# CAYMAN ISLANDS



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A BILL FOR A LAW TO ESTABLISH A HUMAN TISSUE TRANSPLANT COUNCIL FOR THE PURPOSE OF MONITORING THE DONATION OF TISSUE BY LIVING PERSONS AND THE REMOVAL OF TISSUE FROM DECEASED PERSONS; TO REGULATE THE COLLECTION AND USE OF HUMAN TISSUE FOR MEDICAL PURPOSES; TO REGULATE COMMERCIAL DEALINGS IN HUMAN TISSUE; AND FOR INCIDENTAL AND CONNECTED PURPOSES

## THE HUMAN TISSUE TRANSPLANT BILL, 2013

# MEMORANDUM OF OBJECTS AND REASONS

This Bill seeks to regulate the collection and use of human tissue in the Cayman Islands and to establish a council, to be called the Human Tissue Transplant Council, for the purpose of monitoring compliance with the provisions of the legislation.

Part 1 of the Bill contains preliminary provisions and is comprised of clauses 1 to 3. Clause 1 provides the short title and commencement of the legislation. Clause 2 defines various terms for the purposes of the legislation.

Clause 3 prescribes the activities to which the legislation does not apply (for example, the collection or use of foetal tissue, spermatozoa or ova).

Part 2 of the Bill deals with the Human Tissue Transplant Council and is comprised of clauses 4 and 5. These clauses, together with the Schedule, establish the Council, set out its procedure, and specify its functions (which include monitoring tissue donations, and regulating any business carried on in or from within the Islands in respect of the buying of tissue).

Part 3 of the Bill deals with donations of tissue by living persons and contains clauses 6 to 16. By virtue of clause 2(1), the term "tissue" is defined as follows -

"tissue", in relation to a human, includes -

- (a) an organ, or a part, of a human body; or
- (b) a substance extracted from, or from a part of, the human body,

but excludes foetal tissue, spermatozoa or ova".

Clause 6 enables an adult (that is, a person who is eighteen years of age or over) to consent to the removal from his body of regenerative tissue (other than blood) for any permitted purpose. The terms "regenerative tissue" and "permitted purpose" are defined in clause 2(1).

Clause 7 enables an adult to consent to the removal from his body of non-regenerative tissue for the purpose of the transplantation of the tissue to the body of another living person. The term "non-regenerative tissue" is defined in clause 2(1).

Clause 8 prohibits a person from removing tissue, from the body of a living adult who lacks capacity to consent to the removal of the tissue, for the purpose of the transplantation of the tissue to the body of another living person.

Clause 9 of the Bill empowers a medical practitioner to certify that consent given under clause 6 or 7 was freely given in the practitioner's presence.

By virtue of clause 10, the requisite consent, together with a medical practitioner's certificate, is sufficient authority to enable another medical practitioner to remove tissue from a living adult donor, other than an adult who lacks capacity to consent.

Clause 11 prohibits a person from removing non-regenerative tissue from the body of a living child (that is, a person under eighteen years of age) for the purpose of the transplantation of the tissue to the body of another living person.

Clause 12 prohibits a person from removing regenerative tissue from the body of a living child for the purpose of the transplantation of the tissue to the body of another living person, except as allowed under the legislation.

Clause 13 of the Bill enables the parent of a child to consent to the removal from the body of the child of regenerative tissue for the purpose of the transplantation of the tissue to the body of another living person. The clause also enables a medical practitioner to certify that the parent's consent was freely given in the practitioner's presence.

By virtue of clause 14, the requisite consent, together with a medical practitioner's certificate, is sufficient authority to enable another medical practitioner to remove regenerative tissue from a living child.

Clause 15 prescribes the circumstances under which consent to the removal of tissue from a living donor, may be revoked.

Clause 16 makes provision for a case where a living donor no longer agrees to the donation of tissue.

Part 4 of the Bill deals with donations of tissue after death and contains clauses 17 to 19. Clauses 17 and 18 enable a registered medical practitioner, a prescribed person or a person belonging to a prescribed class of persons to remove tissue for a permitted purpose from the body of a deceased person where the deceased person had expressed the wish for, or consented to, the removal after his death of tissue from his body for such purpose.

Clause 19 prohibits the removal of tissue from the body of the deceased person unless a Coroner has given his consent to the removal if an inquest is to take place.

Part 5 of the Bill deals with trading in human tissue and contains clauses 20 to 23. Clauses 20 and 21 prohibit the unauthorised selling and buying of human tissue. In special circumstances, the Human Tissue Transplant Council may issue a permit authorizing a person to buy tissue.

Clause 22 empowers a person who owns or controls a tissue bank to charge an amount to recover certain costs associated with various activities at a tissue bank (for example, the evaluation, storage and processing of tissue).

Clause 23 prohibits a person from advertising the selling or buying of tissue unless the proposed advertisement has been approved by the Human Tissue Transplant Council and contains a statement to that effect.

Part 6 of the Bill contains miscellaneous provisions and is comprised of clauses 24 to 27. Clause 24 contains provisions excluding the liability of a person acting in pursuance of any consent or authority under the legislation.

Clause 25 contains confidentiality provisions.

Clause 26 specifies various activities which are offences under the legislation (for example, the unauthorized removal of tissue from the body of a person, and making a false statement in a certificate).

Clause 27 empowers the Governor in Cabinet to make regulations to give effect to the legislation.



### THE HUMAN TISSUE TRANSPLANT BILL, 2013

# ARRANGEMENT OF CLAUSES

#### PART 1 - PRELIMINARY

- 1. Short title and commencement
- 2. Interpretation
- 3. Non-application of the Law

# PART 2 - THE HUMAN TISSUE TRANSPLANT COUNCIL

- 4. Human Tissue Transplant Council
- 5. Functions of the Council

## **PART 3 - DONATIONS OF TISSUE BY LIVING PERSONS**

#### **Donations by adults**

- 6. Consent by adult donor to removal of regenerative human tissue
- 7. Consent by adult donor to removal of non-regenerative human tissue
- 8. Prohibition on removal of tissue from living adult who lacks capacity to consent
- 9. Certificate of consent
- 10. Effect of consent under section 6 or 7

## **Donations by children**

- 11. Removal of non-regenerative tissue from a child
- 12. Removal of regenerative tissue from a child
- 13. Consent to removal of regenerative tissue from a child
- 14. Effect of consent under section 13(1)

#### **Revocation of consent or agreement**

- 15. Revocation of consent
- 16. Child or adult no longer in agreement

## PART 4 - DONATIONS OF TISSUE AFTER DEATH

- 17. Effect of authority under section 25
- 18. Authority to remove tissue after death
- 19. Coroner's consent

# PART 5 - PROHIBITION OF TRADING IN HUMAN TISSUE

- 20. Unauthorised selling of human tissue prohibited
- 21. Commercial dealings in human tissue prohibited
- 22. Recovery of costs of tissue banks

23. Advertising restrictions

# **PART 6 - MISCELLANEOUS PROVISIONS**

- 24. Exclusion of liability when acting in pursuance of consent or authority
- 25. Confidentiality
- 26. Offences
- 27. Power to make Regulations Schedule The Human Tissue Transplant Council

A BILL FOR A LAW TO ESTABLISH A HUMAN TISSUE TRANSPLANT COUNCIL FOR THE PURPOSE OF MONITORING THE DONATION OF TISSUE BY LIVING PERSONS AND THE REMOVAL OF TISSUE FROM DECEASED PERSONS; TO REGULATE THE COLLECTION AND USE OF HUMAN TISSUE FOR MEDICAL PURPOSES; TO REGULATE COMMERCIAL DEALINGS IN HUMAN TISSUE; AND FOR INCIDENTAL AND CONNECTED PURPOSES

ENACTED by the Legislature of the Cayman Islands.

#### PART 1 - PRELIMINARY

1. (1) This Law may be cited as the Human Tissue Transplant Law, 2013.

(2) This Law shall come into force on such date as may be appointed by Order made by the Governor in Cabinet and different dates may be appointed for different provisions of this Law and in relation to different matters.

2. (1) In this Law -

"adult" means a person eighteen years of age or over;

"child" means a person under the age of eighteen;

"Coroner" means a person appointed as such under the Coroners Law (1995 Revision);

1995 Revision

Short title and

commencement

Interpretation

2005 Revision

"Council" means the Human Tissue Transplant Council established under section 4;

"health services" has the meaning assigned to that expression by the Health Practice Law (2005 Revision);

"next of kin" -

(a) in relation to a deceased child, means -

- (i) where a parent of the child is available, a parent of the child;
- (ii) where a parent of the child is not available, a brother or sister of the child who is an adult and who is available; or
- (iii) where no person referred to in subparagraph (i) or (ii) is available, a person who was the guardian of the child immediately before the death of the child and who is available; and
- (b) in relation to a deceased adult, means -
  - (i) where the person, immediately before the person's death, had a spouse and that spouse is available, the spouse;
  - (ii) where the person, immediately before the person's death, did not have a spouse or the spouse is not available, a son or daughter of the person who is an adult and who is available;
  - (iii) where no person referred to in subparagraph (i) or (ii) is available but a parent of the person is available, that parent; or
  - (iv) where no person referred to in subparagraph (i), (ii) or (iii) is available, a brother or sister of the person who is an adult and is available;

"non-regenerative tissue" means tissue other than regenerative human tissue;

"permitted purpose", in relation to the removal of regenerative tissue or nonregenerative tissue from a living person or from the body of a deceased person, means removal -

- (a) for the purpose of the transplantation of the tissue to the body of another living person; or
- (b) for use for other therapeutic purposes or for medical or scientific purposes;

"regenerative tissue" means tissue that, after injury or removal, is replaced in the body of a living person by natural processes, including blood;

"registered dentist" means a practitioner who is registered as a dentist under the Health Practice Law (2005 Revision);

2005 Revision

"registered medical practitioner" means a practitioner who is registered as a medical doctor under the Health Practice Law (2005 Revision);

"registered practitioner" has the meaning assigned to that expression by the Health Practice Law (2005 Revision) and includes a person who is employed or engaged by, or who performs work for, a registered practitioner in the performance of health services;

"tissue", in relation to a human, includes -

- (a) an organ, or a part, of a human body; or
- (b) a substance extracted from, or from a part of, the human body,

but excludes foetal tissue, spermatozoa or ova; and

"tissue bank" means a place prescribed by Regulations made under this Law as a place of storage for tissue.

(2) A reference in this Law to the transplantation of tissue includes a reference to the transplantation of any part of the tissue and to the transplantation of a substance obtained from the tissue but does not include -

- (a) the collection and use of foetal stems for use in medical research or otherwise;
- (b) the collection and use of spermatozoa and ova for use in human reproductive technology or otherwise; or
- (c) mandatory blood transfusions.

(3) A reference in this Law to a person's brother or sister is a reference to a brother or a sister whether of the whole blood or the half-blood and includes a reference to a person who was adopted by one or both of the parents of the first-mentioned person.

(4) For the purposes of this Law, a person has died when there has occurred -

- (a) irreversible cessation of circulation of blood in the body of the person; or
- (b) irreversible loss of the capacity of consciousness combined with the irreversible loss of all brain stem functions including the capacity to breathe.

3.

(5) For the purposes of this Law, an adult lacks capacity to consent in relation to a matter if, at the material time, he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain (irrespective of whether or not the impairment or disturbance is permanent or temporary); but a lack of capacity cannot be established merely by reference to -

- (a) the adult's age or appearance, or
- (b) a condition of his, or an aspect of his behaviour, which might lead others to make unjustified assumptions about his capacity.

Non-application of the Law

- This Law does not apply to or in relation to -
  - (a) the collection or use of foetal tissue, spermatozoa or ova;
  - (b) post mortems;
  - (c) anatomical examinations of humans;
  - (d) analysis of donor human tissue;
  - (e) the removal of tissue, whether regenerative or non-regenerative, from the body of a living person -
    - (i) in the course of medical treatment or dental care or a procedure carried out, in the interests of the health of the person, by a registered medical practitioner or, in the case of dental care, by a registered dentist, with the consent, express or implied, given by or on behalf of the person; or
    - (ii) in circumstances necessary for the preservation of the life of the person;
  - (f) the removal of blood or other regenerative tissue from the body of a living person in the course of medical treatment or a procedure (including the testing of blood to determine whether the person has, or may have in the future, a disease or medical condition) carried out, in the interests of the health of the person, by a registered practitioner with the consent, express or implied, given by or on behalf of the person;
  - (g) the use or disposal of the tissue so removed;
  - (h) the embalming of the body of a deceased person; or
  - (i) the preparation, including the restoration of any disfigurement or mutilation, of the body of a deceased person for the purpose of interment or cremation.

# PART 2 - THE HUMAN TISSUE TRANSPLANT COUNCIL

The Human Tissue Transplant Council 4. (1) The Governor in Cabinet shall establish a Council, to be called the Human Tissue Transplant Council, and shall cause notice of the establishment of the Council to be published in the Gazette.

(2) The Schedule has effect with respect to the constitution and procedure Schedule of the Council.

5. (1) The principal functions of the Council are -

#### Functions of the Council

- (a) to advise the Minister responsible for health on policy relating to the collection and use of human tissue for medical purposes in the Islands;
- (b) to monitor the donation of tissue by living persons and the removal of tissue from deceased persons;
- (c) to regulate and supervise any business carried on in or from within the Islands in respect of the buying of tissue or the right to take tissue from the bodies of persons;
- (d) to monitor compliance with this Law; and
- (e) to perform any other duties that may be provided in this Law or as may be specified by the Governor in Cabinet, from time to time.
- (2) In carrying out its functions under this Law, the Council may -
  - (a) collaborate with such persons as it considers necessary in the collection, compilation and publication of statistics relating to the collection and use of human tissue for medical purposes in the Islands; and
  - (b) with the approval of the Governor in Cabinet, enter into arrangements with any department of the Government for the use of the personnel, facilities and services of that department to any extent not incompatible with that department's operation.

(3) No publication of statistics under subsection (2) shall contain any particulars so arranged as to enable any person to identify any particulars relating to any individual person.

(4) Neither the Council, nor any member or employee of the Council, shall be liable in damages for anything done or omitted in the discharge or purported discharge of their respective functions, responsibilities, powers and duties under this Law unless it is shown that the act or omission was in bad faith.

## PART 3 - DONATIONS OF TISSUE BY LIVING PERSONS

#### **Donations by adults**

6. Subject to section 8, an adult may consent to the removal from his body of specified regenerative tissue (other than blood) for any permitted purpose, and any such consent shall be given in the prescribed form.

Consent by adult donor to removal of regenerative human tissue

Consent by adult donor to removal of nonregenerative human tissue 7. (1) Subject to section 8, an adult may consent to the removal from his body, at any time after the expiration of twenty-four hours from the time at which the consent is given, of specified non-regenerative tissue for the purpose of the transplantation of the tissue to the body of another living person; and any such consent shall be given, in the prescribed form.

(2) A consent given under subsection (1) shall specify the time at which the consent is given.

Prohibition on removal of tissue from living adult who lacks capacity to consent to the removal of tissue from his body, for the purpose of the transplantation of the tissue to the body of another living person.

Certificate of consent

Effect of consent under

section 6 or 7

9. A registered medical practitioner shall certify in the prescribed form -

- (a) that the consent in writing of a person under section 6 or 7 was given in the practitioner's presence;
- (b) that the practitioner explained to the person before the consent was given the nature and effect of the removal from the body of the person specified in the consent of the tissue so specified; and
- (c) that the practitioner is satisfied -
  - (i) that the person giving the consent was an adult, at the time the consent was given;
  - (ii) that, at the time, the person was of sound mind and did not lack capacity to consent; and
  - (iii) that the consent was freely given.

10. (1) Subject to subsection (3), a document that purports to be a consent given in accordance with section 6 and which is supported by a certificate given in accordance with section 9 is sufficient authority for a registered medical practitioner, other than the registered medical practitioner who gave the certificate, to remove the regenerative tissue specified in the consent for the purpose or use, as the case may be, specified in the consent.

(2) Subject to subsection (3), a document that purports to be a consent given in accordance with section 7 and which is supported by a certificate given in accordance with section 9 is sufficient authority for a registered medical practitioner, other than the registered medical practitioner who gave the certificate, to remove, at any time after the expiration of twenty-four hours from the time specified in the consent to be the time at which the consent was given, the non-regenerative tissue specified in the consent for the purpose of the transplantation of the tissue to the body of another living person under section 7.

(3) A document that purports to be a consent given in accordance with section 6 or 7 is not sufficient authority for a registered medical practitioner to remove tissue if -

- (a) the practitioner has been informed that the consent has been revoked; or
- (b) the practitioner knows or has reasonable grounds for suspecting that the document contains a false statement.

#### **Donations by children**

11. A person shall not remove non-regenerative tissue from the body of a living child for the purpose of the transplantation of the tissue to the body of another living person.

12. Except as provided by this Part, a person shall not remove regenerative tissue from the body of a living child for the purpose of the transplantation of the tissue to the body of another living person.

13. (1) A parent of a child may give his consent, in the prescribed form, to the removal from the body of the child of specified regenerative tissue for the purpose of the transplantation of the tissue to the body of another living person.

(2) A registered medical practitioner shall certify, in the prescribed form, that the consent of a parent of a child was freely given in the prescribed form in the practitioner's presence, and that the practitioner explained to the parent before the consent was given the nature and effect of the removal from the body of the child of the tissue specified in the consent and the nature of the transplantation of that tissue; and the practitioner shall, in addition, in the prescribed form certify the following (whenever applicable) -

(a) that -

- (i) the practitioner is satisfied that, at the time consent was given, the child was capable of understanding the nature and effect of the removal of the tissue and the nature of the transplantation;
- (ii) the practitioner explained those matters to the child;
- (iii) the child understood those matters;
- (iv) the child was in agreement with the proposed removal and transplantation of tissue; and
- (v) due regard was given to the child's best interests; and
- (b) where the consent relates to the removal of specified regenerative tissue for the purpose of transplantation of the tissue to the body

13

Removal of nonregenerative tissue from a child

Removal of regenerative tissue from a child

Consent to removal of regenerative tissue from a child

of a brother, sister or parent of the child, that the practitioner is satisfied that the brother, sister or parent is likely to die unless the tissue is transplanted to the body of that brother, sister or parent.

14. (1) Subject to subsection (2), a document that purports to be a consent given in accordance with section 13(1) and which is supported by a certificate given in accordance with section 13(2) is sufficient authority for a registered medical practitioner, other than the registered medical practitioner who gave the certificate, to remove the regenerative tissue specified in the consent for the purpose specified in the consent.

(2) A document that purports to be a consent given in accordance with section 13(1) is not sufficient authority for a registered medical practitioner to remove tissue if -

- (a) the practitioner has been informed that the consent has been revoked;
- (b) the practitioner knows or has reasonable grounds for suspecting that the consent is not valid; or
- (c) the practitioner has been informed that the child is no longer in agreement with the removal and transplantation of the tissue.

#### **Revocation of consent or agreement**

Revocation of consent 15. (1) In relation to a consent given for the purposes of this Law, a reference to the donor -

- (a) where the consent is given in respect of a child, means the child; and
- (b) in any other case, means the person who gave the consent.

(2) A person who gives a consent for the purposes of this Law may at any time thereafter revoke that consent by indicating, either orally or in writing, to a registered medical practitioner who is attending the donor in a professional capacity, that the consent is revoked.

(3) Where a person revokes his consent in accordance with subsection (2), the registered medical practitioner to whom the revocation is communicated, shall immediately inform the medical practitioner proposing to rely on the consent in connection with the removal of tissue from the body of the donor that the consent has been revoked.

(4) Upon being informed by the registered medical practitioner to whom the revocation is communicated that the consent has been revoked, a person who

14

Effect of consent under section 13(1)

has in his possession the instrument of consent shall surrender to the person who gave the consent -

- (a) that instrument; and
- (b) if a certificate given in accordance with section 9 or 13(2) is in his possession, that certificate;

but a copy of any such instrument or certificate shall be retained in the donor's medical records.

(5) A registered medical practitioner to whom a person indicates that his consent is revoked under subsection (2) shall immediately record the fact in writing and shall retain the record for not less than three years.

Child or adult no longer in agreement

16. (1) The following provisions of this section apply where a registered medical practitioner has given a certificate in accordance with section 9 or 13(2) and the child or the adult in relation to whom the certificate has been given informs a registered medical practitioner who is attending the child or adult in a professional capacity, that the child or adult is no longer in agreement with the proposed removal and transplantation of tissue.

(2) The registered medical practitioner so informed, shall immediately inform the medical practitioner proposing to remove the tissue from the body of the child or the adult that the child or adult is no longer in agreement with the proposed removal and transplantation of tissue.

(3) A person who is informed that the child or the adult is no longer in agreement with the proposed removal and transplantation of tissue shall, if he has in his possession the instrument of consent that relates to the removal and transplantation of the tissue, surrender to the person who gave the consent -

- (a) that instrument; and
- (b) if the certificate given in accordance with section 9 or 13(2) is in his possession, that certificate;

but a copy of any such instrument or certificate shall be retained in the donor's medical records.

(4) A registered medical practitioner whom a child or an adult informs that he is no longer in agreement with the proposed removal and transplantation of tissue under subsection (1) shall immediately record the fact in writing and shall retain the record for not less than three years.



## PART 4 - DONATIONS OF TISSUE AFTER DEATH

Effect of authority under section 25

17. An authority under section 18 is sufficient authority -

- (a) for a registered medical practitioner other than -
  - (i) a registered medical practitioner who gave the authority; or
  - (ii) a registered medical practitioner who gave a certificate under section 18(3) relating to that authority,

to remove tissue from the body of a deceased person in accordance with section 18; and

(b) for a prescribed person or a person belonging to a prescribed class of persons to remove tissue, or a prescribed class of tissue, from the body of a deceased person in accordance with an authority given by section 18(1).

18. (1) If a registered medical practitioner, a prescribed person or a person belonging to a prescribed class of persons, is satisfied after making such inquiries as are reasonable in the circumstances in relation to a person who has died that -

- (a) the person had, during the person's lifetime, given his consent in writing to the removal after that person's death of tissue from that person's body for the purpose of -
  - (i) its transplantation to the body of a living person; or
  - (ii) its use for other therapeutic purposes or for medical purposes or scientific purposes; and
- (b) the consent had not been revoked,

the registered medical practitioner, prescribed person or person belonging to a prescribed class of persons, may remove or authorize the removal of tissue from that person's body in accordance with the terms and conditions of the consent.

(2) A registered medical practitioner, a prescribed person or a person belonging to a prescribed class of persons, who removes or authorizes the removal of tissue under subsection (1) from the body of a deceased person shall immediately advise the next of kin of the deceased person that he has removed or authorized the removal of, tissue in accordance with the wish or consent of the deceased person.

(3) A registered medical practitioner, a prescribed person or a person belonging to a prescribed class of persons, shall not remove or authorize the removal of tissue under subsection (1) from the body of a deceased adult who at the time that the consent was given lacked capacity to consent.

16

Authority to remove tissue after death

(4) A registered medical practitioner, a prescribed person or a person belonging to a prescribed class of persons, shall not remove or authorize the removal of tissue under subsection (1) -

- (a) from the body of a deceased child; or
- (b) from the body of any other deceased person unless -
  - where the respiration or the circulation of the blood of the deceased person is not being maintained by artificial means, a registered medical practitioner (not being the firstmentioned registered medical practitioner) has certified in writing -
    - (A) that he carried out a clinical examination of the person; and
    - (B) that, in his opinion, the person has died within the meaning of section 2(4); or
  - (ii) where the respiration or the circulation of the blood of the deceased person is being maintained by artificial means, two registered medical practitioners (neither of whom is the first-mentioned registered medical practitioner and each of whom has been for a period of not less than five years a registered medical practitioner) have each certified in writing -
    - (A) that he has carried out a clinical examination of the person while the respiration or the circulation of the blood of that person was being maintained by artificial means; and
    - (B) that, in his opinion, at the time of examination, irreversible cessation of all function of the brain stem of the person had already occurred.

(5) For the purposes of subsection (4), any period during which a person who is a registered medical practitioner practised as a registered medical practitioner, however described, under the law in force in a place outside the Islands is to be taken into account in calculating the period of five years referred to in that subsection.

(6) Without limitation to the foregoing, where a registered medical practitioner, a prescribed person or a person belonging to a prescribed class of persons, has authorized the removal of tissue from the body of a deceased person in accordance with this section, the registered medical practitioner, prescribed person or person belonging to a prescribed class of persons, as the case may be,

may direct that the body of the deceased person be preserved (whether by refrigeration or otherwise) for up to seventy-two hours following the death of the deceased person prior to the removal of such tissue.

Coroner's consent 19. (1) If a registered medical practitioner, a prescribed person or a person belonging to a prescribed class of persons, has reason to believe that the circumstances applicable in relation to the death of a person are such that there may be an inquest to investigate the death of the person pursuant to the Coroners Law (1995 Revision), the registered medical practitioner, prescribed person or person belonging to a prescribed class of persons, as the case may be, shall not authorize the removal of or remove tissue from the body of the deceased person unless a Coroner has given his consent to the removal.

(2) Section 18(1) does not operate in a case in which a Coroner has or may have jurisdiction under the Coroners Law (1995 Revision) to investigate the death of a person unless a Coroner has given his consent to the removal of tissue from the body of the deceased person.

(3) A Coroner may give a direction either before or after the death of a person that his consent to the removal of tissue from the body of the person after the death of the person is not required and, in that event, subsection (1) does not apply to or in relation to the removal of tissue from the body of the person.

(4) A consent or direction by a Coroner under this section may be expressed to be subject to such conditions as are specified in the consent or the direction.

(5) A consent or direction may be given orally by a Coroner, and if so given, shall be confirmed in writing.

## PART 5 - PROHIBITION OF TRADING IN HUMAN TISSUE

Unauthorised selling of human tissue prohibited

20. (1) Subject to this section, a person shall not sell, agree to sell, or agree to receive benefits for, tissue (including his own tissue) or the right to take tissue from his body.

(2) Nothing in subsection (1) applies to a sale, or an agreement to sell, to a person who is, or is reasonably believed by the vendor to be, acting subject to, and in accordance with, a permit granted under section 21(2).

(3) Subsection (1) does not apply to the receiving of reasonable costs associated with the transportation, removal, evaluation, storage and processing of

tissue to, from or at a tissue bank and the distribution from the tissue bank of tissue removed in accordance with this Law.

21. (1) Subject to this section, a person shall not -

- (a) buy, agree to buy, offer to buy, hold himself out as being willing to buy, or inquire whether a person is willing to sell tissue, or the right to take tissue, from the body of another person;
- (b) give or receive benefits for the supply of, or for an offer to supply, tissue;
- (c) seek to find a person willing to supply tissue for benefits;
- (d) offer to supply tissue for benefits;
- (e) initiate or negotiate any arrangement involving the giving of benefits for the supply of, or for an offer to supply, tissue; or
- (f) take part in the management or control of a body of persons corporate or unincorporate whose activities consist of or include the initiation or negotiation of such arrangements.

(2) Subsection (1) does not apply to the giving of reasonable costs associated with -

- (a) the importation and exportation of tissue into and out of the Islands;
- (b) the transportation, removal, evaluation, storage and processing of tissue to, from or at a tissue bank, and
- (c) the distribution from a tissue bank of tissue removed in accordance with this Law.

(3) The Council may, by a permit in writing, authorize a person to buy tissue (other than spermatozoa or ova) or to take tissue (other than spermatozoa or ova) from the body of another person, subject to such conditions and restrictions as may be specified in the permit, if the Council considers it desirable by reason of special circumstances so to do.

(4) Nothing in subsection (1) applies to anything done under and in accordance with a permit granted under subsection (3).

(5) The Council may, at any time, by notice in writing given to a person to whom a permit has been granted under this section, cancel the permit.

(6) Where a permit has been granted under subsection (3) subject to any conditions or restrictions specified in the permit, a person shall not act on the authority of the permit unless the conditions or restrictions, as the case may be, are or have been complied with.

19

Commercial dealings in human tissue prohibited

Recovery of costs of tissue banks

22. (1) A person who owns or controls a tissue bank prescribed by the Regulations may charge an amount to recover the reasonable costs associated with the transportation, removal, evaluation, storage and processing to, from or at the tissue bank and the distribution from the tissue bank of tissue in accordance with this Law.

(2) Section 20(1) does not apply to a person who only charges an amount in accordance with subsection (1).

(3) Section 21(1) does not apply to a person who only pays an amount charged in accordance with subsection (1).

Advertising restrictions 23. A person shall not advertise the selling or buying of tissue or the donation of tissue or of the right to take tissue from the bodies of persons unless the proposed advertisement has been approved by the Council and contains a statement to that effect.

## **PART 6 - MISCELLANEOUS PROVISIONS**

Exclusion of liability when acting in pursuance of consent or authority

- 24. (1) Subject to subsection (2), where -
  - (a) a person carries out a procedure; and
  - (b) a consent or authority given under this Law is sufficient authority under this Law for that person to carry out that procedure,

that person is not liable to any other person in respect of anything done or omitted to be done by that first-mentioned person in the carrying out of that procedure.

(2) Nothing in this section relieves a person from liability for negligence in respect of anything done or omitted to be done by him in the carrying out of a procedure.

Confidentiality

25. (1) Subject to this section, a person to whom this section applies shall not disclose or give to any other person any information or document whereby the identity of a person or a deceased person -

- (a) from whose body tissue has been removed for the purpose of transplantation or for use for other therapeutic purposes or for medical or scientific purposes;
- (b) with respect to whom or with respect to whose body a consent or authority has been given under this Law; or
- (c) into whose body tissue has been, is being, or may be, transplanted,

may become publicly known.

- (2) This section applies -
  - (a) where a consent has been given in accordance with this Law, to a registered medical practitioner who gave a certificate in relation to the consent or any person acting under his authority;
  - (b) where tissue has been removed from the body of a person or a deceased person, to the person who removed the tissue or any person acting under his authority;
  - (c) where tissue has been transplanted into the body of a person, to the registered medical practitioner who performed the transplantation or any person acting under his authority; and
  - (d) where it is proposed that tissue will be transplanted into the body of a person, to the registered medical practitioner who is to perform the transplantation or any person acting under his authority.

(3) Subsection (1) does not apply to or in relation to any information disclosed -

- (a) in pursuance of an order of a court or when otherwise required by any Law;
- (b) for the purposes of administration or bona fide medical research;
- (c) with the consent of the person to whom the information relates;
- (d) when the circumstances in which the disclosure is made are such that the disclosure is or would be privileged; or
- (e) for prescribed purposes, by a prescribed person or a person belonging to a prescribed class of persons.
- 26. (1) A person who -

Offences

- (a) removes tissue from the body of a person whether living or dead except in accordance with a consent or authority that is, under this Law, sufficient authority for the removal of the tissue by that person;
- (b) knowingly or wilfully makes a false statement in a certificate given for the purposes of this Law; or
- (c) contravenes or fails to comply with the provisions of section 11, 12, 18(3) or (4), 19(1), 20(1), 21(1) or (6) or 25(1),

commits an offence and is liable on conviction on indictment to a fine of fifty thousand dollars or to imprisonment for a term of five years, or to both.

(2) A person who contravenes or fails to comply with the provisions of section 15(3), (4) or (5), 16(2), (3) or (4), 18(2) or 23 commits an offence and is liable on summary conviction to a fine of ten thousand dollars or to imprisonment for a term of six months, or to both.

- (3) Nothing in subsection (1) or (2) applies to or in relation to -
  - (a) anything done in pursuance of an order by a Coroner under the Coroners Law (1995 Revision); or
  - (b) any other act authorized by any other Law.

27. (1) The Governor in Cabinet may make Regulations prescribing all matters that are required or permitted by this Law to be prescribed, or are necessary or convenient to be prescribed for giving effect to the purposes of this Law, including Regulations -

- (a) for the purpose of section 17(b), prescribing the person or persons or the class of persons authorized to remove tissue, or a prescribed class of tissue, from the body of a deceased person in accordance with section 18;
- (b) prescribing the form of any consent, certificate, authorization, permit or other document to be used and the particulars to be given in connection with this Law;
- (c) prescribing the fees to be payable in respect of any certificate, authorization, permit or other document issued under this Law;
- (d) prescribing and regulating tissue banks; and
- (e) respecting the content and type of information that may be advertised pursuant to section 23, in respect of the selling and buying of tissue, the donation of tissue and the right to take tissue from the bodies of persons.

(2) Regulations made under this Law may create offences punishable by a fine not exceeding ten thousand dollars.

#### SCHEDULE

(Section 4)

#### THE HUMAN TISSUE TRANSPLANT COUNCIL

Composition of Council

1. (1) The Council consists of five members of whom at least one shall be a registered medical practitioner practising in the Islands.

(2) The members of the Council, including the chairman and deputy chairman of the Council, shall be appointed by the Governor in Cabinet.

(3) The Governor in Cabinet may appoint a secretary to the Council who shall record and keep all minutes of the meetings, proceedings and decisions of the Council but such secretary shall not be a member of the Council and shall have no right to vote.

22

1995 Revision

Power to make Regulations (4) The members of the Council shall hold and vacate office in accordance with the terms of their appointment.

(5) The members of the Council shall be appointed for a term of two years and the Governor in Cabinet shall cause notice of such appointment to be published in the Gazette.

(6) A member of the Council shall be eligible for reappointment.

(7) The Governor in Cabinet may terminate a person's appointment as a member of the Council, if the Governor in Cabinet is satisfied that -

- (a) he has been adjudged bankrupt;
- (b) he is incapacitated by reason of physical or mental illness;
- (c) he has been absent from three consecutive meetings of the Council without the consent of the chairman of the Council; or
- (d) he is otherwise unable or unfit to discharge the functions of a member of the Council.

(8) Where any member ceases to be a member before the normal expiration of his office the Governor in Cabinet in accordance with this Law, may appoint another person to hold that office until the time that the member's office would have expired.

Procedure of Council

2. (1) The Council shall meet at least once every three months and it may decide its own procedures, except so far as its procedures are prescribed by Regulations or this Law.

(2) At every meeting of the Council a quorum shall consist of three members including the chairman, and decisions shall be adopted by a simple majority of the votes of the members present and voting except that in the case of an equality of votes the chairman shall in addition have a casting vote.

(3) The Council may act notwithstanding that a vacancy exists among the members.

(4) The deliberations of the Council shall be confidential but the Council shall cause any decision which affects the members of the public to be published in the Gazette, in a website or in a newspaper of the Islands.

(5) If a member of the Council has any personal or pecuniary interest, direct or indirect, in any matter which is to be determined by the Council, he shall, if present at the meeting of the Council at which such matter is to be determined, as soon as practicable after the commencement thereof, disclose the fact and

remove himself from the meeting, and he shall not take part in the consideration or discussion of such matter or vote on any question with respect thereto.

(6) Minutes of each meeting shall be kept in a proper form and shall be confirmed by the chairman as soon as practicable at a subsequent meeting, and a copy of the minutes as confirmed by the chairman shall be sent to the Minister responsible for health.

Remuneration of members 3. Each of the members of the Council (if they are not in the public service) may receive such remuneration in respect of each meeting attended, and the chairman and deputy chairman (if they are not in the public service) may receive such additional remuneration, as may be determined, from time to time, by the Governor in Cabinet.

Passed by the Legislative	Assembly the	day of	, 2013.

Speaker.

Clerk of the Legislative Assembly.