

BILL NO. 121

(as passed)



*2nd Session, 61st General Assembly
Nova Scotia
59 Elizabeth II, 2010*

Government Bill

Human Organ and Tissue Donation Act

CHAPTER 36 OF THE ACTS OF 2010

The Honourable Maureen MacDonald
Minister of Health

[First Reading](#): November 30, 2010 (LINK TO BILL AS INTRODUCED)

Second Reading: December 9, 2010

[Third Reading](#): December 10, 2010

Royal Assent: December 10, 2010



An Act Respecting Human Organ and Tissue Donation

Be it enacted by the Governor and Assembly as follows:

1 This Act may be cited as the Human Organ and Tissue Donation Act.

2 In this Act,

(a) "best interests" includes consideration of the physical, psychological, emotional and social well-being of the living potential donor;

(b) "binding" means must be followed;

(c) "capacity" means the ability to understand the information that is relevant to the decision to be made and the ability to appreciate the reasonably foreseeable consequences of a decision or lack of a decision;

(d) "Chief Medical Examiner" means the chief medical examiner appointed pursuant to the Fatality Investigations Act;

(e) "common-law partner" of an individual means another individual who has cohabited with the individual in a conjugal relationship for a period of at least one year;

(f) "consent" means a consent given under this Act;

(g) "continuing-care home" means any facility licensed under the Homes for Special Care Act, any facility for which a resident may be approved for admission by the Department of Health or the Department of Community Services and any facility prescribed by the regulations;

(h) "court" means the Supreme Court of Nova Scotia;

(i) "critical functions" means respiration and circulation, endocrine and homeostatic regulation and consciousness;

(j) "death" means the irreversible cessation of the functioning of the organism as a whole as determined by the irreversible loss of the brain's ability to control and co-ordinate all of the organism's critical functions;

(k) "district health authority" has the same meaning as in the Health Authorities Act and, for greater certainty, includes the Izaak Walton Killam Health Centre;

(l) "donation after death" means a donation of any human organs, tissue or body after death in accordance with this Act;

- (m) "donor" means an individual who has consented to donate the individual's organs, tissue or body for transplantation, scientific research or education or in respect of whom a consent has been given;
- (n) "guardian" means a person appointed by the court under the Incompetent Persons Act, a person appointed as the guardian of the person of a child under the Guardianship Act or a person who is a guardian under the Children and Family Services Act;
- (o) "health-card number" means a unique identification number assigned by the Department of Health to individuals insured under the Health Services and Insurance Act and reflected on the Nova Scotia health card;
- (p) "irreversible" means not physically possible to reverse without violating consent law;
- (q) "living donation" means a donation of organs or tissue while living in accordance with this Act;
- (r) "organ" means an organ, whether whole or in sections, lobes or parts;
- (s) "organ-donation program" means the Critical Care Organ Donation Program operated by the Capital District Health Authority, or its successor, or other prescribed entity;
- (t) "personal information" includes medical history and social history;
- (u) "physician" means a duly qualified medical practitioner;
- (v) "pre-death transplantation optimizing interventions" means interventions that are performed on a person before the person's death for the purpose of optimizing the chances of a successful transplantation;
- (w) "spouse" of an individual means another individual who is cohabiting with that individual in a conjugal relationship as married spouse, registered domestic partner or common-law partner;
- (x) "substitute decision maker" means an individual who is authorized to give consent for another under Section 12;
- (y) "tissue" means a functional group of human cells, excluding organs;
- (z) "tissue bank" means the Regional Tissue Bank operated by the Capital District Health Authority or its successor, or other prescribed entity;
- (aa) "transplantation" means the operation of transferring organs or tissues from a donor, whether living or dead, to a living human recipient;
- (ab) "writing" includes a Nova Scotia health card.

3 This Act does not apply to

- (a) blood or blood constituents; or
- (b) zygotes, oocytes, embryos, sperm, semen or ova.

4 A living donation or a donation after death may be done only in accordance with this Act.

5 Only capable individuals may consent, refuse consent or withdraw consent for the purpose of this Act.

LIVING DONATION

6 (1) Any capable individual may, in a writing signed by the individual, consent to donate specific organs or tissues from the individual's living body.

(2) The consent must be

- (a) voluntary and informed; and
- (b) given by a person with the legal authority to give, refuse or withdraw consent.

7 (1) Where an individual lacks the capacity to give a valid consent and the individual has a valid personal directive setting out clear instructions or expressions of wishes that the individual would want to consent to living donation, a person authorized to give consent pursuant to clause 3(1)(b) or Section 14 of the Personal Directives Act who gives voluntary and informed consent may, in a writing signed by that person, consent to the living donation of organs for transplantation on behalf of the individual.

(2) When a person authorized pursuant to subsection (1) is making a decision about living donation by an individual, the person shall follow any instructions of the individual in a personal directive made pursuant to the Personal Directives Act unless

- (a) there are expressions of a contrary wish made subsequently by the individual while capable;
- (b) technological changes or medical advances make the instruction inappropriate in a way that is contrary to the intentions of the individual; or
- (c) circumstances exist that would have caused the individual to set out different instructions had the circumstances been known based on what is known of the values and beliefs of the individual and from any other written or oral instructions.

8 (1) Where an individual lacks the capacity to give a valid consent, and the criteria set out in Section 7 are not met, the individual's organs may not be donated from the individual's living body for transplantation without court authorization.

(2) When the court is deciding whether to authorize a donation for transplantation pursuant to subsection (1), the court shall consider

- (a) whether the proposed recipient has a close personal relationship with the individual;
- (b) a written report by a physician stating that the donation by the individual who lacks capacity is the best option for a successful transplant for the recipient;
- (c) a written report by the ethics program associated with the hospital where the transplant will be performed that has reviewed the case;
- (d) a written psychosocial report about the individual by an independent psychologist or psychiatrist who has experience working with
 - (i) incapable adults if the individual is a adult, or
 - (ii) incapable minors if the individual is a minor;
- (e) a written statement by the substitute decision maker who has the authority to make health-care decisions in respect of the individual consenting to the donation;
- (f) whether the donation
 - (i) where the individual is an adult, is consistent with the known prior capable wishes of the individual or, where such wishes are not known, is in the best interests of the individual, or
 - (ii) where the individual is a minor, is in the best interests of the individual; and
- (g) the current wishes of the individual.

(3) When a substitute decision maker is deciding whether to consent to the donation, the substitute decision maker shall

- (a) where the individual is an adult,
 - (i) act according to what the substitute decision maker believes the wishes of the individual would be based on what the substitute decision maker knows of the values and beliefs of the individual and from any other written or oral instructions, or
 - (ii) where the substitute decision maker does not know the wishes, values and beliefs of the individual, make a decision that the substitute decision maker believes would be in the best interests of the individual; or
- (b) where the individual is a minor, make a decision that the substitute decision maker believes would be in the best interests of the individual.

(4) Upon application of a party or on its own motion, the court may order that a guardian ad litem be appointed for the incapable individual.

(5) Where there is more than one substitute decision maker who has the authority to make health-care decisions, the court may authorize the donation if there is consent from one substitute decision maker.

9 (1) A consent given pursuant to Sections 6 and 7 or a court authorization pursuant to Section 8 is binding and full authority for any physician to

(a) make any examination of the donor that is necessary to assure medical suitability of the organ specified therein; and

(b) remove the specified organ from the body of the donor.

(2) Where for any reason the organ specified in the consent is not removed in the circumstances to which the consent relates, the consent is void.

PRE-DEATH TRANSPLANTATION OPTIMIZING INTERVENTIONS

10 (1) Consent to donate organs does not imply consent to pre-death transplantation optimizing interventions.

(2) Any individual who

(a) is provided with the information listed in clause 13(1)(c); and

(b) gives voluntary and informed consent,

may consent

(c) in a writing signed by the individual; or

(d) orally in the presence of at least two witnesses with contemporaneous documentation of the consent,

to the use of pre-death transplantation optimizing interventions on the individual's body.

(3) Where an individual has not provided consent pursuant to subsection (2), the individual is incapable of consenting and in the opinion of a physician the person's death is imminent, a substitute decision maker shall

(a) follow any instructions in a personal directive made pursuant to the Personal Directives Act unless

(i) there are expressions of a contrary wish made subsequently by the individual while capable,

(ii) technological changes or medical advances make the instruction inappropriate in a way that is contrary to the intentions of the individual, or

(iii) circumstances exist that would have caused the individual to set out different instructions had the circumstances been known based on what is known of the values and beliefs of the individual and from any other written or oral instructions;

(b) in the absence of instructions, act according to what the substitute decision maker believes the wishes of the individual would be based on what the substitute decision maker knows of the values and beliefs of the individual and from any other written or oral instructions.

(4) The consent of a substitute decision maker must be given

(a) in a writing signed by the substitute decision maker;

(b) orally, in person or otherwise, by the substitute decision maker in the presence of at least two witnesses with contemporaneous documentation of the consent signed by two witnesses; or

(c) by telegraphic, recorded telephonic or other recorded message of the substitute decision maker.

(5) Consent given under this Section becomes binding and full authority

(a) when it is made; or

(b) where it is contained in a personal directive made pursuant to the Personal Directives Act or other lawful advance directive, when the personal directive or advance directive is activated.

(6) No person shall act on a consent given under this Section if the person has knowledge that the donor subsequently withdrew the consent.

(7) Where a consent was given by a substitute decision maker under subsection 12(2), no person shall act on a consent given under this Section if the person has personal knowledge of an objection by the donor.

DONATION AFTER DEATH

11 (1) Any individual who gives voluntary consent may consent

(a) in a writing signed by the individual at any time; or

(b) orally in the presence of at least two witnesses with contemporaneous documentation of the consent signed by two witnesses,

to donate the individual's body or specified organs or tissue after the individual's death for transplantation, education or scientific research.

(2) Where the individual consents to donate the individual's organs or tissue after the individual's death for transplantation, the consent is not valid unless the individual is provided with the information listed in subsection 13(1) before consenting.

(3) Notwithstanding subsection (1) and Section 5, a consent given by an individual who was not capable to consent, who did not give consent voluntarily or, where the consent is for donation for transplantation, who was not provided with the information listed in subsection 13(1), is valid for the purpose of this Act if the person who acted upon the consent had no reason to believe that the person who gave consent was not capable to give consent, had not given consent voluntarily or, where the consent is for donation for transplantation, was not provided the information listed in subsection 13(1).

12 (1) In this Section,

(a) "person lawfully in possession of the body" does not include

(i) the chief medical examiner or medical examiner in possession of the body for the purpose of the Fatality Investigations Act,

(ii) where the person died in hospital, the administrative head of the hospital,

(iii) where the person died in a continuing-care home, the administrative head of the continuing-care home,

(iv) the Public Trustee in possession of the body for the purpose of its burial under the Public Trustee Act,

(v) an embalmer or funeral director in possession of the body for the purpose of its burial, cremation or other disposition, or

(vi) the superintendent of a crematorium in possession of the body for the purpose of its cremation;

(b) "substitute decision maker" means, in the following order of priority,

(i) a person authorized to give consent under the Medical Consent Act or the Personal Directives Act, unless the authorization excludes decisions about organ or tissue donation and, where there is more than one delegate authorized pursuant to the Personal Directives Act, the delegate authorized to make health care decisions,

(ii) a guardian,

(iii) a spouse,

- (iv) a child,
- (v) a parent,
- (vi) a person standing in loco parentis,
- (vii) a sibling,
- (viii) a grandparent,
- (ix) a grandchild,
- (x) an aunt or uncle,
- (xi) a niece or nephew,
- (xii) another relative, or

(xiii) the person lawfully in possession of the body.

(2) Where an individual of any age who has not given a consent under Section 11 dies or, in the opinion of a physician, is incapable of giving a consent by reason of injury or disease and the individual's death is imminent, a substitute decision maker for the individual who, except in the case of a minor spouse or a minor parent, is of the age of majority and who gives voluntary consent, may consent

(a) in a writing signed by that person;

(b) orally, in person or otherwise, in the presence of at least two witnesses with contemporaneous documentation of the consent signed by two witnesses; or

(c) by telegraphic, recorded telephonic, or other recorded message of the substitute decision maker,

to donate the individual's body or specified organs or tissue after death for transplantation, education or scientific research.

(3) For greater certainty, where two or more persons who are not described in the same subclause of clause (1)(b) claim the authority to give or refuse consent under that subsection, the one under the clause occurring first in that subsection prevails.

(4) A person referred to in clause (1)(b) shall not exercise the authority given by that subsection unless the person

(a) excepting a spouse, has been in personal contact with the person over the preceding twelve-month period or has been granted a court order to shorten or waive the twelve-month period;

(b) is willing to assume the responsibility for making the decision;

(c) knows of no person of a higher rank in priority who is able and willing to make the decision;
and

(d) makes a statement in writing certifying the relationship to the person and the facts and beliefs set out in clauses (a) to (c).

(5) Where a person in a category in clause (1)(b) fulfils the criteria for a substitute decision-maker as outlined in subsection (4) but refuses to consent to donation on the patient's behalf, the consent of a person in a subsequent category is not valid.

(6) No person shall give a consent under this Section if the person has personal knowledge that the individual who died or whose death is imminent would have refused to give a consent.

(7) Where the substitute decision maker consents on the individual's behalf to donate the individual's organs or tissue after the individual's death for transplantation, the consent is not valid unless the substitute decision maker is provided with the information listed in subsection 13(1) before consenting.

(8) Notwithstanding subsection (6) and Section 5, a consent given by a person who was not capable to consent, who did not give consent voluntarily or, where the consent is for donation for transplantation, who was not provided with the information listed in subsection 13(1), is valid for the purpose of this Act if the person who acted upon the consent had no reason to believe that the person who gave consent was not capable to consent, had not given consent voluntarily or, where the consent is for donation for transplantation, was not provided with the information listed in subsection 13(1).

13 The following information, at a minimum, must be provided to an individual or the individual's substitute decision maker when the individual or the individual's substitute decision maker is making a decision to give consent to donation after death for transplantation:

(a) an explanation of the donation process;

(b) an explanation of the determination of death process;

(c) an explanation of pre-death transplantation optimizing interventions and why they are used, except in cases where the substitute decision maker is being asked for consent after the person has died;

(d) what organs or tissue can be donated;

(e) that by consenting to donation after death for transplantation, the individual or substitute decision maker authorizes the information sharing of the individual's personal information between persons and organizations engaged in the donation, procurement or transplantation of

organs and tissues for the purpose of facilitating organ and tissue donation and transplantation across jurisdictions; and

(f) an explanation of additional tests and procedures conducted to determine medical suitability and confidentiality protections and potential notification requirements regarding this information.

14 (1) Subject to subsections (2) to (5), a consent given under Section 11 or 12 is binding and full authority for the use of the body or the removal and use of the donated organs or tissue for the purposes specified.

(2) No person shall act on a consent given under Section 11 or 12 if the person has

(a) knowledge that the donor subsequently withdrew the consent; or

(b) where a consent was given by a substitute decision maker under subsection 12(2), knowledge of an objection by the donor or by a person of a higher priority category as the substitute decision maker.

(3) A donor's withdrawal of consent may be given

(a) in a writing signed by the donor; or

(b) orally, in person or otherwise, in the presence of at least two witnesses with contemporaneous documentation of the withdrawal signed by two witnesses.

(4) Where a donation after death cannot be used because

(a) the donated body, organs or tissue are medically unsuitable;

(b) there is no need for the donated body, organs or tissue;

(c) all potential recipients are located too far away from the donated body, organs or tissue; or

(d) there is a lack of available resources,

the consent is void and the donated body, organs or tissue must be dealt with as if no consent had been given.

(5) Where, in the opinion of a physician the death of an individual is imminent by reason of injury or disease, the physician has reason to believe that Sections 9 to 12 of the Fatality Investigations Act may apply when death does occur and a consent under this Act has been obtained for donation after death, the chief medical examiner may allow the removal of organs or tissue after the death of the person notwithstanding that death has not yet occurred.

15 The specific medical tests to demonstrate that death has occurred are those established by the medical profession from time to time.

16 (1) For the purposes of organs donated after death for transplantation, the fact of death must be determined by at least two physicians who have skill and knowledge in conducting the specific medical tests established by the medical profession for determining death.

(2) No physician, who has had any association with the proposed organ recipient that might influence physician's judgement, shall take any part in the determination of death of the organ donor.

(3) No physician, who took any part in the determination of death of the organ donor, shall participate in any way in the organ transplant procedures.

17 (1) Where an individual dies, or in the opinion of a physician death is imminent, in a hospital or in circumstances set out in the Fatality Investigations Act, the hospital or the Chief Medical Examiner shall, as soon as possible, provide to the organ donation program and, where so prescribed, to the tissue bank

(a) the age of the individual;

(b) the cause, or expected cause, of death of the individual;

(c) the time of death of the individual, if death has occurred; and

(d) any available past and current personal information that is relevant to organ or tissue transplantation.

(2) The tissue bank and the organ-donation program shall make a determination as to whether the organs or tissue of the individual may be medically suitable for use in another person by assessing the information provided in subsection (1).

(3) Notwithstanding subsection (1), the hospital or the Chief Medical Examiner shall not provide the information in subsection (1) to the tissue bank and the organ donation program if

(a) the individual clearly meets criteria established by the tissue bank and the organ donation program that set out circumstances in which an individual's organs or tissues would not be medically suitable for use in another person;

(b) the individual has communicated that the individual would not give consent to donation for transplantation; or

(c) the individual's substitute decision maker, acting in a manner consistent with the individual's prior express wishes, values and beliefs, has communicated that the individual would not give consent to donation for transplantation.

(4) Where a determination is made pursuant to subsection (2) that the organs or tissue of the individual may be medically suitable for use in another person, the hospital or the Chief Medical Examiner shall, as soon as possible, provide the individual's name and health-card number to the

tissue bank and organ-donation program for the purpose of determining whether the individual has provided a consent pursuant to Section 11.

(5) Where the hospital or the Chief Medical Examiner does not provide the information in subsection (1) for one or more of the reasons listed in subsection (3), the reasons for the decision must be placed in the record of the person.

(6) Where a determination is made pursuant to subsection (2) that a medical or other condition exists that may make the organs or tissue of the individual medically unsuitable for use in another person, the reasons for the determination must be placed in the record of the individual.

18 (1) Where an individual dies, or in the opinion of a physician death is imminent, in a hospital or in circumstances set out in the Fatality Investigations Act, and

(a) the individual is not capable to make a decision about donation after death;

(b) a consent has not been given pursuant to Section 11 or 12;

(c) the individual's organs or tissues may be medically suitable for use in another person as determined by the consultation under subsections 17(1) and (2); and

(d) the conditions under clauses 17(3)(b) and (c) do not exist,

the tissue bank, organ donation program or other person designated by the tissue bank or organ donation program, as soon as possible, shall request consent or cause consent to be requested from the substitute decision maker pursuant to subsection 12(2) for a donation for transplantation.

(2) Consent must not be requested pursuant to subsection (1) if a person designated for the purpose of this Section by the tissue bank and the organ donation program determines that a donation cannot be used because

(a) there is no need for the donated organ or tissue;

(b) all potential recipients are located too far away from the donated organs or tissue; or

(c) there is a lack of available resources.

(3) Where a substitute decision maker refuses consent pursuant to subsection (1), a record of the request and refusal must be placed in the record of the individual.

(4) Where a person designated for the purpose of this Section by the tissue bank and organ-donation program makes a determination pursuant to subsection (2), the reasons for the determination must be placed in the record of the individual.

19 (1) The Chief Executive Officer of each district health authority and the Chief Medical Examiner shall submit a report annually to the Minister of Health.

(2) The report must include

(a) the number of persons who may be medically suitable to be a donor, based upon criteria established by the tissue bank and the organ-donation program, but are not referred to the tissue bank and the organ-donation program pursuant to Section 17;

(b) any actions undertaken or proposed actions to address issues related to clause (a) and their effectiveness; and

(c) any information prescribed.

GENERAL

20 No action or other proceeding for damages lies against any person in respect of 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.

21 (1) Subject to subsections (2) and (3), no person shall buy, sell or otherwise deal in, directly or indirectly, for valuable consideration, any human organs, tissue or body for use in transplantation, education or scientific research.

(2) Valuable consideration does not include reimbursement for reasonable expenses associated with the removal, transplantation, implantation, processing, preservation and quality control, and storage of organs or tissue or remuneration received for participating in or performing a service necessarily incidental to the process whereby a transplant of human tissue is effected or a human body or part of the body is prepared for use for therapeutic purposes or for the purpose of education or scientific research.

(3) Parties who conduct, fund or participate in research involving human organs or tissue donated under this Act may receive payments for products or processes developed for therapeutic purposes as a result of such scientific research.

22 (1) Subject to subsections (2) and (3), no person shall disclose or give to any other person, other than the health-care professionals involved in the person's care and in the transplantation process, any information or document that identifies any person or that person's or deceased donor's substitute decision maker,

(a) who has given or refused to give a consent to donation;

(b) with respect to whom a consent to donation has been given or refused; or

(c) into whose body organs or tissue has been, is being or may be transplanted.

(2) Subsection (1) does not apply if the disclosure

(a) is permitted or required by an enactment or by an order of the court; or

(b) has been agreed to in writing by the person whose identity would be disclosed.

(3) Subsection (1) does not apply as between the donor and the recipient if

(a) an organ or heart valve was donated;

(b) both the recipient of an organ or heart valve or the recipient's substitute decision maker and the donor or the substitute decision maker pursuant to subsection 12(2) voluntarily agree in writing to the exchange of identifying information or to a meeting; and

(c) those agreeing under clause (b) have been informed of the reasonably foreseeable risks of such a meeting or identifying information exchange before they give their consent.

23 (1) This Act applies only to a donation made on or after the date this Act comes into force.

(2) Nothing in this Act invalidates an authorization made under the Human Tissue Gift Act before the coming into force of this Act.

24 Every person who knowingly contravenes this Act is guilty of an offence and on summary conviction is liable to a fine of not more than ten thousand dollars or to imprisonment for a term of not more than six months, or to both.

25 Except as provided in Sections 12, 14 and 15, nothing in this Act affects the operation of the Fatality Investigations Act.

26 (1) The Governor in Council may make regulations

(a) prescribing an entity or entities that are organ-donation programs within the meaning of clause 2(s);

(b) prescribing an entity or entities that are tissue banks within the meaning of clause 2(z);

(c) prescribing information that must be provided in a report or evaluation under clauses 8(2)(b) to (d);

(d) prescribing information to be provided under subsection 13(1);

(e) prescribing when a hospital or the Chief Medical Examiner shall provide information to the tissue bank under Section 17;

(f) prescribing changes in the information required to be included in a report under Section 19;

- (g) prescribing additional reports from relevant bodies;
 - (h) excluding or including certain practices from the meaning of valuable consideration in subsection 21(2);
 - (i) setting the rates of reimbursement to be received under subsection 21(2);
 - (j) including or excluding specific organs or tissue from the donations eligible for a meeting or identifying information exchange under subsection 22(3);
 - (k) defining any word or expression used but not defined in this Act;
 - (l) further defining any word or expression defined in this Act; or
 - (m) respecting any matter or thing the Governor in Council considers necessary or advisable to carry out effectively the intent and purpose of this Act.
- (2) The exercise by the Governor in Council of the authority contained in subsection (1) is regulations within the meaning of the Regulations Act.

27 Subsection 9(1) of Chapter 13 of the Revised Statutes, 1989, the Anatomy Act, is amended by striking out "Tissue Gift" in the fourth line and substituting "Organ and Tissue Donation".

28 Subsection 11(2) of Chapter 13 is amended by striking out "Tissue Gift" in the fifth line and substituting "Organ and Tissue Donation".

29 (1) Subsection 14(1) of Chapter 31 of the Acts of 2001, the Fatality Investigations Act, is amended by striking out "Tissue Gift" in the fourth line and substituting "Organ and Tissue Donation".

(2) Subsection 14(2) of Chapter 31 is amended by striking out "Tissue Gift" in the fourth line and substituting "Organ and Tissue Donation".

30 Chapter 215 of the Revised Statutes, 1989, Human Tissue Gift Act, is repealed.

31 Section 26 of Chapter 379 of the Revised Statutes, 1989, the Public Trustee Act, is amended by striking out "Tissue Gift" in the last line and substituting "Organ and Tissue Donation".

32 This Act comes into force on such day the Governor in Council orders and declares by proclamation.

