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Te Kaunihera Wahine O Aotearoa

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Submission to the Ministry of Health on the Review of the Regulation of Human Tissue and Tissue-Based Therapies

The National Council of Women of New Zealand (NCWNZ) is an umbrella organisation representing 41 nationally organised societies. It has 33 branches throughout the country attended by representatives of those societies and some 150 other societies. The Council's function is to serve women, the family and the community at local, national and international levels through research, study, discussion and action. NCWNZ has a longstanding history of encouraging the promotion of social and health issues, particularly as they affect women.

Members of the Health Standing Committee, Branch members and other interested parties were asked for their input into this document. The following is a summary of their comments.

General Comments:
Some common themes emerged during the process of collating the responses from members, branches and member societies. They included:

- The length of the discussion document: many thought the document too long and complex. It was suggested that it might have been better to split it into more manageable parts. Some had difficulty finishing the document and some may have been put off even attempting to answer it by its size and complexity.
- A number of questions contained multiple parts. In general this is regarded as bad practice. Certainly it made for difficulties in interpreting the answers provided by some respondents.
- Many felt that substantially more effort was required in public education on these important issues. Information needs to be readily accessible and easily understood. Considerable advantages could accrue from a wider public debate.
- Respondents universally condemned the proposal of 'presumed consent'. In general, respondents supported the primacy of 'informed consent' of the principal party involved. This was seen as an ideal and the wishes of the principal party should only be overridden in unusual or exceptional circumstances.
- Most respondents felt the current de facto Donor Register (i.e. driver's licence) was unsatisfactory and should be replaced. Any Donor Register should allow for potential donors to change their minds and should preferably be an 'opt in' system rather than an 'opt out' one. A novel suggestion was that the Census form could be used as a mechanism for requesting consent. This would allow individuals to review or modify their decisions at five yearly intervals.
- It is recognised that the next of kin is the person who can over turn a relatives wish to be a donor. Education is required so that an individual is not only aware of this situation but has properly informed their next of kin.

Many of the suggested regulations appeared to be prescriptive and could inhibit the development and adoption of new technologies. It was felt that rather than constantly changing the regulations

to accommodate proven new technologies, it would be preferable to have flexibility within the regulations to allow for changes following appropriate consultation and guarantees of safeguards.

Some concerns were expressed about the lack of discussion of cost/benefits within the document. The present health funding system appears to be very compartmentalised. This has led to the perception that much of vote health is specifically targeted with little flexibility to move money. It appears that little consideration is given to the overall cost/benefit of a treatment or procedure. The public perception is that the current health system takes little account of the quality of life of health consumers and the hidden costs (i.e. those of the consumer) are not considered.

Members of the Health Standing Committee were provided with the full discussion document and asked to comment on all questions. Some felt they were not qualified or did not have the experience to answer some questions. Branches, member societies and members were asked to comment on a limited number of important issues. They were provided with the appropriate background information and asked to comment on Questions 3, 4, 13, 32, 34, 35, 42, 61 and 62. They were provided with access to the full review document if they wished to comment on other issues.

Specific Comments

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.**

   One respondent commented that it is not very clear whether the definition excludes cellular material for routine diagnostic tests e.g. full blood counts, sputum and urine cytology. If cervical smear cytology is included then logically these other 'cellular tissue' tests should be also be included.

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.

   All respondents agreed with the above.

3. **Do you think that the new legislative framework should have informed consent as its foremost principle?**
   NCWNZ believes that it is essential that the new legislative framework should have informed consent as its foremost principle. Without it, another "unfortunate experiment" or similar could occur. Further, parents should give consent on behalf of their children.

Many respondents commented that more information, education and debate will be required to encourage people to give consent. While recent media interest has helped raise awareness of donor shortages, many people do not know of the need for tissue for research, training purposes and gaining knowledge about uncommon diseases. It is understandable that if the issue of donation has not been discussed previously, that a distressed family dealing with the stress of a sudden or unexpected death may refuse consent at that time. Tissue and organ donation rates might be improved if an education programme encouraged families to discuss the issues and preferably make decisions prior to critical events.

One respondent did not agree with the proposal but no explanation was given.

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.

Responses to this proposal were mixed. The majority of respondents supported the notion that in some circumstances the 'public good' should outweigh 'informed consent', provided that there were appropriate safeguards in place. However, it was stressed that the circumstances in which this provision would apply should be limited. There must be a very good reason for a person's body to be used without their consent. It was acknowledged that currently post mortems are conducted without consent. This may be necessary to establish the cause of death, particularly if the death was sudden or unexpected. Even in these circumstances an appropriate professional should adequately inform the relatives.

Some respondents appreciated that without the ability to collect data in a meaningful way for trend information and research, advances in medical treatment or proper monitoring of current treatment could be compromised. The problems encountered by researchers trying to get meaningful cervical screening data is an example of what happens when there is no principle of 'public good'.

Many respondents agreed that the new regulation of human tissue must balance requirements of individuals and families with the requirements for ongoing medical research, education & training.

NCWNZ believes that it is essential that appropriate safeguards be put in place. The public must have confidence in the system and be assured that it is well supervised. Safeguards should, as a minimum, include:

- Ethics committees;
- Use of anonymised tissue samples;
- Monitoring;
- Auditing; and
- Mentoring.

Decision making at the time of death will be strongly influenced by the emotional reactions of the bereaved, which may be exacerbated by the necessity to take action while the tissue is still viable. Therefore obtaining informed consent ahead of the event is most desirable.

One strategy could be for an information sheet given to patients on registration with a general practitioner or attendance at a hospital, seeking 'generic' (implied) consent for use of any tissue for research, quality control and education.

In practice, obtaining fully informed (explicit) consent for all eventualities may be very difficult and costly, e.g. obtaining consent for archival tissue samples or quality control. If explicit consent is required for all routine tissue samples, then adequate resourcing must be provided.

Those respondents who objected to the proposal were particularly concerned to ensure that there would not be a repeat of the Green Lane affair. One respondent had personal experience of this tragedy and clearly was still distressed that it had happened. Other respondents objected on religious grounds, for example, it was stated that it was against the Jewish faith not to bury all body parts and blood.

Concern was also expressed about the definition of 'public good', who would make decisions and how it would work in practice.

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.**
   NCWNZ support this proposal.

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.**
   NCWNZ strongly support this proposal. There was no support for the notion of 'lack of objection'.

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?**
   Respondents supported this proposal. The comment was made that if this provision is not used in current practice, there is no point in retaining it. In general, respondents believed that bodies used for non-therapeutic purposes should be donated.

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?**
   Most respondents did not think that problems would arise from implementation of this proposal. It was suggested that information sheets could be provided to general practices regarding organ donation or body donation for research or education.

   However, other respondents stated that there was a general shortage of bodies for examination and dissection by medical students. This has made it necessary to use tissues from animals. It was also pointed out that post-coronial bodies were not used for research.

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.**
   NCWNZ supports this proposal. This is in accordance with current practice by schools of anatomy where the principle of informed consent is considered paramount. However, some respondents thought it acceptable that the body of a deceased person be used for anatomical examination if the next of kin gave consent. This was a minority view.

   One respondent stated that although there was public concern over the retention of body parts there were examples where considerable benefits had come from the research work, e.g. the

Brain Bank and increased knowledge about Alzheimer's, Huntingdon's Chorea and Parkinsonism.

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.**
Respondents generally agreed with this proposal, provided appropriate consent was obtained. It was suggested, however, that if families disagreed on the issue of consent, that this could pose ethical difficulties.

Some concern was expressed about informed consent. It should be made clear who had the authority to give informed consent and in what circumstances. It should also be made clear that distressed relatives were not badgered or coerced into giving consent and that the person requesting consent was impartial and had nothing to gain from the situation (i.e. no conflicts of interest).

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.
    The majority of respondents agreed with the proposal. Further it was agreed that for a one off event for clinical purposes, a family member could give consent while for research projects ethics committee approval should be required. Tissue could also be used for a recognised quality assurance programme or external audit.

    There was a minority view that did not support the proposal. They were adamant that consent should have been obtained from person while they were still alive. Further, if consent had not been obtained from the individual prior to death then the tissue should not be used.

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.**
    NCWNZ strongly supports the proposal that the wishes of the individual should be respected.

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.**
    The majority of respondents agreed that the informed wishes of the individual, where possible, should be the principle followed. Further, when the wishes of the individual were not known, then the wishes of the family should be followed. It was acknowledged that there may be circumstances when the wishes of the individual and/or family should be overridden for reasons of 'public good', e.g. safety reasons.

Some respondents suggested that it was highly desirable that there be some flexibility of approach available rather than an absolute requirement, as is current practice. It was suggested that there should be enough flexibility to allow for a case-by-case approach.

Those supporting the proposal made several additional comments or suggestions, including:

- that public education on this topic was essential;
- that the age of consent should be in line with other legal responsibilities and set at 18; and
- that families already have the right to challenge decisions made by a deceased relative.

A substantial minority strongly objected to the proposal. It was clear that they believed that the wish of the individual to donate or not donate was a decision for the individual alone. They believed that the wishes of the individual should always be followed. Further, some respondents stated that the family should not have the right to alter the decision of the individual. The only exception conceded was if the individual was of unsound mind at the time that they made their decision. It was stated that the wishes of the family should always be acknowledged. In cases where the wishes of the individual were not known, family members should make the decision.

Concerns were raised about strong cultural and religious objections. It is against some cultures not to bury a person in their entirety e.g. Maori, Jews. Thus, to retain tissue or organs might cause considerable distress.

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.**
NCWNZ strongly supports this proposal.

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.**
All respondents agreed with this proposal. However, some concern was expressed about the definition of 'legally competent'. Issues were raised about the criteria to be used, who would make the decision and how it would work in practice. It is important that whoever is involved in the decision making process is seen as being independent and that there are no real or perceived conflicts of interest.

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?**
There was no consensus on this issue. However, the majority of respondents believed that both parents should have an equal say. Some expressed the view that only in very exceptional circumstances should the mother alone have the right to say what was to happen to the body of their deceased child.

It was acknowledged that while it was preferable to have consent from both parents there were family circumstances where the decision might be more properly made by one parent alone e.g. a solo parent family where there had been little or no support or contact from the other parent during the child's lifetime. It was also acknowledged that in some cases, the mother's needs might be greater than those of the father (e.g. safety with future pregnancies) and this should be taken into account when the parents are unable to agree. Any dissent should, however, be acknowledged.

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?**
    Respondents believed that consent in writing should be obtained wherever possible. It was acknowledged, however, that there could be circumstances where this was not possible. In these circumstances forms of consent other than in writing could be acceptable as a temporary measure but they should always be followed up by consent in writing. Further, the alternative forms of consent must always be adequately documented, i.e. hard copies. Alternative forms of consent that were suggested included:
    - by phone;
    - by e-mail; or
    - by fax.

    The latter has the advantage that a signature could be included.

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.**
    Very few respondents felt qualified to comment on this question. Those who did respond supported the proposal. Comment was made that codes of practice of tissue management/storage would be required for all licensed premises by the Ministry.

19. **Please tell us your suggestions for what should, or should not, be covered by such a framework and why.**
    Issues that are required by current legislation and Ministry of Health guidelines, together with the issues mentioned in B6.1, page 36.

    Reference was made to the problems associated with recent events regarding the foetal heart collection.

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.**
    Only one respondent felt qualified to comment on this question. They felt that there should not be any exemptions; even Museums and Art Galleries should comply with code.

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.**
    A system based on standards, audit and certification, needs to be developed based on current working guidelines.

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.**
    There was general agreement that such a system would work in New Zealand.

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?**
    The majority of respondents answering this question supported the proposal. Police do provide independent audit but specialist knowledge would be required for proposed monitoring. Designated audit agencies would need to be appointed e.g. College of Pathology. Some suggested that the Police have a supervisory role.

A minority believed that the role of the Polices was largely historical and no longer relevant. Monitoring and auditing are specialist roles that should be carried out by a competent and independent agency.

24. **Please share any suggestions you have for terms that respectfully describe a 'body'. Are either of the following terms acceptable:**
    ***(a)* tüpäpaku, or body of a deceased person?**

    ***(b)* tüpäpaku, or deceased human being?**
    The majority of respondents preferred option (a) "tüpäpaku, or body of a deceased person". Other respondents had no preference.

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?**
    The majority of respondents preferred the third option ("the person with custody or care or control of the body") with a minority supporting the second option ("the person with lawful responsibility for the body").

    There was no support for the first option ("the person with lawful control of the body").

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 (e.g. 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.
    Most respondents supported option (c).

    One respondent supported option (a). They commented that most Hospitals have a Medical Director and this person would be the most appropriate person as they have a clinical role. The CEO, however, has more of an administrative role and therefore was probably not appropriate.

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.**
    Respondents supported the proposal that tissue from stillborn children and foetuses be brought within the new regulatory framework. Because of the huge potential of stem cell research, every effort should be made to obtain informed consent from the parents to ensure that such research can continue. There must, however, be appropriate safeguards in place to prevent exploitation of vulnerable mothers.

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.**

The majority of respondents agreed that more detailed guidelines are required. This was believed to be particularly important in view of rapid advances in genetic testing and stem cell research. One respondent commented that the expertise of trained counsellors for SIDS or SANDS guidelines should be included.

A minority did not support the proposal. They did comment, however, that they were pleased to note the concern indicated about the need for:

- a clear separation between the decision to terminate a pregnancy and the decision to allow the use of foetal tissue for research; and
- a ban on inducements that might be offered to influence the decision of the mother.

Concern was expressed about the possible commercialisation of placenta use. Apparently this has occurred in Europe where they are sold for use in manufacture of cosmetics. It was noted that approaches have already been made in New Zealand.

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.**
The majority of respondents believed that the processes appeared to be sufficient.

Concern was expressed, however, about stem cell research. It was suggested that there should be full public consultation with regards to ethics of stem cell research. The Bioethics Council may be the appropriate body to explore the issues.

30. **What should the main purpose of any additional processes be?**
Obtain public input with regards to the ethics involved. Some respondents thought that public safety should be the focus of any additional processes.

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?**
Some respondents supported the requirement for an ethical review for proposed research into using human stem cell lines in new therapies, transplanting human cells into animals or therapeutic genetic modification of human cells.

Other respondents did not think an ethical review was necessary, with the proviso that the established cell line was not modified. If it was modified then they believed an ethical review should take place.

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.**
NCWNZ supports the extension of the Health Information Privacy Code to address genetic issues.

The general principles should cover genetic information including: informed consent of those involved, the confidentiality of health information, least harm and greatest community benefit. In particular, the Health Information Protection Code needs to be amended to cover the ethical issues arising from advances in technology and research.

Respondents believed there should not be any insurmountable problems with anonymity of information. If researchers needed to access several types of health information about an individual, that could be accomplished by using a unique number to identify the individual. Pathology laboratories and General Practitioners already hold information and exchange information under the individual's name. They could readily code the personal details so that they were anonymous as far as the researcher and the public were concerned. This should be part of the informed consent process.

It was suggested that there might be an issue of whether to inform a donor of any genetic condition discovered that was treatable. The donor could give consent, or not, to this when giving consent to use the sample. There could also be a gap if researchers wished to match genetic information with other health records of the donor. This may sometimes be the only means to confirm links between genetic information and many aspects of human health. The public interest should be paramount here.

There are also occasions when some individuals and/or family members may need to own or know about genetic information derived from analysis of their tissue as in diseases such as Huntingdon's Chorea. Where hereditary diseases only show up occasionally, it would be highly desirable that appropriate tissue was available for research.

Other issues raised included a strong recommendation that adopted children should be able to access genetic information about their biological parents. Today's world with 'mixed-up' families, sperm donors and many medical developments it is essential that people can find out about any potential genetic problems.

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 (i.e., 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.

It is important that health information is retained. Medical notes are currently retained for 10 years. Tissue specimens should also be retained. Laboratory and x-ray reports are included in medical notes but it may be important in some cases, to go back to original tissue specimens either to check the diagnosis or for research purposes. Most routine blood and urine test specimens would not need to be retained. Developing regulations to cope with future advances in technology may be difficult and changes may need to be made, as and when needed, e.g. with advances in genetic testing. There are currently regulations to cover management of health information when a provider ceases to practice.

It was also suggested that documentary evidence should be retained to demonstrate that all aspects were discussed with the donor and signed consent given.

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.**

NCWNZ strongly objects to the first option ("presumed consent"). Respondents universally rejected this option, sometimes in very strong terms. For example, some stated that presumed consent would be arrogant and insensitive and therefore totally unacceptable.

There was no agreement about the other options. There was, however, clear majority support for option 2 ("requirements for wishes to be followed"). Most respondents supporting this option felt that the rights of the individual should always prevail. They stated that a person's body was their own and its disposal should be able to be decided by them alone, either by a statement in their will or by some other legal document. It was noted that if a will is contested, a judge has to decide the issues on the basis of rules laid down. Likewise, if a family contests their relative's decision about donating organs or tissue, some process should be in place to quickly hear their arguments and come to a decision that was not open to appeal. A quick decision with no right of appeal might help grieving relatives accept the deceased person's decision in spite of them disagreeing with it.

There was also substantial support for options 3 ("requirement to state wishes") and 5 ("status quo").

It was recognised by those supporting option 3 that this would mean the need to establish a Register. Most stated that the current driver's licence system was unsatisfactory because, for example, it only applies to those who have a licence. Further, the decision is often made in haste, at the counter, at the time of application for a licence. It would be preferable if it were a carefully considered and informed decision. To achieve this, public education on the issue is essential. There was disagreement on the form of any Register. The majority supported an 'opt in' Register. Others, however, suggested that the Register should be a record of those who do not wish to donate (i.e. an 'opt out' Register). Some saw option 3 as difficult to operate and potentially a bureaucratic nightmare. Of particular concern was the issue of ensuring that all individuals had been given the opportunity to make an informed decision about the issue. This would be essential if the Register were an 'opt out' one. Any such Register would need to be robust and well maintained. The system would need to be able to cope with individuals

changing their mind. Comment was made that the publicity resulting from an error in removing tissue and/or organs from someone by 'mistake' could be damaging to the public image of an organ donor programme.

There was very limited support for option 4 ("requirement to request"). Most respondents who commented were uncomfortable with this option. In general they were concerned that it would be seen as insensitive. However, some believed that there should be an exception with regard to children. In this circumstance they urged that there should be a requirement to request permission of parents to take tissue or organs.

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?**
    There was no consensus on this issue. In general, respondents believed that the wishes of the individual should be followed. Some believed that the rights of the individual were paramount and should always be followed. Others recognised that there may be circumstances when these wishes were not appropriate. Strong cultural or religious beliefs that would cause the family deep distress, or strong evidence that the deceased was pressured in their decision-making, may be reasons for overriding the implied consent.

    Most recognised that strong cultural and/or religious beliefs could be difficult to deal with. A minority stated that cultural and religious beliefs should not be violated. NCWNZ urges that the process be sensitive in relation to these issues. Cultural and religious differences should be recognised and respected where possible.

    Generally it was felt that the best outcomes would be achieved if families were encouraged to discuss the issues among their members before any situation requiring an immediate decision, occurred. To be successful, this would require increased publicity and ready availability of appropriate information.

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.**
    Respondents did not feel qualified to comment on this question.

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.**
    The majority of respondents supported this proposal. Some thought it essential otherwise there would be ethical issues about organ and tissue removal. Others believed it would be useful when discussing issues with or providing explanations to family/whanau.

    A minority stated that a definition was not required in the framework as current expert clinical guidelines were sufficient.

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'.

The majority of respondents agreed with the definition given above.

39. **Do you think that the new regulatory framework should require compliance with the current guidelines for establishing brain death? Why or why not?**
The majority of respondents felt it essential that compliance be required under the new framework. It is important to avoid any misunderstanding by family/whanau.

One respondent, however, didn't feel this was required in the regulatory framework. It was suggested that it would be very difficult to regulate in any case.

40. **Should the new regulatory framework allow for non-heart beating donation to take place, subject to appropriate standards and guidance being developed in this area? Please explain why you agree or disagree.**
Respondents agreed that non-heart beating donation should be permitted. Intensive Care expert standards need to be followed. These standards would require non-transmissible infections to be checked. Technology will change and 'future-proofing' the regulatory framework will be difficult.

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-heart beating donor and those that are involved in transplantation processes. Please describe any other safeguards you think should be considered.**
Informed consent is always needed, and ensuring separation of health professionals in the transplantation process is an important safeguard. It is important that the public have confidence in the procedures and they need to be assured information being provided by health professionals is not biased. They also need to be confident that there are no real or perceived conflicts of interest.

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'?**
There was overwhelming support that, in general, directed donation by deceased donors should not be allowed. Some supporters of the proposal believed that any other option could leave the field open for unscrupulous doctors and others.

Some believed that an 'unconditional gift' was the ideal and should be encouraged, but that there should be a limited capacity for conditions to be placed on the gift. They believed that if a deceased person wished to limit how their organs or tissues could be used, this wish should be respected. For example, if a person were happy to donate tissue for transplant but not cloning, they should be able to make that a condition of donation. Some donors might wish to limit the tissues and/or organs they wanted to donate. For example, some might be comfortable about donating corneas but not a heart. This was thought to be an acceptable condition. However, if a potential donor wished to place unacceptable conditions on donation (e.g. that they placed restrictions on who their kidney could go to), then the gift should be declined.

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?**
The majority of respondents supported the proposal. It was suggested that where there was an agreement to meet, such a meeting should be facilitated by coordinators. Where appropriate, there should be support by separate social workers for each of the parties

involved. Concern was expressed that timing (i.e. timeframe after the event) needed to be carefully considered. Unsuccessful outcomes would also need to be considered in a sensitive way and support would need to be provided where appropriate/necessary.

Other respondents did not generally support the proposal unless both parties specifically requested it. If a meeting was to take place they felt it was essential that there was a facilitator.

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.**
Respondents agreed that additional provisions were not required as the Code, together with Guidelines for Organ and tissue Donation were sufficient.

It was suggested, however, that support should be available to both the donor and the recipient if it is needed.

45. **Do you think the new regulatory framework should formalise safety guidance for whole organ donation? Please explain why or why not.**
The majority of respondents did not support the proposal. Guidelines are already in place and experts should review them on a regular basis. If there were a regulatory framework introduced this would also need regular updating.

One respondent stated that they supported the proposal but gave no reasons for their support.

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.**
NCWNZ believes that it is essential to develop standards for tissue banks, particularly for recipient safety. It would also provide protection of persons responsible for tissue collection. The system would need to be audited and national standards must be developed.

47. **Do you think tissue services should be regulated under the provisions in the Health Act? Please explain why you agree or disagree.**
NCWNZ supports the proposal that tissue services should be regulated. Human tissue should not be bought or sold for profit; appropriate ethics need to be complied with and the service should be audited.

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.**
NCWNZ believes the definitions are adequate.

49. **Do you agree that the products listed on page 83 should be exempt from the regulatory framework? Please explain your views.**
NCWNZ agrees that the product list on page 83 should be exempt from the regulatory framework.

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.

In general the term 'manufacture' and the proposed definition were thought appropriate.

One respondent suggested that human tissue engineered products need to be included (see - British Medical Journal, Vol. 326, page 1159, 31 May 2003). The UK has introduced the new "Medicines and Healthcare Products Regulatory Agency" to cover regulation for medicines and medical devices.

Some respondents did not like the term 'manufactured' but preferred the term 'processed'. Another suggestion was 'preparation process'.

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).

Respondents agreed with the proposed exemptions from the definition and had nothing further to add.

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.**

Ultimately all manufacturers should be licensed and regulated. In the interim, a voluntary code of practice needs to be developed. Hospital settings will have standards set in place and therefore pose less of a risk. Health professionals will need to play a major role in providing clinical evidence about the efficacy and effectiveness of human tissue products, in the 'manufacture' of these products and in the implementation of controls.

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.

Respondents agreed with the categorisation of tissue contained in Table C3 and had nothing further to add.

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.

The same process that Pharmac performs would be required for all tissue-based products.

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, stepparent, step-brother or step-sister; and**

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

Respondents generally agreed with the proposed definition of 'immediate family'. Some concern was expressed about the term 'spouse'. Consideration needs to be given to the status of the spouse or partner. Issues that should be considered include:

- the nature of the relationship i.e. is it current and ongoing;
- the role/rights of a spouse or partner if the parties are separated;
- the role/rights of a spouse or partner if the relationship has been legally dissolved; and
- the role/rights of any other relation if the relationship has not been close.

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

Most respondents agreed that the system would work when there was general agreement within the family. However, it was suggested that if there was no agreement it could become a very complicated process. See also the issues mentioned in the answer to the question above. Other issues that should be considered include:

- the number of family members required to give informed consent i.e. only one or more than one;
- whether the opinion of all family members consulted should carry equal weight;
- that there should be a mechanism for recognising dissent; and
- that it might be necessary to provide support to family members at this stressful time.

It was suggested that it might be appropriate to draw up a 'priority' list of family members that could be used as a guideline. It would need to be used with sensitivity and must recognise many different family relationships and cultural differences.

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.

Respondents generally agreed with the proposal. It was recognised that providing legislation to cover regulation of future technologies could be very difficult. Legislation will need to be reviewed as new technologies develop. However, some basic principles would always remain and could be included in legislation.

In an environment of rapid changes in medicine and medical technologies it is important that legislation be flexible enough to limit old therapies or allow new therapies without the continual need to amend the legislation. There was some support for the legislation containing a section allowing the relevant Minister to recommend to the Governor General that a therapy should be removed from, added to or subject to amendment in the Act after certain criteria have been met, e.g. on the advice of an expert advisory group, following public consultation.

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.**

Respondents agreed that it was desirable that (a) and (b) be at Ministerial level, the relevant Minister having taken appropriate advice. There was general agreement with (c), i.e. that the list should be reviewed from time to time as appropriate but that a review should not simply be triggered by technologies as they become available. The main concern raised in relation to (d) was safety. It is essential that an appropriate risk analysis should be carried out and that benefits should clearly outweigh any risks.

Comment was made that clinical evidence about the efficacy and effectiveness of the tissue technology needs to be balanced against any risk to the individuals concerned and to society/environment. The higher the risk, the greater the regulation required. Human tissue products may carry greater risks than most other medical devices.

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.

NCWNZ agrees that xenotransplantation should be included in the proposed list of prohibited activities. Respondents were particularly concerned about safety issues and believe that authorities should be very cautious about proceeding in this area. The possible release of a new virus into the human population would not be reversible if it occurred. Further, the possibility of transmitting a genetic problem to the next generation would also not be reversible. It would not be wise at this stage to even proceed to clinical trials of xenotransplantation even though they are currently permitted under Part 7A of the Medicines Act.

Some respondents thought that the issue should be revisited if evidence showed that the risks were very low and that there would be substantial health benefits to people in New Zealand.

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?

NCWNZ is interested in participating in ongoing discussion about the acceptability of xenotransplantation in New Zealand.

61. Do you think the new legislation should prohibit the sale and purchase of all human tissue in New Zealand?

The overwhelming majority of respondents supported the proposal that the new legislation should prohibit the sale and purchase of all human tissue in New Zealand. Some felt that permitting the purchase and sale of tissue might be seen as coercion, particularly in the case of vulnerable members of society. Some were of the opinion that if individuals were not paid for tissue then a company should not be able to profit from a donation.

Others indicated that some limited payments might be justified and could assist in improving donation rates. They suggested that donors could be paid for any expenses incurred, i.e. that

they didn't suffer any financial loss. It was also clear that they shouldn't make any net 'profit' from the donation.

Some respondents thought that expenses related to the banking of tissue products ought to be funded, e.g. cornea or skin bank. It was recognised that if New Zealand companies were to invest in and contribute to advances in technology there would need to be appropriate allowances made to assist them to do so. There was no support for the simple 'on sale' of a tissue by a company. However, if the 'manufacture' of a product involved considerable intellectual property or substantial investment in the technology this should be recognised in legislation. Basically, if a company is not permitted to make a profit they won't invest in the technology. However, any such companies should be tightly regulated.

Respondents expressed concern about potential safety issues that would arise if sale or purchase of human tissue were permitted. They recognised that there was a chronic shortage of tissue and this needed to be addressed. Public education was seen as an important issue in attempting to improve donation rates. Sale and purchase was seen as very much a last resort.

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.**
There was no consensus on this issue. The majority of respondents reiterated the view that the sale and purchase of human tissue was highly undesirable. The issue was raised of the situation in China where prisoner's organs are harvested to need. Concern was also expressed about the possibility of disturbed or distressed people selling their organs for money. Others suggested that it would be the 'thin edge of the wedge'.

Some respondents thought that sale and purchase of human tissue should be allowed, but only to allow the use of tissue controls in diagnostic work. The money involved should be to cover expenses only, and not to make a profit out of the sale of human tissue. Others suggested that limited sale or purchase should be permitted between hospitals and research institutions.

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.**
Respondents were in agreement with this proposal. They acknowledged the reasons for the need to import/export tissue. It appears that the present coverage is limited and ad hoc in nature. More comprehensive guidance could and should be provided. The nine issues identified in D5 (pgs 98 & 99) would form the basis of a comprehensive set of guidelines,

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.**
Respondents did not feel they had appropriate experience to enable them to make useful comments on this question.

NCWNZ thanks the Ministry of Health for this opportunity to comment on this review. We support the approach that is being taken and look forward to seeing the outcome of the consultation process.

Beryl Anderson
National President

Catherine Gurnsey
Convener, Health Standing Committee