

# **HUMAN ORGAN AND TISSUE DONATION DRAFT ACT**



**DRAFT**

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**DRAFT HUMAN ORGAN AND TISSUE DONATION ACT**

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## DRAFT *Human Organ and Tissue Donation Act (with commentary)*

### *Introductory Comments*

*This document sets out what legislation could look like for regulating organ and tissue donation in Nova Scotia. Within the document we have provided policy commentary to help provide context for certain sections of the proposed legislation.*

Be it enacted by the Governor and Assembly as follows:

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

### **Definitions**

2 In this Act,

- (a) “best interests” for the purposes of this Act includes consideration of the physical, psychological, emotional and social well being of the potential living donor;
- (b) “binding” means must be followed;

*Commentary - The current Act states that consent to donation is binding. However, in practice, valid consent given by the donor or a substitute decision maker (where there is no valid donor consent) sometimes is not acted on where there is opposition from family. Adding a definition of binding to this Act is designed to make the law even more explicit that valid consent to donation after death cannot be vetoed by another. The Act seeks to protect the autonomy interests of Nova Scotians who give consent to organ and tissue donation by ensuring their decision will be carried out.*

- (c) “body” means a human body;
- (d) “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;
- (e) “consent” means a consent given under this Act;
- (f) "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;
- (g) “capacity” means the ability to understand the nature and consequences of the decision to be made;

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- (h) “court” means the Supreme Court of Nova Scotia;
- (i) “death” means the irreversible cessation of the functioning of the organism as a whole;
- (j) "district health authority" has the same meaning as in the *Health Authorities Act* and for greater certainty includes the Izaak Walton Killam Health Centre;
- (k) “donation after death” means a donation of organs, tissue or a body after death in accordance with Part III and “donated after death” has a corresponding meaning;
- (l) “donor” means a person who has consented to donate his or her organs, tissue or body for transplantation, scientific research or education or in respect of whom a consent has been given;
- (m) “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*;
- (n) “irreversible” means not physically possible to reverse without violating the law on consent;
- (o) “living donation” means a donation of organs or tissue while living in accordance with Part I;
- (p) “Minister” means the Minister of Health;
- (q) “organ” means a human organ, whether whole or in sections, lobes or parts;  
  
*Commentary - Nova Scotia’s current Act includes organs under its definition of tissue. Defining organs and tissue separately in this legislation is intended to reflect current practice and allow the Act to capture differences in organ and tissue donation practices. This definition is taken from Alberta’s legislation, the Human Tissue and Organ Donation Act.*
- (r) “organ donation program” means the Critical Care Organ Donation Program situate in the Queen Elizabeth II Health Sciences Centre in Halifax or its successor or other prescribed entity;
- (s) “physician” means a qualified medical practitioner registered under the *Medical Act*;
- (t) “potential donor” means a person whose body, tissue or organs are being considered for donation;

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- (u) “pre-death transplantation optimizing interventions” means interventions that are performed on a potential donor before his or her death for the purpose of optimizing the chances of a successful transplantation;
- (v) “spouse” means, with respect to any person, a person who is cohabiting with that person in a conjugal relationship as married spouse, registered domestic partner or common-law partner;
- (w) “substitute decision maker” means an individual who is authorized to give consent for another under section 12(3);
- (x) “tissue” means a functional group of human cells, excluding organs;

*Commentary - This definition has been adapted from the definition of tissue contained in Health Canada’s Safety of Cells, Tissues and Organs for Transplantation Regulations.<sup>1</sup>*

- (y) “tissue bank” means the Regional Tissue Bank situate in the Queen Elizabeth II Health Sciences Centre in Halifax or its successor or other prescribed entity;
- (z) “transplantation” means the operation of transferring organs or tissues from a human donor, whether living or dead, to a living human recipient;
- (aa) “Tri-Council Policy Statement” means the policy document developed by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada, entitled *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. 1998 (with amendments) or its successor document.
- (bb) “writing” includes consent indicated on the Nova Scotia Health Card;

*Commentary - This definition is intended to provide greater legal certainty that a signed Nova Scotia Health Card inscribed with the word DONOR is a valid actionable form of consent.*

## Scope of the Act

3 This Act does not apply to the following:

- (a) blood or blood constituents;

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<sup>1</sup> *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*, C. Gaz. 2005. I, online: <<http://canadagazette.gc.ca/partI/2005/20051210/html/regle3-e.html>>.

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(b) zygotes, oocytes, embryos, sperm, semen and ova.

## Compliance with the Act

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

5 Unless otherwise stated, only capable individuals may consent, refuse consent or withdraw consent for the purposes of this Act.

## Part I -- Living organ donation

### Consent

6 Any person who gives free and informed consent may in a writing signed by him or her consent to donate specific organs from his or her living body for transplantation.

### Personal Directives Act authorizations

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 sections 3(b) and 14 of the *Personal Directives Act* who gives free and informed consent may in a writing signed by him or her, consent to the living donation of organs for transplantation on behalf of the individual.

(2) When a person authorized pursuant to clause (1) is making a decision about living donation, the person must follow any instructions in a personal directive made pursuant to the *Personal Directives Act* unless

- (i) there were 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;

*Commentary - The Personal Directives Act does not specifically address the issue of living donation. Where a person has contemplated the issue of living donation and written directions in a personal directive indicating they wish to donate from his or her*

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*living body, then this section seeks to ensure those wishes are acted upon. The delegate appointed in a personal directive may make the decision, or, where no delegate is appointed, the statutory decision-maker authorized to make health care decisions under the Personal Directives Act may make the decision. The delegate and the statutory decision-maker cannot act under this section unless the person has expressed their wishes in a personal directive. The authority for making these decisions is grounded in the Human Organ and Tissue Donation Act, but it was presumed that the person authorized to make health care decisions under the Personal Directives Act is in the best position to make the decision after considering the factors in section 7(2) above.*

### **Incapable adults and immature minors**

- 8(1) Where an adult or minor lacks the capacity to give a valid consent, the adult or minor's organs may be donated from his or her living body for transplantation, if
- (a) the proposed recipient has a close personal relationship with the adult or minor;
  - (b) a physician reports that this is the best option for a successful transplant;
  - (c) the ethics program associated with the hospital where the transplant will be performed has reviewed the case and produced a report;
  - (d) a psychosocial evaluation has been conducted by an independent psychologist/psychiatrist who has experience working with immature minors or incapable adults as the case may be;
  - (e) a substitute decision maker, who has the authority to make health care decisions in respect of the adult or minor, has capacity to consent and gives free and informed consent to the donation; and
  - (f) a court authorizes the donation as being consistent with the known prior capable wishes of the adult or minor, or if such wishes are not known, in the best interests of the adult or minor.
- (2) When a substitute decision maker is making a decision under clause (1)(e), the substitute decision maker must
- (a) in the absence of instructions, act according to what the substitute decision maker believes the wishes of the adult or minor would be based on what the substitute decision maker knows of the values and beliefs of the adult or minor and from any other written or oral instructions; and
  - (b) where the substitute decision maker does not know the wishes, values and beliefs of the adult or minor, make a decision that the substitute decision maker believes would be in the best interests of the adult or minor.

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- (3) When a court is deciding whether to authorize a donation for transplantation under this section, the court must
  - (a) consider all of the information set out in clauses (1)(a)-(e);
  - (b) consider the current wishes of the adult or minor;
  - (c) consider the criteria set out in clauses (2)(a) and (b).
- (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 adult or minor.
- (5) Where there is more than one substitute decision maker who has the authority to make medical decisions, the court may authorize the donation if there is consent from one substitute decision maker.

*Commentary - This section will enable incapable adults and immature minors to be living organ donors in exceptional cases where the incapable adult or immature minor has a close personal relationship with the recipient. The Act recognizes that in these cases, the best interests of incapable adults and immature minors in terms of their psychological, emotional and social well-being may be best served by allowing them to donate an organ to save the life of a close sibling, parent, or caregiver. Safeguards,<sup>2</sup> such as the requirement for court authorization, are designed to ensure that incapable adults and immature minors are not exploited.*

## **Effect of consent**

- 9(1) A consent given pursuant to sections 6 and 7 or a court authorization pursuant to section 8 is full and binding authority for any physician to
  - (a) make any examination necessary to assure medical acceptability of the organs specified therein; and
  - (b) remove the specified organs from the body of the donor forthwith.

## **Consent void**

- (2) If for any reason the organs specified in the consent are not removed in the circumstances to which the consent relates, the consent is void.

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<sup>2</sup> These safeguards incorporate protections recommended as part of a recent CCDT Forum on living donation, “Enhancing Living Donation: A Canadian Forum (Report and Recommendations)” (February 2006) at 34, online: <[http://www.ccdt.ca/english/publications/final-pdfs/Enhancing\\_Living\\_Donation.Final.13Feb07.pdf](http://www.ccdt.ca/english/publications/final-pdfs/Enhancing_Living_Donation.Final.13Feb07.pdf)>

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## Part II – Pre-death transplantation optimizing interventions

### Consent<sup>3</sup>

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

(2) Any person who

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

(b) gives free and informed consent,

may consent,

(c) in a writing signed by the person; 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 his or her body.

(3) Where a person is incapable of consenting and in the opinion of a physician the person's death is imminent, a substitute decision maker

(a) must follow any prior express free and informed wishes of the person with respect to pre-death transplantation optimizing interventions; and

(b) if prior express free and informed wishes are not known, may only consent to pre-death transplantation optimizing interventions if he or she believes the decision to be consistent with the beliefs and values of the person.

(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

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<sup>3</sup> The wording of this section is informed by the following paper: Jocelyn Downie, Chantelle Rajotte & Alison Shea, *Pre-mortem transplantation optimizing interventions: the legal status of consent* Can J. Anesth 55:7 (July 2008).

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- (c) by telegraphic, recorded telephonic, or other recorded message of the substitute decision maker.
- (5) Consent given under this section becomes full and binding authority
- (a) when it is made; or
  - (b) if 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) (a) No person shall act on a consent given under this section if the person has personal knowledge that the donor subsequently withdrew his or her consent;
- (b) Where a consent was given by a substitute decision maker under section 12(3), no person shall act on a consent given under this section if the person has personal knowledge of an objection by the donor.

*Commentary - Pre-death transplantation optimizing interventions, or interventions performed on the potential donor before his or her death to increase the chances of a successful transplantation, are a part of some Canadian organ donation protocols. The most common are ventilation and the administration of medications before death. The current Act permits individuals to consent to the use of his or her organs or tissue after death, but does not provide a legal means for consenting to these pre-death interventions. Free, informed, capable consent is required for these interventions. This consent provision respects the individual's right to bodily integrity and reduces uncertainty and stress for healthcare providers seeking to actualize the donor's or substitute decision maker's consent to donate.*

### Part III -- Donation after death

#### Consent

11 (1) Any person who

- (a) is provided with the information listed in section 13(1); and
  - (b) gives free consent;
- may consent
- (c) in a writing signed by him or her at any time; or
  - (d) orally in the presence of at least two witnesses with contemporaneous documentation of the consent signed by two witnesses,

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to donate his or her body or specified organs or tissue after his or her death for transplantation, education or scientific research.

- (2) Notwithstanding subsection 1(a) - (b) and section 5, a consent given by a person who was not capable to consent, who did not give consent freely, or who was not provided with the information listed in subsection 13(1), is valid for the purposes of this Act so long as 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 freely, or was not provided the information listed in section 13(1).

*Commentary - It is unclear under Nova Scotia's present Human Tissue Gift Act whether donor consent to donation after death must be free, informed and given by a capable person. To correct this, the Act sets out clear requirements for valid donor consent. Recognizing that there are differences between an individual deciding to be a donor after death and a patient making a treatment decision, the Act does not require informed consent as it is understood in the treatment context but rather requires certain information be provided (section 13(1)).*

### **Consent by a substitute decision maker**

12(1) For the purposes of section 12, "person lawfully in possession of the body" does not include

- (a) the chief medical examiner or medical examiner in possession of the body for the purposes of the *Fatality Investigations Act*;
  - (b) where the person died in hospital, the administrative head of the hospital;
  - (c) where the person died in a continuing-care home, the administrative head of the continuing-care home;
  - (d) the Public Trustee in possession of the body for the purpose of its burial under the *Public Trustee Act*;
  - (e) an embalmer or funeral director in possession of the body for the purpose of its burial, cremation or other disposition; or
  - (f) the superintendent of a crematorium in possession of the body for the purpose of its cremation.
- (2) No person shall give a consent under this section if he or she has personal knowledge that the person who died or whose death is imminent would have refused to give a consent.

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(3) Where a person 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 his or her death is imminent, a substitute decision maker with respect to the person from the following categories in descending order of priority:

(a) 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. Where there is more than one delegate authorized pursuant to the *Personal Directives Act*, the delegate authorized to make health care decisions shall take priority;

*Commentary: Where individuals die without having given consent to donate organs or tissues after their death, health care providers need to talk with someone close to the deceased about the decision to donate organs or tissues. The hierarchy of substitute decision makers set out in this section attempts to identify the person who is most likely best able to make the decision on the deceased's behalf. The person authorized under the Medical Consent Act or Personal Directives Act is placed at the top of the hierarchy as it is likely that a person designated by the deceased to make very intimate and personal decisions for him or her while living, would likely be the person the deceased would have wanted to make the personal decision of whether or not to donate organs or tissues after death. It should be noted that an individual's authority under the Medical Consent Act and the Personal Directives Act is only for decisions made while the person is alive and incapable. The rest of the list of substitute decision makers is based on the hierarchies in the Personal Directives Act and the amendments to the Hospitals Act and the Involuntary Psychiatric Treatment Act which were passed by the legislature in May 2008 and came into force on April 1, 2010.*

- (b) guardian;
- (c) spouse;
- (d) child;
- (e) parent;
- (f) person standing in loco parentis;
- (g) sibling;
- (h) grandparent;
- (i) grandchild;
- (j) aunt or uncle;
- (k) niece or nephew;

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(l) other relative;

(m) the person lawfully in possession of the body,

who, except in the case of a minor spouse or a minor parent, is the age of majority and who

(n) is provided with the information listed in subsection 13(1); and

(o) gives free consent;

may consent

(p) in a writing signed by him or her;

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

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

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

(4) Where a person in a category in subsection (3) fulfils the criteria for a substitute decision-maker as outlined in subsection (6) but refuses to consent to donation on the patient's behalf, the consent of a person in a subsequent category is not valid.

(5) Where two or more persons who are not described in the same clause of subsection (2) claim the authority to give or refuse consent under that subsection, the one under the clause occurring first in that subsection prevails.

(6) A person referred to in clauses (c) to (l) of subsection (3) 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).

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- (7) Notwithstanding subsections 2(n) and (o) and section 5, a consent given by a person who was not capable to consent, who did not give consent freely, or who was not provided with the information listed in subsection 13(1), is valid for the purposes of this Act so long as 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 freely, or was not provided with the information listed in subsection 13(1).

### Information to be provided

- 13 (1) The following information, at a minimum, shall be provided to a person or his or her substitute decision maker when making his or her decision to give consent to donation after death:
- (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 potential donor has died;
  - (d) a statement indicating what organs or tissue can be donated and for what uses;
  - (e) a statement indicating that consent to scientific research can be given either for specified organs or tissues to be donated for any future scientific research or for a substitute decision maker to be approached in the future to give consent to a particular research project;
  - (f) a statement indicating that by consenting to donation, the donor or substitute decision maker also consents to the release of the donor's medical information that is relevant to determining medical suitability for donation, to the health care professionals involved in determining medical suitability for donation; and
  - (g) an explanation of additional tests and procedures conducted to determine medical suitability and confidentiality protections and potential notification requirements regarding this information;

*Commentary - By listing the minimum information Nova Scotians should be provided with, this section recognizes the autonomy interests of Nova Scotians and the need for persons before death and substitute decision makers after death to be provided with the same quality of information. We anticipate general information will be provided by a brochure mailed with your health card renewal. Website information and a phone number will be provided for further information, questions and concerns. Currently,*

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*trained staff at the Province's organ donation program are available in hospital and via a telephone help line to respond to questions about donation.*

## Effect of consent

- 14 (1) Subject to subsections (2) – (5), a consent given under sections 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 sections 11 or 12 if the person has
- (a) personal knowledge that the donor subsequently withdrew his or her consent;
  - (b) where a consent was given by a substitute decision maker under section 12(3), personal 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) If a donation under this Part cannot be used because
- (a) the donated body, tissue, or organs are medically unsuitable;
  - (b) there is no need for the donated organs, tissue or body;
  - (c) the geographical distance between the donor and the recipient in need is too great; or
  - (d) there is a lack of available resources,

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

*Commentary - Subsection 4 is intended to address cases where the donation cannot be used, e.g. the body, tissue, or organs are medically unsuitable or there is no need for the organs, tissue, or body in question. In these cases, it is not possible to actualize the wish to donate and the donated body, tissue, or organs are dealt with as if consent had not been given.*

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(5) Where, in the opinion of a physician the death of a person is imminent by reason of injury or disease and 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 Part has been obtained for donation after death, the chief medical examiner, notwithstanding that death has not yet occurred, may allow the removal of organs or tissue after the death of the person.

### Required referral

15(1) Where a person 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 Office of the Chief Medical Examiner shall, as soon as possible, consult with the tissue bank and organ donation program for the purposes of determining whether the existence of a medical or other condition will make the organ or tissue of the person suitable or unsuitable for use in another person.

(2) For the purposes of making a determination pursuant to subsection (1), the hospital or the Office of the Chief Medical Examiner shall provide the tissue bank and organ donation program with the following information about the person:

- (a) age;
- (b) cause, or expected cause, of death;
- (c) time of death, if death has occurred;
- (d) any available past and current medical history which is relevant to organ or tissue transplantation.

(3) Where a determination is made pursuant to subsection (1) that the organ or tissue of the person is suitable for use in another person, the hospital or the Office of the Chief Medical Examiner shall, as soon as possible, consult with the tissue bank and organ donation program for the purposes of determining whether the person has provided a consent pursuant to section 11.

(4) For the purposes of making a determination pursuant to subsection (3), the hospital or the Office of the Chief Medical Examiner shall provide the tissue bank and organ donation program with the following information about the person:

- (a) name;
- (b) provincial health card number.

(5) Notwithstanding subsections (1)–(4), the hospital or the Office of the Chief Medical Examiner shall not consult with tissue bank and organ donation program where

- (a) the person does not meet criteria established by tissue bank and organ donation program that set out circumstances in which a person's organs or tissues would be suitable for use in another person;
- (b) the person or the person's substitute decision-maker has communicated that he or she would not give consent to donation for transplantation.

(6) Where the hospital or the Office of the Chief Medical Examiner makes a determination pursuant to subsection (5), the reasons for the determination shall be placed in the record of the person.

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(7) Where a determination is made pursuant to subsection (1) that a medical or other condition exists that will make the organ or tissue of the person unsuitable for use in another person, the reasons for the determination shall be placed in the record of the person.

*Commentary – The criteria for determining medical suitability to donate tissues and organs is complex and constantly changing. Some conditions disqualify a person from being an organ donor but do not disqualify them from donating tissue. Some conditions used to disqualify a person but now do not. It is not reasonable to expect a health care professional who does not deal with organ and tissue donation regularly to be aware of all the current criteria. The requirement of the hospital to consult with the tissue bank and organ donation program to determine the person’s medical suitability to donate is aimed at ensuring potential donors are appropriately screened. The section attempts to balance privacy issues with the goal of donation by permitting a minimal amount of personal information that would be unlikely to identify the person. Once medical suitability is determined, then the identity of the individual is determined for the purpose of determining whether the person has provided consent pursuant to section 11 of the Act.*

### Required request

16 (1) Where a person 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) a consent has not been given pursuant to section 11 or 12;
- (b) the person’s organs or tissues are suitable for use in another person as determined by the consultation under s.15(1); and
- (c) the condition under subsection 15(5)(b) does 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 section 12(3) for a donation for transplantation.

(2) Consent shall not be requested pursuant to subsection (1) where a person designated for the purpose of this subsection by the tissue bank and organ donation program determines that there is no need for the use of or there are no available resources for the retrieval of any organs or tissue from the body of the deceased person for transplantation.

(3) Where a person designated pursuant to subsection (1) makes a determination pursuant to subsection (2), the reasons for the determination shall be placed in the record of the person.

*Commentary - This section is designed to ensure all substitute decision makers are approached with the option of donation, subject to limited exceptions. In the current Act, they cannot be approached where it is determined that their emotional or physical condition makes the request inappropriate. However, this Act removes that exception, as the presumption that a substitute decision maker’s grief means that he or she does not want to be given the option of donation can result in some substitute decision makers who want to consider organ and tissue donation being denied the opportunity.*

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## Reporting

17(1) A report containing

- (a) the number of persons who meet criteria established by tissue bank and organ donation program to be potential donors but are not referred to tissue bank and organ donation program pursuant to section 15;
- (b) any actions undertaken or proposed actions to address issues related to this section and its effectiveness; and
- (c) any information prescribed

shall be compiled annually by the chief executive officer of the responsible district health authority.

(2) The district health authority shall submit the report prepared pursuant to subsection (1) annually to the Minister.

*Commentary - This Act creates a new accountability mechanism that requires annual reports concerning the effectiveness of the required referral provision be compiled by the CEO of the district health authority.*

## Determination of death<sup>4</sup>

18 (1) The criterion for the determination of death is the irreversible loss of the brain's capacity to control and coordinate the organism's critical functions.

(2) The fulfillment of the criterion may be demonstrated by one or more medical tests. Specific medical tests are to be established by the medical profession.

*Commentary – Legally and ethically, an individual must be declared dead before his or her organs or tissue can be procured. Public confidence in the determination of death is a factor affecting public willingness to donate and uncertainty in the legal timing of death can cause stress for providers. Death is defined at the beginning of this Act. That definition combined with subsections 18(1) and (2) are designed to provide certainty about the legal definition and determination of death. By providing one definition and one criterion for determining death, the subsections clarify that there are not two types of death - brain death or cardiac death - but rather a number of tests to determine whether the one criterion for death has been met.*

(3) For the purposes of organs donated after death, the fact of death shall be determined by at

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<sup>4</sup> Subsections 18(1) –(3) were influenced by the following paper: Jocelyn Downie, Chantelle Rajotte & Alison Shea, *Eligibility for Organ Donation: Defining and Determining Death* (Forthcoming ?where?)

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least two physicians who have skill and knowledge in conducting the specific medical tests determined by the medical profession for determining death.

*Commentary - Where the tests for determining death in the context of organ donation are more complex than those for tissue donation, this Act seeks to ensure that the determination of death is conducted properly by requiring that at least two physicians determine death and that these physicians are qualified to make the determination.*

- (4) For the purposes of tissue donated after death, the fact of death shall be determined by one physician.
- (5) No physician with any association with the proposed recipient, shall take any part in the determination of death of the donor.
- (6) No physician, who took any part in the determination of death of the donor, shall participate in any way in the transplant procedures.

## Part IV – General

### Liability

- 19 No action lies against any person in respect of anything done or omitted to be done in good faith in the performance or intended performance of any duty or the exercise or intended exercise of any authority under this Act.<sup>5</sup>

### Dealing in organs, tissue or bodies prohibited

- 20(1) Subject to subsections (2) and (3), no person shall buy, sell or otherwise deal in, directly or indirectly, for valuable consideration, any organs, tissue or body for use in transplantation, education or scientific research.
- (2) The term 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 purposes of education or scientific research.

*Commentary - Currently in Canada, organ programs and tissue banks charge fees to provincial governments and other health care bodies to recover the costs associated with*

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<sup>5</sup> This section is informed by Alberta's *Human Tissue and Organ Donation Act*, S.A. 2006, cH-14.5, s. 11, *Trillium Gift of Life Network Act*, R.S.O. 1990, c. H.20, s. 9(1), and *Health Protection Act*, S.N.S. 2004, c. 4, s. 12.

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*the transplantation process. Manitoba and New Brunswick have provisions that exempt the charging of cost recovery fees from the prohibition on the buying or selling of organs and tissues. This subsection, modeled on similar provisions in the U.S. National Organ Transplantation Act, and the Manitoba Human Tissue Gift Act is intended to make clear that these cost recovery activities are legally permissible.*

- (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. Research involving organs or tissue donated under this Act must be approved by a research ethics board established and operating in conformity with the Tri-Council Policy Statement or other prescribed criteria.

*Commentary - Subsection (3) is designed to facilitate scientific research of therapeutic benefit to Nova Scotians by excluding payments for products resulting from the research from the prohibition on valuable consideration, while setting out clear rules that preserve the independence of tissue banks and provide a review mechanism to ensure research is conducted ethically.*

### Confidential information

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

*Commentary - Subsection 2, allows information about the donor, the recipient or the substitute decision maker to be released where required by a statute, a court order or where the appropriate individual consents. Currently in practice, as part of donor and recipient recognition activities, such information is released once the consent of the appropriate individual is obtained.*

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

- (a) an organ or heart valve was donated;
- (b) both the recipient of an organ or heart valve or his or her substitute decision maker and the donor or the substitute decision maker pursuant to subsection 12(3) voluntarily agree in writing to the exchange of identifying information or to a meeting; and
- (c) those giving agreement under subsection 3(b) have been informed of the reasonably foreseeable risks of such a meeting or identifying information exchange before they give their consent;

*Commentary - Subsection 3 addresses situations where the recipient and the donor or the donor family wishes to meet or exchange identifying information. The Act recognizes that such a meeting or information exchange may be of benefit to some individuals; however, the Act puts in place safeguards to ensure that both parties are making an informed decision and that they are aware of the potential risks to their well being.*

## Human Tissue Gift Act

22(1) This Act applies only to a donation for transplantation 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.

## Offence and penalty

23 Every person who knowingly contravenes any provision of this Act is guilty of an offence and on summary conviction is liable to a fine of not more than \$10,000 or to imprisonment for a term of not more than six months, or to both.

## Fatality Investigations Act

24 Except as provided in sections 12, 14 and 15, nothing in this Act affects the operation of the *Fatality Investigations Act*.

## Regulations

25 The Governor in Council may make regulations

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(a) prescribing information that must be provided in a report or evaluation under subsections 8(1)(b)-(d);

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

(c) changes in the information required to be included in a report under section 17;

(d) prescribing additional reports from relevant bodies;

(e) excluding or including certain practices from the definition of valuable consideration under subsection 20(2);

(f) setting the rates of reimbursement to be received under subsections 20(2);

*Commentary - This rate setting power is designed to allow the government to intervene in rates charged for the reimbursement of reasonable expenses if necessary.*

(g) designating additional bodies that can review research under subsection 20(3);

(h) including or excluding specific organs or tissue from the donations eligible for a meeting or identifying information exchange under subsection 21(3);

(i) defining any word or expression used but not defined in this Act;

(j) further defining any word or expression defined in this Act; or

(k) deemed necessary or advisable to carry out effectively the intent and purpose of this Act.

### **Coming into force**

26 This Act comes into force on a day to be named by proclamation of the Governor in Council.

### **Anatomy Act amended**

27 amended

### **Public Trustee Act amended**

28 amended

### **Fatality Investigations Act amended**

29 amended

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## Repeals

30 The *Human Tissue Gift Act*, R.S.N.S. 1989, c. 215, is repealed.