Policy Directive

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Donation, Use and Retention of Tissue from Living Persons

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Functional Sub group Corporate Administration - Governance
Clinical/ Patient Services - Human Tissue
Clinical/ Patient Services - Pathology
Population Health - Waste Management
Personnel/Workforce - Conduct and ethics

Summary This policy directive applies to all health organisations where staff may be involved in the removal of human tissue from a living person (including where tissue is removed or expelled in the course of medical, dental or surgical treatment) and is to be retained and consented for use for therapeutic, medical or scientific purposes, including transplantation, educational and research purposes.

Replaces Doc. No. Human Tissue - Consent for Donation of Regenerative Tissue by Young Children & Consent Form [PD2012_014]
Human Tissue-Use/Retention Including Organ Donation, Post-Mortem Examination and Coronial Matters [PD2005_341]

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Applies to Local Health Districts, Board Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, Public Health System Support Division, Dental Schools and Clinics, Government Medical Officers, Private Hospitals and Day Procedure Centres, Public Health Units, Public Hospitals, NSW Health Pathology, Cancer Institute (NSW)

Audience Clinical Governance, Staff of Transplant, Surgical, Pathology and Obstetric Units; Researchers

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

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Policy Manual Not applicable

File No. H14/98392

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This Policy Directive may be varied, withdrawn or replaced at any time.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.

POLICY STATEMENT

DONATION, USE AND RETENTION OF TISSUE FROM LIVING PERSONS

PURPOSE

This policy directive outlines requirements for and restrictions on:

- Consent to remove regenerative or non-regenerative tissue from a living adult during medical, dental or surgical treatment and to use and / or retain the tissue for scientific, therapeutic or medical purposes
- Consent and certification to remove regenerative tissue from a living child for its transplantation into a parent or sibling
- Consent and certification to remove regenerative tissue from a very young living child for its transplantation into a sibling
- Assessing requests for the return of tissue to a patient / next of kin.

MANDATORY REQUIREMENTS

- Written consent for the removal, retention or use of tissue for therapeutic, scientific or medical purposes (apart from diagnostic / treatment purposes) must be obtained in line with the requirements of the *Human Tissue Act 1983* and this policy directive.
- All restrictions and conditions on the use of tissue removed from living adults and children are observed.
- Under the *Human Tissue Act 1983* tissue removed during treatment can be retained for up to 72 hours in order to obtain consent, including consent from the senior available next of kin where the patient dies subsequent to tissue removal.
- Requests for the return of tissue removed / expelled during the course of medical, dental or surgical treatment must be assessed according to the guidelines at Attachment 1. A decision to release tissue to a patient / next of kin must be documented on the form at Attachment 7.

IMPLEMENTATION

Chief Executives of Local Health Districts / Specialty Networks and NSW Health Pathology must ensure that:

- Relevant staff are made aware of their obligations under this policy directive.

Clinicians involved in the donation of tissue from a living person for transplantation or other therapeutic uses must ensure that:

- All necessary consents and certificates are obtained in line with the requirements of the *Human Tissue Act 1983* and this policy directive.

Researchers and staff of tissue or biobanks must ensure that:

- Consent to the removal, use and / or retention of tissue for medical or scientific purposes is obtained in line with the requirements of the *Human Tissue Act 1983* and this policy directive.

Hospital and pathology service staff involved in the retention and release of human tissue must ensure that:

- Tissue is released to a patient / next of kin in line with the requirements of this policy directive.

REVISION HISTORY

Version	Approved by	Amendment notes
February 2016 (PD2016_001)	Deputy Secretary, Population and Public Health	New policy replacing sections 4.1 to 4.4 of PD 2005_341 *Human Tissue- Use /Retention of Including Organ Donation, Post Mortem and Coronial Matters* and PD 2012_014 *Human Tissue – Consent for Donation of Regenerative Tissue by Young Children & Consent Form*.

ATTACHMENTS

1. Donation, Use and Retention of Tissue from Living Persons: Procedures.

Donation, Use and Retention of Tissue from Living Persons

NSW GOVERNMENT Health

PROCEDURES

Issue date: February-2016

PD2016_001

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1 BACKGROUND

1.1 About this document

This policy directive supersedes sections 4.1 to 4.4 of PD 2005_341 *Human Tissue - Use / Retention of Including Organ Donation, Post Mortem and Coronial Matters* and PD 2012_014 *Human Tissue – Consent for Donation of Regenerative Tissue by Young Children & Consent Form.*

This policy directive outlines the requirements for obtaining consent to the removal, collection, use and retention of regenerative and non-regenerative tissue from living persons for medical, scientific or therapeutic purposes (including research or educational purposes) and any restrictions on the removal and use of this tissue.

1.2 Key definitions

Child

A person who has not attained the age of 18 years and who is not married.

Child in care

A child or young person under the age of 18 years who is in any of these categories:

a) Under the parental responsibility of the Minister administering the *Children and Young Persons (Care and Protection) Act 1998*

b) For whom the Director-General of the Department of Community Services or a designated agency has the care responsibility under section 49 of the *Children and Young Persons (Care and Protection) Act 1998*

c) A protected person within the meaning of section 135 of the *Children and Young Persons (Care and Protection) Act 1998*

d) Subject of an out-of-home care arrangement under the *Children and Young Persons (Care and Protection) Act 1998*

e) Subject of a sole parental responsibility order under section 149 of the

Children and Young Persons (Care and Protection) Act 1998

f) Otherwise in the care of a service provider.

Parental responsibility, in relation to a child or young person, means all the duties, powers, responsibilities and authority that, by law, parents have in relation to their child.

Designated Officer

A Designated Officer is a person who in relation to a:

a) Hospital, is appointed under s5(1) (a) of the *Human Tissue Act 1983* to be a Designated Officer for the hospital

b) Forensic institution, is appointed under s5(1)(a) of the *Human Tissue Act 1983* to be a Designated Officer for the forensic institution

c) Private hospital within the meaning of the *Private Hospitals and Day Procedure Centres Act 1988* – is appointed by the governing body (defined in the Act as the licensee) of the hospital.

Medical dental or surgical treatment

Any medical, dental or surgical treatment carried out by or under the supervision of a medical practitioner or dentist with respect to a living person in the interests of the health of that person.

Medical or Scientific purpose

Under the *Human Tissue Act 1983* use of a body or tissue for medical or scientific purposes includes educational purposes connected with medicine or science. This may also include research and other therapeutic purposes.

Person Responsible (*Guardianship Act 1987)*

When a person lacks decision making capacity and it is not an emergency, all health care practitioners are required under law to consult and seek consent to treatment from the Person Responsible. For persons 16 years and older, the Person Responsible is determined according to the hierarchy within the *Guardianship Act 1987* (NSW):

a) An appointed guardian (including enduring guardian) with the function of consenting to medical and dental treatment (or if there is no-one in this category)

b) A spouse or de facto spouse (including same sex partner) who has a close and continuing relationship with the person, where the spouse is not a person under guardianship (or if there is no-one in this category)

c) The carer or person who arranges care regularly or did so before the person went into residential care, and who is unpaid (the carer's pension does not count as payment) (or if there is no-one in this category)

d) A close friend or relative.

Senior Available Next of Kin

For a living child, the senior available next of kin is determined according to the hierarchy within the *Human Tissue Act 1983*:

a) Parent of the child (or, \if not available)

b) A person who is a guardian of the child.

Tissue

Tissue includes an organ or part of a human body and any substance extracted from a human body or part of a human body. There are two types of tissue:

a) Regenerative tissue is tissue that after injury or removal is replaced in the body of a living person by natural processes of growth or repair (e.g. bone marrow)

b) Non-regenerative tissue is tissue other than regenerative tissue.

1.3 Legal and legislative framework

1.3.1 *Human Tissue Act 1983* (the Act)

This policy directive describes requirements for the operation of Part 2 of the *Human Tissue Act 1983* which regulates donations of tissue by living persons. Donation of ova,

semen or foetal tissue is covered under different provisions within the Act or other legislation and is therefore excluded.

In the Act, reference to:

a) The transplantation of tissue includes transplantation of any part of the tissue or any substance obtained from the tissue

b) Tissue that is removed from the body of a living person in the course of medical, dental or surgical treatment includes tissue expelled from the body of the person in the course of treatment, including where the person dies during the course of the treatment.

1.3.2 *Guardianship Act 1987*

Part 5 of the *Guardianship Act 1987* allows that when a person aged 16 years or older lacks decision making capacity and medical or dental treatment is not an emergency, consent for medical and dental treatment may be given by the Person Responsible.

For the purposes of this policy directive the *Guardianship Act 1987* allows a Person Responsible who is consenting to the medical, surgical or dental treatment of a patient to consent to other uses of the tissue that is removed or expelled from a living person.

1.4 Policy framework

NSW Health policy documents relevant to this policy directive:

- PD 2005_406 *Consent to Medical Treatment – Patient Information*
- PD 2015_04 *Kidney Donation - Living (including Directed and Non-Directed Donation)*
- PD 2013_002 *Designated Officer Policy and Procedures*
- GL2006_021 *Human Tissue - Requirements of the Human Tissue Act 1983 in relation to research & use of tissue*
- GL 2007_016 *Human Research Ethics Committees- Standardised Patient Information Sheets (PIS)*
- GL2008_019 *Adult-to-Adult Living Donor Liver Transplantation Guidelines.*

NSW Health State Forms relevant to this policy directive:

- Consent and certification for the donation of tissue by a living adult (*SMR 020.035*)
- Consent and certification for the donation of regenerative tissue by a living child *SMR 020.036*)
- Consent and Certification for regenerative tissue donation: Child not capable of understanding
- Consent and authority for the retention and use of tissue removed or expelled during treatment of a deceased patient (*SMR 020.034*)
- Authorisation to delegate responsibilities of next of kin (*SMR 020.031*)
- Authorisation for the release of human tissue to a patient or next of kin. *(SMR 020.033*)

2 CONSENT TO THE USE OF TISSUE REMOVED DURING MEDICAL DENTAL OR SURGICAL TREATMENT

2.1 Consent requirements

2.1.1 Consent by a person with capacity

Where a person has capacity, their written consent is required if regenerative or non-regenerative tissue removed from their body during medical, surgical or dental treatment is to be used for any medical, therapeutic or scientific purposes(apart from the diagnostic purpose associated with the removal).

The consent must specify the purpose for and any conditions under which the tissue is to be used. For example, the patient should be given a description of the sort of uses to which their tissue may be put, such as scientific and medical research, biobanking, teaching or study).

The consent / request for medical treatment form issued through Policy Directive (PD) 2005_406 *Consent to Medical Treatment-Patient Information* includes an option for consent for the use of tissue removed during the course of treatment. A copy of this consent should also be available to the agency / facility or researcher who receives the tissue for inclusion in their records.

The patient must be informed that consent to the use of tissue is separate from consent to treatment and that treatment procedures are in no way affected by a decision not to consent to use of tissue.

2.1.2 Consent for tissue removed from living persons under guardianship

Attachment A of Policy Directive 2005_406 *Consent to Medical Treatment – Patient Information* sets out the requirements for establishing a person's ability to consent under the *Guardianship Act 1987*.

Where the person from who the tissue is to be removed is under guardianship, the guardian who is consenting to the medical, surgical or dental treatment may also consent to the subsequent use of tissue.

2.1.3 No consent required for tissue blocks and slides

Specific consent is not required to retain tissue in the form of tissue blocks/slides.

2.1.4 Use of tissue removed in the course of medical, dental or surgical treatment

The *Human Tissue Act 1983* allows small samples of tissue that have been lawfully removed from a living person to be used without specific consent for purposes such as testing as part of a quality assurance / quality control program, audit or evaluation or pathology samples retained which are necessary for the accreditation of a hospital, forensic institution, laboratory or research institution.

2.2 Consent Options for Tissue Use

The *Human Tissue Act 1983* allows consent to be general. Unless otherwise stated, such as in the specific uses described below, the patient should be informed that the term

"therapeutic, medical and scientific purposes" has wide meaning and allows tissue to be used for a large variety of purposes. Where a person places limitations on their consent, the tissue may not be used outside the scope of the consent.

2.2.1 Research

Where tissue is removed from a living person as part of a medical, dental or surgical procedure:

a) Written consent for use of the tissue for research must be obtained from the person whilst alive (or the person with parental authority if they are a child) or, if the person has died, from their senior available next of kin after their death

b) Consent must be sought in accordance with the research protocol. Research participants should provided with an information sheet outlining the period of retention and the storage and disposal arrangements and copy of the consent form. See GL 2007_016 *Human Research Ethics Committees- Standardised Patient Information sheets (PIS)*

c) The project must have been approved by a Human Research Ethics Committee constituted in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research.

2.2.2 Tissues donated to tissue banks and biobanks

The person from whom the tissue is removed must consent to its retention and use in a pathology tissue collection, research tissue bank or biobank for uses such as education, training or research. Many research tissue banks or biobanks have their own specific consent forms. Banking of tissue for these purposes may require collection of the person's personal health information (See 2.2.3).

2.2.3 Consent to the collection and use of personal health information related to the retained tissue

If the purpose for which the tissue has been collected requires the collection, storage, linkage or potential disclosure of the person's personal health information this must be acknowledged in the consent documentation.

3 PROCEDURE FOR OBTAINING CONSENT TO THE DONATION OF TISSUE FROM LIVING PERSONS FOR TRANSPLANTATION

3.1 Consent and certification for the removal of the tissue from a living person for transplantation in to another person

Consent should follow the normal consent procedures outlined in PD 2005_406 *Consent to Medical Treatment - Patient Information*. The usual consent / request for medical treatment form should first be completed by the clinician (or their delegate) who will be performing the removal of tissue.

For certain living tissue donations the clinician responsible for the patient will need to ensure that the appropriate consent certificate is completed (see Attachments 2, 3 and 4). All consent forms attached to this policy include the relevant certificates. Restrictions

apply where it is proposed to remove tissue from a child (Sections 3.2.2, 3.3.1, 3.3.3, 3.4 and 3.5).

3.2 Certification requirements

3.2.1 Removal of tissue from a living adult

A medical officer who is **not involved** in the removal of the tissue should issue a certificate stating that

- The nature and effect of the tissue removal were explained before consent was given
- Written consent was given in the presence of the officer.

3.2.2 Removal of tissue from a living child

If tissue is to be removed from a child then the medical officer must state that this has been explained to the parent and the child and that the:

- Options for the use of tissue removed during the procedure have been explained and consented to by the patient/next-of-kin/child (if appropriate)
- Medical officer is satisfied that the patient or the parent / guardian and child were of sound mind and the consent was freely given
- Patient or parental authority has not subsequently revoked the written consent
- Child remains in agreement with the proposed tissue removal and transplantation.

3.3 Restrictions on the use of tissue from living persons

3.3.1 Mandatory 24 hour cooling off period

In all cases the removal of tissue cannot take place until 24 hours after the written consent was given.

3.3.2 Use of non – regenerative tissue from an adult

Apart from removal in the course of treatment carried out for the benefit of the adult, non-regenerative tissue may only be removed from the body of an adult person for transplantation purposes.

3.3.3 Use of non – regenerative tissue from a child

Non-regenerative tissue **may not** be removed from a living child unless removed during the course of treatment carried out for the benefit of the child.

3.4 Use of regenerative tissue from a child

The senior available next of kin may consent in writing to the use of regenerative tissue from a child only for transplant to a parent or sibling.

A senior available next of kin / guardian cannot give consent to or authorise the use of the tissue if it appears (after reasonable inquiry) that the child objects to the use of or purposes for which the tissue is to be used.

Consent to use the tissue may **not** be given if there is another next of kin of the same or higher degree of kinship who objects to the use of the tissue or to the purpose(s) for which the tissue is to be used.

3.5 Use of regenerative tissue from a child not capable of understanding the procedure

Section 11A of the *Human Tissue Act 1983* allows for bone marrow to be removed from a child donor who is too young to understand the procedure, where it is intended for transplantation into the child's sibling. The following conditions must be met before removal of bone marrow in this setting may proceed:

A medical practitioner must certify that:

a) Parental consent was given in the presence of the medical practitioner

b) Before consent was given, the medical practitioner explained the nature and effect of the removal of tissue from the child's body and the intended effect of the proposed transplantation

c) At the time of the consent, the medical practitioner is satisfied that the parent was of sound mind, understood the nature and effect of removal of the tissue, and that consent was freely given

d) The medical practitioner is of the opinion that the pre-conditions for child tissue donation (in this setting) are satisfied:

- The child, by reason of his or her age, is not capable of understanding the nature and effect of the removal of the tissue 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 tissue to be removed from the child is used in their treatment of that brother or sister
- Any risk to the child's health (including psychological or emotional health) caused by removal of tissue is minimal.

The above certification is effective only if a second medical practitioner, who is a specialist in paediatric medicine or paediatric transplantation certifies that:

a) He / she is of the opinion that the 'pre-conditions for child tissue donation' are met

b) He / 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

c) He / she is not responsible for care of the sibling in whose treatment the tissue is to be used.

As an alternative to the procedure set out under the *Human Tissue Act 1983*, 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 1983*. 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.

Public hospitals that carry out bone marrow transplantation must ensure that the provisions in the NSW *Human Tissue Act 1983* or the orders of the Family Court are followed and that local policy supports these provisions.

Should there be a difference of opinion between the Bone Marrow Transplantation specialist and the independent assessor of the patient, a second independent assessment of the donor should take place at another campus.

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.

4 ROLE OF DESIGNATED OFFICER – REVOCATION OF CONSENT

If the donor indicates that they wish to revoke their consent or in the case of child if the child no longer agrees with removal and transplantation of tissue, the Designated Officer for the hospital must be informed and act on this. For further information on the role of the Designated Officer see Policy Directive PD 2013_002 *Designated Officers, Policy and Procedures.*

5 CONSENT TO THE USE OF TISSUE REMOVED FROM LIVING PERSONS WHO SUBSEQUENTLY BECOME DECEASED

5.1 Consent for use of tissue removed from a person who subsequently dies

As outlined elsewhere in this policy it is best to obtain the consent of the person themselves, their senior available next of kin / person responsible / guardian as appropriate for the retention and future use of tissue to be removed during treatment before the prior to treatment commences.

The *Human Tissue Act 1983* allows for tissue removed during treatment to be retained for up to 72 hours in order to obtain consent. These situations may arise for example, where the person was an emergency patient who did not have the opportunity to consent before treatment and died during the course of their treatment.

Where a person was living when the tissue was removed and subsequently dies, only a senior available next of kin (or their delegate) may consent to the use of the deceased person's tissue. Consent must be recorded using the form *Consent and authority for the retention and use of tissue removed or expelled during treatment of a now deceased patient* (Attachment 5).

5.2 Restrictions on the use of tissue from children in the care of the State

Where tissue was removed from a living child who subsequently dies and the child immediately before their death was in care of the State, the tissue may not be used for any medical, therapeutic or scientific purposes other than donation for transplantation.

Where a clinician is unsure about the status of the child, he / she should make an application to the Department of Family and Community Services to ascertain the child's status before obtaining consent.

6 CONSENT OPTIONS FOR DISPOSAL OF TISSUE OR RETURN TO PATIENT OF TISSUE REMOVED DURING MEDICAL, SURGICAL OR DENTAL TREATMENT

If a patient consents to the use of their tissue for medical, therapeutic or scientific purposes, information should be provided at the time of obtaining consent as to how the tissue may be disposed of after the therapeutic, medical or scientific use has expired.

A patient may request that the tissue removed during their medical, surgical or dental treatment be returned to them for disposal. This request is often made in relation to foetal tissue under 20 weeks gestation and in some cultures to other tissues removed during treatment or expelled from the body such as placentas and amputated limbs.

Legally there is no ownership in excised body parts. However, if certain conditions are met there may be no objection to the patient taking home tissue removed or expelled from their body while they are in hospital.

A responsible medical practitioner should be satisfied that the arrangements for returning the tissue to the patient and the eventual method of retention or disposal do not present a public health risk. This will require the provision of additional information to the patient / senior available next of kin on the public health requirements as set out in Appendix 1 and completion of the *Authorisation for the release of human tissue to a patient or next of kin form* (Attachment 7).

If a patient does not consent to their tissue being used for other medical, therapeutic or scientific purposes and does not request its return, the tissue should be disposed of in accordance with usual waste management procedures.

Tissue returned to the patient / senior available next of kin or their delegate for appropriate storage or disposal should be triple packed as required by the National Pathology Accreditation Advisory Council's *Guidelines for Approved Pathology Collection Centres (2012*).

7 FORMS

In NSW standardised State Forms must be used for recording consent to the removal, collection, storage and use of human tissues. All forms in this policy may be obtained through your Local Health District/Specialty Network facility print manager.

8 LIST OF ATTACHMENTS

1. Procedures for the return of human tissue to the patient / next of kin
2. Consent and certification for the donation of tissue by a living adult (SMR 020.035)
3. Consent and certification for the donation of regenerative tissue by a living child (SMR 020.036)

4. Consent and Certification for regenerative tissue donation: Child not capable of understanding
5. Consent and authority for the retention and use of tissue removed or expelled during treatment of a deceased patient (SMR 020.034)
6. Authorisation to delegate responsibilities of next of kin (SMR 020.031)
7. Authorisation for the release of human tissue to a patient or next of kin (SMR 020.033)
8. Letter for travel with human tissue

ATTACHMENT 1

Procedures for the Return of Tissue to Patient / Next of Kin

The patient / next-of-kin may request that tissue be returned to them for disposal. This request may be made in relation to tissue removed during treatment or expelled from the body for example, foetal tissue under 20 weeks gestation, placentas and amputated limbs. For many patients this request will be made for cultural or religious reasons relating to bodily integrity and / or the appropriate disposal of remains.

Legally, there is no ownership in excised body parts and whilst there may be no objection to the patient wishing to take home tissue removed or expelled from their body while they were in hospital, a responsible medical practitioner or health professional should be satisfied that the arrangements for returning such tissue to the patient / next of kin do not present a risk to public health. This requires an assessment of the request by the health organisation and the provision of additional information to be given to the patient / next of kin.

The following guidelines describe the minimum requirements organisations should cover including the assessment process which should be undertaken and the information to be given to the patient / next of kin before the organisation agrees to return the tissue.

Assessment of Requests

Requests for the return of human tissue to the patient / next of kin for disposal should be assessed by the relevant senior medical or health care professional caring for the patient.

Any request made for the release of foetal tissue should be referred for assessment in conjunction with a social worker or counsellor.

Staff should facilitate discussion about what the patient / next of kin intends to do with the tissue and assessment should include:

- The grounds for the request
- The proposed storage and / or final disposal method for the material (which must be in keeping with the requirements of these guidelines)
- Whether the intended disposal method constitutes a public health or other safety risk (see below).

Where a patient indicates that they wish to bury a body on private land specific conditions apply (see below).

The patient / next of kin should be informed of the requirements of this policy and given the opportunity to clarify the requirements.

No trade in tissue

It should be made clear to the patient / next of kin that section 32 of the *Human Tissue Act 1983* makes it an offence to sell or supply (or offer to sell or supply) human tissue to another person for anything of valuable consideration.

Public health and safety requirements

Human tissue cannot be released where

a) It may be contaminated with cytotoxic, chemical or radioactive waste

b) It is reasonably believed to be infected with a prescribed infectious disease as defined in Clause 53 of the *Public Health Regulation 2012*.

Prior to disposal or transfer to another private storage arrangement the human tissue must not to be removed from the container in which it is released.

Disposal or other appropriate storage must take place within eight hours of the tissue being removed from the health organisation.

Documentation

Careful documentation of the assessment and discussion with the patient / next of kin should be made in the patient's medical record.

If a decision is made to release the human tissue for disposal, the form *Authorisation of the Release of Human Tissue to a Patient or Next of Kin* is to be completed by the patient / next of kin who is taking possession of the tissue. The original form should be filed in the medical record. A copy of the form and a letter certifying that the person is travelling with human tissue in their possession (see Attachment 6) should accompany the person with the tissue.

It must be clear to the person who receives the tissue that they are responsible for the safe and secure storage of the transferred tissue.

If the tissue to be returned is from a deceased person, the senior available next of kin should be asked to provide copies of appropriate identification for documentation. The senior available next of kin hierarchy can be found in the *Human Tissue Act 1983*.

Minimum requirements for the preparation and release of tissue

The officer who is preparing the human tissue for release for private disposal should have regard to their organisation's local protocol on the handling, storage and preparation of human tissue for transportation.

The tissue may be immersed in formalin but must be drained and must not be released in formalin. It is important in some cultures that placental tissue IS NOT placed in formalin.

The National Pathology Accreditation Advisory Council's Guidelines on the *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials* recommend triple packaging for the transport of all human tissues and substances.

A label identifying the tissue should be affixed to the container. The outer container should be marked "Tissue for collection by" and include the name of patient / next of kin / mother (for foetal tissue under 20 weeks gestation) and the date of the procedure / miscarriage / death.

The container containing the tissue should be stored in a refrigerated unit by the organisation pending collection by the patient / next of kin / other delegated person who will collect the tissue.

If the tissue is to be transported by the patient / next of kin it should be placed on ice in a waterproof container when released to the patient / next of kin. Dry ice cannot be used as it has potential hazards. Refrigerated transport must be used where the journey is more than eight hours.

Options for tissue disposal for discussion with patient / families

Patients / next of kin may ask what alternative disposal methods the organisation might offer. Staff should give honest information on their organisation's protocol for the disposal of human tissues.

Burial or cremation of tissue at the patient / next of kin's expense

This option is often the choice for patients from cultures where it is important that all bodily remains are eventually reunited at death. Fees for cremation of individual tissues may be expensive and families should be encouraged to check these costs before making a decision.

Crematoriums require a letter from a medical officer certifying that the tissue is the "tissue / limb / etc. of patient x". A letter will also be required from the patient stating that they request cremation of the tissue (limb etc.).

The patient will need to organise transport of the tissue to the crematorium.

Burial or cremation of foetal tissue

Some families may choose to arrange their own funeral service and cremation or burial of fetal tissue (less than 20 weeks gestation), which is at their own expense. Crematoriums require a letter from a medical officer certifying that the tissue is the fetal tissue and noting the gestational age. The family may transport the appropriately packaged tissue to the funeral director / crematorium themselves.

Some Local Health Districts / Specialty Networks offer a service that provides group cremation of fetal tissues and the scattering of the ashes in a memorial garden as an alternative to private arrangements.

Burial on private land

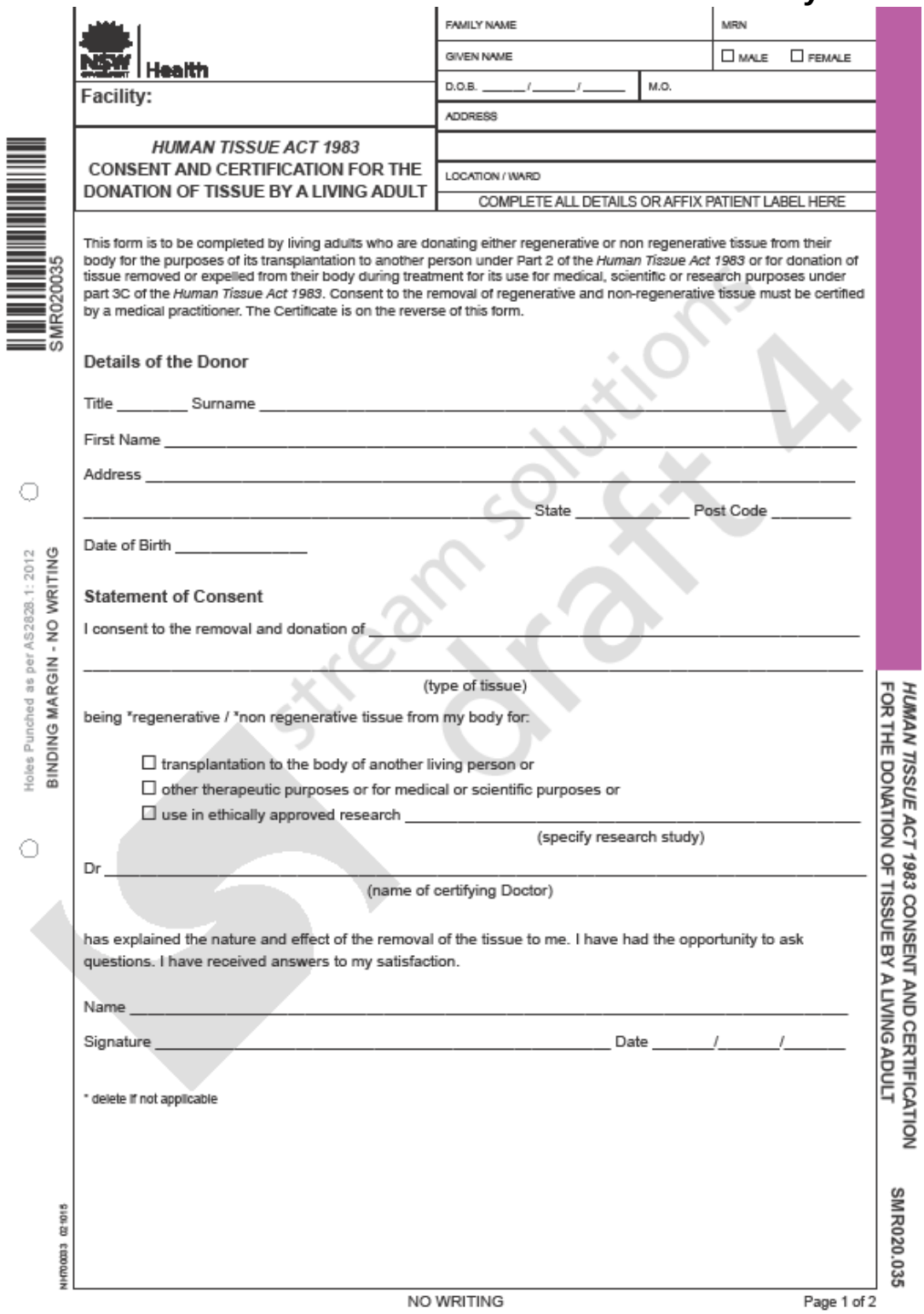
In addition to the public health requirements set out above, burial of a body on private land or in a garden will require council consideration. GL2013_016 *Guidance on Burying a Body on Private Land - Public Health Regulation 2012* outlines the requirements that must be considered. These include:

- The total landholding must be equal to or exceed five hectares
- Bodies must be buried at a minimum depth of 900 millimetres
- Bodies must be placed in a coffin prior to burial
- A geotechnical investigation may be considered if there is any likelihood of contamination of ground waters and/or surface waters.

Full details are available within the guideline.

ATTACHMENT 2:

Consent and Certification for the Donation of Tissue by a Living Adult



NSW Health

Facility:

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

D.O.B. _____/_____/_____ | M.O.

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

HUMAN TISSUE ACT 1983
CONSENT AND CERTIFICATION FOR THE DONATION OF TISSUE BY A LIVING ADULT

SMR020035

Holes Punched as per AS2828.1: 2012
BINDING MARGIN - NO WRITING

This form is to be completed by living adults who are donating either regenerative or non regenerative tissue from their body for the purposes of its transplantation to another person under Part 2 of the *Human Tissue Act 1983* or for donation of tissue removed or expelled from their body during treatment for its use for medical, scientific or research purposes under part 3C of the *Human Tissue Act 1983*. Consent to the removal of regenerative and non-regenerative tissue must be certified by a medical practitioner. The Certificate is on the reverse of this form.

Details of the Donor

Title _____ Surname _____

First Name _____

Address _____

_____ State _____ Post Code _____

Date of Birth _____

Statement of Consent

I consent to the removal and donation of _____

_____
(type of tissue)

being *regenerative / *non regenerative tissue from my body for:

☐ transplantation to the body of another living person or
☐ other therapeutic purposes or for medical or scientific purposes or
☐ use in ethically approved research _____
(specify research study)

Dr _____
(name of certifying Doctor)

has explained the nature and effect of the removal of the tissue to me. I have had the opportunity to ask questions. I have received answers to my satisfaction.

Name _____

Signature _____ Date _____/_____/_____

* delete if not applicable

HUMAN TISSUE ACT 1983 CONSENT AND CERTIFICATION FOR THE DONATION OF TISSUE BY A LIVING ADULT

SMR020.035

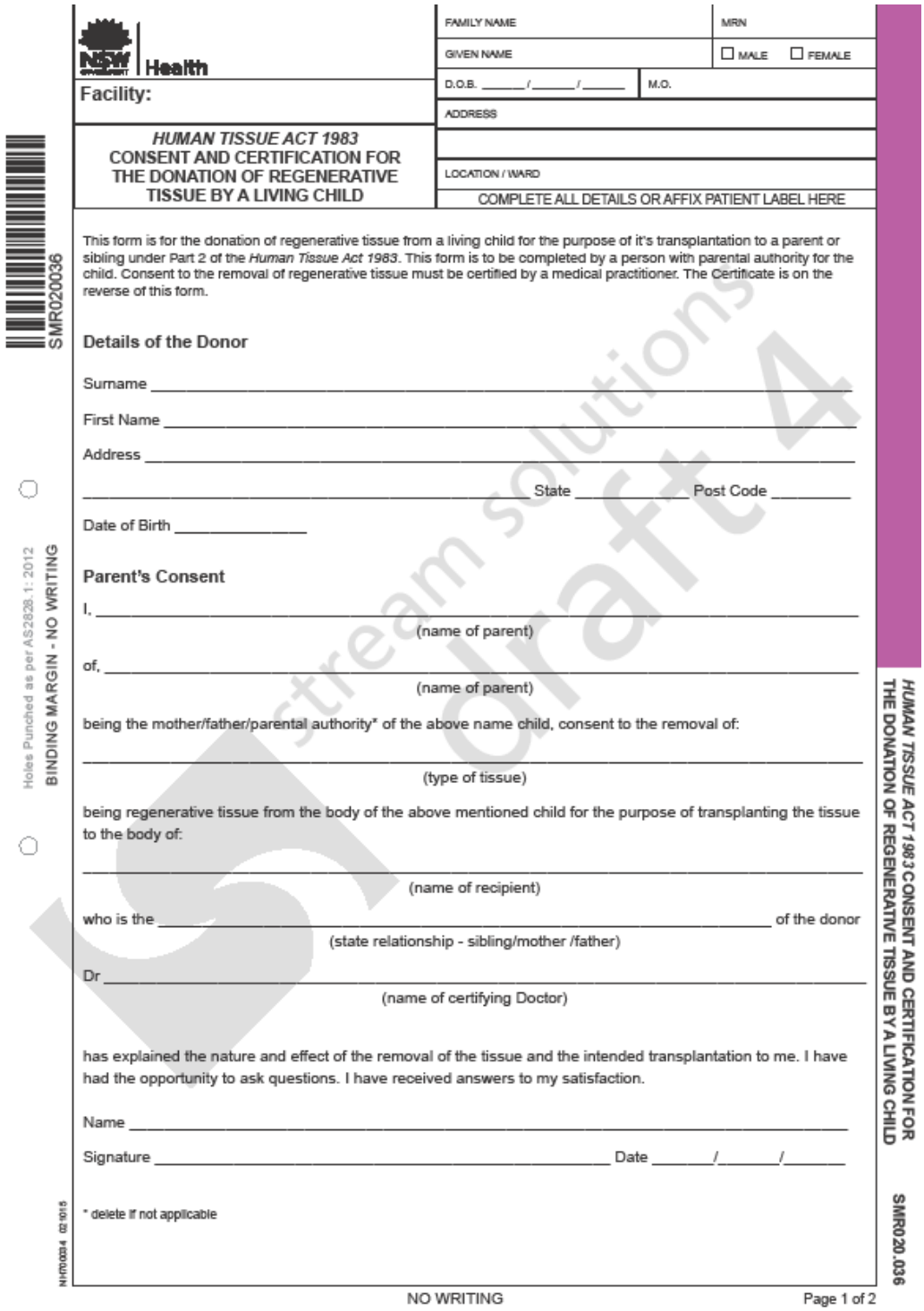
NH70003 02/2015

NO WRITING

Page 1 of 2

ATTACHMENT 3:

Consent and Certification for the Donation of Regenerative Tissue by a Living Child



NSW Health

Facility:

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

D.O.B. _____/_____/_____ | M.O.

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

SMR020036

HUMAN TISSUE ACT 1983
CONSENT AND CERTIFICATION FOR THE DONATION OF REGENERATIVE TISSUE BY A LIVING CHILD

This form is for the donation of regenerative tissue from a living child for the purpose of it's transplantation to a parent or sibling under Part 2 of the *Human Tissue Act 1983*. This form is to be completed by a person with parental authority for the child. Consent to the removal of regenerative tissue must be certified by a medical practitioner. The Certificate is on the reverse of this form.

Details of the Donor

Surname _____

First Name _____

Address _____

_____ State _____ Post Code _____

Date of Birth _____

Parent's Consent

I, _____
(name of parent)

of, _____
(name of parent)

being the mother/father/parental authority* of the above name child, consent to the removal of:

_____
(type of tissue)

being regenerative tissue from the body of the above mentioned child for the purpose of transplanting the tissue to the body of:

_____
(name of recipient)

who is the _____ of the donor
(state relationship - sibling/mother /father)

Dr _____
(name of certifying Doctor)

has explained the nature and effect of the removal of the tissue and the intended transplantation to me. I have had the opportunity to ask questions. I have received answers to my satisfaction.

Name _____

Signature _____ Date _____/_____/_____

* delete if not applicable

HH170034 02.2015

Holes Punched as per AS2828.1: 2012
BINDING MARGIN - NO WRITING

HUMAN TISSUE ACT 1983 CONSENT AND CERTIFICATION FOR THE DONATION OF REGENERATIVE TISSUE BY A LIVING CHILD

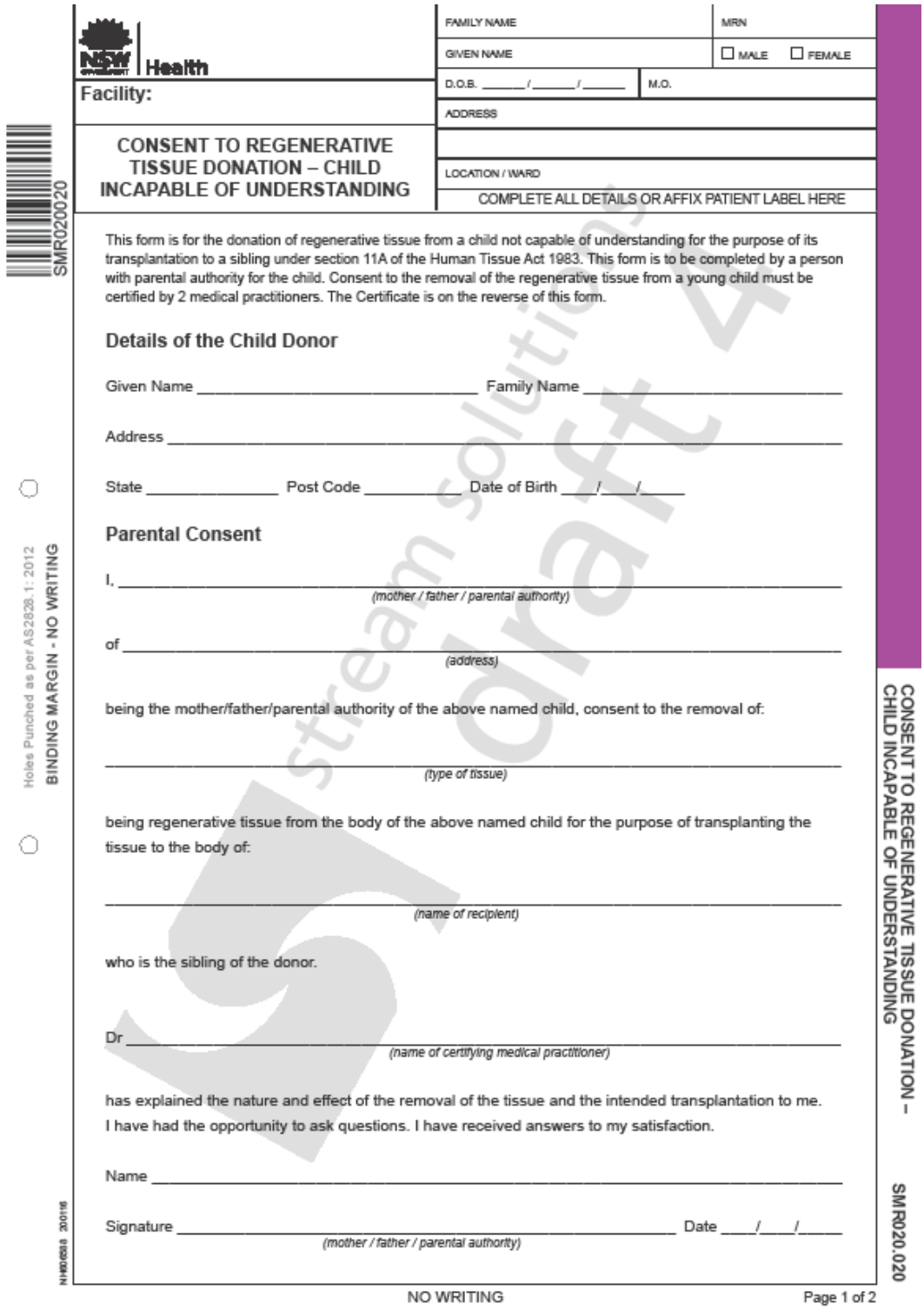
SMR020.036

NO WRITING

Page 1 of 2

ATTACHMENT 4

Consent and Certification for Regenerative Tissue Donation: Child Not Capable of Understanding



NSW Health

Facility:

CONSENT TO REGENERATIVE TISSUE DONATION – CHILD INCAPABLE OF UNDERSTANDING

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

D.O.B. _____/_____/_____ | M.O.

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

SMR020020

This form is for the donation of regenerative tissue from a child not capable of understanding for the purpose of its transplantation to a sibling under section 11A of the Human Tissue Act 1983. This form is to be completed by a person with parental authority for the child. Consent to the removal of the regenerative tissue from a young child must be certified by 2 medical practitioners. The Certificate is on the reverse of this form.

Details of the Child Donor

Given Name _____ Family Name _____

Address _____

State _____ Post Code _____ Date of Birth ___/___/_____

Parental Consent

I, _____
(mother / father / parental authority)

of _____
(address)

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

_____
(type of tissue)

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

_____
(name of recipient)

who is the sibling of the donor.

Dr _____
(name of certifying medical practitioner)

has explained the nature and effect of the removal of the tissue and the intended transplantation to me. I have had the opportunity to ask questions. I have received answers to my satisfaction.

Name _____

Signature _____ Date ___/___/_____
(mother / father / parental authority)

Holes Punched as per AS2828.1: 2012
BINDING MARGIN - NO WRITING

CONSENT TO REGENERATIVE TISSUE DONATION – CHILD INCAPABLE OF UNDERSTANDING

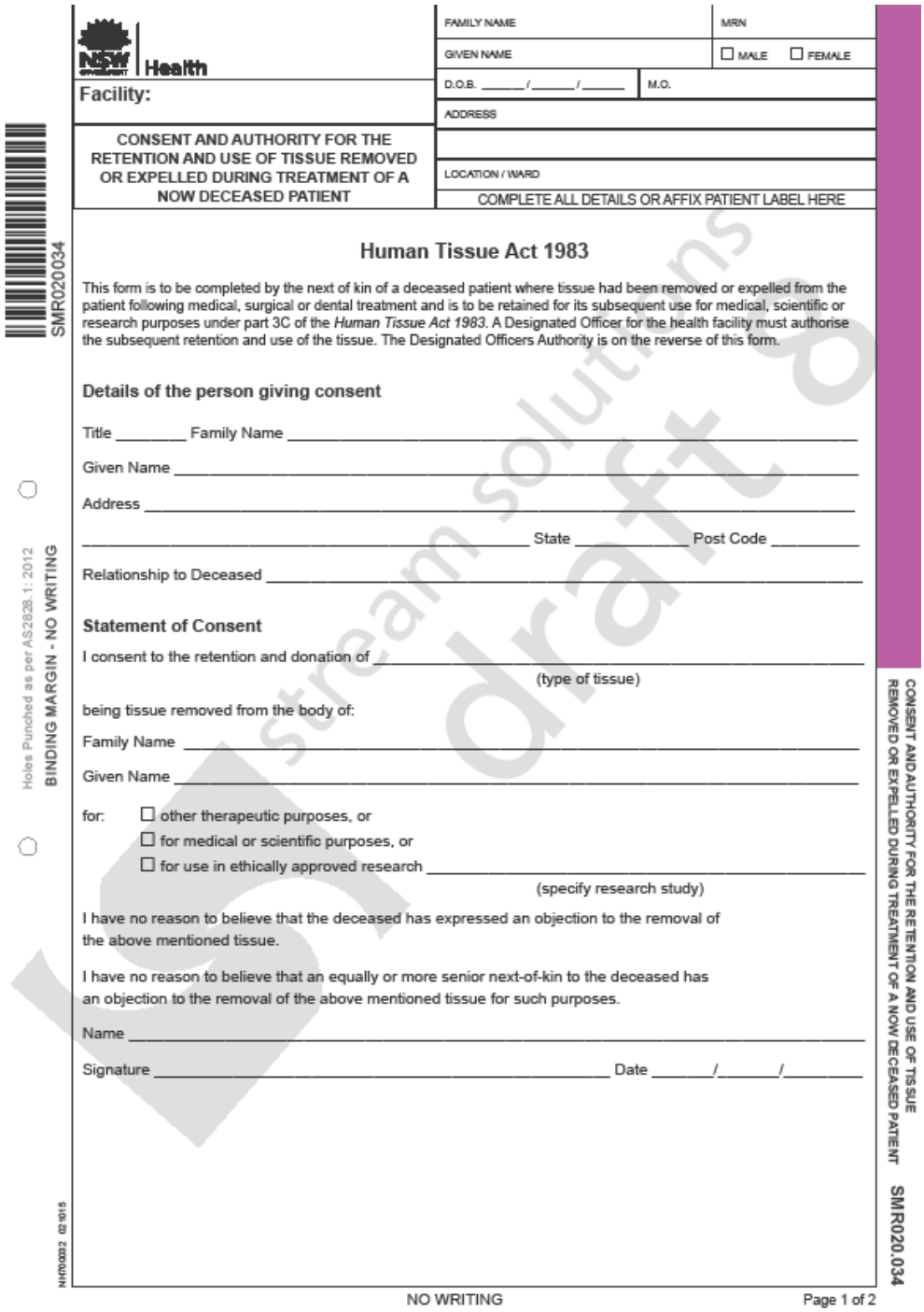
SMR020.020

NO WRITING

Page 1 of 2

ATTACHMENT 5:

Consent and Authority for the Retention and use of Tissue Removed or Expelled During Treatment of a Now Deceased Patient



NSW Health

Facility:

CONSENT AND AUTHORITY FOR THE RETENTION AND USE OF TISSUE REMOVED OR EXPELLED DURING TREATMENT OF A NOW DECEASED PATIENT

FAMILY NAME | MRN
GIVEN NAME | ☐ MALE ☐ FEMALE
D.O.B. ____/____/____ | M.O.
ADDRESS
LOCATION / WARD
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

SMR020034

Holes Punched as per AS2828.1: 2012 BINDING MARGIN - NO WRITING

Human Tissue Act 1983

This form is to be completed by the next of kin of a deceased patient where tissue had been removed or expelled from the patient following medical, surgical or dental treatment and is to be retained for its subsequent use for medical, scientific or research purposes under part 3C of the *Human Tissue Act 1983*. A Designated Officer for the health facility must authorise the subsequent retention and use of the tissue. The Designated Officers Authority is on the reverse of this form.

Details of the person giving consent

Title _____ Family Name _____

Given Name _____

Address _____

_____ State _____ Post Code _____

Relationship to Deceased _____

Statement of Consent

I consent to the retention and donation of _____
(type of tissue)

being tissue removed from the body of:

Family Name _____

Given Name _____

for: ☐ other therapeutic purposes, or
☐ for medical or scientific purposes, or
☐ for use in ethically approved research _____
(specify research study)

I have no reason to believe that the deceased has expressed an objection to the removal of the above mentioned tissue.

I have no reason to believe that an equally or more senior next-of-kin to the deceased has an objection to the removal of the above mentioned tissue for such purposes.

Name _____

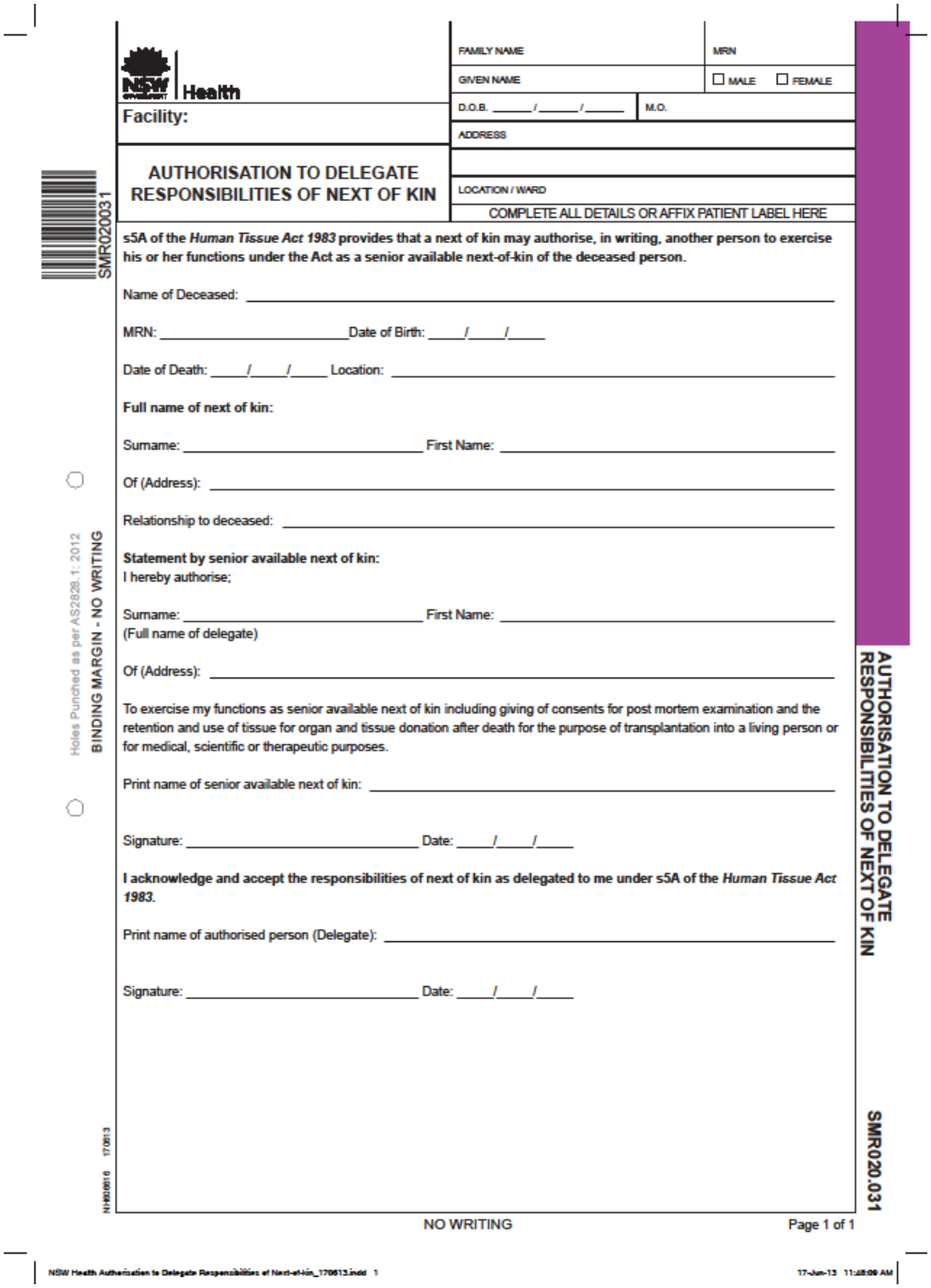
Signature _____ Date ____/____/____

CONSENT AND AUTHORITY FOR THE RETENTION AND USE OF TISSUE REMOVED OR EXPELLED DURING TREATMENT OF A NOW DECEASED PATIENT SMR020.034

NH70032 02:1015

NO WRITING Page 1 of 2

ATTACHMENT 6
Authorisation to Delegate Responsibilities of Next of Kin



NSW Health

Facility:

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

D.O.B. ____/____/____ | M.O.

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

SMR020031

AUTHORISATION TO DELEGATE RESPONSIBILITIES OF NEXT OF KIN

s5A of the *Human Tissue Act 1983* provides that a next of kin may authorise, in writing, another person to exercise his or her functions under the Act as a senior available next-of-kin of the deceased person.

Name of Deceased: _____

MRN: _____ Date of Birth: ____/____/____

Date of Death: ____/____/____ Location: _____

Full name of next of kin:

Surname: _____ First Name: _____

Of (Address): _____

Relationship to deceased: _____

Statement by senior available next of kin:
I hereby authorise;

Surname: _____ First Name: _____
(Full name of delegate)

Of (Address): _____

To exercise my functions as senior available next of kin including giving of consents for post mortem examination and the retention and use of tissue for organ and tissue donation after death for the purpose of transplantation into a living person or for medical, scientific or therapeutic purposes.

Print name of senior available next of kin: _____

Signature: _____ Date: ____/____/____

I acknowledge and accept the responsibilities of next of kin as delegated to me under s5A of the *Human Tissue Act 1983*.

Print name of authorised person (Delegate): _____

Signature: _____ Date: ____/____/____

Holes Punched as per AS2828.1: 2012
BINDING MARGIN - NO WRITING

AUTHORISATION TO DELEGATE RESPONSIBILITIES OF NEXT OF KIN
SMR020.031

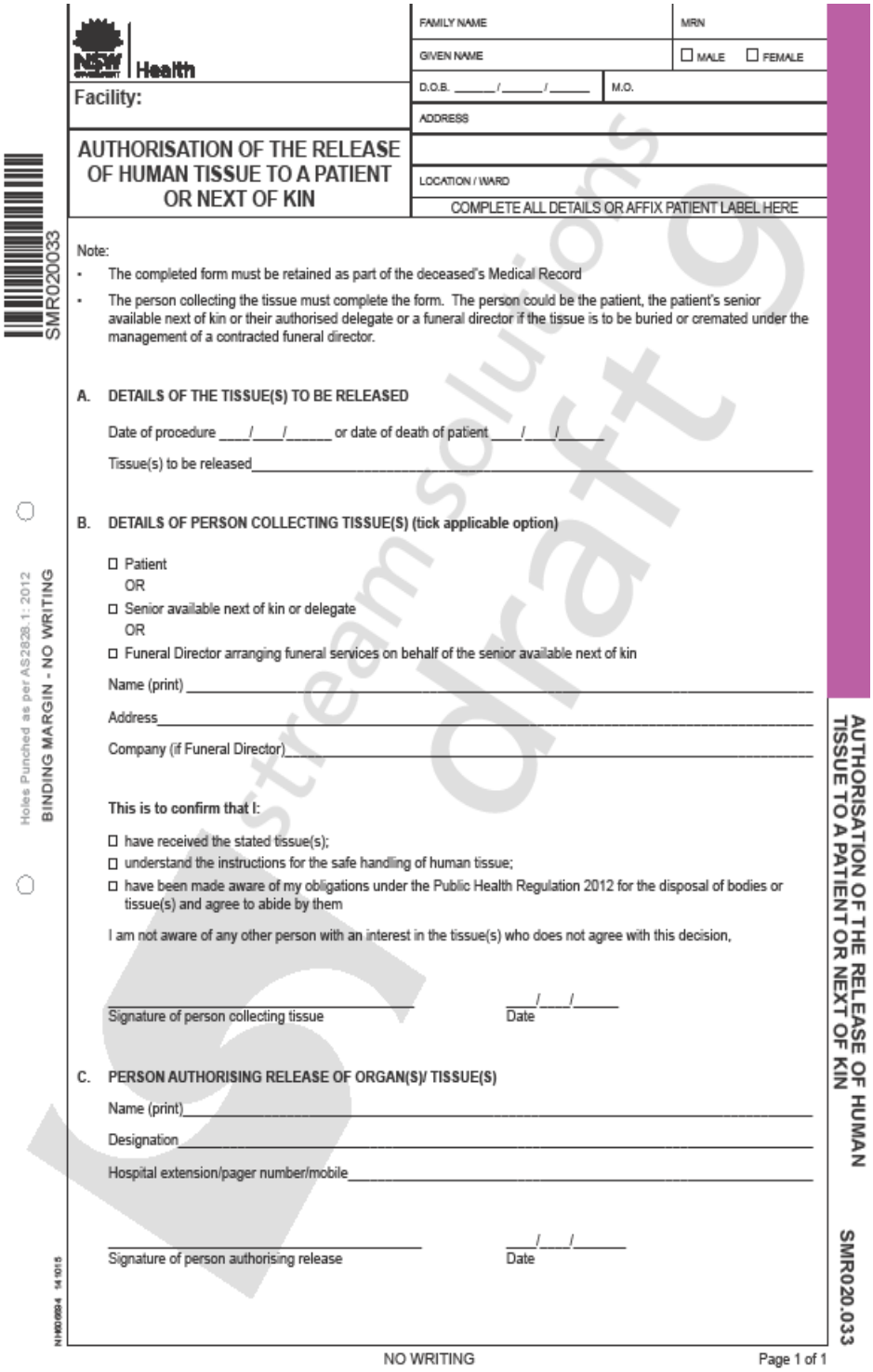
NH900816 170613

NO WRITING

Page 1 of 1

NSW Health Authorisation to Delegate Responsibilities of Next-of-kin_170613.indd 1 17-Jun-13 11:48:06 AM

ATTACHMENT 7
Authorisation for the Release of Human Tissue to a Patient or Next of Kin



NSW Health

Facility:

AUTHORISATION OF THE RELEASE OF HUMAN TISSUE TO A PATIENT OR NEXT OF KIN

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

D.O.B. _____/_____/_____ | M.O.

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

SMR020033

Note:

- The completed form must be retained as part of the deceased's Medical Record
- The person collecting the tissue must complete the form. The person could be the patient, the patient's senior available next of kin or their authorised delegate or a funeral director if the tissue is to be buried or cremated under the management of a contracted funeral director.

A. DETAILS OF THE TISSUE(S) TO BE RELEASED

Date of procedure ____/____/_____ or date of death of patient ____/____/_____

Tissue(s) to be released_____

B. DETAILS OF PERSON COLLECTING TISSUE(S) (tick applicable option)

☐ Patient
OR
☐ Senior available next of kin or delegate
OR
☐ Funeral Director arranging funeral services on behalf of the senior available next of kin

Name (print) _____

Address_____

Company (if Funeral Director)_____

This is to confirm that I:

☐ have received the stated tissue(s);
☐ understand the instructions for the safe handling of human tissue;
☐ have been made aware of my obligations under the Public Health Regulation 2012 for the disposal of bodies or tissue(s) and agree to abide by them

I am not aware of any other person with an interest in the tissue(s) who does not agree with this decision.

_____ ____/____/_____
Signature of person collecting tissue Date

C. PERSON AUTHORISING RELEASE OF ORGAN(S)/ TISSUE(S)

Name (print)_____

Designation_____

Hospital extension/pager number/mobile_____

_____ ____/____/_____
Signature of person authorising release Date

Holes Punched as per AS2828.1: 2012
BINDING MARGIN - NO WRITING

AUTHORISATION OF THE RELEASE OF HUMAN TISSUE TO A PATIENT OR NEXT OF KIN SMR020.033

NH02.0884 141015

NO WRITING Page 1 of 1

ATTACHMENT 8
Example of Letter to be Issued to Person Travelling With Human Tissue in Their Possession (On Facility Letterhead)

To whom it may concern,

This is to certify that _____
(Name of person authorised to travel with human tissue in their possession)

Is travelling with human tissue in their possession.

The tissue is sealed inside a container and there is no risk associated with transporting the tissue stored in this manner.

Person certifying the packaging of the tissue:

Name: _____

Designation: _____

Institution/Hospital: _____

Contact: _____

Signature of authorising person: _____

Date: ____/_____/_____