

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

**Auckland 6 May 2004**

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## **PROCESS**

This public meeting was held in the Carlton Hotel, Auckland from 9.15 am to 4.30 pm on 6 May 2004. The day was divided into two sessions with therapeutic issues being discussed in the morning and non-therapeutic issues in the afternoon. Each of the main sessions began with a presentation by the Ministry of Health and questions from the attendees. The presentation was followed by workgroups to discuss the issues in more detail.

## **SUMMARY OF KEY ISSUES FROM EACH WORKGROUP**

### **Therapeutic uses of tissue (morning session)**

#### Group 1: organ donation

- Informed consent – strongly believe that society and practitioners have a strong environment for informed consent. Informed consent needs to be built into the legislation. Policies and practices need to be developed to facilitate an informed consent process.
- Descriptive compliance more important than prescriptive codes of practice by health professionals.
- Problem areas – directed donation. In principle thought no, but maybe some exceptions. Generally thought donors and recipients should not meet, but maybe some exceptions.

#### Group 2: organ donation

- Consent – support status quo but with more appropriate information and education so people can make an informed decision. Support a requirement to request all families and that all families should be comfortable with decision. Requesting should be audited. Noted that times that families override wishes of the deceased are very few.
- Lengthy discussion about advantages of presumed consent. Could be less distressing and potentially more organs, but public would need a lot more information.
- Definition of death a reassurance to the public. Should be nationally consistent guidelines for determining death and directed donation, and a legal definition of death and brain death.

#### Group 3: organ donation

- Words used to describe the process such as 'consent' and 'donor' bias the discussion.
- For every example of doing things one way there is an equally good example for not doing it that way. Legislation should not be based on anecdotes or practice elsewhere.
- Clinical practice would dominate over legislation. Legislation and practice differ.

#### Group 4: organ donation

- Some difference of opinion, but support for consent options 2 and 3. Want people to provide clear intentions that can then be followed. Requirements for wishes to be positively stated, not presumed consent.

If a positive statement about donation is made families should not override.

- Support unconditional donation. Scientific and clinical reasons why it should go to a particular recipient.

#### Group 5 Safety issues

- Prescriptive/Descriptive approach
  - Clear view that favoured descriptive approach.
  - Guiding principle stated up front in the Act.
  - Structure must work to the principles stated.
  - Transparency essential.
- Commercialisation
  - Need to consider difference between “reimbursement” rather than “payment for”. This applies, for example, petrol costs for donor to come in to make the donation, time off work etc.
  - Need to look at rules around commercialisation very carefully.
- New technologies
  - Innovative procedures - must have ability to apply sanctions until appropriate considerations of the procedure have been undertaken.
  - Dignity and respect and public expectations must be met.
  - Education essential since public and consumers are less aware of what the implications are from these new technologies.

#### **Non-therapeutic uses of tissue (afternoon session)**

##### Group 1 Tissue Oversight and Management

- Ministry should provide overarching principles for oversight management and monitoring. Should not be overly prescriptive, should outline what the outcomes should be - licence and audit. Should ensure best practice is met and include report back to demonstrate outcomes are met. Ministry should set guidelines and principles for implementation by services and ethics committees. Should cover foetal and still born tissue.
- Have comparable standards to overseas to allow transfer of tissue. Additional use of tissue that has been in the bank for some time could be included in standards.
- Consent to use tissue for therapeutic, research, commercial use should be specified in consent. This should be spelt out for present and for future uses.
- Provide guidance around return of tissue. People want the ability to say what they want back .

- Museums should be exempt because of teaching value.

#### Group 2: Informed consent

- Did not reach consensus over whether there should be a distinction between therapeutic and non-therapeutic. Distinction could be artificial. What about for profit/not for profit? Requests often happen at the same time.
- No consensus over the role of individual versus family.
- Definition of family should be broad, family will self define. Family could then determine fate of organs tissue.
- Consent recorded – written not obligatory, but follow verbal with written.
- Sale and purchase – consensus that organs tissue are a gift. System should be predicated on this. Cost recovery ok but profiteering is not.

#### Group 3: Informed Consent

- Dissent – either donor or family, need consent from both before can take tissue. Everyone has to opt-in.
- Māori perspective - individual and collective consent
- Verbal consent is adequate as written consent may be inappropriate
- Informed consent as foremost principle was supported
- Secondary principle – what are the safe guards around public good?

#### Group 4: Tissue Management

- Want some type of framework, overarching principles, but this should not be too prescriptive. What outcomes are we seeking (slides to whole bodies)? Look to ethics committees and institutions to do the detail to meet principles. Hands off for implementation. Look to institutions.
- Import and export needs to be provided for in guiding principles. Should not need multiple ethical approval for research. If research has been approved overseas why redo in it in New Zealand? Adult, still born etc to be included in framework.
- Cell lines. Current practice is ok, although some concerns around commercialisation and profit incentives. Using cell lines for profit is challenging. May need to allow some commercialisation of cell lines to support research. Should be transfer of profits back to the community as a whole, eg research trust. Commercialisation needs to be part of whole spectrum.

## QUESTION BY QUESTION SUMMARY

<b>PART B: NON-THERAPEUTIC USE OF TISSUE</b>	
<b>2.</b>	<p><b>Do you agree that the new regulatory framework should make it clear that:</b></p> <p><b>a) consent to conduct a non-coronial post-mortem examination explicitly includes consent to retain tissue, <i>where that tissue is to be retained for the purposes of the post-mortem only</i>; 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></p> <p><b>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?</b></p> <p><b>Please explain any changes you would make and why. (see pages 24-26)</b></p>
	<p><u>Retention of tissue</u> Retention of material from an autopsy is essential – it provides the evidence of the diagnosis. Cannot perform an autopsy without retaining material, it is part of the autopsy process. Material must be kept permanently. Not practical in many instances to return material. Have strong concerns about returnability of tissue. Recurring theme – what happens with retained tissue when we want to use tissue for something else. Family should be informed after post mortem about what was done and what tissue was retained.</p> <p><u>Consent</u> People may consent to autopsy during life, should this go ahead in all cases? Not clear how this sits with organ donation. Consent for post-mortem should be undertaken by pathologist (arguments for and against). Process is less specific for autopsy. Should there be a different standard for autopsy consent?</p> <p><u>Research consent concerns</u> Difficult process getting consent for use of tissue for a different research purpose some years after original consent. Difficult to get consent for future uses of tissue, with emerging technologies cannot predict future research requirements. Current consent form indicates at the bottom of form that tissue can be used for ongoing quality control.</p> <p><u>Return of tissue</u> Very difficult to return tissue from autopsies, often talking about very small pieces of tissue. Routinely will take a blood sample at autopsy without asking for a specific consent. Must retain that material for future diagnosis.</p>
<b>3.</b>	<p><b>Do you think that the new legislative framework should have informed consent as its foremost principle? (see pages 26-28)</b></p>
	Yes

	<p>Should there be a difference between therapeutic and non-therapeutic regimes for consent? Concern about who may give consent in different situations. What circumstances mean consent requirements should be different?</p> <p>Distinction could be between living and dead as opposed to therapeutic and non-therapeutic. People don't distinguish between therapeutic and non-therapeutic. Identify with the tissue and what it is to be used for.</p> <p>Family role is not protection of the individual, it is to stop the family being upset. There is a spectrum of consent depending on the issue.</p> <p>Have we gone too far with the level of information provided when gaining consent? People tend to want more information, what tissue will be used for, for how long, etc. In non-coronial post-mortems we want the family to know and understand the cause of death.</p>
<b>4.</b>	<p><b>If so, should a secondary principle recognise that in certain circumstances, the public good associated with the use of tissue will outweigh informed consent <i>provided that safeguards are in place</i>? Please explain your reasons for agreeing or disagreeing. (see pages 26-28)</b></p>
	<p>Broad agreement but need a clear definition of 'public good', suggest developing a guideline. Some ambiguity for the community around what constitutes public good.</p>
<b>5.</b>	<p><b>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. (see page 28)</b></p>
	<p>Yes, if have informed consent. Be clear about what consent means.</p>
<b>6.</b>	<p><b>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. (see pages 28-30)</b></p>
	<p>Yes prefer informed consent.</p>
<b>8.</b>	<p><b>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? (see pages 30-31)</b></p>
	<p>Research needs to mirror what is acceptable to society.</p>
<b>9.</b>	<p><b>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. (see pages 31-32)</b></p>
	<p>Yes, family should not be able to consent on the person's behalf.</p>
<b>10.</b>	<p><b>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. (see pages 31-32)</b></p>
	<p>Yes</p>

11.	<p><b>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.</b></p> <p>a) <b>If the proposed use is a one-off event for clinical purposes, consent could be sought from another family member.</b></p> <p>b) <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.</b></p> <p><b>Please describe any other ideas you have. (see page 32)</b></p>
	<p>Concern over how one deals with requests for alternative use of this material for research purposes.</p> <p>At the extreme end could allow people to use tissue for a completely different purpose. Where do Ethics Committees draw the line? Ethics committees are concerned at consent forms that give carte blanche to use of tissue.</p> <p>Should people be able to consent to future research uses of tissue for particular diseases, ie cancer?</p> <p>Currently protocols around consent and when new consent is obtained are not consistent.</p> <p>Should consent for use of tissue for commercial development be obtained if even a remote chance of tissue being used for commercial purposes? If legislation does not cover consent for commercial uses of tissue it will come back to bite health professionals.</p> <p>There could be three levels of consent – consent for therapeutic, consent for research and consent for research that could become commercialised.</p> <p>Much easier for everyone if consent is inclusive, will miss out on some samples but at least have consent.</p> <p>Back to issue of ensuring consent was informed. Time between consent and research development may mean that consent was not informed.</p> <p>Should have an open consent process where the family are involved. Stored with consent and documentation about what is done with tissue after death.</p>
12.	<p><b>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. (see page 33)</b></p>
	<p>Absolutely agree.</p>
13.	<p><b>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)</b></p>
	<p>Whoever says no – individual or family, it needs to be accepted.</p>
14.	<p><b>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</b></p>

	<b>purposes? If you don't agree, please explain why. (see pages 33-34)</b>
	Yes
<b>15.</b>	<b>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. (see pages 33-34)</b>
	Should accept a child's decision if say no. Can say yes with family support. Should not disregard a legally competent person.
<b>16.</b>	<b>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)</b>
	If anyone is unhappy it should be no. Mother's wishes should not be able to prevail.
<b>17.</b>	<b>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? (see page 35)</b>
	Written consent where appropriate – prefer written. Verbal consent is acceptable in exceptional circumstances when well documented. Some Maori consumers are not happy with written consent.
<b>18.</b>	<b>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. (see pages 35-37)</b>
	<p>Need a national framework to govern operations. Support an overarching standard. People are setting up tissue banks in an ad hoc fashion. State outcome and broad guideline in standard. Prescription left to principles and codes of practice. Ethics committees need guidelines.</p> <p>Don't make standard or code overly complicated, it should be understandable, simple and effective.</p> <p>A code of practice for cell lines should be relatively easy to write.</p> <p>If it ain't broke, don't fix it. Could use outcome and institutional codes of practice to achieve outcomes, these are easily amended. Allow code to be developed for particular activities.</p> <p>Animal tissue – code of conduct has to be approved by University of Auckland.</p> <p>Work with existing structure – human ethics committees have a role but need clear guidelines.</p> <p>Appoint someone to audit. Need audit to be commensurate to risk.</p> <p>Audit of process – appropriate guidelines that are clear, don't have high compliance costs and relative to risks.</p> <p>Dot points on pg 36 look very reasonable. Not sure how they compare to other countries. Standards should be comparable to other countries.</p> <p>May be only one entity allowed under legislation.</p>
<b>19.</b>	<b>Please tell us your suggestions for what should, or should not, be covered by such a framework and why. (see pages 35-37)</b>
	Broad guidelines, outcomes, principles.

	<p><u>Return of tissue</u>          If unlink data to anonymise it – how do you give tissue back?          Retain eye tissue for 3-6 months in case people do want it back and then dispose of it.          Tissue co-ordinators do discuss disposal at time of tissue request. Designed for those who change their mind about consent.          How do you return a limb – currently different practices around the country.</p> <p>Must not return blocks and slides – don't even tell people that they have been retained, too hard to explain why they are needed. Disagreement with this approach.          Way to resolve conflict is more information.</p>
<b>20.</b>	<b>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. (see pages 35-37)</b>
	<p>Tissue collections in museums should not be covered. This tissue was collected when there were different expectations around consent. Changes should not be retrospective.</p> <p>People view cell lines differently to whole organs- need a more onerous system for whole organs and bodies.</p>
<b>21.</b>	<b>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)</b>
	<p>Auditing/monitoring should be by some independent, national, multi-disciplinary body constituted of researchers and the general public. Licensing is a good term for the approach. Would be a technical and social audit.          Monitoring sets expectations. Ethics committees should be responsible for ensuring expectations are met. Codes of practice are public documents. Monitoring should also cover import and export of tissue.</p>
<b>22.</b>	<b>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. (see pages 37-38)</b>
	See Q18
<b>23.</b>	<b>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? (see pages 37-38)</b>
	<p>Inspectors of Anatomy work very well. Retain principles.          Need external person to inform you of your obligations.</p>
<b>25.</b>	<b>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)</b>
	<p>Language used is important. Kaitiakitangi "guardianship", "responsible for". People at death are not objects. Tissue is not able to be "owned", language should be more consistent with notion of 'guardianship'.          Ownership means right to sell, dispose, etc. No property rights in a deceased body.</p>

27.	<b>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)</b>
	Yes
28.	<b>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. (see pages 41-42)</b>
	No reason to treat stillborn children and foetal tissue differently from other tissue. Therefore should have the same guidelines as other human tissue.
29.	<b>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)</b>
	Cell lines in tissue banks for very long periods (20 years) – get ethics committee approval. Export to other labs - no problem and ethics committees are coping.

#### **PART C: THERAPEUTIC USE OF TISSUE**

34.	<b>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:</b> 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)
	<p>Changing the law is not a magic bullet – don't want legislation to be ahead of people's expectations. Don't want to induce disrespect for the law.</p> <p>Individual's wishes and the role of the family to be taken into account. Need to allow the family to be involved.</p> <p>Believe in informed consent but people are not well informed.</p> <p>Can choose an option but need to be aware of the wider relationships – do not want to be overly simplistic.</p> <p>State does not have ownership rights.</p> <p>Yes to everyone being offered the option – every family of someone who could potentially be a donor is asked not everyone who enters hospital. This is the status quo but with much more education. But also note that education needs to be presented in the right way.</p> <p>Donor families are the best advocates for donation. Need much more education about donation so that people can make an informed decision. Make it very clear whether consenting for transplantation vs research or education.</p> <p>Issues around those who don't agree to donating being able to be a recipient. Where</p>

would the boundary line? Smokers also off waiting lists?  
Is expressing a view considered to be informed consent?

#### Presumed consent

No to presumed consent.

Presumed consent makes things simpler and clearer for families and would increase the number of donors. Problem with having to register 'opt off', this may disadvantage people who are not well informed. Family still has power of veto. To move to presumed consent requires a huge amount of information for people to make the decision to opt off or not. If don't inform people adequately when bringing in presumed consent then consent is not informed. Think that few people would opt off but wouldn't be informed consent at all.

Presumed consent is an invasion into private rights and freedoms. A dangerous precedent for other freedoms. Maximising donation is not the priority. Explicitly contrary to clinical practice (informed consent). People's intentions are clear if they opt-out, but it is unclear for those who don't opt-out. Presumed consent could lower the donor rate. New Zealanders don't like being told what to do.

The practical implication of presumed consent is that intensivists would still discuss organ and tissue donation with family against background of presumption. Intensivists would be perceived to emphasise and enforce 'presumption', would undermine nature of relationship. There may be public sympathy for this view but individuals would love to make up their own mind.

Opt out system would push people to think about donation.

#### Requirement for wishes to be followed

Some people did not agree with to requirement for wishes to be followed.

Others considered it wrong that family can override an individual's decision "what happens to my body after death is my decision". An increasing number of people are very unhappy that family can override wishes.

Need some legal document of decision. Decisions prior to death can have moral force (advance directives). Have interests that should be respected.

If person has decided and wishes are to be followed, would that help health professionals? Would it remove the 'moral anguish' for health professionals and families? Parallel with Jehovah's Witnesses and blood – relief for some families that the law has stepped in. May help families to some extent – but parallel with Coroner's rules which are devastating for some families.

#### Requirement to request

No support for asking at entry to hospital. Not a suitable time to ask. Should ask at other times.

#### Families and consent

If don't ask families you are making the decision for them. If you go with option 2 or 3 don't need to worry about managing the families, the decision is taken away from them. Doctors would then run the process.

Support that the next of kin have an opportunity to make an informed decisions. Know from experience that the drivers licence does not necessarily reflect people's wishes.

Also believe that families who make this decision consider it very carefully and live with the decision. Encourage people to discuss organ donation with family.

Encourage families to use drivers licence as a guide.

Even if have a legal document stating want to donate, still need discussion with family. Maybe if more information was available families would not override wishes.

Problem that the health professionals are there to provide care for the family, not for the recipient.

People seem to be hung up on families overriding decisions, only very occasionally do families override decisions.

Plenty of parents of young people donate. Those families who do donate take comfort from it.

#### LTSA/drivers licence

Registers have no effect on numbers.

Some thought that the LTSA register should either be binding or got rid of.

Greater percentage of people indicating donor on licence are younger people. Older people may think that they cannot be donor.

If LTSA database is to be used as a indicator it must be accurate – currently it is not.

Concerns about going to a family and saying drivers licence says 'yes' and opening the discussion that way in terms of coercion. Noted concerns would lessen if the legislation changed.

Drivers licence is a good way to generate discussion, but decisions are not informed and not binding. People like having 'donor' on their licence.

If move to enforce 'yes' then have to enforce 'no' as well and could not ask the family to donate.

Most people are under the misapprehension that ticking the donor box is a legal statement. Could take the donor flag off the licence or make it legal.

Is there the ability to add "does the family know your wishes?"

How can the LTSA database be kept current? A NHI register may work.

Register issues – can we look at joining the Australian register?

#### Education

Education should be clear that very few families block people's wishes.

Have a gentle approach to organ donation in New Zealand.

Could provide education on donation in schools.

Education and context is really important.

In UK when things settled after the Birmingham scandal self-referrals from families to donate went up. Education/awareness in itself will raise donor rates.

How much information is the right amount? Nurses working in transplant ICUs are less willing to donate than other nurses. Doing an information campaign may or may not increase donor rates. But more informed people must be better regardless of donor rate. Need to decide what you want out of an information campaign before you design the campaign.

#### Changes to legislation

What works in one country will not necessarily work in our culture. Nature of informed consent, organ donation and sudden death. Not black and white. Must retain families' right to decide.

#### Cultural issues

Status quo, trauma of families.

Maori world view, hold belief in biological body and energy held.

Tikanga best practice in Auckland DHB, different ethic groups hold similar views.

Also need cultural training. Require time for different cultures to consider donation.

	<p>Maori and Pacific do donate, but not as frequently as Caucasian families. The bigger the family the less likely it is consent is obtained. Should not ascribe views to a group. Maori prepared to be recipients not donors a myth. Maori problem is around co-morbidities.</p> <p>Medically suitable donation consent is higher for non-Maori. Living donation is the opposite.</p> <p>To not even offer the option is demeaning for some families.</p> <p>Language barriers can be a problem.</p> <p><u>Language around donation</u></p> <p>Ambiguities around language and its use, especially 'donor' and 'consent'. "Legally in possession of" not "ownership". Legally in possession close to guardianship and implies responsibilities.</p>
<b>35.</b>	<p><b>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)</b></p>
	<p>Families need to have agreement/consensus at the time of consent. Staff who ask families need to be highly trained to manage the situations.</p> <p>Families have to live with the decision.</p> <p>Extensive discussions with family. Family determines own relationships regarding consent.</p> <p>Need to discuss the medical procedures with families.</p>
<b>36.</b>	<p><b>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. (see page 69)</b></p>
	<p>Organ donation co-ordinators haven't experienced problems accessing health information. A lot of the time ICUs ask on the donor's behalf. If working in a hospital have access to hospital records.</p> <p>Issue around how much information tissue banks need, ie don't need names and addresses, can have hospital number and age.</p> <p>Tissue banks don't have any information prior to death, don't find that GPs provide information. Families very helpful and co-ordinators get information from families. If any doubt about suitability family will say no.</p> <p>It would be wrong not to indicate if a person wouldn't be suitable, but if medical history is not known, then can only access information through the GP. Under the Privacy Act the GP is not obliged to provide information to the family.</p> <p>Co-ordinators don't have the right to phone GP for information. Only executor of the will can get GP to provide information. If unsure get the family to ring the GP.</p> <p>Information from GP should be sought by donor services. Families often don't know what medications the person was on.</p> <p>Most of the time the current system works well.</p> <p>Issues around ability for families to discuss donation when request is made by phone.</p> <p>No ability for legal redress against person who gave consent or the person giving consent (eg, over the phone). Need protection for health professionals. Verbal</p>

	consent given over the phone is followed up by written consent.
<b>37.</b>	<b>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. (see pages 69-70)</b>
	Yes – for both cardiac and brain death. A need to reassure the public that organs won’t be taken before they are dead – hence need for legal definition of death. A specific definition should be referred to in the legislation but specified a standard or best practice guidelines so that it can be updated as necessary, ie refer to the ANZICS guideline. Legislation could enforce the existence of New Zealand guidelines that are followed, standardised and consistent. Noted that inclusion of a definition may limit future-proofing.
<b>38.</b>	<b>If you think a definition should be included, is the following a suitable definition? If not, please suggest any changes you would make.</b>  <b>‘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.’ (see pages 69-70)</b>
	Like the Ministry’s definition. Not sure about “all functions of the brain” – can’t test all functions of the brain. Not sure that definition is correct, but need others to advise. Promote consistent definition of death. A good definition.
<b>39.</b>	<b>Do you think that the new regulatory framework should require compliance with the current guidelines for establishing brain-death? Why or why not? (see pages 69-70)</b>
	Need regulatory framework for public reassurance/confidence. Need one national guideline with definitions. Legislation should state that there are nationally agreed guidelines and refer to them. Currently have nationally agreed guidelines for brain death, the ANZICS guidelines. There should be a requirement to follow relevant guidelines. Guided by professional medical associations.
<b>40.</b>	<b>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. (see pages 71-72)</b>
	Yes, allows families to donate who otherwise would not have been able to. Family asked then cool organs and when family is comfortable, take donor to theatre. With consent process, families told that if heart does not stop beating within two hours person cannot be a donor. Would support non-heartbeating donation for families who are desperate to donate but person does not die in the right way. Would need good regulations and guidelines. The outcome for kidneys and livers cooled in this way is good now.  Do not agree with cooling organs before family has consented.
<b>41.</b>	<b>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. (see pages 71-72)</b>

	No procedures should be undertaken before the family gives consent. Need to have different health professionals for ICU vs transplantation. Tissue co-ordinator should be neutral, not aligned with any health team.
<b>42.</b>	<b>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'? (see pages 72-73)</b>
	Yes. Important to have national guidelines. Any flexibility in guidelines needs to be transparent. Allow directed donation for living donors but not after death. Directed donation after death seen as morally repugnant. Directed donation is not a goer – would open a can of worms. Acknowledged there are clinical implications in terms of close tissue matching. Education needed. Two types of directed donation – stipulate organs donated, stipulate recipient.
<b>43.</b>	<b>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? (see pages 72-73)</b>
	Yes, if both parties wish to. Either party should have right of veto regarding meeting. Donor Office will provide support if both parties wish to meet. Would like guidelines if meetings are to occur and support to be provided at meeting and after meeting. Possible pitfalls around donation being a non-conditional gift (not directed). People may have expectations around age, race, socio-economic status. Possible emotional ties and emotional blackmail over recipient. Concept of extended family problematic. Reports of stalking. Real opportunities to destroy the lives of donor or recipients. Should be anonymous under all circumstances. Need to protect individuals.
<b>44.</b>	<b>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. (see pages 73-74)</b>
	Yes with additional provision for oversight. Should be support for time off work.
<b>45.</b>	<b>Do you think the new regulatory framework should formalise safety guidance for whole organ donation? Please explain why or why not. (see pages 74-75)</b>
	Refer to guidelines and current practice (for organ and tissue donation).
<b>46.</b>	<b>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. (see pages 75-77)</b>
	Therapeutic use of tissue could be regulated under a joint scheme with Australia or through a separate scheme.
<b>54.</b>	<b>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)</b>
	Concerned over the need to inform consumers about the legislation and the impact that it may have on them. Public education on tissue regulation important.

Worries about impact of trans-Tasman regulatory agency.

#### Descriptive vs prescriptive

Issues around prescriptive type of legislation– this mechanism is slow to respond, prefer descriptive approach concept.

Basic foundation should be set up on descriptive basis using plain language. Arrange in a structure that works to principles.

Need to balance the requirement for safety against the potential benefits to the patient and community. Some jurisdictions have regulation so prescriptive that consumers suffer through inability of the system to obtain tissues and organs.

Support having an approved Code of Practice in relation to an activity – easy to change/amend as required. Develop own approach and have approved/peer reviewed by professional peers etc.

The Eye Bank develops its own Code of Practice by monitoring overseas developments. Move voluntarily to new amendments. Keen to maintain this approach. Do not favour a prescriptive approach.

Legislation that is too prescriptive can inhibit practice. Need to allow for degree of latitude in certain areas of practice. Being too precautionary can get you into a tangle. Is expediency better than taking risks that you do not know about? How do you define what is too precautionary?

#### Voluntary codes

Voluntary codes have a role but are limited, require agreement among the stakeholders of the system concerned. No mechanism within the current system for new issues to be considered in a consistent fashion across the sector. Require mechanisms for defining, reviewing maintaining common standards. Tissues/organs need to move a further step forward so as to show safety in line with approaches set up for “blood”. Risks to consumers through lack of consistent standards.

Safety question – what is the ideal testing regime for emerging issues across the range of tissue banks? Is this answered by a national committee set up to advise on standards? Need to consider testing to the best standard that New Zealand can afford based on the best advice available.

Require transparent processes for decision making and these processes must involve consumers. Aim for national set of quality standards – need consistent approaches to testing.

#### Consumer representatives

There appears to be a degree of lack of transparency associated with ethics committees and other organisations in relation to research initiatives. Need transparency to ensure public trust. Can be easy for consumer representatives on ethics committees to be influenced by a professional interest group regarding a particular practice. Consumers have become very valuable members of the blood service advisory committee on safety. Blood service is required by law to involve consumers. Transplant organisations involve consumers that are usually recipients/family. What about other consumer representation (not directly associated through recipient status) – should this be a requirement? Consumers interest in technology give a special perspective. Consumers from a particular perspective should not represent all consumers since they have a biased view.

- Clear view that favoured descriptive approach.

	<ul style="list-style-type: none"> <li>• Guiding principle(s) should be stated at the front of the Act.</li> <li>• Structure must work to the principles stated.</li> <li>• Transparency essential.</li> </ul>
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<b>PART D: COMMON CONCERNS FOR ALL USES OF TISSUE</b>	
<b>55.</b>	<p><b>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:</b></p> <p><b>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></p> <p><b>b) any person whose relationship to the deceased is that of step-child, step-parent, step-brother or step-sister; and</b></p> <p><b>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. (see pages 89-90)</b></p>
	<p>What is the purpose of defining immediate family, how would this be used? Definition of family only to be used if family is to be involved. Donation should be the individual's decision.</p> <p>Families self-define. C) is sufficiently broad to cover NZ families (support for allowing families to self-define). Support for definition as proposed, but include English word for whanau – family. Make sure concept of whanau is broad to include all cultures, beyond Maori.</p> <p>If so broad do you need a definition at all?</p> <p>Person may have a spouse and a de facto partner. This could cause problems. Broader implications for next of kin, what other areas do family have a say, ie if die without a will? People don't choose their next of kin according to the law. Need to be careful that definition of family does not prevent normal family processes taking place.</p> <p>If there is dissent within the family need to be clear in legislation. Let the family come to a consensus view, don't use a family hierarchy. Why have a definition of family at all? One size fits all approach may not work for all uses of tissue, ie research may be different to sale and purchase. Suggest having someone to facilitate the discussion who is morally neutral – kaumatua, doctors, or others. Will the rules get in the way of the human circumstances in which conversations take place?</p> <p>Should be descriptive to allow for good practice to evolve. Suggestion that group should include a person nominated as next of kin by the deceased.</p> <p>If family is to be involved then need to have flexibility for several paradigms to play</p>

	out.
<b>57.</b>	<b>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. (see pages 91-93)</b>
	Innovative procedures – this principle has no sanctions at present. Need to have ability to apply sanctions to prevent a procedure going ahead prior to any consideration by an ethics committee or other body. This needs to be covered in legislation. The principle is – if it does not comply with stated principles than you can not do it.
<b>61.</b>	<b>Do you think the new legislation should prohibit the sale and purchase of all human tissue in New Zealand? (see pages 94-97)</b>
	<p>Need to look at the rules around commercialisation very carefully.</p> <p>Initial tissue taken and modified and made into a commercial product that is sold for profit, etc. Would hate to see a blatant statement in regulation that means that one cannot have payment demanded around certain products that are commercially available, originally developed from a tissue sample. The issue of commercial companies coming to New Zealand and providing products made from paid donors (skin) is here now. The concept of approved entities would prevent people coming into market place ahead of appropriate decision making processes being undertaken.</p> <ul style="list-style-type: none"> <li>• Issues are already upon us.</li> <li>• Need to consider difference between “reimbursement” rather than “payment for”. This applies, for example, petrol costs for donor to come in to make the donation, time off work etc.</li> <li>• Issues of cost recovery vs profit.</li> </ul> <p>ANZICS supports prohibition on commercialisation.</p> <p>Tissue collected in New Zealand from New Zealanders should not be able to be bought and sold.</p> <p>Doctors should not be able to buy tissues and organs from overseas.</p> <p>Costs associated with preparation of tissues, cost recovery and manufacture is ok, but not wholesale commercialisation (different moral contract – donation not for profit).</p> <p>Sale and purchase of tissues and organs may cause a negative public reaction to donation.</p> <p>Canada paying donors for immunoglobulin was raised – this hasn’t impacted on the public perception of blood donation.</p> <p>Must retain trust in the system, people feel differently about blood than they do about organs.</p> <p>If people have autonomy over their bodies why can’t they sell things as well? If you prohibit selling then prohibit autonomous decisions.</p> <p>Evidence is that payment for blood reduces safety as people may not to be honest about their health status.</p> <p>If sale of kidney’s is allowed then later donor’s remaining one is damaged, should the public purse support donor’s with one damaged kidney – could require insurance.</p> <p>Sale and purchase introduces coercion and spiritual objection to ‘object’ to sale.</p> <p>Individual choices modify the way we think as a society, the sum of the individual decisions.</p> <p>Sale and purchase of tissue would need societal consent.</p>

	<p>Potential in the future for profit from donated tissue through companies. What is the governance of tissue banks to check on financial gain? Need to give information to the family, that tissue is a gift of charity, no strings. Cannot raise issues of sale later. If tissue is being on-sold, family should be told.</p> <p>Activities within New Zealand related to tissue is on the basis of a gift. Cost recovery is ok, but profiteering is not. Suggest having Crown Entities responsible for tissue banking.</p> <p>Should consent to commercial exploitation be included in consent form? Should monetary benefit go back to individual or to research? Commercialisation of cell lines has been exploited for economic gain for New Zealand and researchers themselves. Some thought that system should allow commercialisation ie. Uniservice system - 1/3 monetary benefit to investigators, 1/3 to institution and 1/3 to Uniservices.</p>
63.	<p><b>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. (see pages 97-99)</b></p>
	<p>Access to tissue banks by overseas researchers is ok if have informed consent for use of tissue for research purposes. Need regulation of New Zealand tissue that is sent overseas, duty bound to ensure tissue goes to tissue banks that meet quality standards of the same standard as New Zealand tissue banks. US approach- tissue donated for research is an unconditional gift. Need to be careful that we don't export/import ethical decisions and apply them to other countries with different ethical views. Tissue that has had ethical approval by an overseas body with an oversight committee should be accepted here.</p>

## **OTHER ISSUES RAISED**

### Organ donation

Acknowledge that current systems work very well – ANZICS, Donor Office. Don't throw out the baby with the bath water.

Avoid prescriptive in preference for descriptive.

In Iran the govt pays \$25k for live organ donors and their donor rate is very high.

### Cultural concerns

Maori have concerns over technology, values, dignity, and respect for tissue/body. Previous consultation on other topics raised consistent concerns regarding implementation of Maori values system, beliefs and cultural aspects- Tikanga Māori.

### Ethics Committees

Presently Ethics Committees have no guidelines on how to consider alternative uses for tissue other than what it was originally taken for (relates to other research requests).

### Dignity and respect for tissue

Dignity – any therapeutic uses of the body must take account/ensure respect/dignity towards the body (values and beliefs). How does this get incorporated into legislation/regulation? Consider putting in front of the Act a statement setting out the purpose of the Act followed by a statement on principles that must apply and be incorporated eg principle covering respect, dignity etc to human tissue. This guides the need to have the discussion.

- Innovative procedures - must have ability to apply sanctions until appropriate considerations of the procedure have been undertaken.
- Dignity and respect and public expectations must be met.
- Education essential since public and consumers are less aware of what the implications are from new technologies.

### Retention of tissue that is not used

Have questions around return of tissue that has been taken and then found to be unsuitable – this relates more to therapeutic uses however.