

# **Human Tissue Act 1983 No 164**

[1983-164]



## **Status Information**

# **Currency of version**

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#### **Provisions in force**

The provisions displayed in this version of the legislation have all commenced.

#### **Responsible Minister**

- · Minister for Health
- · Minister for Regional Health
- · Minister for Mental Health

For full details of Ministerial responsibilities, see the Administrative Arrangements (Minns Ministry—Administration of Acts) Order 2023.

#### **Authorisation**

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# **Human Tissue Act 1983 No 164**



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# **Human Tissue Act 1983 No 164**



An Act relating to the donation of tissue by living persons, the removal of tissue from deceased persons, the conduct of post-mortem examinations of deceased persons, and certain other matters.

# Part 1 Preliminary

#### 1 Name of Act

This Act may be cited as the *Human Tissue Act 1983*.

#### 2 Commencement

- (1) Sections 1 and 2 shall commence on the date of assent to this Act.
- (2) Except as provided by subsection (1), this Act shall commence on such day as may be appointed by the Governor in respect thereof and as may be notified by proclamation published in the Gazette.

#### 3 (Repealed)

#### 4 Definitions

(1) In this Act, except in so far as the context or subject-matter otherwise indicates or requires—

**blood product** means a product or extract derived or extracted from blood by any process of manufacture.

**child** means a person who has not attained the age of 18 years and who is not married.

#### designated officer means—

- (a) in relation to a hospital, a person appointed for the time being under section 5 (1)(a) to be a designated officer for the hospital, or
- (b) in relation to a forensic institution, a person appointed for the time being under section 5 (3) to be a designated officer for the forensic institution.

**designated specialist**, in relation to a hospital, means a person appointed for the time being under section 5 (1) (b) to be a designated specialist for the hospital.

**donor**, in relation to blood, means the person from whom the blood has been removed.

#### exempt supplier-

- (a) in relation to the supply of blood or a blood product, means—
  - (i) the Australian Red Cross Society, or
  - (ii) the governing body of a hospital, or
  - (iii) any other body declared by the regulations to be an exempt supplier for the purposes of this Act, or
- (a1) in relation to the supply of blood products that are therapeutic goods within the meaning of the *Therapeutic Goods Act 1989* of the Commonwealth and that are registered goods within the meaning of that Act—a body that supplies those goods, or
- (a2) in relation to the supply of blood products that are therapeutic goods within the meaning of the *Therapeutic Goods Act 1989* of the Commonwealth and that are exempt goods for the purposes of Part 3–2 of that Act—a body that supplies those goods in compliance with the conditions (if any) of the relevant exemption.
- (b) (Repealed)

exercise a function includes perform a duty.

#### forensic institution means—

- (a) an institution that is under the control of a public health organisation (within the meaning of the *Health Services Act 1997*), or
- (b) an accredited pathology laboratory under the *Health Insurance Act 1973* of the Commonwealth, or
- (c) an institution that is under the control of the Health Administration Corporation,

at which post-mortem examinations of human bodies are carried out, but does not include a hospital.

**function** includes a power, authority or duty.

#### governing body means—

(a) in relation to a hospital—

- (i) in the case of a public hospital that is controlled by a public health organisation within the meaning of the *Health Services Act 1997*—the public health organisation, or
- (ii) in the case of a public hospital within the meaning of the *Health Services Act* 1997 that is controlled by the Crown (including the Minister or the Health Administration Corporation)—the Crown, or
- (iii) in the case of a private health facility within the meaning of the *Private Health* Facilities Act 2007—the licensee of the facility, or
- (b) in relation to a forensic institution—
  - (i) in the case of a forensic institution that is controlled by a public health organisation within the meaning of the *Health Services Act 1997*—the public health organisation, or
  - (ii) in the case of an accredited pathology laboratory under the *Health Insurance*Act 1973 of the Commonwealth—the person in charge of the laboratory (however designated), or
  - (iii) in the case of a forensic institution that is controlled by the Health Administration Corporation—the Health Secretary.

Health Secretary means the Secretary of the Ministry of Health.

#### hospital means—

- (a) a public hospital within the meaning of the Health Services Act 1997, or
- (b) a private health facility within the meaning of the *Private Health Facilities Act* 2007.

inspector means a person appointed as an inspector under Part 7A.

**medical, dental or surgical treatment** means 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 the person.

#### next of kin means—

- (aa) in relation to a child who is living—a person referred to in paragraph (aa) of the definition of **senior available next of kin**, and
- (a) in relation to a deceased child—a person referred to in paragraph (a) of the definition of **senior available next of kin**, and
- (b) in relation to any other deceased person—a person referred to in paragraph (b) of that definition.

non-regenerative tissue means tissue other than regenerative tissue.

premises includes any means of vehicular transport.

**prescribed contaminant** means an organism or substance declared by the regulations to be a prescribed contaminant for the purposes of this Act.

**record** includes book, account, deed, writing, document and any other source of information compiled, recorded or stored in written form, or on micro-film, or by electronic process, or in any other manner or by any other means.

**regenerative tissue** means tissue that, after injury or removal, is replaced in the body of a living person by natural processes of growth or repair.

**regulation** means a regulation made under this Act.

senior available next of kin, other than in Part 4A, means—

- (aa) in relation to a child who is living-
  - (i) a parent of the child, or
  - (ii) if no person referred to in subparagraph (i) is available—a person who is a guardian of the child, and
- (a) in relation to a deceased child—
  - (i) a parent of the child,
  - (ii) where a parent of the child is not available—a brother or sister of the child, being a brother or sister who has attained the age of 18 years, or
  - (iii) where no person referred to in subparagraph (i) or (ii) is available—a person who was a guardian of the child immediately before the death of the child, and
- (b) in relation to any other deceased person—
  - (i) a person who was a spouse of the deceased person immediately before the deceased person's death,
  - (ii) where the deceased person, immediately before death, had no spouse or where the deceased person had a spouse but the person who was then the deceased person's spouse is not available—a son or daughter (if any) of the deceased person, being a son or daughter who has attained the age of 18 years,
  - (iii) where no person referred to in subparagraph (i) or (ii) is available—a parent of the deceased person, or
  - (iv) where no person referred to in subparagraph (i), (ii) or (iii) is available—a

brother or sister of the deceased person, being a brother or sister who has attained the age of 18 years.

#### spouse means—

- (a) the person to whom a person is legally married (including the husband or wife of a person), or
- (b) a de facto partner,

but where more than one person would so qualify as a spouse, means only the last person so to qualify.

#### Note-

"De facto partner" is defined in section 21C of the Interpretation Act 1987.

**supply** means supply by way of sale, exchange or gift, and includes receive, keep or store for the purpose of supply.

**tissue** includes an organ, or part, of a human body and a substance extracted from, or from a part of, the human body.

#### Note-

The *Interpretation Act 1987* contains definitions and other provisions that affect the interpretation and application of this Act.

- (1A) The regulations may—
  - (a) prescribe additional bodily materials or classes or types of bodily materials as tissue for the purposes of this Act, and
  - (b) exclude bodily materials or classes or types of bodily materials from being tissue for the purposes of this Act.
- (2) In this Act—
  - (a) a reference to a parent of a person includes a reference to the following—
    - (i) a step-parent of the person,
    - (ii) an adoptive parent of the person,
    - (iii) the Minister administering the *Children and Young Persons (Care and Protection) Act 1998*, if the Minister has sole parental responsibility in respect of the person (whether under that Act or otherwise),
  - (b) a reference to a son or daughter of a person includes a reference to any person of whom the person is a parent,
  - (c) a reference to a brother or sister of a person includes a reference to any person

who is a son or daughter of a parent of the person, and

- (d) (Repealed)
- (2A) In this Act, except in so far as the context or subject-matter otherwise indicates or requires, a reference to tissue includes a reference to—
  - (aa) blood,
  - (a) ova and semen, and
  - (b) foetal tissue.
- (3) In this Act, a reference to the transplantation of tissue includes a reference to—
  - (a) the transplantation of any part of the tissue, and
  - (b) the transplantation of any substance obtained from the tissue,
  - and, without limiting the generality of the foregoing, includes a reference to the transfusion of blood.
- (4) In this Act, a reference to the removal of blood (however expressed) for any specified purpose includes a reference to the removal of blood so that a product to be derived or extracted from that blood may be used for that purpose.
- (5) In this Act, a reference to tissue removed from the body of a living person in the course of medical, dental or surgical treatment includes—
  - (a) tissue expelled from the body of the person in the course of the treatment, and
  - (b) all tissue removed or expelled from the body of the person in the course of the treatment, even if the person dies during the course of the treatment.
- (6) In this Act, a reference to medical or scientific purposes includes educational purposes connected with medicine or science.
- (7) For the purposes of this Act, a child is *in the care of the State* if—
  - (a) a Minister administering the *Children and Young Persons (Care and Protection) Act* 1998 has sole parental responsibility in respect of the child (whether under that Act or otherwise), or
  - (b) the Secretary under the *Children and Young Persons (Care and Protection) Act* 1998 has sole parental responsibility in respect of the child (whether under that Act or otherwise).
- (8) For this Act, the *principal care officer*, in relation to a child in the care of the State, means the Secretary under the *Children and Young Persons (Care and Protection) Act* 1998.

#### **4A Notes**

Notes included in this Act do not form part of this Act.

#### 5 Designated officers and designated specialists

- (1) The governing body of a hospital may, by instrument in writing—
  - (a) appoint such persons as the governing body considers necessary to be designated officers for the hospital, and
  - (b) except as provided by subsection (2), appoint such persons as the governing body considers necessary to be designated specialists for the hospital.
- (2) The governing body of a hospital shall not appoint a person to be a designated specialist for the hospital unless the person is a medical practitioner—
  - (a) whose appointment as a designated specialist for the hospital is for the time being approved by the Secretary of the Department of Health, or
  - (b) who is a member of a prescribed class of medical practitioners.
- (3) The governing body of a forensic institution may, by instrument in writing, appoint such persons as the governing body considers necessary to be designated officers for the forensic institution.

#### 5A Delegation of functions of next of kin

- (1) A next of kin of a deceased person may from time to time, by instrument in writing, authorise a person to exercise his or her functions under this Act as a next of kin of the deceased person.
- (2) In such a case, the person so authorised—
  - (a) may exercise the functions of a next of kin of the deceased person under this Act (other than the function conferred by subsection (1)), in the place of the person who authorised him or her, and
  - (b) is taken, for the purposes of this Act, to be a next of kin of the deceased person, and
  - (c) for the purposes of the definition of **senior available next of kin** in section 4 (1), is taken to be a next of kin of the same order as the person who authorised him or her to exercise the functions of a next of kin.

#### 5B Delegation of functions of principal care officer

The Secretary under the *Children and Young Persons (Care and Protection) Act 1998* may delegate to a person the Secretary's functions as principal care officer under this Act.

# Part 2 Donations of tissue by living persons

#### Division 1 Exclusion of certain tissue

#### 6 Definition

In this Part, a reference to tissue does not include a reference to ova, semen or foetal tissue.

# **Division 2 Donations by adults**

#### 7 Consents to removal of regenerative tissue from adults

A person, other than a child, may give consent in writing to the removal from the person's body of specified regenerative tissue for the purpose of—

- (a) its transplantation to the body of another living person, or
- (b) its use for other therapeutic purposes or for medical purposes or scientific purposes.

#### 8 Consents to removal of non-regenerative tissue from adults

- (1) A person, other than a child, may give consent in writing to the removal from the person's body, at any time after the expiration of 24 hours after the consent is given, of specified non-regenerative tissue for the purpose of its transplantation to the body of another living person.
- (2) A consent given under subsection (1) shall specify the day on which, and the time at which, it is given.

#### 9 Medical practitioners' certificates

A medical practitioner may certify in writing—

- (a) that the consent in writing of a person, the terms of which consent are set out in the certificate, was given in the presence of the medical practitioner,
- (b) that the medical practitioner explained to the person, before the consent was given, the nature and effect of the removal from the body of that person of the tissue specified in the consent, and
- (c) that the medical practitioner is satisfied that, at the time the consent was given—
  - (i) the person was not a child,
  - (ii) the person was of sound mind, and
  - (iii) the consent was freely given.

# Division 3 Donations by children

#### 10 Consents to removal of regenerative tissue from children

A parent of a child may give consent in writing to the removal from the child's body of specified regenerative tissue for the purpose of its transplantation to the body of a parent (being a biological parent, step-parent or adoptive parent), brother or sister of the child.

Note—

A child must understand the nature and effect of the removal of tissue if a medical practitioner's certificate is to be issued under section 11. If a child is not capable of such understanding, a medical practitioner's certificate must be issued under section 11A and only transplantation to the body of a brother or sister is allowed.

#### 11 Medical practitioners' certificates

A medical practitioner may certify in writing—

- (a) that the consent in writing of a parent of a child, the terms of which consent are set out in the certificate, was given in the presence of the medical practitioner,
- (b) that the medical practitioner explained to the parent and to the child, before the consent was given, the nature and effect of the removal from the child's body of the tissue specified in the consent and the intended effect of its proposed transplantation, and
- (c) that the medical practitioner is satisfied that, at the time the consent was given—
  - (i) the parent and the child were each of sound mind,
  - (ii) the parent and the child each understood the nature and effect of the removal of the tissue and the intended effect of its proposed transplantation,
  - (iii) the consent was freely given, and
  - (iv) the child was in agreement with the proposed removal and transplantation of the tissue.

#### 11A Medical practitioners' certificate—child not capable of understanding

- (1) A medical practitioner who is of the opinion that a child is not, by reason of his or her age, capable of understanding the nature and effect of the removal of tissue from his or her body and the intended effect of its proposed transplantation, may certify in writing that—
  - (a) the consent in writing of a parent of a child, the terms of which consent are set out in the certificate, was given in the presence of the medical practitioner, and
  - (b) the medical practitioner explained to the parent, before the consent was given, the nature and effect of the removal from the child's body of the tissue specified in the consent and the intended effect of its proposed transplantation, and

- (c) the medical practitioner is satisfied that—
  - (i) at the time the consent was given, the parent was of sound mind, and
  - (ii) at the time the consent was given, the parent understood the nature and effect of the removal of the tissue and the intended effect of its proposed transplantation, and
  - (iii) the consent was freely given, and
- (d) the medical practitioner is of the opinion that the following conditions (**the pre-conditions for child tissue donation**) are satisfied—
  - (i) 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 transplantation,
  - (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 tissue intended to be removed from the child is used in the treatment of that brother or sister.
  - (iii) any risk to the child's health (including psychological and emotional health) caused by the removal of the tissue is minimal.
- (2) A certificate by a medical practitioner to the effect that the pre-conditions for child tissue donation are satisfied is effective only if a second medical practitioner, who is a specialist in paediatric medicine or paediatric transplants, also certifies in the certificate that—
  - (a) he or she is of the opinion that those pre-conditions are satisfied, and
  - (b) he or she provides that opinion as an independent medical practitioner, being a medical practitioner—
    - (i) whose primary role in providing an opinion in the case is to ensure the health of the child from whom the tissue is to be removed, and
    - (ii) who is not responsible for the care of the brother or sister in whose treatment the tissue is to be used.

#### **Division 4 Effect of consent**

#### 12 Effect of consent under section 7

Except as provided by section 15, a document that purports to be a consent given in accordance with section 7 is, where a certificate has been given in accordance with section 9 in relation to that consent, sufficient authority for a medical practitioner (other than the medical practitioner who gave the certificate) to remove the regenerative tissue specified in the consent for the purpose or purposes specified in the consent.

#### 13 Effect of consent under section 8

Except as provided by section 15, a document that purports to be a consent given in accordance with section 8 is, where a certificate has been given in accordance with section 9 in relation to that consent, sufficient authority for a medical practitioner (other than the medical practitioner who gave the certificate) to remove (at any time after the expiration of 24 hours after the date and time specified in the consent to be the date on which, and the time at which, the consent was given) the non-regenerative tissue specified in the consent for the purpose specified in the consent.

#### 14 Effect of consent under section 10

- (1) Except as provided by section 15, a document that purports to be a consent given in accordance with section 10 is, where a certificate has been given in accordance with section 11 in relation to that consent, sufficient authority for a medical practitioner (other than the medical practitioner who gave the certificate) to remove the regenerative tissue specified in the consent for the purpose specified in the consent.
- (2) Except as provided by section 15, a document that purports to be a consent given in accordance with section 10 is, where a certificate has been given in accordance with section 11A in relation to that consent, sufficient authority for a medical practitioner (other than either of the medical practitioners who gave the certificate) to remove the regenerative tissue specified in the consent for the purpose specified in the consent.

#### 15 Written consent not to be sufficient authority in certain circumstances

A document that purports to be a consent given in accordance with section 7, 8 or 10 is not sufficient authority for a medical practitioner to remove tissue if the medical practitioner knows or has reasonable grounds for suspecting—

- (a) that the consent is revoked, or
- (b) that the certificate given for the purposes of section 9, 11 or 11A, as the case may be, in relation to that document contains a statement which is false or misleading in a material particular, or
- (c) if a certificate was given for the purposes of section 11—that the child is no longer in agreement with the proposed removal and transplantation of the tissue, or
- (d) if a certificate was given for the purposes of section 11A—that the child has at least some understanding of the procedures involved in the removal of tissue from his or her body and has repeatedly and consistently expressed an unwillingness to undergo any such procedure.

# Division 5 Revocation of consent or agreement

#### 16 Revocation of consent

- (1) A reference in this section, in relation to a consent given in accordance with a provision of this Act, to the donor—
  - (a) in a case in which the consent is given in respect of a child—is a reference to the child, and
  - (b) in any other case—is a reference to the person who gave the consent.
- (2) Where a medical practitioner has given a certificate in accordance with section 9, 11 or 11A and the person by whom the consent the subject of the certificate was given indicates—
  - (a) if the donor is a patient in a hospital—
    - (i) to a designated officer for the hospital,
    - (ii) to a medical practitioner who is attending the donor in a professional capacity, or
    - (iii) to a nurse employed at the hospital, or
  - (b) if the donor is not a patient in a hospital—to a medical practitioner who is attending the donor in a professional capacity,

that the consent is revoked, subsections (3), (4) and (5) have effect.

- (3) Where—
  - (a) the donor is a patient in a hospital, and
  - (b) the person who gave the consent for the purposes of this Act indicates to a person referred to in subsection (2) (a) (ii) or (iii) that the consent is revoked,

the person to whom the indication is given shall forthwith inform a designated officer for the hospital of the revocation of the consent.

Maximum penalty—40 penalty units or imprisonment for 6 months, or both.

(4) The designated officer for the hospital or, where the donor is not a patient in a hospital, the medical practitioner who is attending the donor in a professional capacity shall, if it appears to the designated officer or medical practitioner, as the case may be, after making such inquiries (if any) as are reasonable in the circumstances, that any other medical practitioner is proposing to remove tissue from the body of the donor pursuant to the consent, inform that other medical practitioner forthwith that the consent is revoked.

Maximum penalty—40 penalty units or imprisonment for 6 months, or both.

- (5) A medical practitioner who has possession of—
  - (a) an instrument of consent, or
  - (b) a certificate given in accordance with section 9, 11 or 11A in relation to the consent.

or both, shall, as soon as practicable after becoming aware that the consent is revoked, furnish the instrument or certificate, or both, as the case may be, to the person who gave the consent.

Maximum penalty—40 penalty units or imprisonment for 6 months, or both.

#### 17 Child no longer in agreement with removal or transplantation

- (1) Where a medical practitioner has given a certificate in accordance with section 11 and the child in relation to whom the certificate has been given indicates—
  - (a) if the child is a patient in a hospital—
    - (i) to a designated officer for the hospital,
    - (ii) to a medical practitioner who is attending the child in a professional capacity, or
    - (iii) to a nurse employed at the hospital, or
  - (b) if the child is not a patient in a hospital—to a medical practitioner who is attending the child in a professional capacity,

that the child is no longer in agreement with the proposed removal and transplantation of tissue, subsections (2), (3) and (4) have effect.

- (2) Where—
  - (a) the child is a patient in a hospital, and
  - (b) the child indicates to a person referred to in subsection (1) (a) (ii) or (iii) that the child is no longer in agreement with the proposed removal and transplantation of tissue,

the person to whom the indication is given shall forthwith inform a designated officer for the hospital that the child is no longer in agreement with the proposed removal and transplantation of tissue.

Maximum penalty—40 penalty units or imprisonment for 6 months, or both.

(3) The designated officer for the hospital or, where the child is not a patient in a hospital,

the medical practitioner who is attending the child in a professional capacity shall, if it appears to the designated officer or the medical practitioner, as the case may be, after making such inquiries (if any) as are reasonable in the circumstances, that any other medical practitioner is proposing to remove tissue from the body of the child pursuant to the consent, inform that other medical practitioner forthwith that the child is no longer in agreement with the proposed removal and transplantation of tissue.

Maximum penalty—40 penalty units or imprisonment for 6 months, or both.

- (4) A medical practitioner who has possession of—
  - (a) an instrument of consent, or
  - (b) a certificate given in accordance with section 11 in relation to the consent,

or both, shall, as soon as practicable after becoming aware that the child to whom the consent relates is no longer in agreement with the proposed removal and transplantation of tissue, furnish the instrument or certificate, or both, as the case may be, to the person who gave the consent.

Maximum penalty—40 penalty units or imprisonment for 6 months, or both.

#### Part 3 Blood donations

# **Division 1 Preliminary**

#### 18 Objects of Part

The objects of this Part are—

- (a) to provide for appropriate consents for the removal of blood, and
- (b) to minimise the risks to the public that may arise from the receipt of blood and blood products, and
- (c) to ensure the continued viability of the blood supply.

#### 18A Application of Part

- (1) This Part applies to the removal of blood from the body of a person for the purposes of—
  - (a) its transfusion into another person, or
  - (b) its use, or the use of any of its constituents, for other therapeutic purposes or for medical or scientific purposes, other than for the purpose of the treatment of the person from whom the blood is removed.
- (2) This Part does not apply to the removal of blood from a person for the purpose of using the blood in the treatment of that person.

(3) Part 2 does not apply to or in respect of the removal of blood from the body of a person in accordance with this Part.

#### Division 2 Consent to removal of blood

#### 19 Consent to removal of blood from persons 16 years and over

A person, other than a child who is under the age of 16 years, may consent in writing to the removal of blood from the person's body for the purpose of—

- (a) its transfusion to another person, or
- (b) its use, or the use of any of its constituents, for other therapeutic purposes or for medical or scientific purposes, other than for the purpose of the treatment of the person from whom the blood is removed.

#### 20 Consent to removal of blood from persons under 16 years

A parent or guardian of a child who is under the age of 16 years may consent in writing to the removal of blood from the child's body for a purpose referred to in section 19 (a) or (b), but that consent is only effective if at the time the consent is given—

- (a) the child is in agreement with the removal of the blood from the child's body, and
- (b) a medical practitioner advises the parent or guardian that any risk to the child's health (including psychological and emotional health) caused by the removal of the blood is minimal.

#### 20A Consent to removal of blood from child if child unable to agree

A parent or guardian of a child who is under the age of 16 years may consent in writing to the removal of blood from the child's body without the consent of the child for the purpose of using the blood in the treatment of the child's parent (being the biological parent, step-parent or adoptive parent), brother or sister, but that consent is only effective if—

- (a) a medical practitioner (other than the medical practitioner responsible for treating the child's parent, brother or sister) certifies in writing that, in the opinion of the medical practitioner—
  - (i) the child is unable to understand the nature and effect of the removal of blood from the child's body, and
  - (ii) any risk to the child's health (including psychological and emotional health) caused by the removal of the blood is minimal, and
- (b) a medical practitioner certifies in writing that the parent, brother or sister is likely to die or suffer serious damage to his or her health unless blood removed from the child is used in the treatment.

#### 20B Effect of consent under Division

An effective consent under section 19, 20 or 20A is sufficient authority for the removal of blood from the body of the person who has given the consent, or from the body of the child to whom the consent relates, as the case may be.

# **Division 3 Special provisions concerning donors**

#### 20C Application of Division

This Division applies—

- (a) to blood that is removed from a donor's body for the purpose of—
  - (i) its transfusion to another person, or
  - (ii) its use, or the use of any of its constituents, for other therapeutic purposes or for medical or scientific purposes involving the treatment of a person other than the donor, and
- (b) to blood products derived or extracted from blood of the kind referred to in paragraph (a).
- (c) (Repealed)

#### 20D Certificates by donors

(1) In this section—

**certificate** means a certificate relating to the medical suitability of the donor, being a certificate in a form prescribed by the regulations.

(2) A person must not remove or use a donor's blood for a purpose referred to in section 20C (a) unless the donor has signed a certificate and had the signature witnessed by a person (or a person belonging to a class of persons) (the **prescribed witness**) prescribed by the regulations.

Maximum penalty—100 penalty units.

- (3) A requirement in this section that a donor sign a certificate is satisfied if—
  - (a) in the case of a donor who is illiterate but not physically incapable of signing—the donor makes his or her mark on the certificate and the prescribed witness certifies on the certificate that, before the mark was made, the nature and effect of the certificate were explained to the donor, or
  - (b) in the case of a donor who is physically incapable of signing—a person authorised to do so by the donor signs the certificate, or
  - (c) in the case of a donor who is a child under the age of 16 years—the child's parent

or guardian signs the certificate.

(4) (Repealed)

#### 20E False or misleading statements

A person must not, for the purposes of this Division, sign a certificate that contains any statement that, to that person's knowledge, is false or misleading in a material particular.

Maximum penalty—50 penalty units or imprisonment for one year, or both.

# 20F Restrictions as to legal proceedings involving infection by a prescribed contaminant involving blood

- (1) If—
  - (a) a person has become infected with a prescribed contaminant, or a disease that is attributable to a prescribed contaminant, and
  - (b) the contaminant was or may have been transmitted to that person as a result of a transfusion of blood or a blood product or of any other treatment involving the use of blood or a blood product,

the provisions of subsection (3), (4) or (5) apply according to the circumstances of the case.

- (2) The regulations may make provision for or with respect to prescribing defences (in addition to those provided for in subsections (4) and (5)) as defences to proceedings of the kind referred to in subsections (4) and (5).
- (3) Proceedings for an offence (except an offence against section 20E) or in tort or for a breach of contract arising out of the transmission of a prescribed contaminant as referred to in subsection (1) may not be brought against the donor of the blood concerned in the infection, unless it is proved in the proceedings—
  - (a) that the donor has previously been found guilty of an offence against section 20E or of an offence against a law of another State or a Territory that corresponds to that section, or
  - (b) that the donor would have been found guilty of such an offence had the donor been charged with such an offence.
- (4) If proceedings for an offence or in tort or for a breach of contract arising out of the transmission of a prescribed contaminant as referred to in subsection (1) are brought against a person (other than the donor) in respect of a supply by that person, or an employee of that person, of blood or a blood product, it is a defence in those proceedings for the defendant to prove that—
  - (a) at the time of supply, the defendant was an exempt supplier or an employee of an

#### exempt supplier, and

- (b) if the defendant or an employee of the defendant removed the blood or the blood from which the blood product was derived or extracted from the donor—the defendant or that employee had, before supply, ensured that—
  - (i) the donor had signed either a certificate of the kind referred to in section 20D or a similar document as to the medical suitability of the donor to provide blood for a purpose referred to in section 20C (a), and
  - (ii) the blood or the blood from which the blood product was derived or extracted had been subjected to tests of a kind approved by the Minister for the purposes of this section and those tests had indicated that no prescribed contaminant was present in that blood, and
- (c) if the defendant or an employee of the defendant obtained the blood or blood product from another person—that other person was an exempt supplier or an employee of an exempt supplier, and
- (d) before the time when the blood or blood product was used for transfusion to, or for otherwise treating, the infected person, the defendant had not become aware that the blood or blood product was or was likely to have been contaminated with the prescribed contaminant concerned or, if before that time the defendant had become aware of that fact, the defendant had taken all reasonably practicable steps to ensure that the blood or blood product was not so used.
- (5) If proceedings for an offence or in tort or for a breach of contract arising out of the transmission of a prescribed contaminant as referred to in subsection (1) are brought against the person who carried out the transfusion or treatment or the employer or any supervisor of that person, it is a defence in those proceedings for the defendant to prove that—
  - (a) if the defendant or an employee of the defendant removed the blood or the blood from which the blood product was derived or extracted from the donor directly, the defendant or that employee had ensured that—
    - (i) the donor had signed either a certificate of the kind referred to in section 20D or a similar document as to the medical suitability of the donor to provide blood for a purpose referred to in section 20C (a), and
    - (ii) the blood or the blood from which the blood product was derived or extracted had been subjected to tests of a kind approved by the Minister for the purposes of this section and those tests had indicated that no prescribed contaminant was present in that blood, and
  - (b) if the defendant or an employee of the defendant obtained the blood or blood product from another person—that other person was an exempt supplier or an

employee of an exempt supplier, and

- (c) when the transfusion or treatment was carried out, the defendant was not aware that the blood or blood product was or was likely to have been contaminated with the prescribed contaminant concerned.
- (6) In this section—

**prescribed contaminant** means a contaminant prescribed by the regulations for the purposes of this section.

#### 20G (Repealed)

#### 20H Records

The regulations may provide for the keeping of certificates given for the purposes of this Division and for the making and keeping of records in respect of those certificates.

# Part 3A Regulation of businesses supplying blood and blood products

# 21 Unauthorised persons prohibited from carrying on a business of supplying blood or blood products

- (1) A person, other than an exempt supplier, must not carry on a business of supplying homologous blood or blood products.
  - Maximum penalty—100 penalty units.
- (2) A person must not participate in the management of a business of supplying homologous blood or blood products unless that business is an exempt supplier.
  - Maximum penalty—100 penalty units.
- (3) In this section, a reference to carrying on a business of supplying homologous blood or blood products is a reference to carrying on a business or undertaking of supplying blood or blood products to medical institutions and other persons—
  - (a) for the purpose of transfusing to persons other than the donor some or all of the blood or blood products, or
  - (b) for the purpose of using some or all of the blood or blood products for other therapeutic purposes, or for medical or scientific purposes, involving the treatment of persons other than the donor.

#### 21A Presumptions in certain legal proceedings

If in any legal proceedings relating to an alleged contravention of this Part it is proved that—

(a) a person, other than the donor, has supplied blood or blood products on at least 2

occasions to one or more persons for the purpose of transfusion to other persons or for other therapeutic purposes, or for medical or scientific purposes, involving the treatment of persons, or

(b) a person, other than the donor, has kept on premises occupied by that person blood or blood products in excess of the prescribed quantity,

it is to be presumed for the purposes of those proceedings, unless the contrary is proved, that the person was carrying on a business of supplying homologous blood or blood products within the meaning of section 21.

#### 21B Offences by corporations

- (1) If a corporation contravenes, whether by act or omission, any provision of this Part or a regulation made for the purposes of this Part, each person who is a director of the corporation or who is concerned in the management of the corporation is taken to have contravened the same provision if the person knowingly authorised or permitted the contravention.
- (2) A person may be proceeded against under a provision pursuant to subsection (1) whether or not the corporation has been proceeded against under that provision.
- (3) Nothing in this section affects any liability imposed on a corporation for an offence committed by the corporation against this Part or a regulation made for the purposes of this Part.

#### 21C Injunctions

- (1) If, on the application of the Health Secretary, the Supreme Court is satisfied that a person has engaged, or is proposing to engage, in conduct that constitutes or would constitute one or more of the following—
  - (a) a contravention of section 21,
  - (b) attempting to contravene section 21,
  - (c) aiding, abetting, counselling or procuring a person to contravene section 21,
  - (d) inducing, or attempting to induce, whether by threats or promises or otherwise, a person to contravene section 21,
  - (e) being, directly or indirectly, knowingly concerned in, or party to, the contravention by a person of section 21,
  - (f) conspiring with others to contravene section 21,

the Court may grant an injunction in such terms as the Court determines to be appropriate.

- (2) If an application is made to the Supreme Court for an injunction under subsection (1), the Court may, if in the opinion of the Court it is desirable to do so before considering the application, grant an interim injunction restraining a person from engaging in conduct of the kind referred to in subsection (1) pending the determination of the application.
- (3) The Supreme Court may rescind or vary an injunction granted under subsection (1) or (2).
- (4) If an application is made to the Supreme Court for the grant of an injunction restraining a person from engaging in conduct of a particular kind, the power of the Court to grant the injunction may be exercised—
  - (a) where the Court is satisfied that the person has engaged in conduct of that kind—whether or not it appears to the Court that the person intends to engage again, or to continue to engage, in that conduct, or
  - (b) where it appears to the Court that, in the event of the injunction not being granted, it is likely that the person will engage in conduct of that kind—whether or not the person has previously engaged in conduct of that kind.
- (5) The Health Secretary is not to be required to give any undertaking as to damages or costs in respect of an application under this section.

#### 21D-21E (Repealed)

#### Part 3B

#### 21F-21V (Repealed)

# Part 3C Use of tissue removed during medical, dental or surgical treatment

#### 21W Application

(1) This Part applies with respect to the use of tissue removed from the body of a living person during medical, dental or surgical treatment carried out in the interests of the health of the person. This Part does not authorise the removal of tissue from the body of a person after that person's death or the use of any tissue so removed.

#### Note-

See Parts 4 and 5 in relation to the removal of tissue after a person's death and the use of that tissue.

- (2) This Part does not apply to or in respect of the following—
  - (a) tissue that is removed in accordance with Part 2,
  - (b) blood that is removed in accordance with Part 3.

(c) (Repealed)

#### 21X Authority to use tissue removed from adult

- (1) The use, for therapeutic, medical or scientific purposes, of tissue removed from the body of a person during medical, dental or surgical treatment, is authorised if—
  - (a) the person has given his or her consent in writing to the use of the tissue for that purpose, and
  - (b) the consent has not been revoked.
- (2) The authority conferred by subsection (1) is subject to the terms and any conditions of the consent referred to in that subsection.
- (3) This section does not apply if the person—
  - (a) is a child, or
  - (b) is a patient to whom Part 5 of the Guardianship Act 1987 applies.

## 21Y Authority to use tissue removed from child

- (1) A senior available next of kin of a child may, by instrument in writing, authorise the use, for therapeutic, medical or scientific purposes, of any tissue removed from the body of the child during medical, dental or surgical treatment.
- (2) A senior available next of kin must not grant an authority under subsection (1) if it appears to the senior available next of kin, after making such inquiries as are reasonable in the circumstances, that—
  - (a) the child objects to the use of the tissue for the purposes to be authorised, or
  - (b) there is another next of kin of the same or higher order of the classes in paragraph (aa) of the definition of **senior available next of kin** in section 4 (1) who objects to the use of the tissue for the purposes to be authorised.

Maximum penalty—10 penalty units.

(3) This section does not apply if the child is deceased.

Note-

Section 21ZA may apply if the child is deceased.

#### 21Z Authority to use tissue removed from person under guardianship

(1) A person responsible for a person who is a patient to whom Part 5 of the Guardianship Act 1987 applies may, by instrument in writing, authorise the use, for therapeutic, medical or scientific purposes, of any tissue removed from the body of the patient during medical, dental or surgical treatment.

- (2) This section does not apply if—
  - (a) the patient is a child and the Minister administering the *Children and Young*Persons (Care and Protection) Act 1998 has sole parental responsibility in respect
    of the child (whether under that Act or otherwise), or
  - (b) the patient is a child and the Secretary under the *Children and Young Persons* (Care and Protection) Act 1998 has sole parental responsibility in respect of the child (whether under that Act or otherwise), or
  - (c) the patient (whether or not a child) is deceased.
- (3) In this section—

**person responsible** for a person has the meaning given by Part 5 of the *Guardianship Act 1987*.

#### 21ZA Authority to use tissue removed from deceased person

- (1) A senior available next of kin of a person who is deceased may, by instrument in writing, authorise the use, for therapeutic, medical or scientific purposes, of any tissue that was removed from the body of the deceased person, before that person's death, during medical, dental or surgical treatment.
- (2) A senior available next of kin must not grant an authority under subsection (1) if it appears to the senior available next of kin, after making such inquiries as are reasonable in the circumstances, that—
  - (a) the deceased person had, during the person's lifetime, expressed an objection to the use of tissue removed from the person's body for the purposes to be authorised and had not withdrawn that objection, or
  - (b) there is another next of kin of the same or higher order of the classes in paragraph (a) or (b) of the definition of **senior available next of kin** in section 4(1) who objects to the use of the tissue for the purposes to be authorised.

Maximum penalty—10 penalty units.

#### 21ZB Effect of authority under this Part

- (1) An authority under this Part is sufficient authority for the use, for therapeutic, medical or scientific purposes, of tissue removed from the body of a person during medical, dental or surgical treatment, if the tissue is used in accordance with the terms and any conditions of the authority.
- (2) An authority under this Part does not authorise the removal of tissue from the body of a person.

Note-

Parts 2 and 3 provide authority to remove tissue (including blood) from the body of a living person for purposes such as transplantation and transfusion, and other therapeutic, scientific, and medical purposes. Parts 4 and 5 provide authority to remove tissue from the body of a person who is deceased. In certain cases, an authority under this Act to remove tissue is not required (see section 34 (1) (a)).

## Part 4 Removal of tissue after death

#### 22 (Repealed)

#### 23 Authority to remove tissue where body of deceased at a hospital

- (1) If a designated officer for a hospital is satisfied, after making such inquiries as are reasonable in the circumstances in relation to a person who has died in the hospital or whose dead body has been brought into the hospital, that—
  - (a) the person had, during the person's lifetime, given his or her consent in writing to the removal after that person's death of tissue from that person's body for the purpose of—
    - (i) its transplantation to the body of a living person, or
    - (ii) its use for other therapeutic purposes or for medical purposes or scientific purposes, and
  - (b) the consent had not been revoked,

the designated officer may, by instrument in writing, authorise the removal of tissue from that person's body in accordance with the terms and any conditions of the consent.

- (2) An authority under subsection (1) is not to be given in respect of a deceased child.
- (3) If the designated officer is not satisfied as to the matters referred to in subsection (1), or the deceased person is a deceased child, and the designated officer is satisfied, after making such inquiries as are reasonable in the circumstances in relation to the deceased person, that—
  - (a) the deceased person had not, during the person's lifetime, expressed an objection to the removal of tissue from the person's body after the person's death or, if the person had expressed such an objection, based on the most recent views expressed by the deceased person, the person no longer had an objection to the removal of tissue from the person's body, and
  - (b) a senior available next of kin has given his or her consent in writing, or in any other manner prescribed by the regulations, to the removal of tissue from the person's body, and
  - (c) there is no next of kin of the same or a higher order of the classes in paragraph (a) or (b) of the definition of **senior available next of kin** in section 4 (1) who

objects to the removal of tissue from the person's body,

the designated officer may, by instrument in writing, authorise the removal of tissue from the deceased person's body in accordance with the terms and any conditions of the consent referred to in paragraph (b).

(4) This section does not apply to a deceased child who, immediately before his or her death, was in the care of the State.

#### 23A Authority to remove tissue where body of deceased child in care of State at a hospital

If a designated officer for a hospital is satisfied, after making such inquiries as are reasonable in the circumstances in relation to a child in the care of the State who has died in the hospital or whose dead body has been brought into the hospital, that—

- (a) the deceased child had not, during the child's lifetime, expressed an objection to the removal of tissue from the child's body for the purpose of its transplantation to the body of a living person, and
- (b) the principal care officer for the child has given his or her consent in writing, or in any other manner prescribed by the regulations, to the removal of tissue from the child's body for the purpose of its transplantation to the body of a living person,

the designated officer may, by instrument in writing, authorise the removal of tissue from the deceased child's body for the purpose of its transplantation to the body of a living person in accordance with the terms and any conditions of the consent referred to in paragraph (b).

#### 24 Authority to remove tissue where body of deceased not at a hospital

- (1) If the body of a deceased person (other than a deceased child) is at a place other than a hospital, the removal of tissue from the body of the deceased person for the purpose of its transplantation to the body of a living person, or its use for other therapeutic purposes or for medical purposes or scientific purposes, is authorised if—
  - (a) the deceased person had, during the person's lifetime, given his or her consent in writing to the removal of tissue from the person's body for that purpose, and
  - (b) the consent had not been revoked.
- (2) The authority conferred by subsection (1) is subject to the terms and any conditions of the consent referred to in that subsection.
- (3) If the body of a deceased person is at a place other than a hospital, a senior available next of kin of the person may, by instrument in writing or in any other manner prescribed by the regulations, authorise the removal of tissue from the deceased person's body for the purpose of its transplantation to the body of a living person, or its use for other therapeutic purposes or for medical purposes or scientific purposes.

- (4) A senior available next of kin must not grant an authority under subsection (3) if it appears to the senior available next of kin, after making such inquiries as are reasonable in the circumstances, that—
  - (a) the deceased person had, during the person's lifetime, expressed an objection to the removal of tissue from the person's body after the person's death unless, based on the most recent views expressed by the deceased person, it appears that the person no longer had an objection to the removal of tissue from the person's body, or
  - (b) another next of kin of the same or higher order of the classes in paragraph (a) or(b) of the definition of **senior available next of kin** in section 4 (1) objects to the removal of tissue from the person's body.

Maximum penalty—10 penalty units.

(5) This section does not apply to a deceased child who, immediately before his or her death, was in the care of the State.

# 24A Authority to remove tissue where body of deceased child in care of State not at a hospital

If the body of a deceased child who, immediately before his or her death, was in the care of the State, is at a place other than a hospital, the principal care officer for the child may, by instrument in writing or in any other manner prescribed by the regulations, authorise the removal of tissue from the deceased child's body for the purpose of its transplantation to the body of a living person.

#### 24B Consent and authorisation of principal care officer

- (1) The principal care officer must not give consent under section 23A or grant an authority under section 24A if—
  - (a) it appears to the officer, after making such inquiries as are reasonable in the circumstances, that the deceased child had, during the child's lifetime, expressed an objection to the removal of tissue from the child's body and had not withdrawn that objection, or
  - (b) the officer has not undertaken the consultation and obtained the approvals required by the following subsections.
- (2) Before determining whether or not to give consent under section 23A or grant an authority under section 24A, the principal care officer is to use reasonable efforts to consult with such persons as the officer considers might be appropriate.
- (3) If any of the persons consulted is a person whose approval the principal care officer considers should be obtained before consent is given or an authority is granted, the officer must not give consent or grant an authority unless that person approves.

(4) The principal care officer may determine that more than one person's approval is required under subsection (3).

#### 25 Consent by coroner

- (1) If a coroner has jurisdiction to hold an inquest under the *Coroners Act 2009* in respect of the death of a person, a designated officer for a hospital, a senior available next of kin or the principal care officer must not authorise the removal of tissue from the person's body unless a coroner has given consent to the removal of the tissue.
  - Maximum penalty—40 penalty units or imprisonment for 6 months, or both.
- (2) A consent by a coroner under this section may be given before a person's death if the coroner reasonably believes the coroner will have jurisdiction to hold an inquest under the *Coroners Act 2009* in respect of the person's death.
- (2A) A consent by a coroner under this section may be withdrawn by the coroner at any time.
- (3) If a coroner has jurisdiction to hold an inquest under the *Coroners Act 2009* in respect of the death of a person to whom section 24(1) applies, the removal of tissue from the body of the person is not authorised unless a coroner has given consent to the removal of the tissue.
- (4) A consent by a coroner under this section may be expressed to be subject to such conditions as are specified in the consent.
- (5) A consent by a coroner under this section may be given orally and, if so given, is to be confirmed in writing as soon as practicable.
- (6) A coroner shall, in determining the conditions (if any) to which a consent shall be subject, have regard only to the effect which the removal of tissue from the body of the person to whom the consent relates may have in relation to the conduct of any inquest which a coroner has jurisdiction to hold in respect of that person's death.

#### 26 Certificates required in certain situations

- (1) Where—
  - (a) a person has died in a hospital or the body of a deceased person has been brought into a hospital, and
  - (b) at the time when the person died or at any time thereafter the person's respiration or the circulation of the person's blood was being maintained by artificial means.
  - a designated officer for the hospital shall not give an authority under this Part in respect of the person unless each of 2 medical practitioners (not including the

designated officer) has certified in writing—

- (c) that the medical practitioner carried out a clinical examination of the person while the person's respiration or the circulation of the person's blood was being maintained by artificial means, and
- (d) that, at the time of that examination, irreversible cessation of all function of the person's brain had, in the opinion of the medical practitioner, already occurred.

Maximum penalty—40 penalty units or imprisonment for 6 months, or both.

- (1A) The 2 medical practitioners referred to in subsection (1) must not include—
  - (a) any medical practitioner who is responsible for, or involved in, the removal of tissue from the person's body for the purpose of its transplantation to the body of another person, or
  - (b) any medical practitioner who is responsible for the care of the person who is the intended recipient of the tissue.
- (2) At the time when the clinical examination referred to in subsection (1) is carried out—
  - (a) each of the 2 medical practitioners referred to in that subsection shall have practised medicine for a period or periods totalling not less than 5 years during the 8 years immediately preceding that time, and
  - (b) at least one of those medical practitioners shall be a designated specialist for the hospital referred to in that subsection.
- (3) For the purposes of subsection (2) (a), any period during which a person has practised medicine in a place outside New South Wales in accordance with the law in force in that place shall be taken into account in calculating the period of 5 years referred to in that paragraph.

# 27 Effect of authority under this Part

- (1) An authority under this Part is sufficient authority for a medical practitioner other than—
  - (a) a medical practitioner referred to in section 26 (1), or
  - (b) where the authority was given by a medical practitioner, the medical practitioner by whom the authority was given,
  - to remove tissue from the body of the deceased person referred to in the authority for the purpose or purposes specified in the authority.
- (1A) Without limiting subsection (1), an authority under this Part which authorises the removal of tissue for one or more of the following purposes (whether or not it

authorises the removal of tissue for any other purpose) is sufficient authority for a person other than a medical practitioner to remove tissue from the body of the deceased person referred to in the authority for that purpose if the person removing the tissue is appointed, in writing, by the Health Secretary to remove tissue under this section for that purpose and is not the person by whom the authority was given—

- (a) corneal transplantation,
- (b) skin transplantation,
- (c) the transplantation of cardiovascular tissue,
- (d) the transplantation of musculoskeletal tissue,
- (e) any other purpose prescribed by the regulations.
- (1B) Despite subsection (1A), an authority under this Part which authorises the removal of tissue for the purpose of the transplantation of cardiovascular tissue is not sufficient authority for a person other than a medical practitioner to remove the whole of a heart for the purpose of a heart transplant.
- (2) A contravention by a designated officer of section 26 (1) in relation to the giving of an authority does not affect the validity of the authority.
- (3) An authority under this Part does not authorise the use, for therapeutic, medical or scientific purposes, of any tissue removed from the body of a deceased person—
  - (a) in the course of the medical, dental or surgical treatment performed while the person was still living, or
  - (b) for the purposes of a post-mortem examination.

#### Note-

An authority under Part 3C may be given to authorise the use, for therapeutic, medical or scientific purposes, of any tissue removed in the course of medical, dental or surgical treatment while the person was still living. An authority under Division 2 of Part 5 may be given to authorise the use, for therapeutic, medical or scientific purposes, of any tissue removed for the purposes of a post-mortem examination.

#### 27A Guidelines for removal of tissue after death

The Health Secretary may issue guidelines relating to the removal of tissue after death, including in relation to recording reasons for not proceeding with the removal of tissue from the body of a deceased person, where the deceased person has given consent but the family has objected.

# Part 4A Ante-mortem procedures for donation of tissue after death

#### 27B Definitions

In this part—

**ante-mortem procedure** means the following medical procedures, other than normothermic regional perfusion, carried out to determine, maintain or improve the viability of tissue for a relevant purpose—

- (a) the administration of medication,
- (b) the removal of blood and tissue for testing,
- (c) medical imaging and other diagnostic procedures,
- (d) blood transfusions for the purpose of improving organ viability.

**potential tissue donor** means the person on whom an ante-mortem procedure is to be carried out.

**relevant purpose** means the expected transplantation of tissue, excluding gametes, from a potential tissue donor's body, after the potential tissue donor's death, to the body of another living person.

senior available next of kin, of a potential tissue donor, means—

- (a) in relation to a child who is a potential tissue donor—
  - (i) a parent of the child, or
  - (ii) if a parent of the child is not available—a brother or sister of the child who is at least 18 years of age, or
  - (iii) if no person referred to in subparagraph (i) or (ii) is available—a guardian of the child, and
- (b) otherwise—
  - (i) the potential tissue donor's spouse, or
  - (ii) if the potential tissue donor does not have a spouse or the potential tissue donor's spouse is not available—a child of the potential tissue donor who is at least 18 years of age, or
  - (iii) if no person referred to in subparagraph (i) or (ii) is available—a parent of the potential tissue donor, or
  - (iv) if no person referred to in subparagraph (i), (ii) or (iii) is available—a brother or sister of the potential tissue donor who is at least 18 years of age.

#### 27C Authority to carry out ante-mortem procedures

- (1) A designated officer in relation to a hospital may authorise the carrying out of an ante-mortem procedure if the potential tissue donor provides consent.
- (2) If the potential tissue donor lacks the capacity to provide consent under subsection (1), the designated officer may authorise the carrying out of an ante-mortem procedure if—
  - (a) there are one or more senior available next of kin of the potential tissue donor and a senior available next of kin provides consent under section 27D, or
  - (b) there are no known senior available next of kin of the potential tissue donor and the designated officer is satisfied that—
    - the potential tissue donor has, during the potential tissue donor's lifetime, provided consent in writing to the removal of tissue for a relevant purpose, and
    - (ii) the consent has not been revoked, and
    - (iii) the potential tissue donor has not expressed an objection to the carrying out of an ante-mortem procedure on the potential tissue donor.
- (3) Despite subsections (1) and (2), a designated officer must not give an authorisation unless—
  - (a) the designated officer is reasonably satisfied an authorisation to remove tissue after the death of the potential tissue donor under the Act, Part 4 will be given, and
  - (b) a prescribed practitioner has certified in writing that the prescribed practitioner is reasonably satisfied—
    - (i) the death of the potential tissue donor is imminently expected, and
    - (ii) the carrying out of an ante-mortem procedure on the potential tissue donor will not—
      - (A) hasten the death of the potential tissue donor, or
      - (B) cause more than minimal harm to the potential tissue donor, or
      - (C) cause undue risk to the potential tissue donor.
- (4) In this section—

**experienced medical practitioner** means a medical practitioner who has been a registered medical practitioner for at least 5 years.

**prescribed practitioner** means a designated specialist or, if a designated specialist is not available, an experienced medical practitioner, who is not involved in—

- (a) transplantation procedures, or
- (b) the care of the potential tissue donor, or
- (c) the care of a potential recipient of tissue.

#### 27D Senior available next of kin may consent to ante-mortem procedures

- (1) A senior available next of kin may consent to the carrying out of an ante-mortem procedure on a potential tissue donor.
- (2) The senior available next of kin must not provide consent under subsection (1) unless the senior available next of kin is satisfied that there is no reason to believe the potential tissue donor has expressed an objection to the carrying out of an antemortem procedure on the potential tissue donor.

#### 27E Effect of an authority

An authority under section 27C is sufficient authority for the carrying out of an antemortem procedure on a potential tissue donor.

#### 27F Relationship with Guardianship Act 1987

- (1) An authority under section 27C has effect despite the Guardianship Act 1987.
- (2) Despite subsection (1), an authority under section 27C does not have effect if—
  - (a) a person responsible has given consent to treatment on the potential tissue donor under the *Guardianship Act 1987*, Part 5, and
  - (b) the treatment is incompatible with the ante-mortem procedure.
- (3) In this section—

person responsible has the same meaning as in the Guardianship Act 1987, Part 5.

**treatment** has the same meaning as in the *Guardianship Act* 1987, Part 5.

#### 27G Ante-mortem procedure not to interfere with coroner's functions

Despite the other provisions of this part, an ante-mortem procedure must not be carried out if the procedure is reasonably likely to interfere with the functions of the coroner under the *Coroners Act 2009* in respect of the death of the potential tissue donor.

# **Part 5 Post-mortem examinations**

# Division 1 Authority to conduct post-mortem examinations

#### 28 Authority for post-mortem examination where body of deceased at a hospital

- (1) If a designated officer for a hospital is satisfied, after making such inquiries as are reasonable in the circumstances in relation to a person who has died in the hospital or whose dead body has been brought into the hospital, that—
  - (a) the person had, during the person's lifetime, given his or her consent in writing to the post-mortem examination of that person's body, and
  - (b) the consent had not been revoked,

the designated officer may, by instrument in writing, authorise the post-mortem examination of that person's body in accordance with the terms and any conditions of the consent.

- (2) An authority under subsection (1) is not to be given in respect of a deceased child.
- (3) If the designated officer is not satisfied as to the matters referred to in subsection (1), or the deceased person is a deceased child, and the designated officer is satisfied, after making such inquiries as are reasonable in the circumstances in relation to the deceased person, that—
  - (a) the deceased person had not, during the person's lifetime, expressed an objection to the post-mortem examination of the person's body, and
  - (b) a senior available next of kin has given his or her consent in writing to the postmortem examination of the person's body, and
  - (c) there is no next of kin of the same or a higher order of the classes in paragraph (a) or (b) of the definition of **senior available next of kin** in section 4 (1) who objects to the post-mortem examination of the person's body,

the designated officer may, by instrument in writing, authorise the post-mortem examination of the person's body in accordance with the terms and any conditions of the consent referred to in paragraph (b).

# 29 Authority for post-mortem examination where body of deceased not at a hospital

- (1) If the body of a deceased person (other than a deceased child) is at a place other than a hospital, the post-mortem examination of that person's body is authorised if—
  - (a) the deceased person had, during the person's lifetime, given his or her consent in writing to the post-mortem examination of the person's body after the person's death, and
  - (b) the consent had not been revoked.
- (2) The authority conferred by subsection (1) is subject to the terms and any conditions of the consent referred to in that subsection.

- (3) If the body of a deceased person is at a place other than a hospital, a senior available next of kin of the person may, by instrument in writing, authorise the post-mortem examination of the person's body.
- (4) A senior available next of kin must not grant an authority under subsection (3) if it appears to the senior available next of kin, after making such inquiries as are reasonable in the circumstances, that—
  - (a) the deceased person had, during the person's lifetime, expressed an objection to the post-mortem examination of the person's body and had not withdrawn that objection, or
  - (b) another next of kin of the same or higher order of the classes in paragraph (a) or(b) of the definition of **senior available next of kin** in section 4 (1) objects to the post-mortem examination of the person's body.

Maximum penalty—10 penalty units.

# 30 Consent by coroner

- (1) This section applies to a person in respect of whose death a coroner has jurisdiction to hold an inquest under the *Coroners Act 2009*.
- (2) A designated officer for a hospital or a senior available next of kin shall not authorise the post-mortem examination of the body of a person to whom this section applies unless a coroner has given consent to the examination.
  - Maximum penalty—40 penalty units or imprisonment for 6 months, or both.
- (3) Section 29 (1) does not apply in relation to a person to whom this section applies unless a coroner has given consent to the post-mortem examination of the person's body.
- (4) A consent by a coroner under this section may be expressed to be subject to such conditions as are specified in the consent.
- (5) A consent by a coroner under this section may be given orally and, if so given, is to be confirmed in writing as soon as practicable.
- (6) A coroner shall, in determining the conditions (if any) to which a consent shall be subject, have regard only to the effect which the conduct of a post-mortem examination of the body of the person to whom the consent relates may have in relation to the conduct of any inquest which a coroner has jurisdiction to hold in respect of that person's death.

# 31 Effect of authority under this Division

(1) An authority under this Division is sufficient authority for a medical practitioner (other

than, where the authority was given by a medical practitioner, the medical practitioner by whom the authority was given)—

- (a) to conduct a post-mortem examination of the body of the deceased person referred to in the authority, and
- (b) to remove from that person's body such tissue as is necessary for the purpose of any such examination.
- (2) An authority under this Division does not authorise any person to use any tissue removed from a person's body for any therapeutic, medical or scientific purposes other than the purposes of the post-mortem examination.

#### Note-

An authority under this Division is not required in respect of anything authorised by or under the *Coroners Act 2009* (see section 36 (4) of this Act). An authority under Division 2 of Part 5 may be given to authorise the use, for therapeutic, medical or scientific purposes, of any tissue removed for the purposes of a post-mortem examination. An authority to use, for therapeutic, medical or scientific purposes, tissue removed for the purposes of a post-mortem examination is not required in respect of small samples of tissue that are retained in the form of tissue slides or tissue blocks (see section 34).

(3) (Repealed)

# Division 2 Use of tissue removed for post-mortem examination for other purposes

#### 31A Authority to use tissue removed for post-mortem examination for other purposes

- (1) If a designated officer for a hospital or forensic institution is satisfied, after making such inquiries as are reasonable in the circumstances in relation to a deceased person whose body is being retained at a hospital or forensic institution for the purposes of a post-mortem examination or has been the subject of a post-mortem examination at a hospital or forensic institution, that—
  - (a) the person had, during the person's lifetime, given his or her consent in writing to the use after the person's death of tissue from the person's body for therapeutic, medical or scientific purposes, and
  - (b) the consent had not been revoked,

the designated officer may, by instrument in writing, authorise the use for therapeutic, medical or scientific purposes of any tissue removed from the body of the deceased person for the purposes of the post-mortem examination in accordance with the terms and any conditions of the consent.

- (2) An authority under subsection (1) is not to be given in respect of a deceased child.
- (3) If the designated officer is not satisfied as to the matters referred to in subsection (1), or the deceased person is a deceased child, and the designated officer is satisfied,

after making such inquiries as are reasonable in the circumstances in relation to the deceased person, that—

- (a) the deceased person had not, during the person's lifetime, expressed an objection to the use after the person's death of tissue from the person's body for therapeutic, medical or scientific purposes, and
- (b) a senior available next of kin has given his or her consent in writing to the use of tissue from the body of the deceased person for therapeutic, medical or scientific purposes, and
- (c) there is no next of kin of the same or a higher order of the classes in paragraph (a) or (b) of the definition of **senior available next of kin** in section 4 (1) who objects to the use of tissue for those purposes,

the designated officer may, by instrument in writing, authorise the use for therapeutic, medical or scientific purposes of any tissue removed from the body of the deceased person for the purposes of the post-mortem examination in accordance with the terms of the consent referred to in paragraph (b).

#### 31B Consent by coroner

- (1) If a coroner has jurisdiction to hold an inquest under the *Coroners Act 2009* in respect of the death of a person, a designated officer for a hospital or forensic institution must not authorise the use of any tissue removed from the person's body under section 31A unless a coroner has given consent to the use of the tissue.
  - Maximum penalty—40 penalty units or imprisonment for 6 months, or both.
- (2) A consent by a coroner under this section may be expressed to be subject to such conditions as are specified in the consent.
- (3) The designated officer is to ensure that an authority given under section 31A gives effect to any such conditions.
- (4) A consent by a coroner under this section may be given orally and, if so given, is to be confirmed in writing as soon as practicable.

#### 31C Effect of authority under this Division

An authority given by a designated officer under this Division is sufficient authority for a person to use, for therapeutic, medical or scientific purposes, tissue removed from the body of a deceased person for the purposes of a post-mortem examination if—

- (a) the tissue is used in accordance with the terms and any conditions of the authority, and
- (b) the person who uses the tissue is not the designated officer who gave the authority.

#### Note-

An authority under this Division is not required in respect of anything authorised by or under the *Coroners Act* 2009 (see section 36 (4) of this Act).

## **Division 3 General**

#### 31D General

In the conduct of a post-mortem examination under an authority conferred by this Act, regard is to be had to the dignity of the deceased person.

# Part 6 Prohibition of trading in tissue

#### 32 Trading in tissue prohibited

- (1) A person must not enter into, or offer to enter into, a contract or arrangement under which any person agrees, for valuable consideration, whether given or to be given to any such person or to any other person—
  - (a) to the sale or supply of tissue from any such person's body or from the body of any other person, whether before or after that person's death or the death of that other person, as the case may be, or
  - (b) to the post-mortem examination of any such person's body after that person's death or of the body of any other person after the death of that other person.

Maximum penalty—40 penalty units or imprisonment for 6 months, or both.

- (2) Subsection (1) does not apply to or in respect of the sale or supply of tissue if the tissue has been subjected to processing or treatment and the sale or supply is made for the purpose of enabling the tissue to be used for therapeutic purposes, medical purposes or scientific purposes.
- (3) Subsection (1) does not apply to or in respect of a contract or arrangement providing only for the reimbursement of any expenses necessarily incurred by a person in relation to the removal of tissue in accordance with this Act.
- (4) Where the Minister considers it desirable by reason of special circumstances so to do, the Minister may, by instrument in writing, approve the entering into of a contract or arrangement that would, but for the approval, be void by virtue of subsection (5), and nothing in subsection (1) or (5) applies to or in respect of a contract or arrangement entered into in accordance with such an approval.
- (5) A contract or arrangement entered into in contravention of this section is void.

### Part 7 Definition of death

#### 33 When death occurs

For the purposes of the law of New South Wales, a person has died when there has occurred—

- (a) irreversible cessation of all function of the person's brain, or
- (b) irreversible cessation of circulation of blood in the person's body.

#### **Part 7A Enforcement**

# 33A Appointment of inspectors

- (1) The Health Secretary may appoint any officer of the Department of Health, or any person who the Health Secretary considers is suitably qualified for the purpose, to be an inspector for the purposes of this Act.
- (2) On appointing an inspector under subsection (1), the Health Secretary must issue to the inspector a certificate of authority that authorises the inspector to exercise the powers conferred on an inspector by this Act.
- (3) A certificate of authority must—
  - (a) state that it is issued under the Human Tissue Act 1983, and
  - (b) give the name of the person to whom it is issued, and
  - (c) state the date, if any, on which it expires, and
  - (d) describe the nature of the powers conferred and the source of the powers.

#### 33B Powers of inspectors

- (1) An inspector may at any reasonable time enter and inspect any premises for the purpose of ascertaining whether or not a provision of this Act, or any regulation made under this Act, is being or has been complied with or contravened.
- (2) While on premises entered under this section or under the authority of a search warrant under section 33G, an inspector may do one or more of the following—
  - (a) inspect—
    - (i) all tissue and blood products kept on those premises, or anything the inspector reasonably believes to be tissue or blood products, and
    - (ii) all containers that the inspector reasonably believes to contain or to have contained tissue or blood products, and

- (iii) all equipment kept on the premises that the inspector reasonably believes to be or to have been used for processing, packing or storing tissue or blood products,
- (b) take and remove for analysis or testing a sample of any tissue or blood product kept on the premises, or anything the inspector reasonably believes to be tissue or blood products,
- (c) inspect any records kept on those premises and require any person whom the inspector reasonably believes to have custody or control of those records to produce them for inspection,
- (d) require any person on those premises to answer questions or otherwise furnish information in relation to a contravention of a provision of this Act or the regulations,
- (e) make and take away copies of the whole or any part of any records or other information,
- (f) take away and retain, for such period as may be reasonably necessary, any records or other information, or any part of them, in order to make copies of them,
- (g) take away and retain any records or other information, if the inspector concerned reasonably believes that the records or information are evidence of an offence against this Act or a regulation made under this Act, until proceedings for the offence have been disposed of,
- (h) seize and detain—
  - (i) any tissue or blood product, or anything the inspector reasonably believes to be tissue or a blood product, in relation to which the inspector reasonably believes an offence against this Act or against a regulation under this Act is being or has been committed, and
  - (ii) any container in which any such tissue or blood product, or other thing, is kept, and
  - (iii) any equipment which the inspector reasonably believes is being or has been used in connection with any such offence,
- (i) place anything seized as referred to in paragraph (h) in a container, or in a room, compartment or cabinet located on the premises where they were seized, and mark, fasten and seal that container or, as the case may be, the door or opening providing access to that room, compartment or cabinet,
- (j) take such photographs, films, audio, video and other recordings as the inspector considers necessary.

- (3) Any thing seized under this section may, at the option of the inspector who made the seizure or another inspector acting in place of that inspector, be detained on the premises where it was found or be removed to other premises and detained there.
- (4) Before taking away a record or statement or any thing seized under this section, an inspector must tender an appropriate receipt to the person from whom it is taken.
- (5) This section does not authorise an inspector to enter any part of premises that is being used for residential purposes except—
  - (a) with the consent of the occupier, or
  - (b) under the authority of a search warrant.
- (6) An inspector must, when exercising on any premises any function of an inspector under this section, produce the inspector's certificate of authority if required to do so by the occupier of the premises.

#### 33C Provisions relating to exercise of powers

- A power conferred by this Act to enter premises, or to make an inspection or take other action on premises, may not be exercised unless the inspector proposing to exercise the power—
  - (a) is in possession of a certificate of authority, and
  - (b) gives reasonable notice to the occupier of the premises of the intention to exercise the power, unless the giving of notice would defeat the purpose for which it is intended to exercise the power, and
  - (c) exercises the power at a reasonable time, unless it is being exercised in an emergency, and
  - (d) uses no more force than is reasonably necessary to effect the entry or make the inspection.
- (2) If damage is caused by an inspector exercising a power to enter premises, a reasonable amount of compensation is recoverable as a debt owed by the Crown to the owner of the premises unless the occupier obstructed the exercise of the power.
- (3) This section does not apply to a power conferred by a search warrant issued under the Law Enforcement (Powers and Responsibilities) Act 2002.

#### 33D Requirement to provide information and records

(1) An inspector may, by notice in writing given to a person, require the person to furnish to the inspector such information or records (or both) as the inspector requires by the notice, being information that relates to the question of whether or not a provision of this Act, or any regulation made under this Act, is being or has been complied with or

contravened.

- (2) A notice under this section—
  - (a) must specify the manner in which information or records are required to be furnished and a reasonable time by which the information or records are required to be furnished, and
  - (b) may only require a person to furnish existing records that are in the person's possession or that are within the person's power to obtain lawfully.
- (3) The inspector to whom any record is furnished under this Part may take copies of it.
- (4) If any record required to be furnished under this Part is in electronic, mechanical or other form, the notice requires the record to be furnished in written form, unless the notice otherwise provides.
- (5) This section applies whether or not a power of entry under this Act is being or has been exercised.

## 33E Power of inspectors to require answers

- (1) An inspector may require a person whom the inspector suspects on reasonable grounds to have knowledge of matters in respect of which information is reasonably required for the purposes of this Act to answer questions in relation to those matters.
- (2) An inspector may, by notice in writing, require a corporation to nominate, in writing within the time specified in the notice, a director or officer of the corporation to be the corporation's representative for the purpose of answering questions under this section.
- (3) Answers given by a person nominated under subsection (2) bind the corporation.

# 33F Power to demand name and address

An inspector may require a person whom the inspector suspects on reasonable grounds to have contravened or to be contravening this Act or the regulations to state his or her full name and residential address.

#### 33G Search warrants

- (1) An inspector may apply to an authorised officer for a search warrant for premises if the inspector believes on reasonable grounds—
  - (a) that a provision of this Act or the regulations is being or has been contravened on the premises, or
  - (b) that there is on the premises evidence of a contravention of a provision of this Act or the regulations.

- (2) An authorised officer to whom such an application is made may, if satisfied that there are reasonable grounds for doing so, issue a search warrant authorising an inspector named in the warrant—
  - (a) to enter and inspect any premises, and
  - (b) to exercise the powers, or any specified powers, of an inspector under this Part.
- (3) Division 4 of Part 5 of the *Law Enforcement (Powers and Responsibilities) Act 2002* applies to a search warrant issued under this section.
- (4) In this section—

**authorised officer** has the same meaning as it has in the *Law Enforcement (Powers and Responsibilities) Act 2002*.

#### 33H Offences

- (1) A person who, without lawful excuse, neglects or fails to comply with a requirement made of the person by an inspector under this Act is guilty of an offence.
- (2) A person who furnishes any information or does any other thing in purported compliance with a requirement made by an inspector under this Act, knowing that it is false or misleading in a material respect, is guilty of an offence.
- (3) A person who hinders or obstructs an inspector in the exercise of any of the powers conferred by this Act is guilty of an offence.
- (4) A person is not guilty of an offence of failing to comply with a requirement made by an inspector unless it is established by the prosecutor that the inspector concerned warned the person that a failure or refusal to comply with the requirement was an offence.
- (5) A person is not guilty of an offence of hindering or obstructing an inspector in the exercise of the inspector's powers at any premises unless it is established by the prosecutor that—
  - (a) the inspector concerned produced at the relevant time the certificate of authority issued to the inspector under this Part, and
  - (b) the person was informed by the inspector concerned, or otherwise knew, that the inspector was empowered to exercise the power to which the offence relates.

Maximum penalty—10 penalty units or imprisonment for 3 months, or both.

# 33I Disallowance of seizure

(1) Any person claiming to be entitled to any seized item may, within 10 days after the date on which the seizure took place, make an application to the District Court for an

- order disallowing the seizure.
- (2) An application made under subsection (1) must not be heard unless the applicant has previously served a copy of the application on the Health Secretary.
- (3) The Health Secretary is entitled to appear as respondent at the hearing of an application made under subsection (1).
- (4) The District Court must, on the hearing of an application made under subsection (1), make an order disallowing the seizure—
  - (a) if it is proved by or on behalf of the applicant that the applicant would, but for the seizure, be entitled to the seized item and if it is not proved by or on behalf of the respondent beyond all reasonable doubt that an offence was being or had been at the time of the seizure, committed in relation to the seized item, or
  - (b) if, in the opinion of the Court, there are exceptional circumstances justifying the making of an order disallowing the seizure.
- (5) In any other case, the District Court must refuse the application.
- (6) If on the hearing of an application made under subsection (1) it appears to the District Court that the seized item that is the subject of the application is required to be produced in evidence in any pending proceedings in connection with an offence against this Act or the regulations, the Court may, either on the application of the respondent or on its own motion, adjourn the hearing until the conclusion of those proceedings.
- (7) If the District Court makes an order under subsection (4) disallowing the seizure of any seized item, the Court must also make one or both of the following orders—
  - (a) an order directing the respondent to cause the seized item to be delivered to the applicant or to such other person as appears to the Court to be entitled to it,
  - (b) if the seized item cannot for any reason be so delivered or has in consequence of the seizure depreciated in value, an order directing the Health Secretary to pay to the applicant such amount by way of compensation as the Court considers to be just and reasonable.
- (8) The award of costs with respect to the hearing of an application made under subsection (1) is at the discretion of the District Court.
- (9) If the District Court makes an order for the payment of any amount as compensation under subsection (7) (b) or awards any amount as costs under subsection (8), that order is enforceable as a judgment of the Court.
- (10) In this section—

seized item means anything seized by an inspector under section 33B (2) (h).

#### 33J Disposal of seized items

- (1) If—
  - (a) no application for disallowance of the seizure of a seized item has been made within the period allowed by section 33I (1), or
  - (b) any such application has been made within that period and the application has been refused or withdrawn before a decision in respect of the application has been made.

the seized item is forfeited to the Crown and may be destroyed or disposed of in such manner as the Health Secretary directs.

- (2) Subsection (1) does not apply in respect of any seized item that has been disposed of or destroyed as referred to in subsection (3) or (7).
- (3) If the Health Secretary is satisfied that there has been no failure to comply with or contravention of this Act or the regulations in relation to any seized item, the Health Secretary must immediately cause the seized item to be delivered to such person as appears to the Health Secretary to be entitled to it.
- (4) Subsection (3) does not apply in respect of any seized item that has been forfeited or destroyed as referred to in subsection (1) or (7).
- (5) If—
  - (a) any seized item is forfeited to the Crown under this section because no application for disallowance of the seizure was made within the period allowed by section 33I (1), and
  - (b) the Health Secretary is satisfied that there has been no failure to comply with or contravention of this Act or the regulations in relation to the seized item, and
  - (c) the seized item has not been disposed of or destroyed in a manner that would prevent it from being dealt with in accordance with this subsection,

the Health Secretary must immediately cause the seized item to be delivered to such person as appears to the Health Secretary to be the person who would, but for the forfeiture, have been entitled to it.

- (6) If any seized item is delivered to a person in accordance with subsection (5), such proprietary and other interests as existed immediately before the forfeiture are revived.
- (7) If an inspector who has seized any tissue or blood product under section 33B (2) (h) is satisfied on reasonable grounds that the tissue or blood product contains a prescribed

contaminant, and the tissue or blood product is not required or is no longer required to be retained for the purposes of any legal proceedings, the inspector is to cause the tissue or blood product to be destroyed.

(8) In this section—

**seized item** means anything seized by an inspector under section 33B (2) (h).

### Part 8 Miscellaneous

## 34 Act does not prevent specified removals of tissue

- (1) Without affecting the operation of any other Act or law, this Act does not operate so as to prohibit—
  - (a) the removal of tissue from the body of a living person in the course of medical, dental or surgical treatment carried out by a dentist or a medical practitioner in the interests of the health of the person and—
    - (i) except as provided by subparagraphs (ii) and (iii)—with the consent (express or implied) given by or on behalf of the person,
    - (ii) where it is not reasonably practicable for the dentist or medical practitioner to seek that consent and the dentist or medical practitioner is not aware that that consent has been refused—without that consent, or
    - (iii) in circumstances in which the dentist or medical practitioner is of the opinion that the person is in imminent danger of dying and that the removal of the tissue is necessary for the preservation of the life of the person,
  - (b) the use of tissue so removed for the purposes of the medical, dental or surgical treatment,
  - (b1) the use, for therapeutic, medical or scientific purposes, of small samples of any tissue that is lawfully removed from the body of a person (whether living or deceased) and retained in the form of a tissue slide or tissue block which enables microscopic examination of the tissue,
  - (b2) the retention of tissue lawfully removed from the body of a person (whether living or deceased) in prescribed circumstances for such period as the regulations authorise for the purpose of obtaining an authority under this Act to use the tissue for therapeutic, medical or scientific purposes,
  - (b3) the use of small samples of any tissue that is lawfully removed from the body of a person (whether living or deceased) for the purpose of carrying out analyses or tests—
    - (i) 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
- (ii) that are 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,
- (b4) the provision of a gamete by a living person to an ART provider in accordance with the *Assisted Reproductive Technology Act 2007*,
- (b5) (Repealed)
- (c) the embalming of the body of a deceased person, or
- (d) the preparation (including the restoration of any disfigurement or mutilation) of the body of a deceased person for the purpose of interment or cremation.
- (2) Nothing in subsection (1) allows the removal of blood from a person in contravention of Part 3.
- (3) Information relating to any test, analysis, investigation or research carried out under subsection (1)(b5) may not be published in a generally available publication (within the meaning of the *Health Records and Information Privacy Act 2002*) if it is in a form that could reasonably be expected to identify any person the subject of the test, analysis, investigation or research.
- (4), (5) (Repealed)

## 34A Authority not to be given in respect of child in care of the State

- (1) A person must not—
  - (a) authorise the removal of tissue from the body of a deceased child for any purpose (other than for the purpose of its transplantation to the body of a living person) if the child was, immediately before his or her death, in the care of the State, or
  - (b) authorise the post-mortem examination of the body of a deceased child if the child was, immediately before his or her death, in the care of the State, or
  - (c) authorise the use of tissue removed during the post-mortem examination of the body of a deceased child for any purpose (other than the purposes of the post-mortem examination) if the child was, immediately before his or her death, in the care of the State.

Maximum penalty—40 penalty units or imprisonment for 6 months, or both.

- (2) Subsection (1) applies despite any other provision of this Act.
- (3) This section does not apply to or in respect of anything done under the *Coroners Act* 2009 or any other law.
- (4) (Repealed)

#### 35 Exclusion of liability of persons acting in pursuance of consent or authority

- (1) Where—
  - (a) a person carries out a procedure, and
  - (b) a consent or authority under this Act is sufficient authority under this Act for the person to carry out the procedure,
  - the person is not liable to any other person in respect of anything done or omitted to be done by the firstmentioned person in the carrying out of the procedure.
- (2) Subsection (1) does not relieve a person from liability for negligence in respect of anything done or omitted to be done by the person in the carrying out of a procedure.

#### 36 Offences

- (1) A person shall not remove tissue from the body of any other person (whether living or deceased) except in accordance with a consent or authority that is, under this Act, sufficient authority for the removal of the tissue by the firstmentioned person.
  - Maximum penalty—40 penalty units or imprisonment for 6 months, or both.
- (1A) A person must not use any tissue that is removed from the body of a living person in the course of medical, dental or surgical treatment carried out in the interests of the health of the person for any purpose (other than for the purposes of treating the person) except in accordance with an authority that is, under this Act, sufficient authority for the firstmentioned person to use the tissue for that purpose.
  - Maximum penalty—40 penalty units or imprisonment for 6 months, or both.
- (2) A person shall not conduct a post-mortem examination of the body of a person except in accordance with an authority that is, under this Act, sufficient authority for the firstmentioned person to conduct the post-mortem examination.
  - Maximum penalty—40 penalty units or imprisonment for 6 months, or both.
- (2A) A person must not use any tissue that is removed from the body of a deceased person for the purposes of a post-mortem examination for any purpose (other than the purposes of that examination) except in accordance with an authority that is, under this Act, sufficient authority for the firstmentioned person to use the tissue for that purpose.

Maximum penalty—40 penalty units or imprisonment for 6 months, or both.

- (3) A person shall not—
  - (a) give an authority under this Act without having made the inquiries that the person is required by this Act to have made, or
  - (b) for the purposes of this Act (Division 3 of Part 3 excepted), sign a certificate which contains any statement which to that person's knowledge, is false or misleading in a material particular.

Maximum penalty—40 penalty units or imprisonment for 6 months, or both.

- (4) Subsections (1), (2) and (2A) do not apply to or in respect of anything authorised by or under—
  - (a) the Coroners Act 2009, or
  - (b) the Anatomy Act 1977, or
  - (c) any other law.

#### 37 Disclosure of information

- (1) This section applies—
  - (a) where a consent has been given pursuant to this Act—to a medical practitioner who has given a certificate in relation to the consent,
  - (b) where an authority has been given pursuant to this Act by a designated officer for a hospital—to the designated officer,
  - (c) where tissue other than blood has been removed from the body of a person (whether living or deceased)—to the medical practitioner who removed the tissue and, if the tissue was removed at a hospital, to each person who was employed at the hospital when the tissue was removed or who has since been employed at the hospital,
  - (ca) where blood has been removed from the body of a person (whether living or deceased)—
    - (i) by a medical practitioner,
    - (ii) by an employee or member of the Australian Red Cross Society or of a body prescribed for the purpose of this subparagraph, or
    - (iii) by any other person of a class prescribed for the purpose of this subparagraph,

to-

- (iv) the medical practitioner, any person who was the employer or partner of that practitioner when the blood was removed and any person who was an employee of that practitioner when the blood was removed or who has since been employed by that practitioner,
- (v) the Australian Red Cross Society or body so prescribed and any person who was an employee or member of that Society or body when the blood was removed or who has since been employed by that society or body, or
- (vi) that other person, any person who was the employer or partner of that other person when the blood was removed and any person who was an employee of that other person when the blood was removed or has since been employed by that other person,
- (cb) where blood has been removed from the body of a person (whether living or deceased) at a hospital or at premises prescribed, or at premises of a class prescribed, for the purposes of this paragraph—to any person who was employed at the hospital or premises when the blood was removed or who has since been employed at the hospital or premises,
- (d) where tissue has been transplanted into the body of a person—to the medical practitioner who performed the transplantation and, if the tissue was transplanted at a hospital, to each person who was employed at the hospital when the transplantation was performed or who has since been employed at the hospital, and
- (e) where it is proposed that tissue be transplanted into the body of a person—to a medical practitioner who proposes to perform the transplantation and, if the tissue is to be transplanted at a hospital, to each person who is employed at the hospital or who is subsequently employed at the hospital.
- (2) A person to whom this section applies shall not disclose information or publish a record whereby the identity of a person (whether living or deceased)—
  - (a) from whose body tissue has been, is being or may be removed for the purpose of its transplantation or its use for other therapeutic purposes or for medical purposes or scientific purposes,
  - (b) with respect to whom or with respect to whose body a consent or authority has been given under this Act, or
  - (c) into whose body tissue has been, is being or may be transplanted,

may become publicly known.

Maximum penalty—10 penalty units.

- (3) Subsections (1) and (2) do not apply to or in respect of the disclosure of information or the publication of a record—
  - (a) with the consent of the person (not being a child) to whom the information or record relates.
  - (a1) for information about a deceased person—with the consent of the person's next of kin,
  - (b) in connection with the administration or execution of this Act,
  - (c) in connection with bona fide medical research.
  - (d) for the purposes of any legal proceedings or of any report of any such proceedings, or
  - (e) with other lawful excuse.
- (4) For the purposes of this section, a person shall be deemed to have published a record if that person permits or facilitates access to that record by another person.

# 37A Recovery of costs incurred by the State in connection with the supply of blood and blood products to approved health providers

(1) In this section—

# approved health provider means—

- (a) (Repealed)
- (b) a private health facility licensed under the Private Health Facilities Act 2007, or
- (c) an accredited pathology laboratory under the *Health Insurance Act 1973* of the Commonwealth (other than any such laboratory that is under the control of a public health organisation within the meaning of the *Health Services Act 1997*), or
- (d) any health provider of a class prescribed by the regulations.

**blood product** does not include a product that is declared by the regulations not to be a blood product for the purposes of this section.

#### **blood** supplier means—

- (a) the Australian Red Cross Society, or
- (b) any other person or body prescribed by the regulations.
- (2) The object of this section is to encourage approved health providers that use blood or blood products supplied by blood suppliers—
  - (a) to make the best use of available resources of blood and blood products, and

- (b) to adopt an appropriate level of financial and performance accountability in relation to the use of those resources,
- by enabling the Health Secretary to recover the costs incurred by the State in connection with the supply of blood and blood products to those health providers.
- (3) If an approved health provider is supplied with any blood or blood products by a blood supplier, the health provider is required to pay the Health Secretary the costs incurred by the State in connection with the supply of the blood or blood products.
- (4) The arrangements for paying those costs and the manner in which they are assessed may be determined by the Health Secretary.
- (5) Any amount that is payable under this section is recoverable by the Health Secretary as a debt due to the State.
- (6) For the purposes of facilitating the assessment by the Health Secretary of the amounts payable by approved health providers under this section, a blood supplier is, in accordance with any written directions by the Health Secretary, required to provide the Health Secretary with information relating to the blood and blood products supplied by the blood supplier for use in New South Wales.
- (7) For the purposes of this section, the costs incurred by the State in connection with the supply of blood or blood products to an approved health provider includes the costs incurred by the State in collecting, transporting, processing or distributing any such blood or blood products.
- (8) This section does not allow an approved health provider to charge a patient for the supply of any blood or blood product to that patient.
- (9) However, nothing in this Act prevents an approved health provider that supplies blood or blood products to another approved health provider from recovering from the other health provider any amount that the health provider has paid under this section in relation to that supply.

# 38 Proceedings for offences

Proceedings for an offence against this Act or the regulations may be dealt with before the Local Court.

#### 39 Regulations

- (1) The Governor may make regulations not inconsistent with this Act for or with respect to any matter that by this Act is required or permitted to be prescribed or that is necessary or convenient to be prescribed for carrying out or giving effect to this Act.
- (1A) In particular, the regulations may make provision for or with respect to the following—

- (a) the making and keeping of records in connection with the removal of tissue from the body of a person (whether living or deceased), including the removal of tissue in the course of medical, dental or surgical treatment, and the retention or use of the tissue for any purposes,
- (b) the making and keeping of records in connection with the use of any deceased person's body for any therapeutic, medical or scientific purposes under an authority under this Act,
- (c) the information to be provided to the Health Secretary, or to any other specified person concerned in the administration of this Act, about any removal, retention or use of tissue from the body of a person, or any use of a deceased person's body for any therapeutic, medical or scientific purposes under an authority under this Act.
- (d) the standards to be complied with in connection with anything authorised by this Act, including by requiring those standards to be complied with as a condition of an authority conferred by or under this Act,
- (e) the safety of blood and blood products, including testing for prescribed contaminants.
- (2) A regulation may impose a penalty not exceeding 5 penalty units for any breach thereof.
- (3) A provision of a regulation may—
  - (a) apply generally or be limited in its application by reference to specified exceptions or factors.
  - (b) apply differently according to different factors of a specified kind, or
  - (c) authorise any matter or thing to be from time to time determined, applied or regulated by any specified person or body,
  - or may do any combination of those things.
- (4) The regulations may apply, adopt or incorporate, wholly or in part and with or without modification, any guidelines or other document (such as a code of practice), as in force at a particular time or as in force from time to time, prescribed or published by the National Health and Medical Research Council or by any other person or body.

# 40 Savings, transitional and other provisions

Schedule 1 has effect.

# Schedule 1 Savings, transitional and other provisions

(Section 40)

# Part 1 Preliminary

# 1 Regulations

(1) The regulations may contain provisions of a savings or transitional nature consequent on the enactment of the following Acts—

Human Tissue and Anatomy Legislation Amendment Act 2003

Health Legislation Amendment Act 2004 (but only to the extent that it amends this Act)

Human Tissue Amendment (Children in Care of State) Act 2008

Assisted Reproductive Technology Act 2007 (but only to the extent that it amends this Act)

Human Tissue Legislation Amendment Act 2012

- (2) Any such provision may, if the regulations so provide, take effect from the date of assent to the Act concerned or a later date.
- (3) To the extent to which any such provision takes effect from a date that is earlier than the date of its publication in the Gazette, the provision does not operate so as—
  - (a) to affect, in a manner prejudicial to any person (other than the State or an authority of the State), the rights of that person existing before the date of its publication, or
  - (b) to impose liabilities on any person (other than the State or an authority of the State) in respect of anything done or omitted to be done before the date of its publication.

# Part 2 Provisions consequent on enactment of Human Tissue and Anatomy Legislation Amendment Act 2003

# 2 Appointment of inspectors

An inspector appointed under section 21P before its repeal by the *Human Tissue and Anatomy Legislation Amendment Act 2003* and whose appointment was in force under that section immediately before that repeal is taken to have been appointed under section 33A.

# Part 3 Provisions consequent on enactment of Health Legislation

### **Amendment Act 2004**

#### 3 Consent

A consent to the removal of blood from a person that was obtained from a person in accordance with Part 3 of the Act before the commencement of Schedule 2 [3] to the *Health Legislation Amendment Act 2004* does not authorise the removal of blood from a person after that commencement.

#### 4 Previous offences

A reference in sections 20F and 20G to an offence against section 20E includes a reference to an offence against section 21D as in force before its repeal by the *Health Legislation Amendment Act 2004*.

#### **5** Certificates

A certificate signed by a donor in accordance with section 21C before the repeal of that section by the *Health Legislation Amendment Act 2004* is taken to be a certificate signed by a donor in accordance with section 20D.

#### 6 Regulations

This Part has effect subject to any regulations made pursuant to clause 1.

# Part 4 Provisions consequent on enactment of Human Tissue Amendment (Children in Care of State) Act 2008

# 7 Authorities in respect of deceased children in care of State

An amendment made to this Act by the *Human Tissue Amendment (Children in Care of State) Act 2008* applies only in respect of the death of a child that occurs on or after the commencement of the amendment.

# Part 5 Provision consequent on enactment of Human Tissue Legislation Amendment Act 2012

#### 8 Authority to remove tissue where prior objection or views expressed

Sections 23 and 24, as amended by the *Human Tissue Legislation Amendment Act 2012*, extend to any relevant expression of objection or views that occurred before the commencement of that Act.

#### 9 Review of amendments

(1) The Minister is to review this Act to determine whether the amendments made by the *Human Tissue Legislation Amendment Act 2012* have been effective in achieving an increase in the rate of tissue donation in the State.

- (2) In conducting the review the Minister is to consider any matters affecting the effectiveness of those amendments, including matters relevant to the administration of this Act.
- (3) The review is to be undertaken as soon as possible after the period of 5 years from the commencement of the *Human Tissue Legislation Amendment Act 2012*.
- (4) A report on the outcome of the review is to be tabled in each House of Parliament within 12 months after the end of the period of 5 years.

# Part 6 Provision consequent on enactment of Health Legislation (Miscellaneous) Amendment Act (No 2) 2022

#### 10 Consent of principal care officer

- (1) A consent or authority to remove tissue from a deceased child's body given by a principal care officer under this Act and in force immediately before the commencement day is not affected by the amendment made to section 4 by the amending Act and is sufficient authority for a medical practitioner to remove the tissue for the purposes of the consent.
- (2) In this clause—

**amending Act** means the *Health Legislation (Miscellaneous) Amendment Act (No 2)* 2022.

**commencement day** means the day on which the amendment made to section 4 by the amending Act commences.