

HUMAN TISSUE TRANSPLANT ACT

CHAPTER 28:07

Act
13 of 2000

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CHAPTER 28:07

HUMAN TISSUE TRANSPLANT ACT

An Act to make provision for the removal of human tissue for transplantation and blood for transfusion and for matters connected therewith. 13 of 2000.

[30TH SEPTEMBER 2001]

Commencement.
[174/2001].

PART I

PRELIMINARY

1. This Act may be cited as the Human Tissue Transplant Act. Short title.

2. In this Act— Interpretation.

“blood” means human blood and includes—

- (a) any substance derived from blood; and
- (b) any part of the body which can be used as a source from which to derive a constituent of blood for therapeutic use or for the preparation of a substance for therapeutic use;

“blood transfusion” means the transfusion of blood, or any of the constituents of blood, into a person and includes the operation of removing all or part of the blood of a person and replacing it with blood taken from another person;

“Coroner” has the same meaning as in the Coroners Act; Ch. 6:04.

“designated officer” means a person appointed under section 3 to be the designated officer of the hospital;

“guardian” means a person appointed by a will or by order of a Court to be guardian of child;

“hospital” means any hospital designated by the Minister, by Order, to be a hospital for the purposes of this Act;

“Medical Chief of Staff” means a medical practitioner who is in charge of a hospital or having the control and management of the affairs of a hospital;

“medical practitioner” means a member, other than a provisionally registered member, of the Medical Board of Trinidad and Tobago established under the Medical Board Act; Ch. 29:50.

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“Minister” means the Minister to whom the responsibility for health is assigned;

“minor” means a person under eighteen years of age, but does not include a person who is married or a parent;

“nearest relative” means in strict order of priority—

- (a) a spouse;
- (b) a child who is not a minor;
- (c) a parent or guardian; or
- (d) a brother or sister over eighteen years of age;

“non-regenerative tissue” means tissue other than regenerative tissue;

“regenerative tissue” means tissue that, after injury within or after removal from the body of a living person, is replaced in the person’s body by natural processes;

“relative” means a spouse, child, parent, brother or sister;

Ch. 45:55.

“spouse” means a partner by a subsisting legal marriage or a cohabitant as defined in the Cohabital Relationships Act;

“therapeutic purposes” includes transplant purposes;

“tissue” includes an organ, a part of a human body and a substance extracted from the human body or a part of the human body, but does not include—

- (a) spermatozoa or ova;
- (b) an embryo or a foetus or a part of an embryo or a foetus; or
- (c) blood or a blood constituent;

“transplant” means the removal of tissue from a human body, whether living or dead, and its implantation into another living human body.

PART II

DESIGNATED OFFICERS

Designated officers.

3. (1) The Medical Chief of Staff or the Chief Medical Officer may in writing nominate at least one medical practitioner, who has been in practice for a period of not less than three years, as the designated officer or designated officers of a hospital for a period not exceeding two years for the purposes of this Act.

(2) A nomination under subsection (1), shall be submitted to the Minister and on being satisfied the Minister shall appoint such person or persons as designated officer or officers for the hospital concerned and such officer or officers may exercise such powers and shall be subject to such duties conferred and imposed on designated officers by this Act.

(3) The Minister, on the advice of the Medical Chief of Staff or the Chief Medical Officer or in his own discretion, may revoke the appointment of a person as a designated officer for a hospital by serving on that person a notice of revocation.

(4) A designated officer shall not participate in any of the medical procedures involved in the removal of tissue from or transplant to the body of a person to which Parts III and V relate.

PART III

DONATION OF TISSUE BY ADULTS

4. (1) Subject to this Act, a person who—

- (a) is not a minor;
- (b) is of sound mind; and
- (c) in the light of medical advice given to him by a medical practitioner, with which advice he agrees,

Donation of regenerative tissue by adults.

may, in writing signed by him in the presence of a designated officer consent to the removal from his body of the regenerative tissue specified in the consent—

- (d) for the purpose of the transplantation of the tissue to the body of another living person, or
- (e) for use for other therapeutic purposes or for medical or scientific purposes.

(2) A person who has given a consent referred to in subsection (1), may, at any time before the removal of the regenerative tissue to which the consent applies, revoke in writing, his consent to such removal.

(3) The designated officer shall, before removal of the regenerative tissue, certify in writing, that—

- (a) all requirements referred to in subsection (1) have been complied with;

- (b) he explained to the donor the implications of removal of regenerative tissue from the body; and
- (c) the donor understood the implications of removal of the regenerative tissue from the body.

Form A of Schedule.

(4) The certification referred to in subsection (3), shall be in the manner set out in Form A of the Schedule.

Consent under section 4.

5. A subsisting consent under section 4(1) and the certification under section 4(3), shall be sufficient authority for a medical practitioner, other than the designated officer and the medical practitioner referred to in section 4(1)(c), to remove the regenerative tissue referred to in the consent.

Donation of non-regenerative tissue by adults.

- 6.** (1) A person who—
- (a) is not a minor;
 - (b) is of sound mind; and
 - (c) in the light of medical advice given to him by a medical practitioner, with which advice he agrees,

may, in writing signed by him in the presence of a designated officer, consent to the removal of non-regenerative tissue from his body after the expiration of a period of at least twenty-four hours from the time at which the consent is signed, for the purpose of the transplantation of the tissue to the body of another living person.

(2) A person who has given a consent referred to in subsection (1), may, at any time before the removal of the non-regenerative tissue to which the consent applies, revoke in writing, his consent to such removal.

(3) The designated officer shall, before removal of non-regenerative tissue, certify in writing, that—

- (a) all requirements referred to in subsection (1) have been complied with;
- (b) he explained to the donor the implications of removal of the non-regenerative tissue from the body; and
- (c) the donor understood the implications of removal of the non-regenerative tissue from the body.

(4) The certification referred to in subsection (3), shall be in the manner set out in Form B of the Schedule.

Form B
Schedule.

7. A subsisting consent under section 6(1) and certification under section 6(3), shall be sufficient authority for a medical practitioner, other than the designated officer and the medical practitioner referred to in section 6(1)(c), to remove, after the expiration of a period of at least twenty-four hours from the time at which the consent was given, the non-regenerative tissue referred to in the consent.

Consent under
section 6.

DONATION OF TISSUE BY MINORS

8. No person may remove or consent to the removal of non-regenerative tissue from the body of a living minor for the purpose of transplantation of such non-regenerated tissue to the body of another living person or for use for other therapeutic purposes or for medical or scientific purposes.

Prohibition of
removal of non-
regenerative
tissue.

9. (1) A parent or guardian of a minor may consent in writing to the removal of regenerative tissue specified in the consent from the body of the minor for the purpose of transplantation to the body of a natural brother, sister or parent of the minor, so long as—

Removal of
regenerative
tissue where
minor
understands.

- (a) the parent or guardian has obtained advice from a medical practitioner, other than the practitioner due to transplant the tissue, regarding the nature and effect of the removal of the tissue and the nature of the transplantation;
- (b) the minor has the mental capacity to understand the nature and effect of removal and the nature of the transplantation; and
- (c) the minor has agreed to the removal of the regenerative tissue for the purpose of its transplantation to the body of the person receiving the tissue.

(2) The consent referred to in subsection (1), shall be in the manner set out in Form C of the Schedule.

Form C of
Schedule.

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(3) A person who has given a consent referred to in subsection (1), may, at any time before the removal of the regenerative tissue to which the consent applies, revoke in writing, his consent to such removal.

(4) In this section a reference to a parent of the minor does not include a person standing in *loco parentis* to the minor.

(5) The designated officer shall, before the removal of tissue by a medical practitioner, certify in writing, that—

- (a) all requirements referred to in subsection (1) have been complied with;
- (b) he explained to the parent or guardian the implications of removal of the regenerative tissue from the body of the minor; and
- (c) the parent or guardian understood the implications of the removal of regenerative tissue from the body of the minor and the minor has agreed to the removal.

(6) The certification referred to in subsection (5) shall be in the manner set out in Form D of the Schedule.

Form D of Schedule.

Consent under section 9.

10. The consent given by the parent or guardian of the minor and the agreement of the minor under section 9(1)(c) and the certification given under section 9(5) shall be sufficient authority for a medical practitioner to remove the regenerative tissue from the body of the minor, unless such consent or agreement has been revoked at any time prior to the removal.

Removal of regenerative tissue where minor does not understand.

11. (1) A parent or guardian of a minor may consent in writing to the removal of regenerative tissue specified in the consent from the body of the minor for the purpose of transplantation to the body of a natural brother, sister or parent of the minor, so long as—

- (a) advice from a medical practitioner, other than the medical practitioner due to transplant the tissue, regarding the nature and effect of the removal of the tissue and the nature of the transplantation is obtained;

- (b) the minor is not capable of understanding the nature and effect of the removal of tissue and the nature of transplantation; and
- (c) a medical practitioner, other than the medical practitioner due to transplant the tissue, certifies in writing that unless the tissue specified in the consent is transplanted to the said brother or sister or parent, as the case may be, such person would die.

(2) The consent of the parent or guardian referred to in subsection (1), shall be in the manner set out in Form E of the Schedule and certification referred to in subsection (1)(c) shall be in the manner set out in Form F of the Schedule.

Form E of
Schedule.

Form F of
Schedule.

(3) A person who has given a consent referred to in subsection (1), may, at any time before the removal of the regenerative tissue to which the consent applies, revoke in writing, his consent to such removal.

(4) In this section, a reference to a parent of the minor does not include a person standing in *loco parentis* to the minor.

(5) The designated officer shall, before the removal of tissue by the medical practitioner, certify in writing, that—

- (a) all the requirements referred to in subsection (1) have been complied with;
- (b) he explained to the parent or guardian of the minor the implications of removal of regenerative tissue from the body of the minor; and
- (c) the parent or guardian understood the implications of the removal of regenerative tissue from the body of the minor.

(6) The certification referred to subsection (5) shall be in the manner set out in Form G of the Schedule.

Form G of
Schedule.

12. A subsisting consent given by the parent or guardian of the minor and the certification by the medical practitioner under section 11(1)(c) and the certification under section 11(5), shall be sufficient authority for a medical practitioner to remove the regenerative tissue from the body of the minor.

Consent under
section 11.

PART IV

BLOOD DONATION

Consent by adult to removal of blood.

- 13.** A person who—
- (a) is not a minor; and
 - (b) is of sound mind,

may consent to the removal of blood from his body for transfusion to another person or for use of the blood for therapeutic, medical or scientific purposes.

Removal of blood from minor.

14. The parent of a minor may consent to the removal of blood from the body of the minor for transfusion to another person or for use of the blood for therapeutic, medical or scientific purposes if—

- (a) a medical practitioner advises that the removal will not be prejudicial to the health of the minor; and
- (b) the minor agrees in writing to the removal of the blood.

Consent to be sufficient authority for removal of blood.

15. Consent under section 13 or consent under section 14 and the agreement under section 14(b) shall be sufficient authority for the removal of blood from the body of the person who has given the consent or from the body of the person on whose behalf consent was given.

PART V

DONATION OF TISSUE AFTER DEATH

Authority to remove tissue after death.

16. Subject to section 17, a designated officer may authorise, for the purposes stated in this section, the removal of tissue from the body of a person who has died in hospital or whose body has been brought into the hospital, for—

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

17. (1) The authorisation referred to in section 16 shall only be given where, after making such inquiries as are reasonable in the circumstances, a designated officer—

Conditions under which designated officer may exercise authority.

- (a) is satisfied that the deceased person during his lifetime expressed the wish for, or consented to, the removal of tissue from his body after his death, for the purpose or a use referred to in section 16 and had not withdrawn the wish or revoked the consent; or
- (b) has no reason to believe that the deceased person has expressed an objection to the removal of tissue from his body after his death for the purpose or a use referred to in section 16 and the designated officer is satisfied that the nearest relative of the deceased person consents to the removal of tissue from the body of the deceased person for the purpose or a use referred to in section 16,

and shall be in the manner set out in Form H of the Schedule.

Form H of Schedule.

(2) The authorisation of a designated officer under section 16 shall be restricted by the expressed terms of the wishes or consent of the deceased person, or the consent of his nearest relative, as the case may be, both as to the tissue which may be removed and as to the purpose or use of such tissue.

(3) The nearest relative of a person may make it known to a designated officer at any time when the person is unconscious and before death that he consents to the removal, after death of the person, of tissue from the body of the person for the purpose of a use referred to in section 16, but the designated officer shall not act on such an indication if such person recovers consciousness.

18. No tissue may be removed from the body of the donor under this Part until death has occurred.

Removal of tissue only after death.

19. (1) For the purposes of this Part, a person is considered dead when there has occurred—

When death occurs.

- (a) irreversible cessation of all functions of the brain stem of that person; or

(b) irreversible cessation of circulation of blood in the body of that person.

(2) Death shall be determined by two medical practitioners on the staff of the relevant hospital, in accordance with the prescribed criteria, save, however, that—

(a) no medical practitioner who has a familial or professional relationship with the proposed recipient shall take any part in the determination of the fact of the death of the donor of the tissue;

(b) no medical practitioner who had taken part in the determination of death under paragraph (a) shall participate in the transplantation of the tissue to the recipient; and

(c) where the tissue is to be removed for therapeutic purposes, no medical practitioner who is due to remove or transplant the tissue, may determine the occurrence of death or may be a part of any team or process by whom or which death is determined.

(3) The Minister shall, by regulations, prescribe the criteria for determining the irreversible cessation of all functions of the brain stem of the person referred to in subsection (1).

Concurrence of
Coroner.

Ch. 6:04.

20. (1) Where a designated officer has reason to believe that the circumstances applicable to the death of a person are such that a coroner has jurisdiction to hold a preliminary inquiry or an inquest into the manner and cause of death of the person under the provisions of the Coroner's Act, the designated officer shall not, under and in accordance with section 17, authorise the removal of tissue from the body of the deceased person unless the coroner has stated that he has no objection to the removal.

(2) A coroner may give a statement after the death of a person that he has no objection to the removal of tissue from the body of the person and, in that event, subsection (1) does not apply to or in relation to the removal of tissue from the body of the person.

(3) A statement by a coroner under this section may be given orally or in writing and where given orally, shall be

confirmed in writing and shall be subject to such conditions as are specified in the statement.

PART VI

PROHIBITION ON TRADING IN HUMAN TISSUE

21. (1) No person shall remove or cause to be removed human tissue or blood from the body of a donor for the purposes of trading that tissue or blood for valuable consideration.

Trade in human tissue and blood.

(2) Subject to this section, any contract or arrangement under which a person agrees, for valuable consideration, whether given or to be given to himself or to another person, to the sale or supply of any tissue from his body or from the body of another person, or to the sale or supply of blood whether before or after his death or the death of the other person, as the case may be, is void.

(3) A person who contravenes subsection (1) or enters into a contract or arrangement of the kind referred to in subsection (2), commits an offence and is liable on conviction to a fine not exceeding fifty thousand dollars and to imprisonment for a term of two years.

22. (1) No person shall advertise, issue or cause to be issued any blood or advertisement relating to the buying or selling of any tissue from the body of a person.

Advertisement relating to buying or selling of tissue prohibited.

(2) In this section, "advertisement" includes every means of advertising, whether in a publication, or by the display of any notice or signboard, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other documents, or by words inscribed on any article, or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting or television, or in any other way, and any reference to the issue of an advertisement shall be construed accordingly.

(3) Any person who contravenes or fails to comply with subsection (1) or (2) commits an offence and is liable on summary conviction to a fine not exceeding fifty thousand dollars and to imprisonment for a term of two years.

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PART VII

MISCELLANEOUS

Exemption from liability.

23. No personal liability shall attach to any medical practitioner or other person given any function under this Act, for anything done, permitted or omitted to be done in good faith in the exercise of any authority under this Act, or done by reason of, or as a result of a consent, agreement or authority given or purported to have been given under this Act.

Limitation of application of Act.

24. Nothing in this Act shall apply to, or in relation to—

- (a) the removal of any tissue from the body of a living person in the course of a procedure or operation carried out, in the interest of the health of the person, by a medical practitioner with the consent, express or implied, given by or on behalf of the person or in circumstances necessary for the preservation of the life of a person by the use of any tissue so removed;
- (b) the removal of any tissue from the body of a deceased person during the course of a post-mortem examination;
- (c) the embalming of the body of a deceased person; or
- (d) the preparation, including the restoration of any disfigurement or mutilation, of the body of a deceased person for the purpose of interment or cremation.

Offences in relation to removal of tissue.

25. (1) No person shall remove or cause to be removed any tissue from the body of a deceased person except in accordance with this Act.

(2) No person shall remove or cause to be removed any blood or tissue from the body of a living person, for any purpose except in accordance with this Act.

(3) Any person who contravenes or fails to comply with subsection (1), commits an offence and is liable on summary conviction to a fine not exceeding one hundred thousand dollars and to imprisonment for a term of five years.

26. (1) Any person who—

Offences.

- (a) fails to comply with the requirements, which by this Act required compliance before certification; or
- (b) removes tissue or blood from the body of a donor for the purpose of trading,

commits an offence and is liable on summary conviction to a fine of fifty thousand dollars.

(2) Where a designated officer is convicted under subsection (1), in addition to the fine imposed, his appointment as designated officer shall be deemed to be revoked.

27. (1) Notwithstanding any other law to the contrary and subject to this section, a person shall not disclose or give to any other person any information or document whereby the identity of a person—

Disclosure of information.

- (a) from whose body any tissue has been removed for the purpose of transplantation;
- (b) with respect to whom a consent or authority has been given under this Act; or
- (c) into whose body any tissue has been, or is being transplanted,

may become publicly known.

(2) Subsection (1), shall not apply to or in relation to any information disclosed—

- (a) in pursuance of an order of a Court;
- (b) for the purposes of continued care or *bona fide* medical research; or
- (c) with the consent of the person to whom the information relates.

(3) Any person who contravenes or fails to comply with subsection (1), commits an offence and is liable on summary conviction to a fine of five thousand dollars and to imprisonment for a term of six months.

28. The Minister may make Regulations for matters that are required or permitted by this Act to be prescribed and for matters

Regulations.

that are necessary or convenient for carrying out or giving effect to this Act, and in particular—

- (a) to the screening and testing of tissue and blood before and after removal from a body;
- (b) to the transportation, storage and handling of tissue and blood;
- (c) to the conditions subject to which transplantation of tissue shall be carried out;
- (d) to the criteria for determining the irreversible cessation of all functions of the brain stem of a person; and
- (e) to the allocation of tissues.

[Section 4(4)].

SCHEDULE

FORM A

REPUBLIC OF TRINIDAD AND TOBAGO

I, certify that ,
(Name of designated officer) (Name of donor)

being an adult of sound mind, and who has been given relevant medical advice by a medical practitioner, with which advice he/she agrees, has consented in writing to the removal from his/her body of the following regenerative tissue for the purpose of the transplantation of the tissue to the body of another living person/therapeutic/medical/scientific purposes:

.....
.....
.....

I further certify that I have explained to the
(Name of donor)
implications of the removal of the regenerative tissue from his/her body and I am of the opinion that he/she understood the implications of the removal.

Date
Signature of designated officer

FORM B

[Section 6(4)].

REPUBLIC OF TRINIDAD AND TOBAGO

I, certify that ,
(Name of designated officer) *(Name of donor)*

being an adult of sound mind, and who has been given relevant medical advice by a medical practitioner, with which advice he/she agrees, has consented in writing to the removal from his/her body of the following non-regenerative tissue for the purpose of the transplantation of the tissue to the body of another living person/therapeutic/medical/scientific purposes:

.....
.....
.....

I further certify that I have explained to the
(Name of donor)
implications of the removal of the non-regenerative tissue from his/her body and I am of the opinion that he/she understood the implications of the removal.

Date
Signature of designated officer

[Section 9(2)].

FORM C

REPUBLIC OF TRINIDAD AND TOBAGO

I, parent/guardian of
(Name of donor)

(a minor), consent to the removal of the undermentioned regenerative tissue from his/her body for the purpose of transplantation to the body of
(Name of recipient)

his/her natural brother/sister/mother/father

.....

.....

.....

I certify that:

I have obtained advice from a medical practitioner, other than the practitioner due to transplant the tissue, regarding the nature and effect of the removal of the tissue and the nature of the transplantation.

..... has the mental capacity to
(Name of donor)

understand the nature and effect of the removal and the nature of the transplantation.

..... has agreed to the removal of
(Name of donor)

the regenerative tissue for the purpose of its transplantation to the body of
(Name of recipient) his/her natural brother/sister/mother/father.

Date
Signature of parent/guardian

FORM D

[Section 9(6)].

REPUBLIC OF TRINIDAD AND TOBAGO

I, certify that
(*Name of designated officer*)

parent/guardian of, a minor, has consented to the removal of the undermentioned regenerative tissue from the body of the minor for the purpose of transplantation to the body of, the minor's natural brother/sister/mother/father:

.....
.....
.....

I further certify that:

the parent/guardian of the minor has obtained medical advice from a medical practitioner, other than the practitioner due to transplant the tissue, regarding the nature and effect of the removal of the tissue and the nature of the transplantation

the minor has the mental capacity to understand the nature and effect of the removal and the nature of the transplantation and has agreed to the removal of the regenerative tissue for the purpose of its transplantation to the body of the person receiving the tissue

I explained to the parent/guardian the implications of the removal of the regenerative tissue from the body of the minor and the parent/guardian appeared to understand the implications of the removal.

Date
Signature of designated Officer

[Section 11(2)].

FORM E

REPUBLIC OF TRINIDAD AND TOBAGO

I, parent/guardian of
(Name of donor)

(a minor), consent to the removal of the undermentioned regenerative tissue from his/her body for the purpose of transplantation to the body of his/her natural brother/sister/mother/father:
(Name of recipient)

.....
.....
.....

I certify that:

I have obtained advice from a medical practitioner, other than the practitioner due to transplant the tissue, regarding the nature and effect of the removal of the tissue and the nature of the transplantation.

..... does not have the mental capacity
(Name of donor)

to understand the nature and effect of the removal and the nature of the transplantation

a medical practitioner, other than the medical practitioner due to transplant the tissue, has certified in writing that unless the above-mentioned tissue is transplanted to the body of
(Name of recipient)

he/she (the recipient) would die.

Date
Signature of parent/guardian

FORM F

[Section 11(2)].

REPUBLIC OF TRINIDAD AND TOBAGO

I, medical practitioner,
hereby certify that unless the undermentioned tissue, which is the same tissue
specified in the consent of parent/guardian of
....., a minor, is transplanted to the body of
(Name of recipient)
the natural brother/sister/mother/father of the minor, he/she (the recipient)
would die.

I further certify that I will not participate in any of the medical procedures
involved in transplantation of the tissue.

Date
.....
Signature of medical practitioner

[Section 11(6)].

FORM G

REPUBLIC OF TRINIDAD AND TOBAGO

I, certify that
(Name of designated officer)

parent/guardian of, a minor, has consented to the removal of the undermentioned regenerative tissue from the body of the minor for the purpose of transplantation to the body of, the minor's natural brother/sister/mother/father:

.....
.....
.....

I further certify that:

the parent/guardian of the minor has obtained medical advice from a medical practitioner, other than the practitioner due to transplant the tissue, regarding the nature and effect of the removal of the tissue and the nature of the transplantation

the minor does not have the mental capacity to understand the nature and effect of the removal and the nature of the transplantation

a medical practitioner, other than the medical practitioner due to transplant the tissue, has certified in writing that unless the above-mentioned tissue is transplanted to the body of, he/
(Name of recipient)

she (the recipient) would die

I explained to the parent/guardian the implications of the removal of the regenerative tissue from the body of the minor and the parent/guardian appeared to understand the implications of the removal.

Date
Signature of designated officer

FORM H

[Section 17(1)].

REPUBLIC OF TRINIDAD AND TOBAGO

I, hereby authorise the removal of the
(Name of designated officer)

undermentioned tissue from the body of
(Name of donor)

deceased, for transplantation to the body of a living person/use for therapeutic/
medical/scientific purposes:

.....
.....
.....

I certify that I have made enquiries as are reasonable in the circumstances and
(delete as appropriate):

am satisfied that the deceased during his/her lifetime expressed the wish
for, or consented to, the removal of tissue from his/her body after death
for any purpose or use referred to above and had not withdrawn the
wish or revoked the consent

have no reason to believe that the deceased had expressed an objection
to the removal of tissue from his/her body after death for any purpose or
use referred to above and I am satisfied that the nearest relative of the
deceased consents to the removal of tissue from the body of the deceased
for any such purpose or use.

Date

.....
Signature of designated officer

SUBSIDIARY LEGISLATION

HUMAN TISSUE TRANSPLANT REGULATIONS

ARRANGEMENT OF REGULATIONS

REGULATION

1. Citation.
2. Interpretation

PART A

GENERAL

3. Restrictions on the transplantation of tissue.
4. Screening of donors and testing of tissue.
5. Preservation and harvest of tissue.
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SCHEDULE.

[Subsidiary]

314/2004. **HUMAN TISSUE TRANSPLANT REGULATIONS**
made under sections 19(3) and 28

Citation. **1.** These Regulations may be cited as the Human Tissue Transplant Regulations.

Interpretation. **2.** In these Regulations—
“Act” means the Human Tissue Transplant Act;
“approved” means approved by the Chief Medical Officer;
“brain stem death” means the irreversible cessation of all functions of the brain stem of a person;
“Chief Medical Officer” means the Chief Medical Officer in the Ministry of the Minister with responsibility for health;
“donor” means a person from whom blood or tissue may be, is intended to be, is being or has been removed, for use by another person;
“harvest” means to remove tissue from a donor for therapeutic, medical or scientific purposes;
“harvested tissue” means tissue which has been removed from a donor but has not yet been implanted into the body of a recipient;
“nurse” means a person fully registered with the Nursing Council of Trinidad and Tobago, to practise nursing;
“recipient” means a person who may receive, is intended to receive, is receiving or has received blood or tissue from a donor.

PART A

GENERAL

Restrictions on the transplantation of tissue. **3.** (1) Tissue shall be transplanted only in a hospital, by a person trained in transplanting tissue, working under aseptic conditions.

(2) The Medical Chief of Staff of a hospital shall ensure that tissue is transplanted in accordance with these Regulations and any policies or guidelines approved by the Chief Medical Officer.

(3) Tissue shall not be implanted unless it is viable.

4. (1) A donor shall be evaluated to determine whether his tissue may be accepted for transplantation and the evaluation shall include—

Screening of donors and testing of tissue.

- (a) serological tests;
- (b) physical tests;
- (c) evaluation of the tissue; and
- (d) any other test determined by the Chief Medical Officer.

(2) Precautions shall be taken to ensure that the donor does not have any of the international contraindications for acceptance of tissue.

(3) A donor shall be screened and his tissue tested by a person trained for the purpose, working under aseptic conditions.

5. (1) Subject to subregulation (2), tissue shall be preserved as soon as practicable after the death of a donor, by placing the cadaver of the donor in a controlled, refrigerated environment or in a cool chamber surrounded by ice, and, in the case of ocular tissue, by placing ice over the closed eyelids.

Preservation and harvest of tissue.

(2) Subregulation (1) shall not apply where a donor has been diagnosed with brain stem death but has a beating heart.

(3) Twelve hours shall be the maximum time period allowed to elapse between the death of a donor and the harvest of his tissue.

(4) A medical practitioner who harvests tissue from a donor shall make a record of Form A of the Schedule.

Form A Schedule.

6. (1) Harvested tissue shall be individually packaged and sealed, where appropriate, with a seal capable of revealing whether there has been tampering with the package.

Storage of tissue.

(2) A package of harvested tissue shall be placed in a properly labelled, water-proof, sterile container with a large sticker stating “HUMAN TISSUE, DO NOT FREEZE”.

(3) The container shall be secured in a controlled or refrigerated environment or in a chamber surrounded by ice, for a period of time approved by the Chief Medical Officer, before transplantation, to avoid the possibility of the harvested tissue becoming damaged or contaminated.

(4) Harvested tissue for implantation shall be assigned a unique identification number.

(5) The container in which the harvested tissue is stored shall clearly indicate—

- (a) the time and date of death of the donor, where applicable;
- (b) the time of harvesting;
- (c) the type of tissue; and
- (d) the results of any tests performed on the tissue.

(6) An appropriate storage medium shall be used and users shall be guided by the recommendations of the manufacturer as to date, temperature and other factors.

(7) Harvested corneal tissue shall be stored in an approved medium and sclera shall be stored in Glycerol or any other approved medium.

(8) A record shall be made on the label of a package of harvested tissue, of the medium used to store the tissue.

(9) Harvested tissue for implantation shall not be frozen.

Delivery and receipt of harvested tissue.

7. (1) Where harvested tissue, other than ocular tissue, is intended to be used for a transplantation, it shall be delivered, along with a Form A completed in respect of the tissue, to the surgeon or another medical practitioner, involved in performing the transplantation.

(2) Where harvested ocular tissue is intended to be used for a transplantation, it shall be delivered, along with a Form A completed in respect of the tissue, to an ophthalmologist, a physician or a trained technician, involved in performing the transplantation.

(3) The person who receives the harvested tissue shall give written confirmation as to the condition of the harvested tissue when received and notwithstanding subregulation (1), the surgeon shall be ultimately responsible for assessing the suitability for transplantation, of the harvested tissue received.

(4) A note shall accompany the harvested tissue that is delivered, disclaiming any warranty as to the merchantability or fitness for a particular purpose of the tissue.

(5) A record of the delivery and receipt of the harvested tissue shall be kept by the designated officer.

(6) A person involved in the transport of harvested tissue shall receive adequate practical training with respect to his handling of containers containing harvested tissue and his role in the process of transplantation.

(7) Overall responsibility for the transportation of harvested tissue shall rest with a person designated by the Minister, to co-ordinate transport.

8. (1) Harvested tissue shall be allocated in a fair and equitable manner.

Allocation of harvested tissue.

(2) Access to harvested tissue shall be provided without regard to the sex, age, religion, race, creed or colour of the recipient.

(3) Harvested tissue shall be allocated on a first-come, first-serve basis in accordance with guidelines made by the Chief Medical Officer.

(4) A request, for implantation or research, for—

(a) harvested tissue, other than ocular tissue, shall be made by a specialist surgeon on Form B of the Schedule; and

(b) harvested ocular tissue, shall be made by an ophthalmologist on Form B of the Schedule,

Form B.

and may be transmitted electronically.

(5) The Chief Medical Officer shall establish a procedure for the recall of harvested tissue.

(6) Tissue harvested from a cadaver shall be exported only in cases where local needs are satisfied.

Records of transplantations.

9. (1) A surgeon or another medical practitioner involved in performing a transplantation of ocular, renal or cardiac tissue, as the case may be, shall within forty-eight hours after the transplantation, make a record of the transplantation on an approved form.

(2) The record under subregulation (1) shall state—

- (a) the acceptance of transplanted tissue by a recipient and the surgical procedures used for transplantation; and
- (b) any adverse reactions of the recipient that are attributable to the transplantation, including communicable and other transmitted diseases and dysfunction of the transplanted tissue.

Keeping of records.

10. (1) Records to be kept under these Regulations shall be kept by the Medical Chief of Staff, for a minimum of five years from the date the record was made.

(2) Confidentiality shall be maintained at all times and where software packages are used for storing records, security shall be observed by allowing access only to authorised personnel.

(3) The Medical Chief of Staff shall ensure that duplicates of records to be kept under these Regulations, are immediately sent to the Chief Medical Officer.

PART B

TRANSPLANTATION OF OCULAR TISSUE

Harvest, assessment and storage of ocular tissue.

11. (1) Assessment of ocular tissue shall include slit lamp, microbiological tests, microbial tests and specula microscopy.

(2) Ocular tissue for non-surgical purposes, including research, shall be clearly labelled and need not have the tests referred to in subregulation (1).

(3) A serological test for ocular tissue to be transplanted shall be—

- (a) performed on blood drawn from a donor at the time of harvesting of the tissue and include tests for—
 - (i) Human Immunodeficiency Virus Types I and II antibody;
 - (ii) Human Immunodeficiency Virus Types I and II antigen;
 - (iii) Hepatitis B surface antigen;
 - (iv) Hepatitis C antibody;
 - (v) Syphilis, ELISA or FTA, for *Treponema pallidum*;
 - (vi) Human T Cell Lymphotropic Type I and II antibody;
 - (vii) ABO/Rhesus factor; and
 - (viii) any other matter determined by the Chief Medical Officer;
- (b) completed within the period in which the ocular tissue is being processed to determine its suitability for transplantation; and
- (c) conducted and its results obtained,

before the ocular tissue may be used.

(4) The surgeon harvesting the tissue shall record the results of the screening and testing of the blood of the donor and submit a copy of the record to the person responsible for processing and storing the tissue.

(5) Documentation of data related to the processing and storage of tissue shall be the responsibility of the person who processed and stored the tissue.

(6) Cornea and sclera shall be stored in a refrigerated environment at between 2°C to 6°C.

(7) A refrigeration unit shall be fitted with a device for the continuous monitoring of temperature, which produces a printed record of the temperature inside the storage chamber throughout the day.

(8) Loss of temperature control within the storage chamber shall be certified immediately upon discovery and a determination shall be made as to whether the tissue is still viable.

Transplantation of ocular tissue.

12. Transplantation of ocular tissue shall be carried out in a hospital equipped for microsurgical ophthalmic surgery.

PART C

TRANSPLANTATION OF RENAL TISSUE

Medical facilities.

13. Transplantation of renal tissue shall only be performed in a hospital in which there are—

- (a) in-house dialysis facilities with bicarbonate bath;
- (b) in-house facilities for renal imaging studies such as ultra sonography with Doppler, studies or nuclear medicine capabilities or both, in the case of transplantation of cadaveric renal tissue;
- (c) laboratory facilities or access to the facilities, to provide Complete Blood Count, Blood Glucose, Blood Urea Nitrogen, Serum Creatinine, Electrolytes and Liver Function tests on an emergency basis; and
- (d) facilities to obtain cyclosporine levels within twenty-four hours.

Personnel.

14. (1) The Medical Chief of Staff in a hospital involved in the transplantation of renal tissue shall—

- (a) identify teams of medical practitioners to harvest renal tissue;
- (b) ensure that the services of—
 - (i) a pathologist capable of interpreting renal transplantation biopsy material;
 - (ii) medical personnel skilled in the management of critically ill persons; and
 - (iii) a transportation co-ordinator,
 are available to the hospital.

(2) A team of medical practitioners referred to in subregulation (1)(a) shall comprise a surgeon skilled, certified or experienced in surgical procedures of transplantation and a physician skilled, trained or experienced in managing immunosuppressive therapy and its complications.

15. The Medical Chief of Staff in a hospital involved in the transplantation of renal tissue shall, in the case of a cadaveric donation, ensure that renal tissue is harvested only where the donor had attained between three to fifty-five years of age, had a good output of urine and had no history of—

Criteria for cadaveric donation.

- (a) prolonged hypotension;
- (b) systemic infection;
- (c) renal disease;
- (d) hypertension;
- (e) malignancy; or
- (f) diabetes.

16. The following tests shall be conducted before renal tissue is harvested from a donor:

Test before harvest of renal tissue.

- (a) ABO blood typing;
- (b) Tissue typing: Histocompatibility testing: Human Leucocyte Antigen (HLA typing) A, B and DR;
- (c) test for Syphilis, ELISA or FTA, for *Treponema pallidum*;
- (d) Human Immunodeficiency Virus I and II antibody and antigen;
- (e) Hepatitis B Surface antigen;
- (f) Cytomegalovirus Serology, including IgG and IgM;
- (g) T and B Cell Cross-matching, where the serum of a recipient is tested against the tissue of a donor;
- (h) Hepatitis C Virus antibody; and
- (i) any other test determined by the Chief Medical Officer.

Storage and handling of renal tissue.

17. (1) Harvested cadaveric renal tissue shall be stored either by cold storage or using ice or by machine perfusion, for a period of time approved by the Chief Medical Officer, before transplantation.

(2) Where the method of cold storage is used, the renal tissue shall be flushed with Colin's solution or any other approved solution, separated, placed on ice in sterile containers and transported to a hospital.

Allocation of renal tissue.

18. (1) Renal tissue shall be allocated according to ABO compatibility.

(2) T and B cell cross-matches between donor and recipient shall be negative.

(3) Subject to subregulations (1) and (2), the best antigenic match shall be used, where possible and the greatest weight in matching shall be given to HLA-B and DR antigen similarity.

(4) Recipients who have been on the national waiting list the longest shall be given preference in the allocation of harvested renal tissue.

(5) Renal tissue shall be allocated only where a recipient demonstrates that he can comply with medical instructions and procedures necessary to maintain transplanted renal tissue.

(6) A recipient may receive more than one transplantation of renal tissue.

(7) Where the previous sensitization of a recipient was positive and the recipient currently has a negative cross-match, the recipient shall be given greater consideration for transplantation.

Administrative procedures.

19. The Medical Chief of Staff in a hospital involved in the transplantation of renal tissue shall ensure that—

(a) harvested renal tissue is delivered to the directed destination in accordance with regulation 7;

(b) a person is designated to receive harvested renal tissue and an area is designated in which harvested renal tissue is to be received;

- (c) a quality assurance programme is implemented in the hospital to provide ongoing monitoring and evaluation of renal transplantations;
- (d) a file on adverse reactions is kept;
- (e) annual reviews of manuals for procedures are developed; and
- (f) any other information deemed necessary for quality assurance is recorded.

PART D

TRANSPLANTATION OF CARDIAC TISSUE

20. A person shall only be considered as a candidate for transplantation of cardiac tissue where he has—

Candidate for transplantation of cardiac tissue.

- (a) terminal heart failure, that is, refractory to optimal conventional medical or surgical therapy or both, including persons on failed inotropic support; and
- (b) a life expectancy which has been limited to no more than twelve months,

and shall be evaluated by a multi-disciplinary team with expertise in the management of heart failure, high risk surgical intervention and transplantation.

21. The clinical signs of terminal heart failure shall include the following common causes:

Clinical signs of terminal heart failure.

- (a) cardiomyopathy;
- (b) coronary artery disease;
- (c) valvular heart disease; and
- (d) complex forms of congenital heart disease.

22. The criteria for screening and selection of a donor shall include—

Screening and testing of cardiac tissue and blood before and after removal from donor.

- (a) no evidence of heart injury as reflected by a normal electrocardiogram, chest X-ray, echocardiogram and coronary angiogram, where feasible, for males over thirty-five years and

females over forty years with acceptable haemodynamic parameters;

- (b) no evidence of active infection with Human Immunodeficiency Virus I and II, Gagprotein 24, Hepatitis B, Tuberculosis, Cytomegalovirus, Human T Lymphotropic Virus, *Tripanosoma Cruzi*;
- (c) ABO compatibility;
- (d) no malignancy apart from brain tumours;
- (e) an age of under forty-five years for males and under fifty years for females;
- (f) a weight of not more than twenty-five per cent over or under the weight of the recipient; and
- (g) projected ischaemic time under four to six hours from the onset of cardiac arrest during organ procurement to cardiac reperfusion on completion of transplantation.

Transportation, handling and storage of cardiac tissue and blood.

23. (1) Cardiac tissue shall be placed in saline solution of 4°C using double sterile bags and thereafter placed into a protective, watertight bucket for transport in a cooler packed with ice.

(2) The safe time limit for the storage technique shall be no more than six hours.

Allocation of cardiac tissue.

24. The allocation of cardiac tissue shall be based on the —

- (a) urgency attaching to the need of the recipient;
- (b) physical proximity of the donor to the recipient; and
- (c) length of time the name of the recipient has been on the national waiting list.

PART E

BRAIN STEM DEATH

Diagnosis of brain stem death.

25. (1) Brain stem death shall be diagnosed on the demonstration of the absence of reflexes of the brain stem in a person with a known cause of severe and irreversible brain damage.

(2) A person shall not be diagnosed with brain stem death—

- (a) until at least six hours after the onset of a coma; or
- (b) where cardiac arrest was the cause of the coma, until twenty-four hours after the circulation of blood throughout the body has been restored.

(3) Diagnosis shall be made either by electrophysiological, radiological or other tests or by simple, reliable bedside demonstrations of the absence of reflexes of the brain stem.

26. The clinical criteria for the diagnosis of brain stem death shall be that—

Clinical criteria for the diagnosis of brain stem death.

- (a) the person is in a coma and totally dependent on ventilatory support;
- (b) there is no doubt that the coma is due to irremediable, structural brain damage;
- (c) a diagnosis of a disorder that can lead to brain stem death has been made; and
- (d) there is no evidence that a depressant drug, hypothermia, a metabolic or endocrine disturbance, is responsible for or contributes to the coma, or that respiration has been impaired by neuromuscular blocking agents or other drugs.

27. (1) The clinical signs of brain stem death shall be that—

Clinical signs of brain stem death.

- (a) reflexes of the brain stem are absent and this is evident where—
 - (i) the pupils are fixed and do not react to sharp changes in the intensity of incident light;
 - (ii) there are no corneal reflexes in response to firm stimulation of the cornea;
 - (iii) there are no responses to caloric stimulation and no eye movement occurs during or after the slow injection of twenty millilitres of cold water into each external auditory meatus, clear access to the tympanic membrane having been established by direct inspection; and

- (iv) no motor response can be elicited from any cranial or spinal nerve distribution with adequate stimulation of the relevant somatic area and where there is an injury to the spinal cord, the stimulus shall be applied above the level of the injury; and
- (b) respiratory movements do not return on disconnecting the ventilator, despite an adequate partial pressure of carbon dioxide of 6.65 Pascals.

(2) Where a ventilator is to be disconnected for the purpose of looking for respiratory movements in a person, the anaesthetist shall, as far as possible, reduce the risk of hypoxia during disconnection by oxygenating the blood of the person before disconnection from the ventilator with the concentration of oxygen at 100 per cent and delivering oxygen at 6 l min⁻¹ through a catheter into the trachea.

- (3) Where a person has a chronic respiratory disease—
- (a) the test at subregulation (2) shall not be used;
 - (b) and the respiratory centre of the person is unresponsive to carbon dioxide, careful monitoring of partial pressure of oxygen and oxygen saturation is essential;
 - (c) a normal, for that person, set of blood gases should be produced during the disconnection test by giving only a small amount of oxygen, then partial pressure oxygen should be allowed to decrease by a further 1–2 Pascals and the chest observed for respiratory movement.

(4) Where a person's eyes or ears have been injured either before or during the episode leading to brain stem death, other signs for example, where there is a perforated eardrum and cold water is syringed into the ear, may be helpful in making the diagnosis since, if the brain stem is dead, nothing will happen and if the brain stem is alive, a decrease in heart rate and blood pressure will be seen.

(5) In addition to the tests referred to in subregulation (4), the following tests may be used:

- (a) brain blood flow studies;
- (b) brain stem evoked audiometry response;
- (c) whether the patient has doll's eye movement; and
- (d) atropine tests.

28. The diagnosis of brain stem death shall be made by—

- (a) two medical practitioners acting independently, with each examining the person on not less than two separate occasions, which shall be at least two hours apart; or
- (b) two medical practitioners jointly carrying out a set of tests on each of two occasions, which shall be at least six hours apart, with one of the medical practitioners carrying out the tests and the other recording the results.

Medical practitioners to diagnose brain stem death.

29. (1) The Medical Chief of Staff shall prepare a list of medical practitioners who may assess a person and determine brain stem function viability.

Selection of medical practitioners.

(2) Where the Medical Chief of Staff has a personal interest in the transplantation of harvested tissue or, for any other reason, is disqualified from selecting medical practitioners pursuant to subregulation (1), the Board responsible for the hospital shall appoint another person to prepare a list of medical practitioners.

(3) A medical practitioner who has been selected shall be—

- (a) a Consultant or Senior Registrar with at least five years experience in any of the specialties listed at paragraph (b); or
- (b) practising as one of the following specialists:
 - (i) physician or internist;
 - (ii) pediatrician;
 - (iii) general surgeon;
 - (iv) subspecialty surgeon;

- (v) neurosurgeon;
- (vi) neurologist;
- (vii) obstetrician or gynaecologist; or
- (viii) anaesthetist.

(4) A medical practitioner who has an active role in transplantation shall be disqualified from participation in the diagnosis of brain stem death.

(5) Where a hospital has insufficient staff to meet the criteria for diagnosing brain stem death, it may use staff from another hospital for this purpose.

(6) Only medical practitioners approved by the Medical Chief of Staff of the other hospital may be used to determine brain stem death.

Communicating
with relatives of
the person.

- 30.** (1) Communication with the nearest relative, shall—
- (a) be commenced prior to the initial examination of a person for brain stem death; and
 - (b) not take place in public and,

where the nearest relative cannot be contacted, the attempts made to contact him shall be recorded.

(2) The medical practitioners and nurses of the team of the Intensive Care Unit of a hospital may participate in the process of communication with the nearest relative provided that the medical practitioner having prime responsibility for the care of the person plays the major role in the process.

(3) A record of the discussion, strategy and communication shall be made.

(4) The decision to discontinue a system of life support shall rest with the medical practitioner having prime responsibility for the care of the person.

(5) The nearest relative shall be notified by the medical practitioner with prime responsibility for the care of the person or by a person authorised by the medical practitioner, when a diagnosis of brain death is confirmed.

[Regulation 8(4)].

FORM B

REQUEST FOR HARVESTED TISSUE

Type of tissue:
.....
.....

Name of each type of tissue:
.....
.....

Purpose for request: () Implantation () Research

Where tissue is for implantation:

Name of Patient:

Date of Birth:/...../.....
dd/ mm/ yy

Diagnosis:
.....
.....

...../...../.....
dd/ mm/ yy

.....
Signature of Surgeon