

Review of the Regulation of Human Tissue and Tissue-based Therapies: Meeting Report

Ethics Committee Chairs consultation 10 & 11 May 2004, Wellington

PROCESS

This invitation-only meeting was held in Turnbull House on 10 May 3.30 pm to 5.50 pm and at the Ministry of Health on 11 May from 10.00 am to 11.30 am. The meetings began with a presentation by the Ministry of Health and questions from the attendees. The presentation was followed by discussion of the following main themes from the Discussion Document:

- Options for organ and tissue donation
- Informed consent for non-therapeutic uses of tissue
- A standard for tissue management
- Other issues e.g. stillborn children, import and export of tissue.

QUESTION BY QUESTION SUMMARY

PART A: INTRODUCTION	
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. (see page 2)
	<ul style="list-style-type: none"> If blood is currently well regulated, why can't that be the model for regulating other tissues? Why not include blood?

PART B: NON-THERAPEUTIC USE OF TISSUE	
11.	<p>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.</p> <p>a) If the proposed use is a one-off event for clinical purposes, consent could be sought from another family member.</p> <p>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.</p> <p>Please describe any other ideas you have. (see page 32)</p>
	<ul style="list-style-type: none"> Ethics committees are very concerned about blanket forms of consent. Because it is blanket, it can't be informed. Ethics committees look at how sympathetic the original consent is to the proposed use of the tissue. If the tissue is to be used for a different purpose than that for which it was collected, have to get new consent.
13.	<p>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 <i>required</i> to be followed and if there should be any exceptions to this requirement. (see page 32)</p>
	<ul style="list-style-type: none"> When a person provides consent, they give consent for a procedure, then the individual has an option for after their death – appoint an executor, if not, the default is the family. An executor could be an extension of the role of a Personal Care Attorney. Such a provision could make tissue less readily available. Executor is obliged to carry out

	<p>the last will and testament.</p> <ul style="list-style-type: none"> • Wishes of the deceased are paramount. Individual's wishes should be upheld, unless there is a recognised cultural issue when the wishes of the family should prevail. • Regarding pharmaceutical research – genetic information is not just about the individual but also about the whānau. In that sense related family may have very strong views about use of the tissue. • If the individual has agreed, do not need the consent of the family. • Can see both points of view. Individuals who consent should have wishes honoured, but family also has input. Genetic aspect complicates the issue. • European New Zealanders are concerned about genetics. Consider it wouldn't be a problem to make genetics an exception to consent rules. Need to be clear what the tissue is to be used for.
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? (see pages 33-34)
	<ul style="list-style-type: none"> • Generally consent of both parents should be obtained. • However, seems reasonable that mother should be able to give consent over the father where disagreement, but difficult to make rules for every situation.
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. (see pages 37-38)
	<ul style="list-style-type: none"> • Happy for monitoring but did not want another Occupational Health and Safety requirements. • Noted that enforcement is always difficult in any legislation.
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? (see pages 39-40)
	<ul style="list-style-type: none"> • No property in whole bodies, so can't have an owner. Has anyone considered 'legal guardian'? If legal guardian then a different set of presuppositions. Concepts of being responsible and having guardianship. • Person in possession – would be better not to talk about possession but "responsibility". • Page 40, would prefer either of the second two options – custody, care, responsibility. Probably the second option is best.
27.	Do you think that stillborn children and fetuses should be brought within the coverage of the new regulatory framework? If not, please explain why. (see pages 41-42)

	<ul style="list-style-type: none"> • If have to register the birth, then should be the same process as any other baby. Stillborn babies should be treated as any other dead person or baby. • Foetus can be treated as a recipient of health care, but has no legal rights. • Fourteen day cut-off for embryos under HART legislation – individualisation takes place at this stage. Want to rule out production of embryos to produce compatible tissue for siblings. Don't regard the very early foetus simply as a collection of tissue.
29.	<p>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. (see pages 43-46)</p>
	<ul style="list-style-type: none"> • Issue of stem cell research is important and has cost-benefit issues. • It isn't the tissue that is actually taken that would be used, would be the propagation of stem cells grown from the donated tissue. • Stem cells that have been propagated are not the same as blood and organs donated and transplanted into another person. • Stem cells have DNA, when a person gives consent can a family say no? • If donate tissue that contains DNA then whether you need the consent of the family depends on what you are planning to use the tissue for.

PART C: THERAPEUTIC USE OF TISSUE

34.	<p>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:</p> <ol style="list-style-type: none"> 1) presumed consent 2) requirement for wishes to be followed 3) requirement to state wishes 4) requirement to request 5) status quo. (see pages 61-69)
	<ul style="list-style-type: none"> • If have presumed consent with an opt-out provision it would need to be circumscribed. What would the overall impact on organ donation be? Opt-off option disadvantages certain groups in society. If health professionals are starting the request from a position of presumed consent it may make things easier. • Given numbers of people who are able to be donors are low, don't take a sledgehammer to crack a nut. • Bottom line for the public is that the process is fair and ethical, and they are given enough information to make the decision about donation. • In some communities the integrity of the body is a key consideration. • Comes down to education. If people are given more information it can help them understand the outcome. Education couldn't be a one-off

	event, but has to be an ongoing programme. A cultural shift is needed.
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? (see pages 61-69)
	<ul style="list-style-type: none"> • Family can overturn lots of wishes that have been recorded in a person's will, eg, organ donation or cremation. • Differences regarding cremation/burial often arise. Where there are insolvable differences, take the view that funerals are for the living, however where instructions are in the will, those should prevail. • A person stating that they are willing for a procedure to go ahead does not oblige the physician to providing that procedure. Acknowledge that it is very difficult for the clinicians to go against the wishes of the family. • Who are the family to over rule your wishes? Families are often estranged from the person or don't share the same views – why should the family have a greater say? • Generally individuals expect their wishes to be followed.
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. (see pages 87-88)
	<ul style="list-style-type: none"> • Very difficult to make standards for spiritual/moral concerns.

PART D: COMMON CONCERNS FOR ALL USES OF TISSUE

61.	Do you think the new legislation should prohibit the sale and purchase of all human tissue in New Zealand? (see pages 94-97)
	<ul style="list-style-type: none"> • Developed vaccines have been hugely beneficial. Who is entitled to benefit from those vaccines? How much of that profit should go back to the source? • Should commercialisation/payment happen at all? Should it just be left to the market/contracts to sort out?

OTHER ISSUES RAISED

The problem Ethics Committees' have with the collection of tissue is that the tissue is very rarely from the dead. Most concerns are about the retention of tissue from living people or multinational companies establishing collections of tissue.

The Wellington Ethics Committee has given approval to the use of tissue samples where there was no consent in the first place.

Agree that the ethics committees should be allowed to give approval along the same lines as Right 7(10).

Interested in cultural differences. Issues around someone remaining with the body and Pacific views on blood.

Māori tend not to donate but use donated organs. Some very challenging issues for Māori and Pacific.

It is arrogant to assume Māori and Pacific won't donate. At the end of the day Māori families may become more accepting if they have been able to discuss donation in marae settings so that it wasn't just a horrific thing that occurred in ICUs.