new regulatory framework? If not, please explain your reasons.

7. Are there any reasons why the provision in the Human Tissue Act allowing the use of unclaimed bodies for non-therapeutic purposes should be retained?

8. If the provision were removed, do you foresee any problems being created for the practice of anatomical examination, education or research? If so, do you have suggestions for how these could be addressed?
9. Do you agree that it is not appropriate for the body of a deceased person to be used for anatomical examination if the views of the deceased person about this use are not known? Please explain any comments.

10. Do you agree that the new legislative framework should allow tissue from deceased persons to be used for non-therapeutic purposes (other than anatomical examination) with appropriate informed consent? If not, please explain your reasons.

11. When tissue has been collected during the life of a person and is wanted for uses after that person’s death for a reason where the wishes of the deceased person are not known, should the new legislation allow these uses with appropriate safeguards? If so, are the following suggested safeguards appropriate.
   a) If the proposed use is a one-off event for clinical purposes, consent could be sought from another family member.
   b) If the proposed use is a research project, or audit, the tissue could not be used unless the research had been approved by an ethics committee, or the tissue was to be used for a professionally recognised quality assurance programme, an external audit or evaluation of services that was undertaken to assure or improve the quality of services.

   Please describe any other ideas you have.

12. Do you agree that, where a person is known to object to their body being used after their death for non-therapeutic purposes, this objection should be respected and their body should not be able to be used for these purposes, as is currently in the Human Tissue Act 1964? If you disagree please explain your reasons.

13. Do you think that the new legislation should allow families to have the final say over the donation of tissue from their deceased loved one for non-therapeutic purposes? If not, please explain why you think the wishes of the deceased should be required to be followed and if there should be any exceptions to this requirement.

14. Do you agree that consent from the parents or guardians should always be gained for tissue from a deceased child to be used for non-therapeutic purposes? If you don’t agree, please explain why.

15. If a child or young person is legally competent, and their wishes in relation to the non-therapeutic uses of their tissue are known, then should the same procedures as with adults apply? If you don’t agree, please explain why.

16. Should both parents have an equal say in what happens to the body of their deceased child, or are there circumstances where the mother's wishes should prevail?

17. Are there situations in which consent for non-therapeutic uses of human tissue may be given other than in writing? If so, should any safeguards or special procedures apply? Are there alternative forms of consent that may be acceptable?
18. Do you think that an overarching standard or code for tissue management that can be applied flexibly to different agencies is appropriate? Please explain why or why not.

19. Please tell us your suggestions for what should, or should not, be covered by such a framework and why.

20. Please tell us if you think there are agencies for which, or specific occasions when, there should be exemptions from the requirements of such a framework.

21. Please share your ideas on possible approaches to monitoring tissue management practices that allow for robust monitoring to take place without imposing unnecessary compliance costs on the health and disability support sector.

22. Do you think that a system based on standards, audit and certification could work in New Zealand? Please tell us why or why not, and share any other ideas you have.

23. Do you think that the New Zealand Police should continue to be involved in the monitoring and audit of non-therapeutic tissue use? What type of role should the Police fulfil?

24. Please share any suggestions you have for terms that respectfully describe a ‘body’. Are either of the following terms acceptable:
   a) tūpāpaku, or body of a deceased person?
   b) tūpāpaku, or deceased human being?

25. Please tell us your ideas for a phrase that may be preferable to ‘the person lawfully in possession of the body’. Are the phrases ‘the person with lawful control of the body’, ‘the person with lawful responsibility for the body’ or the person with custody or care or control of the body’ appropriate?

26. Please tell us your ideas for removing the ambiguity created by the term ‘the person in charge (of an institution)’. In the case of hospitals, which of the following three options do you prefer for the new legislation:
   a) a particular position within a hospital designated as the person lawfully in possession (eg, the institution’s chief executive or medical director)?
   b) a requirement that institutions appoint or nominate for appointment a particular person from time to time?
   c) a particular position within the District Health Board, likely to be the chief executive, with the ability for this responsibility to be delegated as appropriate?

   Please share any other suggestions you have.

27. Do you think that stillborn children and foetuses should be brought within the coverage of the new regulatory framework? If not, please explain why.
28. Currently, New Zealand does not have separate guidance for ethics committees and researchers to follow when dealing with research using stillborn children and foetal tissue. Do you think guidance in addition to the general guidelines detailed on page 42 is needed? Please explain your response.

29. Are the current processes outlined in Table B4 (on page 45) for reviewing the ethical and safety dimensions of research applications using cells and tissues (specifically stem cells) sufficient, or should such research be subject to any additional review processes before it can proceed? If so, please explain your reasons.

30. What should the main purpose of any additional processes be?

31. Do you think there are any circumstances in which established cell lines should be subject to ethical review, and if so what would the purpose of such a review be?

32. The implications of access to genetic information are complex and affect people beyond the individual who is the source of the information. We are seeking your thoughts on whether the coverage of the Health Information Privacy Code should be extended to specifically address genetic issues. If so, please tell us your views on any or all of the issues listed above.

33. Following the passage of the Health (National Cervical Screening Programme) Amendment Act, changes are able to be made to the Health (Retention of Health Information) Regulations 1996 to cover the retention of specimens as well as other health information.

The Ministry is proposing that the following changes be made to the regulations:

a) the definition of a ‘specimen’, beyond ‘a bodily sample or tissue sample taken from a person’, should be covered by the regulations (ie, the sorts of specimens the regulations should apply to)

b) the purposes for which different sorts of specimens should be retained

c) the minimum period or periods for which specimens should be retained and any particular period for which particular specimens should be retained

d) particular storage conditions that may be required for specimens (including whether different arrangements are needed for different types of specimens), and the practical issues that arise from any storage requirements

e) the implications for specimens of health information being able to be returned to the individual concerned

f) ways that the regulations can be designed to anticipate future developments in technology

g) the management of health information (including specimens) when a provider ceases to practise or be in business.

Are there matters in addition to those listed above that you think need to be considered when changes are made to the regulations? Please explain your suggestions and share your initial thoughts about what should be covered by the regulations in relation to these issues.
Part C

34. The new legislative framework could consider five options (with combinations) to consent for organ and tissue donation. Of the options below, please tell us which you think may be better and why. The options are:
   1) presumed consent
   2) requirement for wishes to be followed
   3) requirement to state wishes
   4) requirement to request
   5) status quo.

35. If you think one of the options (other than status quo) would be better for New Zealand, do you think there should be any time when families/whānau should be able to override the wishes of the deceased person? Why or why not? If not, do you have suggestions for managing a situation when the wishes of the deceased person are not the same as those of the family/whānau?

36. The Ministry is interested in the processes and experiences of the tissue donation sector in accessing information about the medical suitability of potential donors. Please share any experiences, difficulties or good practice in this area – including experience of the operation and interpretation of the Health Information Privacy Code.

37. Do you think that the new regulatory framework should contain a definition of ‘death’? Please explain what you think the advantages or disadvantages of including this definition would be.

38. If you think a definition should be included, is the following a suitable definition? If not, please suggest any changes you would make.
   ‘A person is dead when there is irreversible cessation of circulation of blood in the body of the person, or irreversible cessation of all function of the brain of the person.’

39. Do you think that the new regulatory framework should require compliance with the current guidelines for establishing brain-death? Why or why not?

40. Should the new regulatory framework allow for non-heartbeating donation to take place, subject to appropriate standards and guidance being developed in this area? Please explain why you agree or disagree.

41. As well as informed consent, one particular safeguard that needs to be in place is a separation between the health professionals that assess a non-heartbeating donor and those that are involved in transplantation processes. Please describe any other safeguards you think should be considered.

42. Should the new legislative framework make it clear that donation of organs or tissue from people who have died should only be on the basis that the organs or tissue are an ‘unconditional gift’?
43. Do you think that, if both parties wish to, donor families and recipients should be able to meet? If so, what type of support should be offered for this to happen?

44. Live organ and tissue donation in New Zealand is regulated through the Code of Health and Disability Services Consumers’ Code of Rights, in particular the requirement to ensure that informed consent is obtained before such procedures (either donation or transplantation) take place. Do you think the new regulatory framework should include any additional provisions? If so, please explain what these should be and why.

45. Do you think the new regulatory framework should formalise safety guidance for whole organ donation? Please explain why or why not.

46. Do you think tissue banking services should be regulated under the Health and Disability Services (Safety) Act, noting that this would mean the development of a national standard for tissue banking that was then audited and providers being certified accordingly? Please explain why you agree or disagree.

47. Do you think tissue services should be regulated under the provisions in the Health Act? Please explain why you agree or disagree.

48. Do you think the definition of human cells, tissue and cellular and tissue-based products (on page 82) adequately describes the ‘subject’ of the proposed new regulatory framework for tissue-based therapeutic products? Please explain any changes you would make.

49. Do you agree that the products listed on page 83 should be exempt from the regulatory framework? Please explain your views.

50. Do you think the term ‘manufacture’ and the definition proposed for that term on page 84 are appropriate for tissue-based therapeutic products? If not, please share your suggestions for a better term or definition.

51. Is the proposed exemption from the definition of ‘manufacture’ appropriate? Are there other activities you think should be exempt from the definition? Please explain your suggestions (see page 84).

52. Your suggestions on potential exemptions from licensing requirements for particular people are sought. Consideration of this issue needs to be done in the context of:
   a) other exemptions proposed for particular products or manufacturing activities
   b) any differences in the risks posed by the processing of tissue in a hospital setting compared to other settings
   c) whether exemptions for custom-made products are appropriate
   d) how we distinguish between medical practice and supply and manufacture of tissue-based therapeutic products, and the impact of any regulation on clinical decision-making.
53. What do you think of the categorisation of tissue contained in Table C3 on page 86? Would you assign any activities differently? Please explain your comments.

54. Your comments are sought on the proposed regulatory approach to tissue-based therapeutic products and any concerns you have about how it may impact on the practice of health care.

Part D

55. Do you think the definition of ‘immediate family’ given below is suitable for new legislation for both the therapeutic and non-therapeutic uses of human tissue? Please explain any changes you think should be made. (Please note that this definition is not proposed for use in the risk framework for tissue-based therapeutic products described in section C5.2.6. It is only proposed for times when consent is needed.) The proposed definition is:
   a) any person who was the spouse of the deceased including de facto and same-sex partners, or a parent, grandparent, child, brother or sister, or guardian or ward, of the deceased; and
   b) any person whose relationship to the deceased is that of step-child, step-parent, step-brother or step-sister; and
   c) any person who, in accordance with the traditions and customs of the community or whānau of which the deceased is a member, had the responsibility for, or an interest in, the welfare of the deceased.

56. Please tell us how you think the proposed definition of ‘immediate family’ would work in practice.

57. Do you think the inclusion of a section that enables particular activities to be restricted until full consideration can be given to the implications of the activity and any special requirements that might be needed before the activity can be undertaken (such as safety procedures, or record keeping requirements) provides sufficient ‘future-proofing’ of the new legislation? Please explain your response and share any other ideas you have for future-proofing the legislation for new technologies.

58. If you think a section restricting certain activities would be useful, please share your ideas about the following issues:
   a) the level of authority needed to place an activity on the list
   b) the level of authority needed to take an activity off the list
   c) whether the activities on the list should be reviewed periodically, and whether a time period should be set for such a review
   d) any criteria an activity may have to meet before it is placed on the list or removed from the list.
59. Pending further work on the public acceptability and safety of xenotransplantation and the development of any special requirements that may be needed if xenotransplantation is to be undertaken in New Zealand, do you agree that xenotransplantation should be included in the proposed new list of prohibited activities? If not, please explain why.

60. Are you interested in being involved in any ongoing discussion of the acceptability of xenotransplantation in New Zealand? Toi te Taiao – the Bioethics Council has agreed to undertake work in this area: may the Ministry give the Bioethics Council your contact address so that you can be sent any material on xenotransplantation?

61. Do you think the new legislation should prohibit the sale and purchase of all human tissue in New Zealand?

62. If you think some sale and purchase of human tissue should be allowed, please explain what types of tissue this should apply to, for what purpose it should be allowed to be bought or sold, and who should be permitted to sell it.

63. Do you think the new legislative framework should provide more comprehensive coverage of the import and export of human tissue? If not, please explain why.

64. Are there issues for the import and export of tissue other than those identified that you think should be covered by the new legislative framework? Please explain your reasons.