

# **HUMAN TISSUE DONATION ACT**

# PLEASE NOTE

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If you find any errors or omissions in this consolidation, please contact:

Legislative Counsel Office Tel: (902) 368-4292

Email: <u>legislation@gov.pe.ca</u>



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# HUMAN TISSUE DONATION ACT

#### INTERPRETATION

#### 1. Definitions

In this Act

- (a) repealed by 2008, c.8, s. 14;
- (b) "death" includes brain death as determined by generally accepted medical criteria;
- (b.1) "donor" means an individual who has consented to donate his or her tissue or body for transplantation, therapeutic purposes, medical education or scientific research or for whom such a consent has been given in accordance with this Act;
- (c) "non-regenerative tissue" means tissue other than regenerative tissue;
- (d) "Official Guardian" means the person appointed under subsection 33(1) of the *Judicature Act* R.S.P.E.I. 1988, Cap. J-2.1 as the Official Guardian;
- (e) "regenerative tissue", in a living human body, means tissue that, on injury or removal, replaces itself;
- (f) repealed by 2008, c.8, s.14;
- (g) "tissue" means any part of a living or dead human body, but does not include
  - (i) spermatozoa or ova,
  - (ii) an embryo or fetus, or
  - (iii) blood or blood constituents;
- (h) "**transplant**" means the removal of tissue from a human body, whether living or dead, and the implantation of the tissue in a living human body. 1992, c.34, s.1; 2008,c.20,s.72(43); 2008,c.8,s.14; 2011,c.36,s.2.

#### 2. Compliance with Act

A consent to the removal of tissue for the purposes of this Act may be given in accordance with this Act, but not otherwise. 1992, c.34, s.2.

## **DONATION OF TISSUE AFTER DEATH**

# 3. Consent to transplant after death

(1) A person who is sixteen years of age or over and understands the nature and consequences of transplanting tissue from his or her body after death may consent to the removal of tissue or

such tissue as may be specified in the consent from his or her body after death for the purpose of implanting the tissue in a living human body.

#### Validity of consent

(2) Notwithstanding subsection (1), a consent given by a person who did not understand the nature and consequences of transplanting tissue from his or her body after death is valid for the purposes of this section if the person who acts on it has no reason to believe that the person who gave it did not understand the nature and consequences of transplanting tissue from his or her body after death. 1992, c.34, s.3.

#### 4. Hospital record regarding discussion of tissue donation

Where the death of a person who is a patient in a hospital is imminent, the hospital shall record, in such form and manner as may be prescribed,

- (a) whether any attending medical practitioner of the patient or other person designated by the hospital, discussed tissue donation with any of the persons authorized to provide a consent on behalf of a patient under subsection 5(2); and
- (b) if no discussion referred to in clause (a) occurred, the reason why it did not. 1992, c.34, s.4: 2011,c.36,s.4.

#### 5. Substituted consent

- (1) After the death of a person who has not given a consent under section 3, who is under sixteen years of age or who did not understand the nature and consequences of transplanting tissue from his or her body after death, a person referred to in subsection (2) may consent to the removal of tissue or such tissue as may be specified in the consent from the body of the deceased
  - (a) for the purpose of implanting the tissue in a living human body; or
  - (b) for the purposes referred to in section 12.

#### Persons who may give substituted consent

- (2) A consent referred to in subsection (1) may be given by any one of the following:
  - (a) a guardian of the person of the deceased before death;
  - (b) the spouse of the deceased;
  - (c) a child of the deceased;
  - (d) a parent of the deceased;
  - (e) a brother or sister of the deceased;
  - (f) any other of the next of kin of the deceased;
  - (g) a person other than a spouse who shared a residence with the deceased immediately before the deceased died and has knowledge of the wishes of the deceased.

#### Determination of dispute, priority of classes

(3) In the event of a dispute between persons in two or more of the classes of persons referred to in subsection (2), the dispute shall be decided in accordance with the order in which those classes are listed in subsection (2).

# **Consent by coroner**

(4) If no consent is provided under subsection (1) and the coroner, after making reasonable efforts, is unable to locate any of the persons listed in subsection (2), the coroner may give a consent referred to in subsection (1).

#### **Invalid consent**

- (5) No consent may be given under this section by a person who
  - (a) is under sixteen years of age;
  - (b) does not understand the nature and consequences of transplanting tissue from the body of the deceased after death; or
  - (c) has reason to believe that the deceased would have objected to the consent. 1992, c.34, s.5; 2011,c.36,s.5.

### **DONATION OF TISSUE DURING LIFE**

#### 6. Consent to transplant during life

(1) A person who is sixteen years of age or over and understands the nature and consequences of transplanting tissue from his or her body during his or her life may consent to the removal of the tissue specified in the consent from his or her body during his or her life for the purpose of implanting the tissue in another living human body.

#### **Quality of consent**

(2) If there is reason to believe that a person who gives a consent under this section may not understand the nature and consequences of transplanting tissue from his or her body during his or her life, no transplant may be carried out pursuant to that consent unless the results of an independent assessment conducted in accordance with section 8 indicate that the transplant should be carried out.

# Non-regenerative tissue, independent assessment required

(3) No transplant of non-regenerative tissue may be carried out pursuant to this section unless the results of an independent assessment conducted in accordance with section 8 indicate that the transplant should be carried out. 1992, c.34, s.6.

#### 7. Transplant during life re person under sixteen

(1) A person who is under sixteen years of age and understands the nature and consequences of transplanting tissue from his or her body during his or her life may consent to the removal of the regenerative tissue specified in the consent from his or her body during his or her life for the purpose of implanting the tissue in another living human body.

#### Bone marrow transplant, person under sixteen

(2) Notwithstanding subsection (1), bone marrow may be removed from a person who is under sixteen years of age and does not understand the nature and consequences of transplanting tissue from his or her body during his or her life for the purpose of implanting the bone marrow in a biological brother or biological sister of the person.

# Parental consent also required

- (3) No transplant may be carried out
  - (a) pursuant to a consent given under subsection (1), unless a parent or guardian of the donor also consents to the transplant; or
  - (b) pursuant to subsection (2), unless a parent or guardian of the person under sixteen years of age consents to the transplant on behalf of the person.

#### Independent assessment required

(4) No transplant may be carried out pursuant to this section unless the results of an independent assessment conducted in accordance with section 8 indicate that the transplant should be carried out. 1992, c.34, s.7; 2011,c.36,s.7.

#### INDEPENDENT ASSESSMENT

### 8. Independent assessment

(1) If an independent assessment is required pursuant to this Act, it shall be conducted in accordance with this section and the regulations.

#### **Persons**

(2) An independent assessment shall be conducted by not fewer than three persons appointed by the Minister of Health and Wellness, of whom one shall be a medical practitioner.

#### Independence

(3) No person who has or has ever had an association with the donor of tissue or with the prospective recipient of the tissue shall conduct the independent assessment.

#### **Notice**

- (4) The persons conducting an independent assessment shall provide notice of the date, time and place of the independent assessment to
  - (a) the donor of the tissue;
  - (b) if the donor is under sixteen years of age, the parent or guardian of the donor and the Official Guardian; and
  - (c) if the donor is sixteen years of age or over and there is reason to believe that the donor may not understand the nature and consequences of transplanting tissue from his or her body during his or her life, the parent or guardian of the person of the donor and the Official Guardian.

#### **Representation by Official Guardian**

(5) On receiving a notice under subsection (4), the Official Guardian shall represent the donor at the independent assessment unless the Official Guardian is satisfied that another person other than the parent or guardian of the person of the donor will represent the donor.

#### Factors to be considered

- (6) The persons conducting an independent assessment shall consider the following:
  - (a) whether the transplant is the medical treatment of choice for the prospective recipient;
  - (b) with respect to a transplant under section 7, whether all adult members of the family of the prospective recipient have been eliminated, for medical or other reasons, as more or equally appropriate persons to donate tissue to the prospective recipient;
  - (c) whether coercion has been exerted on, or an inducement has been offered to, the donor for the purpose of obtaining his or her consent to the transplant;
  - (d) whether the removal of the tissue from the body of the donor will create a substantial health or other risk to the donor;
  - (e) whether this Act and the regulations, as they relate to that transplant, have been complied with.

#### **Decision**

- (7) The persons conducting an independent assessment shall
  - (a) make a decision as to whether a transplant that has been proposed pursuant to section 6 or 7 should or should not be carried out;
  - (b) provide written reasons for the decision; and
  - (c) provide notice of that decision and the reasons for the decision to the persons who received notice of the independent assessment under subsection (4). 1992, c.34, s.8; 1995, c.20, s.1; 2005,c.40,s.16; 2010,c.31,s.3; 2011,c.36,s.9.

#### 9. Appeal

(1) A person may, within three days after a decision has been made under subsection 8(7), appeal to the Supreme Court the decision of the persons who conducted an independent assessment.

#### Decision

- (2) On hearing an appeal, the court may
  - (a) quash, vary or confirm the decision of the persons who conducted the independent assessment; or
  - (b) refer the matter back to the persons who conducted the independent assessment for further action in accordance with the directions of the court.

#### Bone marrow to sibling, consent by parent

(3) On hearing an appeal to which subsection 7(2) applies, the court may make an order authorizing a parent or guardian of the donor to consent to the transplant on behalf of the donor.

#### Transplant suspended pending appeal

(4) No transplant in respect of which an appeal has been commenced under subsection (1) shall be carried out until the appeal has been concluded. 1992, c.34, s.9; 2008,c.20,s.72(43).

#### CONSENT

#### 10. Effect of consent for donation during life

- (1) A consent given under section 6 or 7 that complies with this Act is binding and is authority for a medical practitioner
  - (a) to make any examination of the donor necessary to assure the medical acceptability of the tissue referred to in the consent; and
  - (b) to remove the tissue referred to in the consent from the donor in accordance with the consent.

# Effect of consent for donation after death

(1.1) A consent given under section 3 or clause 5(1)(a) that complies with this Act is binding and is authority for a medical practitioner or a person directed by a medical practitioner

- (a) to make any examination of the body of the donor necessary to assure the medical acceptability of the tissue referred to in the consent; and
- (b) to remove the tissue referred to in the consent from the body of the donor in accordance with the consent.

#### Effect of consent for other purposes

(1.2) A consent given under clause 5(1)(b) or section 12 that complies with this Act is binding and is authority for the use of the body or tissue from the body of the donor for therapeutic purposes, medical education or scientific research as specified in the consent.

#### **Defective consent**

- (2) Notwithstanding subsection (1), (1.1) or (1.2), no person shall act on a consent if the person has reason be believe that
  - (a) in the case of a consent under section 3, 6, 7 or 12, the person who gave the consent subsequently withdrew or would have objected to the consent; or
  - (b) in the case of a consent under section 5, the person on whose behalf the consent was given would have objected to the consent.
- (3) Notwithstanding subsection (1), (1.1) or (1.2), no medical practitioner shall act on a consent or direct another person to act on a consent where
  - (a) the donor died under any of the circumstances set out in section 5 of the *Coroners Act* R.S.P.E.I. 1988, Cap. C-25.1 warranting an investigation by a coroner; or
  - (b) in the opinion of a medical practitioner the death of the donor is imminent and the medical practitioner has reason to believe that clause (a) will apply when the donor dies,

unless a coroner has given directions authorizing the medical practitioner to do so.

#### Use of removed tissue for other purposes

(4) If any tissue that has been removed pursuant to a consent given under section 3, 5, 6 or 7 cannot for any reason be implanted in a living human body, the tissue shall be disposed of as if no consent relating to the tissue had been given, unless the donor has consented to the use of the tissue for therapeutic purposes, medical education or scientific research in accordance with section 12. 1992, c.34, s.10; 2006,c.29,s.59; 2011,c.36,s.10.

#### 11. Determination of death

(1) The fact of death of a donor of tissue shall be determined by at least two medical practitioners in accordance with accepted medical practice.

#### Independence of medical practitioner

(2) No medical practitioner who has had any association with the proposed recipient of tissue shall take any part in the determination of the fact of death of the donor of that tissue.

#### Idem

(3) No medical practitioner who took any part in the determination of the fact of death of the donor of tissue shall participate in any way in the transplant of that tissue.

#### Application of subsection (1)

(4) The requirement in subsection (1) for the fact of death to be determined by at least two medical practitioners does not apply where

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- (a) only non-perfusible tissue is to be removed from the donor; and
- (b) the fact of death of the donor has been determined by a medical practitioner following cessation of the donor's heart function.

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#### Application of subsections (2) and (3)

(5) Subsections (2) and (3) do not apply to a medical practitioner in respect of non-perfusible tissue. 1992, c.32, s.11; 1995, c.20, s.2; 2011,c.36,s.11.

#### **DONATION OF BODY**

#### 12. Consent for other purposes

Notwithstanding anything in this Act, a person who is sixteen years of age or over and understands the nature and consequences of such a decision may consent to the use of his or her body or tissue from his or her body specified in the consent after death for therapeutic purposes, medical education or scientific research. 1992, c.34, s.12; 2011,c.36,s.13.

#### DISCLOSURE OF INFORMATION

#### 13. Disclosure of information

- (1) Except where required by law, no person shall disclose or give to any other person any information or document whereby the public may learn the identity of a person
  - (a) who has given or refused to give a consent to the removal of tissue;
  - (b) with respect to whom a consent to the removal of tissue has been given or refused; or
  - (c) into whose body tissue has been, is being or may be implanted.

#### **Exceptions**

- (2) Notwithstanding subsection (1),
  - (a) a donor of tissue or a person who gave consent under subsection 7(3) may disclose or authorize another person to disclose information relating only to the donor that the donor or such person has authorized for disclosure;
  - (b) a recipient of tissue, or a person who gave consent to implantation on behalf of the recipient, may disclose or authorize another person to disclose information relating only to the recipient that the recipient or such person has authorized for disclosure; and
  - (c) a person who gave a consent under section 5 on behalf of a deceased may disclose or authorize another person to disclose information relating only to the deceased that the person who gave the consent has authorized for disclosure. 1992, c.34, s.13.

#### **GENERAL**

#### 14. Protection from liability

No person is liable for anything done or omitted to be done in good faith and without negligence in the exercise or intended exercise of any authority under this Act. 1992, c.34, s.14.

#### 15. Commerce prohibited

(1) No person shall buy, sell or otherwise for remuneration or other financial benefit deal in, directly or indirectly, any tissue, body or body part.

# Saving

(2) Any dealing with a body or tissue that was lawful before this Act came into force shall continue to be lawful, provided this Act is complied with.

#### Offence

(3) A person who contravenes this section is guilty of an offence and liable on summary conviction to a fine of not more than \$10,000 or to imprisonment for not more than one year, or to both. 1992, c.34, s.15.

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#### 16. General offence

A person who contravenes a provision of this Act, except section 15, is guilty of an offence and liable on summary conviction to a fine of not more than \$1,000 or to imprisonment for not more than three months, or to both. 1992, c.34, s.16; 2011,c.36,s.16.

# 17. Regulations

The Lieutenant Governor in Council may make regulations. 1992, c.34, s.17.

#### 18. Repeal

Repeals. 1992, c.34, s.18.