MINISTRY OF HEALTH

MANATŪ HAUORA

Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes

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Preface

In June 2006, the Ministry of Health released the *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes: Discussion Document* for public consultation. The discussion document contained information about the regulatory framework and requirements for the use of human tissue for future unspecified research. It outlined the consent, ethical and cultural issues surrounding the use of human tissue for future unspecified research and invited feedback on the proposed *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes*.

Submissions closed on 11 August 2006. Forty-eight submissions were received. In general most submitters supported the proposed guidelines which allowed researchers to obtain consent for the use of human tissue for future unspecified research. Submitters however, raised a number of issues relating to consent and de-linking a donor's identity with their tissue sample. The Ministry has prepared a summary of submissions document which discusses the key concerns raised by submitters. This document is available on the New Zealand Health and Disability Ethics Committee's website, http://www.newhealth.govt.nz/ethicscommittees

The proposed *Guidelines on the Use of Human Tissue for Future Unspecified Research Purposes* were reviewed in light of the submissions received. The finalised Guidelines are presented in this document and are also available at http://www.newhealth.govt.nz/ethicscommittees. The guidelines make it clear that New Zealand researchers may obtain consent to use human tissue for future unspecified research subject to donors being provided with specific information and sufficient options before gaining their consent.

The guidelines will sit underneath the *Operational Standard for Ethics Committees* and will guide Health and Disability Ethics Committees when they consider applications for research concerning the use of human tissue for future unspecified research.

Definition

Human tissue – means any material collected from a living or deceased person that is or includes human cells. However, for the purposes of these guidelines, human tissue does not include gametes and embryos and established cell lines derived from human embryos. These guidelines also apply to any information that is derived from *human tissue*.

Unidentified/de-linked tissue – means that the identity and personal information of an individual who has donated human tissue is no longer identifiable or linked to that individual's tissue sample.

Part One: Consent

1. Consent may be given for the use of tissue in future unspecified research. The requirements for informed consent are set out in the *Operational Standard for Ethics Committees* and within these guidelines.

2. Consent to the future unspecified use of a person's tissue samples must be distinct from consent to collect the sample and distinct from consent to use the sample in specified research.

3. In the situation of child donors, consent must be obtained from the child in accordance with Appendix 1 of the *Operational Standard for Ethics Committees*. Where a child lacks the competency to give legally effective consent, the child's legal guardians can give proxy consent for the use of their child's tissue sample for future unspecified research, including for the tissue sample to be de-linked.

4. Consent may be given for the unidentified or de-linked use of the donor's tissue sample. However, in such situations, the donor must be informed that they will not be able to withdraw their consent for the use of their tissue sample in the future.

Part Two:
Information to be Provided

Information that must be provided to potential donors before seeking consent for future unspecified use of their tissue sample must include the following.

5. An indication of the type and nature of the research to be carried out and its implications for the donor, where possible, and an explanation of why the potential donor is being approached for their tissue and specifically what tissue is being sought.

6. Known possible researchers or institutions that might use the tissue sample, if possible.

7. Whether the donor's sample is going to be, or is likely to be sent overseas, and where possible, to what country or countries.

8. Acknowledgement that all future unspecified research in New Zealand will be subject to ethical review. However, when a tissue sample is sent overseas, unless it is sent in conjunction with a New Zealand research project, future research is likely to be considered by an overseas ethics committee without New Zealand representation.

9. Whether the donor's identity and details will remain linked with the sample or whether the sample will be de-linked.

10. A statement that if a donor consents to a tissue sample being unidentified or de-linked, they relinquish their right to withdraw consent in the future.

11. Whether the donor may be contacted in the future regarding their tissue sample. Whether or not, and under what circumstances, information about the future unspecified research will be made available to the donor and/or (where relevant) their clinician.

12. Acknowledgement that the donor will not own any intellectual property that may arise from any future research.

13. Whether there is provision to withdraw consent for the use of human tissue samples in the future. Where there is provision to withdraw consent, only tissue samples remaining at the time of a request to withdraw and any information held for future unspecified research may practically be withdrawn. Tissue samples or information used in research before the request to withdraw is received is unlikely to be able to be returned or destroyed.

14. Acknowledgement that the donor's decision regarding the consent for use of their tissue sample for unspecified future research will in no way affect the quality of a donor's current or future clinical care.

15. Where and for how long a tissue sample will be stored, how it will be disposed of and whether there is a cultural protocol for its disposal. For example, information about the institution holding the tissue sample: its aims, research procedures and research governance.

16. Whether or not tissue samples could be provided to other researchers and institutions, and whether or not such provision could include sending samples to other countries.

17. Whether or not collected samples will be provided to commercial biomedical companies or will be used in commercial research collaborations, if known.

18. What provisions will be made to ensure patient confidentiality.

19. That different cultural views may inform choice about donation of tissue; for example, for some Māori, human tissue contains genetic material that is considered to be collectively owned by whānau, hapū and iwi.

20. That cultural concerns may arise when tissue samples are sent overseas, including how tissue samples are stored and disposed of. Processes for monitoring and tracking what happens to samples may not be acceptable to donors.

21. That donors may want to discuss the issue of donation with those close to them, for example; family, whānau, hapū and iwi.

Part Three:
Options for consent

Consent forms must offer sufficient options to help donors understand the nature of the choices that are open to them. Where practicable, options could include the following.

22. A donor refusing consent for the use of their tissue sample in future unspecified research.

23. A donor permitting only unidentified or de-linked use of their tissue sample for any future unspecified research; or for specific research.

24. A donor permitting identified or linked use of their tissue sample for any future unspecified research; or for specific research, with the requirement to recontact the donor in the future to gain further consent from the donor.

25. A donor permitting identified or linked use of their tissue sample for any kind of future study; or specific research, without the need for future consent.

Part Four:
Ethics Committee Approval

Before granting ethical approval, the ethics committee needs to be satisfied around the following points.

26. Donors of tissue samples will be presented with available information about potential future uses of their tissue sample, including any options for consent available to them.

27. There are procedures and processes in place to ensure ongoing protection of donor confidentiality.

28. There are appropriate procedures and processes in place to recontact the donor or their clinician where researchers have agreed to provide clinically relevant information that arises from the research.

29. The organisation(s) storing tissue samples in New Zealand or overseas have adequate governance structures, procedures and processes in place to ensure the donor's choices are respected; such as, appropriate storage facilities, control of access to tissue samples and information, and appropriate disposal methods.

30. If the donor's tissue sample is going overseas, appropriate consent must be given, either for the tissue sample to be used overseas without a New Zealand ethics committee approval or to ensure that ongoing research has appropriate New Zealand ethical approval.

31. If tissue samples are being sent overseas and will not be subject to review by an ethics committee approved by the New Zealand Health Research Council of New Zealand, any future use of tissue samples or the information derived from them must have ethical and scientific review by a committee or institutional review

board that conforms to the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Council for International Organizations of Medical Sciences and World Health Organization 2002).

Part Five: Delegated authority

32. The chairperson of an ethics committee may have delegated authority to approve requests for the use of de-linked human tissue samples.