Use of Human Tissue for Research

Summary This Guideline describes the application of the Human Tissue Act 1983 (NSW) to human research in NSW. It provides simplified guidance about the principles and processes about use of human tissue for research in NSW Public Health organisations.

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Audience Research Office Staff;Researchers;Clinicians;Heads of Departments Hosting and Supporting Research;Directors of Research;All Chief Executives

NSW Health

GUIDELINE

Use of Human Tissue for Research

GUIDELINE SUMMARY

This Guideline represents NSW Health's interpretation of the requirements of the *Human Tissue Act 1983* (NSW) for consent to the use of human tissue for research purposes.

It has been developed to assist health professionals, researchers and research support office staff to ensure that research involving human tissue and biospecimens is in accordance with the *Human Tissue Act 1983* (NSW), the *National Statement on Ethical Conduct in Human Research (2007)* and *NSW Health Consent Toolkit (2018)*.

It also provides clarity and consistency for Human Research Ethics Committees assessing research applications involving human tissue.

KEY PRINCIPLES

A person may legally consent to the use of their tissue for research purposes in general or for a limited scope, given the individual is sufficiently informed according to relevant sections of the *National Statement on Ethical Conduct in Human Research (2007)* (National Statement).

Human tissue removed prior to 1 November 2003 from a deceased person for the purpose of post-mortem examination can be lawfully used for research purposes. Otherwise, consent must be obtained from a person authorised by relevant legislation and a Designated Officer of a hospital.

Human tissue removed prior to 1 November 2003 from a living person as part of standard care procedures can be legally used for research purposes. Access to the tissue for research purposes may require consent according to National Statement Section 3.2.5. Informed consent is required prior to removing human tissue for research purposes.

Human tissue removed on or after 1 November 2003 from a living person as part of standard care procedures can only been used for research purposes if consent has been obtained from that person (or their parent or guardian if they are a child) before or after the removal. If the person passed away without giving consent, consent must be obtained from their next-of-kin.

Human tissue removed on or after 1 November 2003 from a deceased person can only be used for research purposes, written consent to the use of the tissue for research purposes needs to be obtained from their next-of-kin.

Under no circumstances are tissues to be removed from the body of a deceased child who is or was a ward of the state for research purposes, with or without consent.

Human Research Ethics Committees (HRECs) must adhere to legal requirements as well as standards set out in the National Statement when assessing research protocols involving

human tissue. Its decision to grant waiver of consent is subject to the legal requirements and must be made according to the requirements in the National Statement.

The *Human Tissue Act 1983* (NSW) allow the use of lawfully removed small tissue samples to be used for analyses or tests as part of certain quality assurance programs or as necessary for accreditation or the delivery of services at or by certain entities.

REVISION HISTORY

Version	Approved By	Amendment Notes
GL2023_008 April-2023	Deputy Secretary, Population and Public Health & Chief Health Officer	Clarification of guidance for use of human tissue research for research purposes. Revisions to existing guidance with new section including a decision tree.
GL2006_021 November-2006	Director General	New Guideline

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1. BACKGROUND

1.1. About this document

This Guideline is based on the principles described in the latest version of the following documents:

- The *Human Tissue Act 1983* (NSW) [the Act]
- The *National Statement on Ethical Conduct in Human Research (2007)* (the National Statement)
- The NSW Health Consent Toolkit.

The Act was amended 1 November 2003, establishing distinct obligations for the use of tissue collected before and after this date.

The Act was subsequently amended in 2006, altering the consent requirements for the use of small tissue samples in service delivery, quality assurance and accreditation activities.

The Act sets out legal requirements for consent to the use of human tissue that must be followed. The National Statement sets out ethical requirements to be followed when conducting research involving the use of human tissue.

In all cases, but especially where those provisions conflict, the Act is to be applied first and then the National Statement.

1.2. Key definitions

Designated Officer	A Designated Officer means: • In relation to a hospital, a person appointed under section 5(1)(a) of the *Human Tissue Act 1983* (NSW), to be a Designated Officer for the hospital, or • In relation to a forensic institution, a person appointed under section 5(3) of the *Human Tissue Act 1983* (NSW), to be a Designated Officer for the forensic institution, or • In relation to a private hospital within the meaning of the *Private Health Facilities Act 2007* (NSW) a person appointed by the governing body (defined in the Act as the licensee) of the hospital.
Human Research Ethics Committee (HREC)	A committee constituted in accordance with the *National Statement on Ethical Conduct in Human Research (2007)* to review and, where appropriate, approve and monitor the ethical and scientific aspects of human research.

National Statement (NS)	*National Statement on Ethical Conduct in Human Research (2007)* released by the National Health and Medical Research Council (NHMRC). Reference to specific paragraphs of the National Statement will be in the format NS 2.2.6.
Tissue	Organ, or any part of a human body or any substance extracted from a human body.

1.3. Legal and legislative framework

This Guideline must be read in conjunction with relevant provisions of the *National Statement on Ethical Conduct in Human Research (2007)*, the *Human Tissue Act 1983* (NSW) and the NSW Health Policy Directive *Designated Officer Policy and Procedures* (PD2013_002).

2. RESEARCH CONSENT

The *Human Tissue Act 1983* (NSW) 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.

The National Statement (NS Chapter 2.2) outlines the information that should be communicated to participants to meet the standard for "informed consent" unless the requirement for consent is waived in accordance with the National Statement (NS Chapter 2.3.9-2.3.12). Where the consent requirements of the law are general, then the more specific requirements of the National Statement are to be applied.

3. HUMAN TISSUE REMOVED PRIOR TO 1 NOVEMBER 2003

Tissue removed for the purposes of a post-mortem examination prior to 1 November 2003 does not require consent for it to be lawfully used for research. However, the National Statement indicates that if there is no wish expressed by the person regarding the use of their tissue post-mortem, then researchers must obtain consent from the person(s) authorised by relevant legislation (NS 3.2.5).

The law allows consent to be waived in accordance with the National Statement.

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 3.2.5 are met. The law overrides the ability in the National Statement to waive consent.

3.1. Medical, dental or surgical procedure

Where the tissue was removed prior to 1 November 2003 from a living person during a medical, dental or surgical procedure, the law does not require any consent for its use for research.

However, the National Statement (NS 2.2.18) indicates that consent to access tissue must be sought unless it is suitable to waive consent under the National Statement (NS 3.2.5).

The law allows consent to be waived in accordance with the National Statement.

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.

4. HUMAN TISSUE REMOVED AFTER 1 NOVEMBER 2003

4.1. Tissue blocks and tissue slides

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 2.2.18 indicates that consent should usually be obtained unless the requirements of NS 3.2.5 are met.

The law allows consent to be waived in accordance with the National Statement.

4.2. Tissue other than tissue blocks and tissue slides

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 2.3.10 are met. The law overrides the ability in the National Statement to waive consent.

4.2.1. Medical, dental or surgical procedures

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 2.3.10 are met. The law overrides the ability in the National Statement to waive consent.

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 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 2.3.10 are met. The law overrides the ability in the National Statement to waive consent.

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.

5. ETHICS REVIEW OF RESEARCH INVOLVING USE OF HUMAN TISSUE

Human Research Ethics Committees must consider both the law and the requirements set out in the National Statement when assessing research protocols involving human tissue.

The requirements of the law override the provisions of the National Statement. Therefore, if the law requires consent, the Human Research Ethics Committee may not waive the requirement for consent even if it considers the requirements of NS 2.3.10, which allow waiver in some circumstances, are met. National Statement (NS 2.2.18) outlines that data or tissue additional to those listed in the original consent may be needed for research. In this case, consent to the use of this tissue must be sought from potential participants unless the need for this consent is waived by an ethical review body.

Human Research Ethics Committees must not approve research protocols which contemplate an unlawful use of human tissue. Human Research Ethics Committees are to examine the research protocol to determine whether the proposed use of tissue is lawful. If the proposed use is lawful, then the Human Research Ethics Committee is to apply the National Statement in determining whether to give ethics approval (except that it may not waive consent if consent is required by law).

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 Human Research Ethics Committee is to reject the proposal because it involves unlawful conduct. The Human Research Ethics Committee must explain the reason for rejection to the researcher.

Where it is unclear whether the use of tissue proposed in the research protocol is lawful, the Human Research Ethics Committee must require the researcher to give an explanation of the use of the tissue. The researcher must be given a copy of this Guideline in order to explain the requirements of the law.

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 Human Research Ethics Committee is satisfied that this is reasonable, then it may give approval (after ethical review) but is to make its approval conditional upon adherence to the law. The conditions included in the letter of approval must be specific. Relevant conditions from those listed below should be used in the approved letter.

- 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.
- For tissue removed prior to 1 November 2003, from a living person, the researcher 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.

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

6. HUMAN TISSUE FOR SERVICE DELIVERY, QUALITY ASSURANCE AND ACCREDITATION ACTIVITIES

Additional amendments to the *Human Tissue Act 1983* (NSW) to facilitate the use of tissue samples for the purpose of carrying out analyses or tests commenced on 1 January 2006.

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
- 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.

7. APPENDICES

1. *Human Tissue Act 1983* (NSW) Decision Tree

7.1. Human Tissue Act 1983 (NSW) Decision Tree

Flowchart for the requirements of the *Human Tissue Act 1983* (NSW) in relation to research and use of tissue.