

Human Tissue - Consent to Removal of Regenerative Tissue from Young Children and Consent Form

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

Summary This Policy Directive informs health professionals of legislative changes to the Human Tissue Act that permit the provision of bone marrow by a young child for a sick sibling. Removal of this type of regenerative tissue was previously only permitted by children old enough to understand the procedure. This legislative change is accompanied by specific consent requirements and limits on who may receive a bone transplant from such donors. This Policy Directive should be read in conjunction with PD2005_341.

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Community Health Centres, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, NSW Dept of Health, Public Health Units, Public Hospitals

Audience Clinical, including medical, nursing, allied health, Area Health Services GPs

Distributed to Public Health System, Community Health Centres, Dental Schools and Clinics, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

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Director-General

Compliance with this policy directive is mandatory.

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

This Policy Directive should be read in conjunction with Policy Directive 2005_341 Human Tissue – Use/Retention Including Organ Donation, Post-Mortem Examination & Coronial Matters. The attached consent form (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, as described below.

1. Effective 1 January 2006, amendments have been made to the Human Tissue Act 1983 which set out new requirements for lawful provision of bone marrow (a regenerative tissue) for transplantation by a child not capable of understanding the procedure because of their very young age.
2. In the setting where the child is too young to understand the procedure, bone marrow may only be removed where it is intended for transplantation into the child’s sibling. 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;

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- 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. Public hospitals that carry out bone marrow transplantation must ensure that the provisions in the Human Tissue Act are followed and that local policy supports these provisions.

Robyn Kruk
Director-General

FORM B.1

HUMAN TISSUE ACT 1983
DONATION OF REGENERATIVE TISSUE BY A YOUNG CHILD

Name of Donor _____ Aged _____

Address of donor _____

PARENT'S CONSENT

I, _____
(name of mother or father)

of _____
(address of mother or father)

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

(type of tissue)

being a regenerative tissue, from the body of my abovenamed 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**

FORM 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 _____