

## Consent Requirements for the Use of Human Tissue in New South Wales

### Research Ethics Guidelines

*The Sydney Children's Hospitals Network Human Research Ethics Committee (SCHN HREC)*

---

#### Human Tissue Act 1983 (NSW)

The Human Tissue Act 1983 (NSW) outlines the legal requirements for consent to the use of human tissue in research in New South Wales. 'Tissue' is defined in the Act as *'an organ, or part, of a human body and a substance extracted from, or from a part of, the human body.'*

The Act was amended on 01 November 2003, establishing distinct obligations for the use of tissue collected before and after this date.

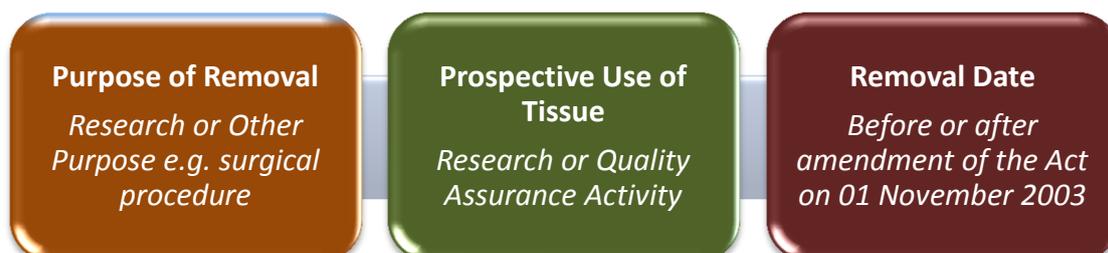
The Act was subsequently amended in 2006, altering the consent requirements for the use of small tissue samples in service delivery, quality assurance and accreditation activities.

As the Act forms part of New South Wales law, it supersedes the guidance regarding consent for research outlined in the National Statement on Ethical Conduct in Human Research 2007 (updated 2018). The Act is thus to be applied first (*refer to pages 1-3*) and then the National Statement (*refer to pages 3-4*).

#### NSW Health Guideline to the Requirements of the Human Tissue Act 1983 (GL2006\_021)

The NSW Health Guideline provides guidance for applying the Human Tissue Act. The following information referring to the Act is a thematic summary of the NSW Health Guideline.

When ascertaining the consent requirements for your proposed use of human tissue in research, it is recommended to first assess the purpose of the removal of tissue, then the purpose for which the tissue will be used and lastly, the date of removal as per the diagram below:



### Tissue Removed for Purpose of Research

If tissue is **removed for the purpose of research**, regardless of the date of removal and whether the person is alive or deceased, **consent MUST be obtained**. Otherwise, this removal is considered to be battery at common law.

#### *Exception to rule above*

Note: There is one scenario, where tissue cannot lawfully be removed for the purposes of research even **WITH consent**. This applies to a deceased child who is a ward of the state.

**Tissue Lawfully Removed for Research or Other Purposes**

**AND now to be used for Quality Assurance Activities within Research**

A **Waiver of Consent** may be granted by the HREC for small tissue samples lawfully removed from living or deceased persons AND are prospectively used for research involving quality assurance activities.

**Tissue Removed for Purpose Other than Research**

**AND now to be used for Research**

**AND it was Removed before 01 November 2003**

**Waiver of Consent** can be granted by a HREC for tissue removed from:

- ❖ Tissue removed from deceased person for purpose of post mortem examination.
- ❖ Tissue removed from living person in the course of a medical, dental or surgical procedure.

**Consent MUST be obtained** for tissue removed from:

- ❖ Deceased person other than for purpose of post mortem (oral / written consent of deceased person whilst alive, or next of kin AND written authorisation of designated officer of the hospital).

**Tissue Removed for Purpose Other than Research**

**AND now to be used for Research**

**And it was Removed from 01 November 2003 Onwards**

**Waiver of Consent** can be granted by a HREC for:

- ❖ Removed tissue that is held in a tissue block / tissue slide.

**Written Consent MUST be obtained** for tissue **NOT** held in a tissue block / slide which has been removed from:

- ❖ A deceased person (for purposes of post mortem OR otherwise).

	<p>Consent must be obtained from the deceased person before death or their next of kin). Written authorisation of a designated officer of the hospital is also required.</p> <ul style="list-style-type: none"> <li>❖ Living person after 01 Nov 2003 as part of medical, dental or surgical procedure, and the person is still alive (or from parent / guardian if a child) either before or after removal.</li> <li>❖ Living person after 01 Nov 2003 as part of medical, dental or surgical procedure, and the person is now deceased, written consent for use of 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.</li> </ul>
--	--

### Waiver of Consent - Additional Guidance

Once you have established that a waiver of consent may be permissible by law for your research, a waiver can be requested from the HREC for the use of the tissue.

However, please note that there are additional requirements outlined section 2.3.10 of the National Statement which will determine whether a waiver is granted by the HREC including:

- a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants
- b) the benefits from the research justify any risks of harm associated with not seeking consent
- c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)
- d) there is no known or likely reason for thinking that participants would not have consented if they had been asked
- e) there is sufficient protection of their privacy

- f) there is an adequate plan to protect the confidentiality of data
- g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)
- h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled
- i) the waiver is not prohibited by State, federal, or international law.

*For more information and to access the waiver of consent application, please refer to the SCHN Research Ethics Office - Resources / Templates webpage:*

<http://www.schn.health.nsw.gov.au/research/ethics-governance/ethics/resources-templates>

### Queries?

Contact the SCHN Research Ethics Team at:

[SCHN-Ethics@health.nsw.gov.au](mailto:SCHN-Ethics@health.nsw.gov.au) / (02) 98451253