

List of Consultation Questions

Part A

1. As you go through this document and consider the many issues within it, please consider the definition of tissue on page 2 and let the Ministry know if you think the definition should be changed and why.

Part B

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

Please explain any changes you would make and why.

3. Do you think that the new legislative framework should have informed consent as its foremost principle?
4. If so, should a secondary principle recognise that in certain circumstances, the public good associated with the use of tissue will outweigh informed consent *provided that safeguards are in place*?
Please explain your reasons for agreeing or disagreeing.
5. Do you agree that it is acceptable for tissue samples to be used for the purposes of laboratory quality control, so long as the person giving the sample is told beforehand that their tissue may be used for this purpose and the sample is made anonymous? If you disagree, please explain why.
6. Do you agree that the concept of 'informed consent' is preferable to 'lack of objection' and that this should be included in the new regulatory framework? If not, please explain your reasons.
7. Are there any reasons why the provision in the Human Tissue Act allowing the use of unclaimed bodies for non-therapeutic purposes should be retained?
8. If the provision were removed, do you foresee any problems being created for the practice of anatomical examination, education or research? If so, do you have suggestions for how these could be addressed?



9. Do you agree that it is not appropriate for the body of a deceased person to be used for anatomical examination if the views of the deceased person about this use are not known? Please explain any comments.
10. Do you agree that the new legislative framework should allow tissue from deceased persons to be used for non-therapeutic purposes (other than anatomical examination) with appropriate informed consent? If not, please explain your reasons.
11. When tissue has been collected during the life of a person and is wanted for uses after that person's death for a reason where the wishes of the deceased person are not known, should the new legislation allow these uses with appropriate safeguards? If so, are the following suggested safeguards appropriate.
 - a) If the proposed use is a one-off event for clinical purposes, consent could be sought from another family member.
 - b) If the proposed use is a research project, or audit, the tissue could not be used unless the research had been approved by an ethics committee, or the tissue was to be used for a professionally recognised quality assurance programme, an external audit or evaluation of services that was undertaken to assure or improve the quality of services.

Please describe any other ideas you have.

12. Do you agree that, where a person is known to object to their body being used after their death for non-therapeutic purposes, this objection should be respected and their body should not be able to be used for these purposes, as is currently in the Human Tissue Act 1964? If you disagree please explain your reasons.
13. Do you think that the new legislation should allow families to have the final say over the donation of tissue from their deceased loved one for non-therapeutic purposes? If not, please explain why you think the wishes of the deceased should be *required* to be followed and if there should be any exceptions to this requirement.
14. Do you agree that consent from the parents or guardians should always be gained for tissue from a deceased child to be used for non-therapeutic purposes? If you don't agree, please explain why.
15. If a child or young person is legally competent, and their wishes in relation to the non-therapeutic uses of their tissue are known, then should the same procedures as with adults apply? If you don't agree, please explain why.
16. Should both parents have an equal say in what happens to the body of their deceased child, or are there circumstances where the mother's wishes should prevail?
17. Are there situations in which consent for non-therapeutic uses of human tissue may be given other than in writing? If so, should any safeguards or special procedures apply? Are there alternative forms of consent that may be acceptable?



18. Do you think that an overarching standard or code for tissue management that can be applied flexibly to different agencies is appropriate? Please explain why or why not.
19. Please tell us your suggestions for what should, or should not, be covered by such a framework and why.
20. Please tell us if you think there are agencies for which, or specific occasions when, there should be exemptions from the requirements of such a framework.
21. Please share your ideas on possible approaches to monitoring tissue management practices that allow for robust monitoring to take place without imposing unnecessary compliance costs on the health and disability support sector.
22. Do you think that a system based on standards, audit and certification could work in New Zealand? Please tell us why or why not, and share any other ideas you have.
23. Do you think that the New Zealand Police should continue to be involved in the monitoring and audit of non-therapeutic tissue use? What type of role should the Police fulfil?
24. Please share any suggestions you have for terms that respectfully describe a 'body'. Are either of the following terms acceptable:
 - a) tūpāpaku, or body of a deceased person?
 - b) tūpāpaku, or deceased human being?
25. Please tell us your ideas for a phrase that may be preferable to 'the person lawfully in possession of the body'. Are the phrases 'the person with lawful control of the body', 'the person with lawful responsibility for the body' or the person with custody or care or control of the body' appropriate?
26. Please tell us your ideas for removing the ambiguity created by the term 'the person in charge (of an institution)'. In the case of hospitals, which of the following three options do you prefer for the new legislation:
 - a) a particular position within a hospital designated as the person lawfully in possession (eg, the institution's chief executive or medical director)?
 - b) a requirement that institutions appoint or nominate for appointment a particular person from time to time?
 - c) a particular position within the District Health Board, likely to be the chief executive, with the ability for this responsibility to be delegated as appropriate?

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



28. Currently, New Zealand does not have separate guidance for ethics committees and researchers to follow when dealing with research using stillborn children and foetal tissue. Do you think guidance in addition to the general guidelines detailed on page 42 is needed? Please explain your response.
29. Are the current processes outlined in Table B4 (on page 45) for reviewing the ethical and safety dimensions of research applications using cells and tissues (specifically stem cells) sufficient, or should such research be subject to any additional review processes before it can proceed? If so, please explain your reasons.
30. What should the main purpose of any additional processes be?
31. Do you think there are any circumstances in which established cell lines should be subject to ethical review, and if so what would the purpose of such a review be?
32. The implications of access to genetic information are complex and affect people beyond the individual who is the source of the information. We are seeking your thoughts on whether the coverage of the Health Information Privacy Code should be extended to specifically address genetic issues. If so, please tell us your views on any or all of the issues listed above.
33. Following the passage of the Health (National Cervical Screening Programme) Amendment Act, changes are able to be made to the Health (Retention of Health Information) Regulations 1996 to cover the retention of specimens as well as other health information.

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

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

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



Part C

34. The new legislative framework could consider five options (with combinations) to consent for organ and tissue donation. Of the options below, please tell us which you think may be better and why. The options are:
- 1) presumed consent
 - 2) requirement for wishes to be followed
 - 3) requirement to state wishes
 - 4) requirement to request
 - 5) status quo.
35. If you think one of the options (other than status quo) would be better for New Zealand, do you think there should be any time when families/whānau should be able to override the wishes of the deceased person? Why or why not? If not, do you have suggestions for managing a situation when the wishes of the deceased person are not the same as those of the family/whānau?
36. The Ministry is interested in the processes and experiences of the tissue donation sector in accessing information about the medical suitability of potential donors. Please share any experiences, difficulties or good practice in this area – including experience of the operation and interpretation of the Health Information Privacy Code.
37. Do you think that the new regulatory framework should contain a definition of ‘death’? Please explain what you think the advantages or disadvantages of including this definition would be.
38. If you think a definition should be included, is the following a suitable definition? If not, please suggest any changes you would make.
- ‘A person is dead when there is irreversible cessation of circulation of blood in the body of the person, or irreversible cessation of all function of the brain of the person.’
39. Do you think that the new regulatory framework should require compliance with the current guidelines for establishing brain-death? Why or why not?
40. Should the new regulatory framework allow for non-heartbeating donation to take place, subject to appropriate standards and guidance being developed in this area? Please explain why you agree or disagree.
41. As well as informed consent, one particular safeguard that needs to be in place is a separation between the health professionals that assess a non-heartbeating donor and those that are involved in transplantation processes. Please describe any other safeguards you think should be considered.
42. Should the new legislative framework make it clear that donation of organs or tissue from people who have died should only be on the basis that the organs or tissue are an ‘unconditional gift’?



43. Do you think that, if both parties wish to, donor families and recipients should be able to meet? If so, what type of support should be offered for this to happen?
44. Live organ and tissue donation in New Zealand is regulated through the Code of Health and Disability Services Consumers' Code of Rights, in particular the requirement to ensure that informed consent is obtained before such procedures (either donation or transplantation) take place. Do you think the new regulatory framework should include any additional provisions? If so, please explain what these should be and why.
45. Do you think the new regulatory framework should formalise safety guidance for whole organ donation? Please explain why or why not.
46. Do you think tissue banking services should be regulated under the Health and Disability Services (Safety) Act, noting that this would mean the development of a national standard for tissue banking that was then audited and providers being certified accordingly? Please explain why you agree or disagree.
47. Do you think tissue services should be regulated under the provisions in the Health Act? Please explain why you agree or disagree.
48. Do you think the definition of human cells, tissue and cellular and tissue-based products (on page 82) adequately describes the 'subject' of the proposed new regulatory framework for tissue-based therapeutic products? Please explain any changes you would make.
49. Do you agree that the products listed on page 83 should be exempt from the regulatory framework? Please explain your views.
50. Do you think the term 'manufacture' and the definition proposed for that term on page 84 are appropriate for tissue-based therapeutic products? If not, please share your suggestions for a better term or definition.
51. Is the proposed exemption from the definition of 'manufacture' appropriate? Are there other activities you think should be exempt from the definition? Please explain your suggestions (see page 84).
52. Your suggestions on potential exemptions from licensing requirements for particular people are sought. Consideration of this issue needs to be done in the context of:
 - a) other exemptions proposed for particular products or manufacturing activities
 - b) any differences in the risks posed by the processing of tissue in a hospital setting compared to other settings
 - c) whether exemptions for custom-made products are appropriate
 - d) how we distinguish between medical practice and supply and manufacture of tissue-based therapeutic products, and the impact of any regulation on clinical decision-making.



53. What do you think of the categorisation of tissue contained in Table C3 on page 86? Would you assign any activities differently? Please explain your comments.
54. Your comments are sought on the proposed regulatory approach to tissue-based therapeutic products and any concerns you have about how it may impact on the practice of health care.

Part D

55. Do you think the definition of ‘immediate family’ given below is suitable for new legislation for both the therapeutic and non-therapeutic uses of human tissue? Please explain any changes you think should be made. (Please note that this definition is not proposed for use in the risk framework for tissue-based therapeutic products described in section C5.2.6. It is only proposed for times when consent is needed.) The proposed definition is:
- a) any person who was the spouse of the deceased including de facto and same-sex partners, or a parent, grandparent, child, brother or sister, or guardian or ward, of the deceased; and
 - b) any person whose relationship to the deceased is that of step-child, step-parent, step-brother or step-sister; and
 - c) any person who, in accordance with the traditions and customs of the community or whānau of which the deceased is a member, had the responsibility for, or an interest in, the welfare of the deceased.
56. Please tell us how you think the proposed definition of ‘immediate family’ would work in practice.
57. Do you think the inclusion of a section that enables particular activities to be restricted until full consideration can be given to the implications of the activity and any special requirements that might be needed before the activity can be undertaken (such as safety procedures, or record keeping requirements) provides sufficient ‘future-proofing’ of the new legislation? Please explain your response and share any other ideas you have for future-proofing the legislation for new technologies.
58. If you think a section restricting certain activities would be useful, please share your ideas about the following issues:
- a) the level of authority needed to place an activity on the list
 - b) the level of authority needed to take an activity off the list
 - c) whether the activities on the list should be reviewed periodically, and whether a time period should be set for such a review
 - d) any criteria an activity may have to meet before it is placed on the list or removed from the list.



59. Pending further work on the public acceptability and safety of xenotransplantation and the development of any special requirements that may be needed if xenotransplantation is to be undertaken in New Zealand, do you agree that xenotransplantation should be included in the proposed new list of prohibited activities? If not, please explain why.
60. Are you interested in being involved in any ongoing discussion of the acceptability of xenotransplantation in New Zealand? Toi te Taiao – the Bioethics Council has agreed to undertake work in this area: may the Ministry give the Bioethics Council your contact address so that you can be sent any material on xenotransplantation?
61. Do you think the new legislation should prohibit the sale and purchase of all human tissue in New Zealand?
62. If you think some sale and purchase of human tissue should be allowed, please explain what types of tissue this should apply to, for what purpose it should be allowed to be bought or sold, and who should be permitted to sell it.
63. Do you think the new legislative framework should provide more comprehensive coverage of the import and export of human tissue? If not, please explain why.
64. Are there issues for the import and export of tissue other than those identified that you think should be covered by the new legislative framework? Please explain your reasons.

