

PARLIAMENT OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

TRANSPLANTATION OF HUMAN TISSUES ACT, No. 48 OF 1987

[Certified on 11th December, 1987]

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Transplantation of Human Tissues Act, No. 48 of 1987

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L.D.—O. 6/82.

An Act to provide for the donation of human bodies and tissues for therapeutic, scientific, educational and research purposes; for the removal of such tissues and their use on living persons; for the preservation of such tissues; and for matters connected therewith or incidental thereto.

BE it enacted by the Parliament of the Democratic Socialist Republic of Sri Lanka as follows:—

1. This Act may be cited as the Transplantation of Human Tissues Act, No. 48 of 1987.

Short title.

2. Any person above the age of twenty-one years, may consent to the donation, to take effect upon his death, of his body or any part thereof or any tissue (hereinafter referred to as a "donation effective upon death") to be used for the advancement of medical and dental education, for the purposes of research, for the advancement of medical science or therapy or for use on any living person.

Donations to be taken effect upon death.

3. (1) The consent for a donation effective upon death may be given by the donor by writing attested by two or more competent witnesses or on the prescribed form attested by two or more competent witnesses or orally in the presence of at least two competent witnesses.

How the consent for a donation effective upon death is to be given.

- (2) The fact that the donor has not specified in his consent the purpose of the donation effective upon death shall not by itself be sufficient to invalidate an otherwise valid donation effective upon death.
- 4. (1) A donation effective upon death may be made Donees.
 - (a) any government hospital;
 - (b) any medical practitioner;
 - (c) any dentist; or
 - (d) any prescribed institution.
- (2) Where the donor has not specified the donee, or where the donee is not available the government hospital or any prescribed institution nearest to the place where the donor died shall be sleemed to be the donee.

Relatives
of any
deceased
person who
may give
consent to
remove the
body or
any part
thereof or
any tissue
of such
deceased
person.

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- 5. (1) On the death of any person who has not given consent for a donation effective upon death, it shall be lawful for the next of kin of such deceased person, who is above the age of twenty-one years, to give prior consent in writing for the removal of the body of such person or such part or such tissue as may be specified in such consent, for any of the purposes specified in section 2, if such deceased person had not at any time during his life expressed any contrary intention.
- (2) On the death of any child, it shall be lawful for both parents, or in the absence or incapacity of one parent, for the other parent, or in the absence of both parents, for the guardian of such child, to give prior consent in writing, for the removal of the body of such child or such part thereof or such tissue as may be specified in such consent for any of the purposes of section 2.
- (3) No consent given under subsection (1) or subsection (2) shall be valid unless the donee is specified in such consent.
- (4) The donee under this section shall be the same as specified in section 4.

Donor may revoke the consent given for a donation effective upon death.

- 6. A donor may, during his life time and without the consent of the donee or any other person, revoke the consent given for a donation effective upon death, in whole or in part,—
- (a) by means of a writing subsequent to the writing by
 which the consent for such donation effective upon
 death is given; or
- (b) in case of a consent given for a donation effective upon death by a prescribed form, by intimating in writing to the donee his intention to do so.

Consent by adult living person for the removal during life of nonregenerative tissues for transplantation

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7. (1) Any person above the age of twenty-one years may file his consent in writing with the Director-General of Health Services, for the removal during his life time, (hereinafter referred to as a "donation during life") from his body, of such non-regenerative tissue, as may be specified by him in such consent, for any of the purposes specified in section 2.

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- (2) Where such consent is given by any person under subsection (1), a Medical Consultant, other than a medical consultant attached to the transplantation team preparing to use such tissue, shall certify in writing, before the donation during life of such non-regenerative tissue is made—
 - (a) that he explained to such person before such consent was given the nature and effect of such donation during life of the tissue specified in such consent, from the body of such person;
 - (b) that at the time such consent was given, such person—
 - -(i) had attained the age of twenty-one years; and
 - (ii) was of sound mind; and
 - (c) that such person gave his consent freely in his presence.
- (3) Notwithstanding anything to the contrary in any other written law, it shall be lawful for any prescribed technician to remove from the body, and prepare for use, such non-regenerative tissue in respect of which consent has been given under this section.
- Any person who filed his consent under subsection
 may withdraw such consent in writing at any time
 before the donation during life is made.
- (5) The donees under this section shall be the same as specified in section 4.
- 8. (1) Both parents of a child or, in the absence or incapacity of one parent, the other parent or, in the absence of both parents, the guardian of such child may file his consent in writing with the Director-General of Health Services, for the donation during life, from the body of such child, such re-generative tissue as may be specified in such consent for the purpose of the transplantation of such tissue to the body of another member of the family of such child.

(2) Any person above the age of twenty-one years may file his consent in writing with the Director-General of Health Services, for the donation during life, from the body of such person, of such re-generative tissue as may be specified in such consent for the purpose of the transplantation of such tissue to the body of another member of the family of such person.

Donation during life of re-generative tissues.

- (3) Where such consent is given under subsections (1) and (2), a medical consultant, other than a medical consultant attached to the transplantation team preparing to use such tissue, shall certify in writing, before the donation during life of such re-generative tissue is made—
- (a) that he explained to such parents, guardian or person, as the case may be, before such consent was given, the nature and effect of such donation during life of the tissue specified in such consent from the body of such child or person, as the case may be; and
 - (b) that such consent was given freely in his presence.
- (4) Notwithstanding anything to the contrary in any other written law, it shall be lawful for any prescribed technician to remove from the body, and prepare for use, such re-generative tissue in respect of which consent has been given under this section.
- (5) Any parent, or guardian or person who filed his consent under subsections (1) and (2) may withdraw such consent in writing at any time before the donation during life is made.
- (6) The donees under this section shall be the same as specified in section 4.

Authority to remove the body or any part thereof or any tissue of a deceased person.

9. (1) Where a person, who has given the consent for a donation effective upon death, dies, next of kin, or any person lawfully in possession of the body, after the death of such person, other than a person entrusted with such body for the purposes only of its interment or cremation, or for any purpose incidental to such interment or cremation, may, unless such next of kin, or person lawfully in possession of such body, as the case may be, has reason to believe that the consent given for such effective upon death has subsequently been revoked as provided for by section 6, authorize the removal by the donee of such body or such part or such tissue as is specified in such consent as referred to in section 2, and thereupon the donee shall have a right to such body or such part or such tissue, as the case may be, to utilize it for any of the purposes referred to in section 2, where no specific purpose out of such purposes has been specified in such consent.

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- (2) Any prescribed technician may, after the death of such person has been certified by a medical practitioner, remove from the body and prepare for use, such part of tissue.
- 10. (1) Where it appears to the prescribed officer in any hospital, after making such inquiries as may be reasonable in the circumstances, that any person whose death occurred in such hospital or whose body has been brought into such hospital,—
 - (a) had given the consent for a donation effective upon death; and
 - (b) had not revoked such consent as provided for in section 6,

such prescribed officer may, in the prescribed form for the purpose of this section, authorize the removal by the donee of the body of such person or such part thereof or such tissue thereof as may be specified in such consent.

- (2) Any prescribed technician may, after the death of such person has been certified by any medical practitioner, remove from the body and prepare for use, such part or tissue.
- 11. (1) Where it appears to the Superintendent of Prisons of any prison, or such other officer as may be authorized by him in that behalf, after making such inquiries as may be reasonable in the circumstances, that any prisoner whose death occurred in such prison—
- Authority to remove the body, any part or any tissue thereof of a prisoner who dies inside a prison.
- (a) had given the consent for a donation effective upon death; and
- (b) had not revoked such consent as provided for by section 6.

such Superintendent or other officer may, where the body of such prisoner has been claimed by the guardian with the consent of such guardian authorize, in writing, after the magisterial inquiry into such death has been made, the removal by the donee of the body of such prisoner, or such part of tissue thereof as may be specified in such consent.

Authority to remove the body, any part, or tissue thereof of a person who dies in, or whose body has been brought into, a hospital.

(2) Any prescribed technician may, after the death of such person has been certified by a medical practitioner, remove from the body and prepare for use, such part or tissue.

Power to authorize the removal of unclaimed bodies, for . post-mortem examinations and anatomical research.

or tissue

for which it is donated.

Any human body, or part thereof not to use for other purpose than

- 12. Where any dead body is lying unclaimed in any hospital or other institution for over seven days from the date of death, the prescribed officer in such hospital or other institution may authorize the removal of such dead body for any post-mortem examination, and thereafter to any prescribed institution for any anatomical research.
- 13. Any person who uses any body, any or tissue thereof donated under this Act for any purpose other than a purpose specified—
 - (a) in the consent of the donor in any case where the purpose has been specified in such consent; or
 - (b) in section 2, in any case where no purpose has been specified in the consent,

shall be guilty of an offence, and on conviction after summary trial before a Magistrate, be liable to imprisonment of either description for a period of one year or to a fine not exceeding one thousand rupees or to both such imprisonment and fine.

Preservation of tissues.

14. Where a tissue is removed from a human body under this Act it shall be the duty of the prescribed technician who removes it from the body to keep and preserve it in any such place and under such conditions as may, from time to time, be prescribed, until it is duly transplanted:

Provided, however, the provisions of this section shall not apply to any case where the medical practitioner performing the transplantation considers it fit to perform the removal of any tissue from a body and the transplantation of same immediately, without sending it to any such place of preservation.

Meaning of death.

- (1) For the purpose of this Act, the death of a person occurs when an irreversible cessation of all functions of the brain of such person has occurred.
- (2) The irreversible cessation of the functions of the brain may be determined by the prolonged absence of spontaneous circulatory and respiratory functions.

- (3) When the determination of the prolonged absence of spontaneous circulatory and respiratory functions is made impossible by the use of artificial means of support, the irreversible cessation of brain functions shall be determined by any means recognized by the ordinary standards of current medical practice.
- 16. (1) Any medical practitioner who has certified the death of any person shall not participate in any transplantation of any tissue or part of the body of such person.

Medical parctitioner certifying death not to praticipate in transplantation.

- (2) Any medical practitioner acting in contravention of subsection (1) shall be guilty of an offence and on conviction after summary trial before a Magistrate, be liable to imprisonment of either description for a period of one year or to a fine not exceeding one thousand rupees or to both such imprisonment and fine—
- (3) Nothing in this section shall, in any way, affect a medical practitioner who participates in the transplantation of cornea.
- 17. (1) No person shall buy, sell, dispose of, or otherwise deal in, directly or indirectly, for a valuable consideration, any body or any tissue or part thereof for any of the purposes referred to in section 2, without the prior written approval of the Minister.

Any sale, dealing in or disposal of a body, or any part or tissue thereof prohibited.

- (2) The Minister shall not grant such approval unless he is satisfied that adequate facilities are available to such person to collect, store and transplant any such body, tissue or part thereof and that such body, tissue or part thereof will be used by such person only for any of the purposes specified in section 2 of this Act.
- (3) Any person acting in contravention of subsection (1) shall be guilty of an offence and, on conviction after summary trial before a Magistrate, be liable to imprisonment of either description for a period not exceeding two years or to a fine not exceeding one thousand five hundred rupees or to both such imprisonment and fine.
- 18. (1) Except where legally required to do so, no person shall disclose or give to any other person any information or document whereby identity of any person—

Disclosure of information.

(a) who has given or refused to give a consent under this Act; or

- (b) with respect to whom a consent has been given under this Act; or
- (c) into whose body a tissue has been, is being or may be transplanted,

may become publicly known.

(2) Any person acting in contravention of subsection (1) shall be guilty of an offence and, on conviction after summary trial before a Magistrate, be liable to imprisonment of either description for a period not exceeding one year or to a fine not exceeding one thousand rupees or to both such imprisonment and fine.

Nothing in this Act shall apply to inquiries held into deaths. 19. Nothing in this Act shall apply to any inquiry held by any Inquirer under the Code of Criminal Procedure Act, No. 15 of 1979, into the death of any person for the purpose of establishing or confirming the cause of such death, or of investigating into the existence or nature of abnormal conditions leading to such death.

Advisory Council.

- 20. (1) There shall be a Council which shall be called the Technical Advisory Council on Human Tissue Transplantation (hereinafter referred to as the "Council") consisting of the following members:—
 - (a) medical consultants in the field of surgery and medical consultants in the field of general medicine, appointed by the Minister (hereinafter referred to as the "appointed members");
 - (b) five other members (hereinafter referred to as "ex officio members"), who shall be the persons for the time being holding office as—
 - (i) the Director-General of Health Services, who shall be the Chairman of the Council;
 - (ii) the Director-General of Teaching Hospitals;
 - (iii) the Deputy Director-General of Health Services
 (Laboratory Services) who shall be the
 Secretary of the Council;
 - (iv) the Judicial Medical Officer, Colombo; and
 - (v) any other Medical Officer working in a similar capacity.
 - (2) Every appointed member shall, unless he vacates office earlier by death, resignation or removal hold office for a period of three years.
 - (3) The Minister may, if he considers it expedient so to do, remove any appointed member, without assigning any reason therefor.

- (4) Any appointed member may at any time resign his office by letter to that effect addressed to the Minister.
- (5) If an appointed member dies, resigns or is removed from office, the Minister may appoint another person to be a member in place of the member whom he succeeds.
- (6) Any member who is appointed under subsection (5) shall hold office for the unexpired period of the term of office of the member whom he succeeds.
- (7) Any appointed member who vacates office, otherwise than by removal, shall be eligible for reappointment, after the expiry of the period of three years referred to in subsection (2).
- (8) The quorum for any meeting of the Council shall be three members.
- (9) The Council may regulate the procedure in regard to its meetings and the transaction of business at such meetings.
- (10) No act or proceedings of the Council shall be deemed to be invalid by reason only of the existence of any vacancy in the Council or the defect in the appointment of any member of the Council.
- 21. It shall be the duty of the Council to advise the Minister on matters arising out of the administration and implementation of the provisions of this Act or the regulations made thereunder.

Duties of the Council.

22. (1) The Minister may make regulations in respect of the matters required by this Act to be prescribed or, in respect of which regulations are required or authorized to be made. Regulations.

- (2) Every regulation made by the Minister shall be published in the *Gazette* and shall come into operation on the date of such publication or on such later date as may be specified in the regulation.
- (3) Every regulation so made by the Minister shall, as soon as may be convenient after its publication in the Gazette, be brought before Parliament for approval. Any regulation which is not so approved shall be deemed to be rescinded as from the date of such disapproval, but without prejudice to anything previously done thereunder.

(4) Notification of the date on which any regulation is deemed to be so rescinded shall be published in the Gazette.

Interpretation.

- 23. In this Act, unless the context otherwise requires—
 "child" means a person under the age of twenty-one
 years:
 - "competent witness" means a witness not less than eighteen years of age;
 - "dentist" means a person registered as a dentist under the Medical Ordinance;
 - "medical consultant" means a person registered as a medical practitioner under the Medical Ordinance and who possesses any of the prescribed post-graduates qualifications
 - "medical practitioner" means a person registered as a medical practitioner under the Medical Ordinance;
 - "non-regenerative tissue" means tissues other than regenerative tissues;
 - "prison" has the same meaning as in the Prisons Ordinance;
 - "re-generative tissue" means a tissue that, after injury or removal, is replaced in the body of a living person by natural process of growth or repair; and
 - "tissue" means any human flesh, organ, bone or body fluid, or part thereof.