Guideline

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Human Tissue - Requirements of the Human Tissue Act 1983 in relation to research & use of tissue

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Summary Outlines the requirements of the Human Tissue Act 1983 and subsequent amendments in relation to research utilising human tissue: guidance for human research ethics committees. Also takes into account amendments to the Human Tissue Act which came into effect in January 2006.

Replaces Doc. No. Human Tissue Requirements of the Human tissue Act 1983 in Relation to Research [GL2005_046]

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Affiliated Health Organisations - Declared, Dental Schools and Clinics, Divisions of General Practice, Ministry of Health, Private Hospitals and Day Procedure Centres, Public Hospitals

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HUMAN TISSUE: REQUIREMENTS OF THE HUMAN TISSUE ACT 1983 IN RELATION TO RESEARCH AND USE OF TISSUE

Status

This Guideline updates and replaces Guideline 2005_046 to take into account amendments to the Human Tissue Act which came into effect in January 2006.

Format of this Guideline

1. This Guideline provides guidance for:
   - HRECs when reviewing research proposals involving human tissue;
   - researchers to determine the requirements of the law and the manner in which HRECs should review research proposals involving human tissue; and
   - persons in charge of laboratories that store and use human tissue samples.

2. Reference to paragraphs of the *National Statement on Ethical Conduct in Research Involving Humans* (the **"*National Statement*"**) is as follows: NS 2.1 refers to paragraph 2.1 of the *National Statement*

3. **"HREC"** refers to NSW Health Human Research Ethics Committees

Background

4. In 2003, there were amendments to the Human Tissue Act 1983 which affect the way HRECs assess applications for research involving human tissue.

5. The amendments relate to the legal requirement for consent to the use of human tissue for research purposes.

6. The amendments are not retrospective. That means there are different consent requirements for tissue removed before and after the commencement of the amendments. The amendments commenced on **1 November 2003**

7. Additional amendments to the Human Tissue Act commenced on **1 January 2006** relating to the use of small samples of human tissue for service delivery, quality assurance, and laboratory accreditation activities.

A. USE OF HUMAN TISSUE FOR RESEARCH

The requirements of the Human Tissue Act 1983 in relation to tissue removed prior to 1 November 2003

8. The following is an outline of the consent requirements of the Human Tissue Act in relation to human tissue which is proposed to be used for research.

9. Tissue removed for the purposes of a post mortem examination prior to 1 November 2003 does not require any consents for it to be lawfully used for research. However, the National Statement indicates that consent should usually be obtained (NS 15.4), unless it is suitable to waive consent under NS 15.8. **The law allows consent to be waived in accordance with the NS.**

10. Tissue removed from a deceased person prior to 1 November 2003 other than for the purposes of a post mortem examination can only be used with the oral or written consent of the deceased person given whilst alive, or their next of kin. The written authorisation of a designated officer of a hospital is also required. **The law does not allow consent to be waived even if the requirements of NS 15.8 are met. The law overrides the ability in the NS to waive consent.**

11. Where the tissue was removed prior to 1 November 2003 from a living person in the course of a medical, dental or surgical procedure, the law does not require any consents for its use for research. However, NS 15.4 indicates that consent should usually be obtained, unless it is suitable to waive consent under NS 15.8. **The law allows consent to be waived in accordance with the NS.**

12. Where tissue is removed from a person prior to 1 November 2003 for the purposes of research, the common law requires the person's consent to the removal, otherwise the removal would be a battery. **The law does not allow consent to be waived.**

The requirements of the Human Tissue Act 1983 in relation to tissue removed after 1 November 2003

Tissue blocks and tissue slides

13. Where tissue is removed after 1 November 2003 and is held in a tissue block or tissue slide, the law allows the tissue to be used for research without any consent being obtained. However, NS 15.4 indicates that consent should usually be obtained unless the requirements of NS 15.8 are met. **The law allows consent to be waived in accordance with the NS.**

Tissue other than tissue blocks and tissue slides

14. Where the tissue was removed from a deceased body (either for the purposes of a post mortem examination or otherwise), and is not a tissue block or tissue slide, written consent to the use of the tissue for research (from the deceased person before death or their next of kin) is required. The written authorisation of a designated officer of the hospital is also required. **The law does not allow consent to be waived even if the**

requirements of NS 15.8 are met. The law overrides the ability in the NS to waive consent.

15. Where the tissue was removed from a living person after 1 November 2003 as part of a medical dental or surgical procedure, and the person is still alive, written consent for use of the tissue for research must be obtained from that person (or their parent or guardian if they are a child) either before or after the removal. **The law does not allow consent to be waived even if the requirements of NS 15.8 are met. The law overrides the ability in the NS to waive consent.**

16. Where the tissue was removed from a living person after 1 November 2003 as part of a medical dental or surgical procedure, and the person is now deceased, written consent for the use of the tissue for research must have been obtained from the person whilst alive (or their parent or guardian if the they were a child) or from their next of kin after their death. **The law does not allow consent to be waived even if the requirements of NS 15.8 are met. The law overrides the ability in the NS to waive consent.**

17. Where tissue is removed from a person after 1 November 2003 for the purposes of research, the common law requires the person's consent to the removal, otherwise the removal would be a battery. **The law does not allow consent to be waived.**

18. **In no circumstances is tissue to be removed from the body of a deceased child who is or was a ward of the state for research purposes, either with or without consent from any person.**

How specific must consent be?

19. The Human Tissue Act allows consent to be general. A person may consent to the use of their tissue for research at large, and this will be sufficient at law for the tissue to be used for any research project. However, if the person consenting limits their consent, then the tissue may not be used outside the scope of the limited consent. For example, if the person consents to the use of their brain tissue for "research into Parkinson's Disease", it cannot be used for research which is not related to Parkinson's Disease.

20. NS 15.5 states that consent should be specific to the purpose for which the tissue is to be used, unless the requirement for consent is waived in accordance with NS 15.6 and 15.8. Therefore, where the NS requires consent, it may be stricter than the requirements of law. The more specific requirements of the National Statement should be applied, if the requirements of the law are general.

What should an HREC do when assessing research applications involving use of human tissue?

21. HRECs must have regard for the law AND the requirements of the National Statement when assessing research protocols involving human tissue.

22. The requirements of the law override the provisions of the National Statement (NS preamble). Therefore, if the law requires consent, the HREC may not waive the requirement for consent even if the HREC considers the requirements of NS 15.8, which allow waiver in some circumstances, are met.

23. HRECs must not approve research protocols which contemplate an unlawful use of human tissue.

24. HRECs should examine the research protocol to determine whether the proposed use of tissue is lawful. If the proposed use is lawful, then the HREC should apply the *National Statement* in determining whether to give ethical approval (except that it may not waive consent if consent is required by law).

25. If it is clear from a research proposal that the researcher intends to use tissue without obtaining consent in circumstances where the law requires consent, the HREC should reject the proposal because it involves unlawful conduct. The HREC should explain the reason for rejection to the researcher.

26. Where it is unclear whether the use of tissue proposed in the research protocol is lawful, the HREC should require the researcher to give an explanation of the use of the tissue. The researcher should be given a copy of this circular in order to explain the requirements of the law.

27. If the protocol is returned stating that tissue samples will be identified according to the requirements of the law, and with undertakings by the researcher to comply with the law, and the HREC is satisfied that this is reasonable, the HREC may give approval (after ethical review) but should make its approval conditional upon adherence to the law.

28. The conditions included in the letter of approval should be specific, not general. Relevant conditions from those listed below should be used in the approval letter.

29. For tissue removed prior to 1 November 2003, from a deceased body, the researcher must ensure that the tissue was removed either:

    - for the purposes of a post mortem examination; OR
    - with the consent of deceased person's next of kin and with the authorisation of a designated officer of a hospital

30. For tissue removed prior to 1 November 2003 from a living person, the research must ensure that the tissue was removed either:
    - in the course of a medical, dental or surgical procedure; OR
    - for the purposes of research with consent

31. For tissue removed after 1 November 2003, from a deceased body (either for the purposes of a post mortem examination or otherwise) and is not in the form of a tissue block or slide, the researcher must ensure that consent was obtained by the next of kin AND authorisation given to the removal and use by the hospital designated officer. Consent is mandatory under NSW law.

32. For tissue removed after 1 November 2003, from a living person as part of a medical dental or surgical procedure, the tissue is not in the form of a tissue block or slide, and the person is still alive, the researchers must ensure that consent for use of the tissue for research has been obtained (either before or after the removal). Consent is mandatory under NSW law.

33. Where the tissue was removed after 1 November 2003, from a living person as part of a medical dental or surgical procedure, the tissue is not in the form of a tissue block or slide, and the person is now deceased, the researchers must ensure that consent for the use of the tissue has been obtained from the next of kin. Consent is mandatory under NSW law.

34. Where the tissue was removed from a living person after 1 November 2003 specifically for research purposes, the researchers must ensure that consent for the removal and use of the tissue was obtained from the person. Consent is mandatory under NSW law.

B. USE OF HUMAN TISSUE FOR SERVICE DELIVERY, QUALITY ASSURANCE AND ACCREDITATION ACTIVITIES

35. Additional amendments to the Human Tissue Act to facilitate the use of tissue samples for the purpose of carrying out analyses or tests commenced on 1 January 2006.

36. These changes allow small tissue samples which have been lawfully removed from living or deceased persons to be used without consent for the purposes of carrying out analyses or tests:

    - that are part of a program (including any quality assurance program, quality control program, audit or evaluation) to ensure, or improve, the quality of services carried out at or by a hospital, a forensic institution, a laboratory, an educational or research institution or a supplier of blood or blood products; or

- that are necessary for the delivery of services carried out at or by a hospital, a forensic institution, a laboratory, an educational or research institution or a supplier of blood or blood products or for the accreditation under any Act of a hospital, a forensic institution, a laboratory, an educational or research institution or a supplier of blood or blood products.

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