TASMANIA

HUMAN TISSUE AMENDMENT BILL 2006

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HUMAN TISSUE AMENDMENT BILL 2006

(Brought in by the Minister for Health and Human Services, the Honourable Larissa Tahireh Giddings)

A BILL FOR

An Act to amend the Human Tissue Act 1985

Be it enacted by His Excellency the Governor of Tasmania, by and with the advice and consent of the Legislative Council and House of Assembly, in Parliament assembled, as follows:

1. Short title

This Act may be cited as the *Human Tissue* Amendment Act 2006.

2. Commencement

This Act commences on the day on which this Act receives the Royal Assent.

3. Principal Act

In this Act, the *Human Tissue Act 1985** is referred to as the Principal Act.

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^{*}No. 118 of 1985

4. Section 3 amended (Interpretation)

Section 3(1) of the Principal Act is amended as follows:

- (a) by inserting the following definition before the definition of "child":
 - "affected deceased person" means a deceased person whose death is a reportable death within the meaning of the *Coroners Act* 1995;
- (b) by inserting the following definitions after the definition of "designated officer":
 - "diagnostic purposes" means the purposes of determining
 - (a) the cause of a deceased person's death; or
 - (b) other medical issues, or the extent of other medical issues, relating to the health a deceased person;
 - "hospital manager" means the person that has the day-to-day administrative control of the hospital;
- (c) by inserting the following definition after the definition of "next of kin":

- "non-coronial autopsy" means an autopsy that is authorised under Part IIIA;
- (d) by omitting "available;" from paragraph (b)(iv) of the definition of "senior available next of kin" and substituting "available; or";
- (e) by inserting the following subparagraph after subparagraph (iv) in paragraph (b) of the definition of "senior available next of kin":
 - (v) where no person referred to in subparagraph (i), (ii), (iii) or (iv) is available and the deceased person is an Aboriginal person within the meaning of the Aboriginal and Torres Strait Islander Commission Act 1989 of the Commonwealth a person who is an appropriate person according to the customs and the tradition of the community or group that the deceased person belonged to;
- (f) by inserting the following definition after the definition of "senior available next of kin":

"therapeutic, medical or scientific purpose" includes –

- (a) the teaching of therapeutic techniques, medicine or science; and
- (b) medical or scientific research; and
- (c) any other purpose prescribed in the regulations for this definition;

5. Section 4 substituted

Section 4 of the Principal Act is repealed and the following section is substituted:

4. Designated officers

- (1) For the purposes of this Act, the hospital manager, by instrument in writing, may appoint such medical practitioners as are necessary to be designated officers for the hospital.
- (2) A designated officer must not act in that capacity under Part IIIA in respect of a deceased person if the designated officer
 - (a) before the deceased person's death, was involved in the provision of medical care to the person; or
 - (b) is likely to be involved in –

- (i) the performance of a noncoronial autopsy on the deceased person; or
- (ii) the removal of tissue at such an autopsy.

6. Section 7 amended (Consent by adult living donor to removal of regenerative tissue)

Section 7(b) of the Principal Act is amended by omitting "therapeutic purposes or for medical or scientific purposes" and substituting "therapeutic, medical or scientific purposes".

7. Section 18 amended (Consents by adults to removal of blood)

Section 18(b) of the Principal Act is amended by omitting "therapeutic purposes or for medical or scientific purposes" and substituting "therapeutic, medical or scientific purposes".

8. Section 23 amended (Authority to remove tissue where body of deceased at a hospital)

Section 23 of the Principal Act is amended as follows:

(a) by omitting from subsection (1)(a)(ii) "therapeutic purposes or for medical or scientific purposes" and substituting

- "therapeutic, medical or scientific purposes";
- (b) by omitting subparagraph (iv) from subsection (2)(b) and substituting the following subparagraph:
 - no objection has been made by (iv) any other next of kin (of the same or a higher order of the classes referred to in paragraphs (a) and (b) of the definition of "senior available next of kin" in section 3(1)) to the removal of tissue from the body of the deceased person for any purpose including the purpose, or any of the purposes, specified in that consent -

9. Section 24 amended (Authority to remove tissue where body of deceased not at a hospital)

Section 24(1)(b) of the Principal Act is amended by omitting "therapeutic purposes or for medical or scientific purposes" and substituting "therapeutic, medical or scientific purposes".

10. Section 25 repealed

Section 25 of the Principal Act is repealed.

11. Part IIIA inserted

After section 26 of the Principal Act, the following Part is inserted:

PART IIIA – NON-CORONIAL AUTOPSIES AND MEDICAL EXAMINATIONS

Division 1 – General

26A. Non-coronial autopsies to be dignified

In the performance of a non-coronial autopsy under this Act, regard is to be had to the dignity of the deceased person.

Division 2 – Consent to non-coronial autopsies

26B. Authority to perform non-coronial autopsy

- (1) A designated officer, by instrument in writing, may authorise a non-coronial autopsy of the body of a deceased person if, after making reasonable enquiries, the designated officer is satisfied that
 - (a) the deceased person is not a deceased child; and
 - (b) the deceased person had, during his or her lifetime, given written consent to the non-coronial autopsy; and
 - (c) the consent had not been withdrawn or revoked before the deceased person's death; and

- (d) if the deceased person is an affected deceased person, the coroner has consented under section 28A to the non-coronial autopsy.
- (2) A designated officer, by instrument in writing, may authorise a non-coronial autopsy of the body of a deceased person if, after making reasonable enquiries, the designated officer
 - (a) is not satisfied of the matters referred to in subsection (1); but
 - (b) is satisfied that
 - (i) the deceased person did not, during his or her lifetime, object to a noncoronial autopsy being performed after his or her death; and
 - (ii) the senior available next of kin of the deceased person has given written consent to the noncoronial autopsy; and
 - (iii) the consent of the senior available next of kin has not been withdrawn or revoked; and
 - (iv) no objection to the noncoronial autopsy has been

made by any other next of kin (of the same or of a higher order of the classes of next of kin specified in the definition of "senior available next of kin" in section 3); and

- (v) if the deceased person is an affected deceased person, the coroner has consented under section 28A to the noncoronial autopsy.
- (3) However, subsection (2)(b)(ii), (iii) and (iv) do not apply if, after making reasonable enquiries, a designated officer is unable to locate, or ascertain the existence of, any of the deceased person's next of kin.
- (4) The consent of a deceased person or senior available next of kin of a deceased person to a non-coronial autopsy of the deceased person may be given conditionally or unconditionally.

26C. Removal of tissue during non-coronial autopsy

(1) A designated officer, by instrument in writing, may authorise the removal of tissue for use for therapeutic, medical or scientific purposes during a non-coronial

autopsy if, after making reasonable enquiries, the designated officer is satisfied that –

- (a) the deceased person is not a deceased child; and
- (b) the deceased person had, during his or her lifetime, given written consent for the removal and use of tissue for such purposes; and
- (c) the consent had not been withdrawn or revoked before the deceased person's death; and
- (d) if the deceased person is an affected deceased person, the coroner has consented under section 28A to the removal of tissue.
- (2) A designated officer, by instrument in writing, may authorise the removal of tissue for use for therapeutic, medical or scientific purposes during a non-coronial autopsy if, after making reasonable enquiries, the designated officer
 - (a) is not satisfied of the matters referred to in subsection (1); but
 - (b) is satisfied that
 - (i) the deceased person did not, during his or her lifetime, object to tissue

being removed for use for therapeutic, medical or scientific purposes after his or her death; and

- (ii) the senior available next of kin of the deceased person has given written consent for the removal and use of tissue for such purposes; and
- (iii) that consent of the senior available next of kin has not been withdrawn or revoked; and
- (iv) no objection to the removal and use of the tissue has been made by any other next of kin (of the same or of a higher order of the classes of next of kin specified in the definition of "senior available next of kin" in section 3); and
- (v) if the deceased person is an affected deceased person, the coroner has consented under section 28A to the removal of tissue.

- (3) However, subsection (2)(b)(ii), (iii) and (iv) do not apply if, after making reasonable enquiries, a designated officer is unable to locate, or ascertain the existence of, any of the deceased person's next of kin.
- (4) The consent of a deceased person or senior available next of kin of a deceased person to the removal of tissue for use for therapeutic, medical or scientific purposes during a non-coronial autopsy may be given conditionally or unconditionally.
- (5) An authorisation under this section is not required to remove tissue for diagnostic purposes during a non-coronial autopsy.

26D. Effect of authorisation under this Part

- (1) In this section
 - "conditions of consent" means the conditions attached to –
 - (a) a consent for the performance of a non-coronial autopsy; or
 - (b) a consent for the removal of tissue for use for therapeutic, medical or scientific purposes during a non-coronial autopsy.
- (2) An authorisation given under section 26B is authority for a medical practitioner,

other than the designated officer giving the authorisation, to –

- (a) perform, in accordance with the conditions of consent, a noncoronial autopsy on the body of the deceased person specified in the authorisation; and
- (b) remove such tissue from the deceased person during a non-coronial autopsy as is necessary for diagnostic purposes.
- (3) An authorisation given under section 26C is authority for
 - (a) a medical practitioner, other than the designated officer giving the authorisation, to remove, in accordance with the conditions of consent, tissue from a deceased person during a non-coronial autopsy in accordance with the authorisation; and
 - (b) the removed tissue to be used, in accordance with the conditions of consent, for therapeutic, medical or scientific purposes.
- (4) If the same tissue is required for diagnostic purposes and for therapeutic, medical or scientific purposes, the tissue is to be used for diagnostic purposes first.

Division 3 – Consent to medical examination

26E. Medical examination of stillborn child

(1) In this section –

"conditions of parental consent"
means the conditions attached to
the consent of a parent of a
stillborn child for –

- (a) the performance of a medical examination of the stillborn child; or
- (b) the removal of tissue for use for therapeutic, medical or scientific purposes during a medical examination of a stillborn child;

"stillborn child" means a child who is stillborn and –

- (a) is at least 20 weeks in gestation; or
- (b) if it cannot be reliably established whether the period of gestation is at least 20 weeks, has a body mass of at least 400 grams at birth.
- (2) A designated officer, by instrument in writing, may authorise a medical

- examination of a stillborn child if a parent of the stillborn child has given consent in writing to the examination.
- (3) An authorisation under subsection (2) is authority for a medical practitioner, other than the designated officer who gave the authorisation, to
 - (a) perform, in accordance with the conditions of parental consent, the medical examination of the stillborn child specified in the authorisation; and
 - (b) remove such tissue from the stillborn child during the medical examination as is necessary for medical testing.
- (4) A designated officer, by instrument in writing, may authorise the removal of tissue for use for therapeutic, medical or scientific purposes during a medical examination of a stillborn child if a parent of the stillborn child has given written consent for the tissue to be removed for use for therapeutic, medical or scientific purposes.
- (5) An authorisation under subsection (4) is authority for
 - (a) a medical practitioner, other than the designated officer who gave the authorisation, to remove, in accordance with the conditions of

- parental consent, tissue from a stillborn child during a medical examination in accordance with the authorisation; and
- (b) the removed tissue to be used, in accordance with the parental conditions of consent, for therapeutic, medical or scientific purposes.
- (6) The consent of a parent of a stillborn child to a medical examination of the stillborn child, or to the removal of tissue for use for therapeutic, medical or scientific purposes from the stillborn child, may be given conditionally or unconditionally.
- (7) If the same tissue is required for medical testing and for therapeutic, medical or scientific purposes, the tissue is to be used for medical testing first.

Division 4 – Procedure

26F. Secretary to approve or issue guidelines

- (1) This section applies to a hospital where non-coronial autopsies, or medical examinations of stillborn children, are performed in accordance with this Act.
- (2) A hospital manager is to submit draft guidelines to the Secretary.

- (3) The draft guidelines
 - (a) must include guidelines on any matter specified by the Secretary; and
 - (b) may include guidelines on the following matters:
 - (i) procedures relating to obtaining consent for non-coronial autopsies or medical examinations of stillborn children;
 - (ii) hospital procedures and protocols for all stages of non-coronial autopsies or medical examinations of stillborn children;
 - (iii) the collection and recording of information relating to non-coronial autopsies or medical examinations of stillborn children; and
 - (c) may include other guidelines relating to the performance of non-coronial autopsies or medical examinations of stillborn children.
- (4) The draft guidelines may amend, or replace, the existing guidelines for the hospital.

- (5) The Secretary may
 - (a) approve the draft guidelines as guidelines; or
 - (b) refuse to approve the draft guidelines.
- (6) The Secretary may issue guidelines, without having first received a submission under subsection (2), that
 - (a) put guidelines in place for a hospital; or
 - (b) amend the existing guidelines of a hospital; or
 - (c) replace the existing guidelines of a hospital.
- (7) If the Secretary issues guidelines that amend the existing guidelines, the amendment, unless it states otherwise, is incorporated into the existing guidelines.
- (8) If the Secretary issues guidelines that replace the existing guidelines, the existing guidelines are rescinded unless the replacement guidelines state otherwise.
- (9) The Secretary may specify in the guidelines the hospital, or hospitals, to which the guidelines apply.

12. Section 28A inserted

After section 28 of the Principal Act, the following section is inserted in Part V:

28A. Consent by coroner

- (1) Before
 - (a) a senior available next of kin consents to the removal of tissue from the body of an affected deceased person; or
 - (b) a designated officer authorises the removal of tissue from the body of an affected deceased person; or
 - (c) a designated officer authorises the performance of a non-coronial autopsy of an affected deceased person –

a coroner must have consented to the removal of the tissue or, as the case may be, the performance of the non-coronial autopsy.

(2) However, before or after the death of an affected deceased person, a coroner may give a direction that his or her consent is not required under this section and, in that event, the deceased person is no longer an affected deceased person for the purposes of this Act.

- (3) A consent or direction by a coroner under this section
 - (a) if the coroner makes the consent or direction orally, is to be confirmed in writing as soon as practicable; and
 - (b) may be on such conditions as are specified in the consent or direction.
- (4) Sections 24(3) and 26D do not apply in relation to an affected deceased person until a coroner has given his or her consent under subsection (1).

13. Section 30 amended (Offences)

Section 30 of the Principal Act is amended as follows:

- (a) by omitting from the penalty under subsection (1) "10 penalty units" and substituting "50 penalty units";
- (b) by inserting the following subsection after subsection (1):
 - (1A) A person must not perform a noncoronial autopsy on the body of a deceased person, or a medical examination of a stillborn child, except in accordance with a consent or authority that is, under this Act, sufficient authority for

the performance of the noncoronial autopsy or the medical examination by that person.

Penalty: Fine not exceeding 50 penalty units or imprisonment for a term not exceeding 6 months, or both.

14. Section 31 amended (Disclosure of information)

Section 31(1)(a) of the Principal Act is amended by omitting "therapeutic purposes or for medical or scientific purposes" and substituting "therapeutic, medical or scientific purposes".

15. Section 32 substituted

Section 32 of the Principal Act is repealed and the following section is substituted:

32. Regulations

- (1) The Governor may make regulations for the purposes of this Act.
- (2) Without limiting the generality of subsection (1), the regulations may
 - (a) provide for the making and keeping of records in connection with the removal of tissue from the body of a person (whether

living or deceased), including records relating to –

- (i) the removal of tissue in the course of medical, dental or surgical treatment; and
- (ii) the use of the tissue for any purpose; and
- (b) provide for the making and keeping of records relating to
 - (i) a non-coronial autopsy under this Act; and
 - (ii) the use of any tissue removed under this Act for therapeutic, medical or scientific purposes; and
- (c) prescribe information to be provided to the Secretary, or to any other specified person concerned in the administration of this Act, relating to
 - (i) the removal of tissue under this Act from the body of a person (whether living or dead); and
 - (ii) the use of the tissue for any purpose; and

- (d) prescribe how tissue is to be dealt with once it is no longer required for the purposes of this Act.
- (3) The regulations may be made so as to apply differently according to such factors as are specified in the regulations.
- (4) The regulations may
 - (a) provide that a contravention of any of the regulations is an offence; and
 - (b) in respect of such an offence, provide for the imposition of a fine not exceeding 50 penalty units and, in the case of a continuing offence, a further fine not exceeding 10 penalty units for each day during which the offence continues.
- or in part and with or without modification, and either specifically or by reference, any standards, rules, codes or specifications whether or not the standards, rules, codes or specifications are published or issued before or after the commencement of this Act.
- (6) A reference in subsection (5) to standards, rules, codes or specifications includes a reference to an amendment to those standards, rules, codes or specifications, whether the amendment is

published or issued before or after the commencement of this Act.