

CAYMAN ISLANDS



**THE HUMAN TISSUE TRANSPLANT LAW, 2013
(LAW 15 OF 2013)**

**THE HUMAN TISSUE DONATION AND TRANSPLANT
REGULATIONS, 2018**

CONSULTATION DRAFT

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The Cabinet, in exercise of the powers conferred by section 27 of the Human Tissue Transplant Law (Law 15 of 2013), makes the following Regulations -

PART 1 - PRELIMINARY

1. (1) These Regulations may be cited as the Human Tissue Donation and Transplant Regulations, 2018. Citation and commencement

(2) These Regulations come into force immediately after the Human Tissue Transplant Law, 2013 comes into force. Law 15 of 2013

2. (1) In these Regulations - Definitions

“designated health care facility” means a health care facility designated under Regulation 10(1) to operate a tissue bank or a transplant centre, or both;

“donation” means the act of giving human tissue for a permitted purpose;

“donor” means a person who registers to donate or donates one or more tissues, whether the donation occurs during the person’s lifetime or after death;

“health care facility” means a health care facility as defined in section 2 of the Health Practice Law (2017 Revision); (2017 Revision)

“parent”, in relation to a child, means -

- (a) the child’s natural mother or father;
- (b) the legal guardian of the child;
- (c) a person who has adopted the child pursuant to an adoption order; and
- (d) the spouse of the natural mother or father of the child who has been cohabiting with that person for not less than one year.

“organ” means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy and includes a part of an organ if -

- (a) its function is to be used for the same purpose as the entire organ in the human body; and
- (b) that part maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy;

“Register” means the Cayman Islands Human Tissue Donation Register established by Regulation 4;

“tissue bank” means a place operated by a designated health care facility where a transplant coordinator or transplant team or unit undertakes the procurement, storage and supply of human tissues for permitted purposes;

“transplant centre” means a designated health care facility where the transplantation of human tissues or organs is carried out; and

“transplant co-ordinator” means a registered medical practitioner employed by a designated health care facility to coordinate the activities of a tissue bank or transplant centre.

(2) Where these Regulations confer a duty or a liability on a tissue bank or transplant centre, the duty is imposed on, or the liability is incurred by, the health care facility designated to operate the tissue bank or transplant centre.

Non-application of Regulations

3. These Regulations do not apply to blood or blood products or their storage or removal from the body of a person, whether living or deceased.

PART 2 - HUMAN TISSUE DONATION REGISTER

Human Tissue Donation Register

4. (1) The Council shall maintain, in physical or electronic form, a Cayman Islands Human Tissue Donation Register.

- (2) The Council shall record the following information in the Register -
 - (a) details of persons residing in the Islands who wish to become donors;
 - (b) any particular tissue that a donor chooses to donate; and
 - (c) any particular tissue that a donor chooses not to donate.

(3) The Register shall be the only human tissue Register having legal validity for purposes of a donation in the Islands.

5. (1) An adult may register to donate tissues from the adult's body by signing and submitting to the Council the registration form contained in Schedule 1. Eligibility for registration

(2) The Council shall record all donations in the Register in the form set out in Schedule 1.

6. (1) The Council shall only register a person as a donor if it is satisfied that the person - Registration as a donor

- (a) is an adult;
- (b) is not suffering from a mental disorder that renders the person incapable of understanding the nature and consequences of the donation;
- (c) is making the donation voluntarily, of the person's own free will; and
- (d) is adequately informed about and understands the nature and consequences of the donation.

(2) Before registering a person as a donor, the Council may require the person to submit a certificate from a registered medical practitioner confirming that the person meets the criteria in paragraph (1)(b) or (d).

7. (1) The Council shall amend the Register whenever it is necessary or appropriate to do so in order to give effect to these Regulations, to bring the Register up to date or to correct any erroneous or incomplete information entered into it. Role of the Council

(2) The Council shall not allow access to the information contained in the Register except to -

- (a) a donor or the donor's next of kin, in respect of a donation made by the donor or registered in the donor's name; and
- (b) a tissue bank or transplant centre, for the purpose of determining whether a person is a registered donor.

8. (1) A person registered as a donor under this Part may, at any time, apply to the Council to retract the offer to donate a particular tissue. De-registration

(2) The Council shall forthwith cancel a person's registration as a donor or amend the Register to reflect any changes respecting the person's proposed donation on receipt of -

- (a) an application under paragraph (1); or
- (b) a notice from a registered medical practitioner who is attending the donor in a professional capacity indicating that the person has

revoked the the person's consent under section 15(2) of the Law or is no longer in agreement with proposed donation as described in section 16(1) of the Law.

PART 3 - CERTIFICATES OF CONSENT

- Prescribed certificates
9. The following certificates are prescribed for the purposes of the Law -
- (a) consent of a parent under section 13(1) of the Law to the removal of regenerative tissue from the body of a child for the purpose of transplantation to the body of another living person (Schedule 2);
 - (b) consent by an adult under section 6 of the Law to the removal of regenerative tissue from the adult's body for a permitted purpose (Schedule 3);
 - (c) consent by an adult to the removal of non-regenerative tissue from the adult's body for the purpose of transplantation to the body of another person (Schedule 4); and
 - (d) registered medical practitioner's certificate under section 18 of the Law authorizing removal of tissue from a person's body after death (Schedule 5).

PART 4 - TISSUE BANKS AND TRANSPLANT CENTRES

- Designation of health care facility to operate tissue bank or transplant centre
10. (1) A health care facility listed in Schedule 6 is hereby designated to operate a tissue bank or transplant centre.
- (2) A designated health care facility may apply to the Council for a permit to import or export human tissue for the purposes of its business for a period of up to twelve months from the day that the permit is granted.
- Suspension of designation
11. (1) The Council may suspend a health care facility's designation to operate a tissue bank or transplant centre if the facility -
- (a) is charged with an an offence under the Law; or
 - (b) has failed to comply with the requirements of the Law.
- (2) Prior to suspending a health care facility's designation under paragraph (1), the Council shall serve a notice on the health care facility stating that it intends to suspend its designation, with effect from the date specified in the notice, and identifying -
- (a) the requirements of the Law that the health care facility is contravening;
 - (b) the action which the health care facility is required to take to bring itself into compliance with the Law; and

- (c) the time within which the the action identified in subparagraph (b) shall be taken.

(3) If a designated health care facility fails to comply with the requirements set out in a notice served under paragraph (2) within the specified time, the Council shall suspend the health care facility's designation to operate the tissue bank or transplant centre.

- (4) A suspension under this Regulation -
 - (a) shall be for such period as the Council considers necessary, having regard to the reasons for the suspension;
 - (b) may be total or limited to -
 - (i) a particular activity or activities carried out at the tissue bank or transplant centre; or
 - (ii) the procurement, storage or supply of particular tissues; and
 - (c) shall be vacated if, in the case of suspension of a designated health care facility charged with an offence under the Law, the health care facility is acquitted, or the charge is dropped.

12. (1) The Cabinet may, on the recommendation of the Council -

Revocation of designation

- (a) revoke a health care facility's designation to operate a tissue bank bank or transplant centre and strike the name of the facility from the list of designated health care facilities in Schedule 6; or
- (b) issue an order limiting a health care facility's designation to -
 - (i) a particular activity or activities carried out at a tissue bank or transplant centre; or
 - (ii) the procurement, storage or supply of particular tissues.

(2) Prior to recommending revocation or limitation of a health care facility's designation under paragraph (1), the Council shall serve a notice on the health care facility stating its intention to make the recommendation, with effect from the date specified in the notice, and identifying -

- (a) the requirements that the health care facility is contravening;
- (b) the action which the health care facility is required to take to bring itself into compliance with the Law; and
- (c) the time within which such action shall be taken.

(3) If the health care facility fails to comply with the requirements set out in the notice within the specified time, the Council shall recommend to Cabinet revocation or limitation of the health care facility's designation, as the case may be.

13. (1) A designated health care facility shall have in place guidelines approved by the Council to assess all potential live tissue donors in order to

Guidelines for assessment of live tissue donors

decide whether to supply human tissue for transplant, based on the following criteria -

- (a) in the case of donation between blood relatives and family members who are not blood relatives, the tissue shall be donated to an identified recipient;
- (b) in other non-related donations a pre-existent close emotional link shall be present between the donor and the recipient for such a donation to be acceptable; and
- (c) in the case of a non-directed altruistic tissue donation, the principle of distributive justice shall be adopted, by which the donated tissue shall be allocated to a recipient according to the recipient's medical needs.

(2) Every designated health care facility shall maintain updated and peer-reviewed guidelines approved by the Council respecting the diagnosis of irreversible cessation of brain stem function.

Record-keeping
requirements

14. (1) A designated health care facility shall maintain written records of the activities of the tissue bank or transplant centre in procuring, testing, processing, preserving, storing and distributing human tissue intended for transplant, including the identities of donors, registered medical practitioners performing transplants and recipients of transplanted tissue, including the details of -

- (a) every donation of tissue (whether regenerative or non-regenerative) by a living person;
- (b) every removal of tissue from a deceased person;
- (c) any arrangement negotiated or initiated by the health care facility involving the giving of benefits for the supply of, or for an offer to supply, tissue;
- (d) every import or export of tissue by or on behalf of the health care facility; and
- (e) the costs incurred in the operation of the tissue bank or transplant centre associated with -
 - (i) importing and exporting of tissue;
 - (ii) the transportation, removal, evaluation, storage and processing of tissue; and
 - (iii) the distribution and transplantation of tissue removed in accordance with the Law.

(2) A designated health care facility shall, on request by the Council, produce any record maintained under this Regulation and permit the Council to -

- (a) inspect and take copies of, or extracts from, any book, document, computer data or record, in whatever form it is held at the premises of the tissue bank or transplant centre;

- (b) take possession of any human tissue samples for examination and analysis; and
- (c) question any person found on the premises of the tissue bank or transplant centre whom the Council has reasonable cause to believe is able to give information that is relevant to the functions of the Council or to a record required to be provided by the health care facility.

15. (1) A designated health care facility that knowingly does or participates in any of the following commits an offence and is liable on summary conviction to a fine of ten thousand dollars -

Trafficking in human tissue

- (a) makes use of illicitly removed human tissue for a permitted purpose;
- (b) supplies human tissue from a donor for transplantation to the body of another person, knowing that the transplantation will be carried out in contravention of the Law;
- (c) prepares, preserves or stores an illicitly removed human tissue; or
- (d) transports, transfers, receives, imports or exports an illicitly removed human tissue.

(2) Any person employed by a designated health care facility, or who is a member of a transplant team or unit operating in conjunction with a tissue bank or transplant centre, who knowingly commits or participates in an offence committed by a designated health care facility under paragraph (1) is guilty of the same offence and liable to the same penalty as the health care facility.

(3) In this Regulation, illicitly removed human tissue is tissue that is removed from a living or deceased donor in any of the following circumstances -

- (a) where the removal is performed -
 - (i) without the free, informed and specific consent of the living donor; or
 - (ii) in the case of a deceased donor, in contravention of the requirements of section 18(4)(b) of the Law, or without being consented to as required by the Law; or;
- (b) where, in exchange for the removal of the tissue, the donor or a third party has been offered or has received a financial gain or comparable advantage.

PART 5 - IMPORT AND EXPORT OF HUMAN TISSUE

16. (1) No person or designated health care facility shall import human tissue into the Islands for the purpose of transplant unless -

Import or export of human tissue prohibited unless certain requirements are met

- (a) the importation is made by or on behalf of a tissue bank or transplant centre;
 - (b) the tissue -
 - (i) meets standards of quality and safety approved by the Council; and
 - (ii) can be traced from the donor to the recipient and vice versa in accordance with procedures established by the Council;
 - (c) the designated health care facility has made an application for a permit for the importation under Regulation 10(2) and the application has been approved by the Council.
- (2) No person or designated health care facility shall export human tissue from the Islands unless -
- (a) the export is made by or on behalf of a tissue bank or transplant centre; and
 - (b) the designated health care facility has made an application for a permit for the export under Regulation 10(2) and the application has been approved by the Council.
- (3) A designated health care facility or person that contravenes paragraph (1) or (2) commits an offence and is liable on summary conviction to a fine of ten thousand dollars.

SCHEDULE 1

(Regulation 5(2))

REGISTRATION AS A DONOR UNDER THE LAW

1. Name of donor:

First

Middle

Last

2. Contact information:

Permanent Address:

Present Address:

Telephone number: _____

Email address: _____

3. Personal information:

Date of birth: _____

Gender (Check one) : Male Female

4. Tissues donated:

I wish to become a donor under the Human Tissue Transplant Law, 2013 for the purpose of (Check one)

Transplant only; OR

Transplant / organ and tissue research

I wish to donate (Check one)

- Any needed tissue or organ(s);
- The following tissue or organ(s) only:
.....
.....
.....
..... OR

Any needed tissue or organs **except** for those indicated below:
(Check only tissue and organ(s) that you **do not** want to donate)

- Kidneys Heart Eyes Bone
- Liver Lungs Skin Pancreas
- Bone Marrow Other

I do not wish my donated tissues or organs to be used as a cadaver for medical or scientific purposes

5. Declaration:

I declare that I am donating the tissue and organ(s) listed above voluntarily of my own free will and that I am adequately informed about, and understand the nature and consequences of, the donation.

By signing below, I am consenting to be a tissue or organ donor after my death.

(Signature of Donor)

Date

(Signature of Witness)

Date

SCHEDULE 2

(Regulation 9(a))

CONSENT OF PARENT TO THE REMOVAL OF REGENERATIVE TISSUE
OR ORGAN FROM THE BODY OF A LIVING CHILD

PART 1 - Consent of Parent to Removal of regenerative tissue or organ

I,,
parent of,
(Name of donor)

a child under the age of 18 years, HEREBY CONSENT to
the removal of the following regenerative tissue from the
child's body for the purpose of transplant to the body of
another living person

.....
(Tissue or organ to be removed for transplant)

I CERTIFY THAT:

- (a) I have obtained advice from a medical practitioner (other than the practitioner who will be transplanting the tissue or organ) regarding the nature and effect of the removal of the tissue or organ and the nature of the transplantation;
- (b) has the mental capacity to
(Name of donor)
understand the nature and effect of the removal and the nature of the transplantation; and
- (c) has agreed to the removal of
(Name of donor)
the regenerative tissue or organ for the purpose of its transplantation to the body of another living person.

Date
(Signature of parent)

PART 2 - Certification by medical practitioner

I, , CERTIFY THAT
(Name of registered medical practitioner)

....., a parent of
(Name of parent of donor)

....., a child under
(Name of donor)

the age of 18 years, has consented to the removal of the following regenerative tissue or organ from the body of the child for the purpose of transplantation to the body of

.....
(Name of recipient)

.....
(Tissue or organ to be removed for transplant)

I FURTHER CERTIFY THAT:

- (a) I am satisfied that, at the time consent was given, the child was capable of understanding the nature and effect of the removal of the tissue or organ and the nature of the transplantation;
- (b) I explained those matters to the child, who understood them;
- (c) the child was in agreement with the proposed removal and transplantation of the tissue or organ; and
- * (d) I am satisfied that the brother/ sister/ parent is likely to die unless the tissue or organ is transplanted to the body of that brother, sister or parent.
(Paragraph (d) applies only where the consent relates to the removal of any specified regenerative tissue or organ for the purpose of transplantation to the body of a brother, sister or parent of the child.)

Date
(Signature of registered medical practitioner)

* Strike through as necessary

SCHEDULE 3

(Regulation 9(b))

CONSENT BY ADULT UNDER SECTION 6 OF THE LAW TO
THE REMOVAL OF REGENERATIVE TISSUE OR ORGAN
FROM THE ADULT'S BODY

PART 1 - Consent to Removal of regenerative tissue or organ

I,
(Name of donor)

HEREBY CONSENT to the removal from my body, while I am
alive, of the following regenerative tissue or organ for the purpose
of:

(Check one)

- transplantation to the body of another living person; or
 other therapeutic purposes or for medical or scientific purposes

.....
(Tissue or organ to be removed)

PART 2 - Certification by medical practitioner

I,, CERTIFY THAT
(Name of registered medical practitioner)

....., being an adult of sound mind,
(Name of donor)

gave the above written consent in my presence.

I FURTHER CERTIFY THAT I have explained to

..... the implications of the removal
(Name of donor)

of the regenerative tissue or organ from his/her body and I am of the opinion
that he/she understood the implications of the removal.

Date

(Signature of registered medical practitioner)

SCHEDULE 4

(Regulation 9(c))

CONSENT BY ADULT UNDER SECTION 7 OF THE LAW TO
THE REMOVAL OF NON-REGENERATIVE TISSUE OR
ORGAN(S) FROM THE ADULT'S BODY

PART 1 - Consent to Removal of non-regenerative tissue or organ(s)

I,
(Name of donor)

HEREBY CONSENT to the removal from my body, while I am alive, of the
following non-regenerative tissue or organ(s):

.....
(Tissue or organ(s) to be removed)

for the purpose of transplant to the body of another living person.

Time of consent: o'clock AM / PM

Date:
(Signature of donor)

PART 2 - Certification by medical practitioner

I,, CERTIFY THAT
(Name of registered medical practitioner)

....., being an adult of sound mind,
(Name of donor)

gave the above written consent in my presence.

I FURTHER CERTIFY THAT I have explained to

..... the implications of the removal
(Name of donor)

of the non-regenerative tissue or organ(s) from his/her body and I am of the
opinion that he/she understood the implications of the removal and freely
consents to it.

Date
(Signature of registered medical practitioner)

SCHEDULE 5

(Regulation 9(d))

CERTIFICATE OF REGISTERED MEDICAL PRACTITIONER UNDER SECTION 16 OF THE LAW AUTHORIZING REMOVAL OF TISSUE OR ORGAN(S) FROM A PERSON'S BODY AFTER DEATH

I,, AUTHORIZE
(NAME OF REGISTERED MEDICAL PRACTITIONER)
the removal of the following tissue

.....
(Tissue or organ(s) to be removed)

from the body of....., deceased
(Name of donor)

for the purpose of: (Check one)

- transplantation to the body of another living person; or
- other therapeutic purposes or for medical or scientific purposes.

I CERTIFY THAT

- *(a) another registered medical practitioner has carried out a clinical examination of the deceased and has certified in writing that, in his/her opinion, the person has died; OR
- *(b) two other registered medical practitioners (each of whom has been registered as a medical practitioner for a period of not less than five years) have carried out a clinical examination of the deceased while the respiration or the circulation of the blood of that person was being maintained by artificial means; and have certified in writing that, in his/her opinion, at the time of examination, irreversible cessation of all function of the brain stem of the person had already occurred.

I FURTHER CERTIFY THAT I have made such enquiries as are reasonable in the circumstances and that

- (a) I am satisfied that the deceased during his/her lifetime -

- * (i) expressed the wish for, or consented to, the removal of the tissue or organ(s) from his/her body after death for any purpose or use referred to above and that the deceased had not withdrawn the wish or revoked the consent; OR
 - * (ii) never expressed any objection to the removal of the tissue or organ(s) from his/her body after death for any purpose or use referred to above and I am satisfied that the next of kin of the deceased consents to the removal of the tissue or organ(s) from the body of the deceased for any such purpose or use; AND
- (b) I have no reason to believe that the deceased, at the time that his/her consent was given, lacked capacity to consent.

Date
(Signature of registered medical practitioner)

* Strike through as necessary

SCHEDULE 6

(Regulation 10(1))

DESIGNATED HEALTH CARE FACILITIES

- 1.
 - 2.
 - 3.
-