

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-sister⁴⁶
- 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 law⁴⁸ 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.

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 controversy⁴⁹
- 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

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.