

Human Tissue - Consent for Donation of Regenerative Tissue by Young Children & Consent Form

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Functional Sub group Clinical/ Patient Services - Baby and child
Clinical/ Patient Services - Human Tissue

Summary This policy directive outlines the conditions for consent applicable when a very young child is to provide regenerative tissue (bone marrow) to a sick sibling under certain conditions and includes the requisite consent form.

Replaces Doc. No. Human Tissue - Consent to Removal of Regenerative Tissue from Young Children and Consent Form [PD2006_010]

Author Branch Research Ethics and Public Health Training

Branch contact Julie Letts 9391 9465

Applies to Local Health Districts, Speciality Network Governed Statutory Health Corporations, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Affiliated Health Organisations, Community Health Centres, Government Medical Officers, Public Health Units, Public Hospitals

Audience Clinical, including medical, nursing, allied health, GPs

Distributed to Public Health System, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, Ministry of Health, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

Review date 13-Feb-2017

Policy Manual Patient Matters

File No. 03/8369

Status Active

Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

HUMAN TISSUE – CONSENT FOR REMOVAL OF REGENERATIVE TISSUE FROM YOUNG CHILDREN

PURPOSE

Effective 1 January 2006, amendments were made to the NSW *Human Tissue Act 1983* setting out new requirements for lawful removal of regenerative tissue (primarily bone marrow but not blood) from a child who is not capable of understanding the procedure. This policy outlines the consent standards for such a procedure.

MANDATORY REQUIREMENTS

1. Under the Human Tissue Act, where the child donor is too young to understand the procedure, bone marrow may only be removed where it is intended for transplantation into the child's sibling.
2. Certain conditions must be met before removal of bone marrow in this setting may proceed:
 - a. A medical practitioner must certify:
 - i. Parental consent was given in the presence of the medical practitioner;
 - ii. The medical practitioner explained, before the consent was given, the nature and effect of the removal of tissue from the child and the intended effect of its proposed transplantation;
 - iii. The medical practitioner is satisfied that, at the time of consent, the parent was of sound mind, understood the nature and effect of removal of the tissue, and that consent was freely given; and
 - iv. The medical practitioner is of the opinion that the following 'pre-conditions for child tissue donation' (in this setting) are satisfied:
 - The child, by reason of age, is not capable of understanding the nature and effect of the procedure and the intended effect of its proposed donation;
 - The brother or sister of the child is likely to die or suffer serious and irreversible damage to his or her health unless the bone marrow intended to be removed from the child is used in their treatment; and
 - Any risk to the child's health (including psychological or emotional health) caused by removal of tissue is minimal.
 - b. The above certification is effective only if a second medical practitioner, who is a specialist in paediatric medicine or paediatric transplants, also certifies the following:
 - i. He or she is of the opinion that the 'pre-conditions for child tissue donation' are satisfied;
 - ii. He or she is acting as an independent medical practitioner, meaning their primary role in providing this opinion is to ensure the health of the child from whom tissue is being removed; and
 - iii. He or she is not responsible for care of the sibling in whose treatment the tissue is to be used.

3. As an alternative to the procedure set out under the NSW *Human Tissue Act*, the Family Court of Australia may authorise the removal of tissue when it has found that the removal of tissue is in the child's best interests. The Family Court is empowered by federal law and is not subject to the limitations set out in the *Human Tissue Act*. For example, the Family Court may authorise donations to others apart from siblings, such as first cousins, as was the case in *Re Inaya (Special Medical Procedure)* [2007] FamCA 658.
4. Public hospitals that carry out bone marrow transplantation must ensure that the provisions in the NSW *Human Tissue Act* or the orders of the Family Court are followed and that local policy supports these provisions.

IMPLEMENTATION

The Sydney Children's Hospital Network (SCHN) is responsible for:

- Ensuring relevant clinical groups are aware of this revised policy;
- Providing an escalation process should there be a difference of opinion between the Bone Marrow Transplantation specialist and the independent assessor of the patient. This should entail second independent assessment of the donor at the other campus, with or without notification of administration. It should be noted that the Family Court may make orders with respect to donation of regenerative tissue by minors that may override parental and/or medical consensus in some circumstances; and
- Providing routine donor follow up in accordance with applicable accreditation standards (such as Foundation for the Accreditation of Cellular Therapy Standards) and agreed SCHN standard practice and policy.

This Policy Directive should be read in conjunction with Policy Directive PD2005_341 Human Tissue – Use/Retention Including Organ Donation, Post-Mortem Examination & Coronial Matters.

REVISION HISTORY

Version	Approved by	Amendment notes
February 2012 (PD2012_014)	Chief Health Officer	Addition of comment on escalation process if a difference of opinion arises, and donor follow-up. Replaced PD2006_010
February 2006 (PD2006_010)	Director General	New Policy

ATTACHMENTS

1. Form No.3 B.1: Parental Consent and Medical Practitioners Certificate

The attached consent form (SMR 020.020 Form No.3 B.1 – Human Tissue Act 1983, Donation of Regenerative Tissue by a Young Child, Medical Practitioner's Certificate) should be used in this setting.



FAMILY NAME

MRN

GIVEN NAME

MALE FEMALE

D.O.B. ____ / ____ / ____

M.O.

Facility:

ADDRESS

CONSENT FOR DONATION OF REGENERATIVE TISSUE BY YOUNG CHILDREN AND CONSENT FORM

LOCATION

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE



SMR020020

**FORM 3 B.1
HUMAN TISSUE ACT 1983
DONATION OF REGENERATIVE TISSUE BY A YOUNG CHILD**

Name of Donor _____ Aged _____

Address of donor _____

PARENTAL CONSENT

I, _____
(name of mother or father)

of _____
(address of mother or father)

being the mother/father of the above named child, consent to the removal of:

(type of tissue)

being a regenerative tissue, from the body of my above named child for the purpose of transplanting the tissue to the body of:

(name of recipient)

who is the _____ of the donor.
(brother/sister)

Dr _____
(name of the certifying doctor)

has explained to me to my satisfaction the nature and effect of the removal of the tissue and the intended effect of transplantation.

Signature of parent _____

Date _____

* Delete if not applicable

Holes punched as per AS2828-1999

BINDING MARGIN - NO WRITING

NH606588 070212

CONSENT FOR DONATION OF REGENERATIVE TISSUE BY YOUNG CHILDREN AND CONSENT FORM

SMR020.020



FAMILY NAME		MRN
GIVEN NAME		<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE
D.O.B. ____/____/____	M.O.	
ADDRESS		
LOCATION		
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE		

Facility:

CONSENT FOR DONATION OF REGENERATIVE TISSUE BY YOUNG CHILDREN AND CONSENT FORM

**FORM 3 B.1
HUMAN TISSUE ACT 1983
DONATION OF REGENERATIVE TISSUE BY A YOUNG CHILD
MEDICAL PRACTITIONER'S CERTIFICATE**

I, _____
(name of medical practitioner)

of _____
being a medical practitioner registered in NSW, hereby certify that:

- (a) the above consent was given in my presence;
- (b) I explained to the above named parent(s), before the consent was given, the nature and effect of the removal on the child's body of the tissue specified in the consent and the intended effect of the proposed transplantation;
- (c) I am satisfied that, at the time the consent was given:
 - 1. The parent(s) were of sound mind;
 - 2. The parent(s) each understood the nature and effect of the removal of the tissue and the intended effect of its proposed transplantation into the child's sibling;
 - 3. The consent was freely given; and
 - 4. The following 'pre-conditions for child tissue donation' (in this setting) are satisfied:
 - i) The child, by reason of age, is not capable of understanding the nature and effect of the procedure and the intended effect of its proposed donation;
 - ii) The brother or sister of the child is likely to die or suffer serious and irreversible damage to his or her health, unless the bone marrow intended to be removed from the child is used in their treatment; and
 - iii) Any risk to the child's health (including psychological or emotional health) caused by removal of tissue is minimal.

Signature of medical practitioner _____

Date _____

Second medical certification:

I, _____
(name of medical practitioner)

of _____

being a medical practitioner registered in NSW and practising as a specialist in paediatric medicine or paediatric transplantation, hereby certify that:

- (a) The 'pre-conditions for child tissue donation' described above are met;
- (b) I am an independent practitioner, that is my primary role in providing this opinion is to ensure the health of the child from whom tissue is being removed; and
- (c) I am not responsible for care of the sibling in whose treatment the tissue is to be used.

Signature of medical practitioner _____

Date _____

Holes punched as per AS2828-1999
BINDING MARGIN - NO WRITING

