LEGAL NOTICE NO. 314

REPUBLIC OF TRINIDAD AND TOBAGO

THE HUMAN TISSUE TRANSPLANT ACT, 2000

REGULATIONS

MADE BY THE MINISTER UNDER SECTIONS 19(3) AND 28 OF THE HUMAN TISSUE TRANSPLANT ACT

THE HUMAN TISSUE TRANSPLANT REGULATIONS, 2004

Citation

1. These Regulations may be cited as the Human Tissue Transplant Regulations, 2004.

Interpretation

Act No. 13 of 2000

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.

Screening of donors and testing of tissue

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

(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.

Preservation and harvest of tissue

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.

(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

Storage of tissue

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.

(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 processs of transplantation.

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

Allocation of harvested tissue

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

(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—

Form B

(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,

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 authorized 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 Lymphotrophic 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 immuno-suppressive therapy and its complications.

Criteria for cadaveric donation

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—

(a) prolonged hypotension;

(b) systemic infection;

(c) renal disease;

(d) hypertension;

(e) malignancy; or

(f) diabetes.

Test before harvest of renal tissue

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

(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 compatability.

(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

Candidate for transplantation of cardiac tissue

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

(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.

Clinical signs of terminal heart failure

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

(a) cardiomyopathy;

(b) coronary artery disease;

(c) valvular heart disease; and

(d) complex forms of congenital heart disease.

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

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

(a) no evidence of heart injury as reflected by a normal electrocardiogram, chest X-ray, echocardiogram and coronary angiogram, where feasable, 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 Lymphotrophic 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.

Clinical criteria for the diagnosis of brain stem death

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

(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, hypothemia, 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.

Clinical signs of brain stem death

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

(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 1 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.

Medical practitioners to diagnose brain stem death

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.

Selection of medical practitioners

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.

(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 authorized by the medical practitioner, when a diagnosis of brain death is confirmed.

(6) The nearest relative shall be given an opportunity to be present on the occasion of the final discontinuance of a system of life support and his religious and cultural requests shall be met as far as possible, before and after the discontinuance.

SCHEDULE

FORM A

[Regulation 5(4)]

Name of Donor .....

Date and time of death of Donor .....*(where applicable)* ...../...../..... *dd/ mm/ yy* ..... *a.m./p.m.*

Date and time of harvesting of tissue ...../...../..... *dd/ mm/ yy* ..... *a.m./p.m.*

Identification No. of Harvested Tissue .....

Type of tissue harvested .....

.....

.....

.....

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

.....
Signature of Surgeon/Assistant Surgeon

FORM B

[Regulation 8(4)]

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*

Dated this 19th day of October, 2004.

J. RAHAEL
Minister of Health

PRINTED BY THE GOVERNMENT PRINTER, PORT-OF-SPAIN
REPUBLIC OF TRINIDAD AND TOBAGO—2004