
BILLS**SUPPLEMENT No. 17****24th December, 2021****BILLS SUPPLEMENT***to The Uganda Gazette No. 92, Volume CXIV, dated 24th December, 2021*Printed by UPPC, Entebbe, by Order of the Government.

Bill No. 35*Uganda Human Organ Donation and
Transplant Bill***2021****THE UGANDA HUMAN ORGAN DONATION AND
TRANSPLANT BILL, 2021****MEMORANDUM****1. POLICY AND PRINCIPLES**

The object of this Bill is to establish a legal framework for the regulation of organ, cell and tissue donation and transplantation in Uganda. The law aims at protecting the dignity and identity of every person and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to donation and transplantation of organs, tissues and cells of human origin.

Uganda does not have any law governing human organ donation and transplantation which is increasing becoming an area of health care used to cure non communicable diseases that are rising rapidly.

It is therefore imperative to enact an enabling law to address the existing challenges taking into account that healthcare is continuously evolving.

2. DEFECTS IN THE EXISTING LAW

The Bill seeks to address the current lacuna that is existent in both the law and the health care in Uganda in relation to organ, cell and tissue donation and transplant system.

Due to the vacuum in the law, there has been concern about the increase in the illicit trade in and trafficking of human organs, cells and tissue. Further, due to the fact that Uganda does not have any law regulating organ and tissue donation and transplantation, many Ugandan citizens are seeking for medical care from countries like India, United Kingdom and Kenya among others in cases where organ donation and transplantation is the solutions to their health problems.

There is therefore need to regulate organ, cell and tissue donation and transplantation in order to enforce Principle XX of the National Objectives and Directive Principles of the State Policy of the Constitution of the Republic of Uganda which provides that the State shall take all practical measures to ensure the provision of basic medical services to the population. This will protect Ugandans from being potential victims of organ, cell and tissue trafficking.

3. REMEDIES PROPOSED TO DEAL WITH THE DEFECTS

The object of the Uganda Human Organ Donation and Transplant Bill, 2021, is to establish a legal framework for organ, cell and tissue transplant in Uganda. The Bill seeks to—

- (a) establish the Uganda Organ and Transplant Council to oversee and regulate organ, cell and tissue donation and transplantation in Uganda;
- (b) designate Mulago National Referral Hospital as the pioneering transplant centre;
- (c) prescribe a criteria to be followed when designating a hospital as an organ, tissue or cell donation and transplant center;
- (d) regulate the conduct of donation and transplant activities;

- (e) establish policies and procedures for designated transplant centers and approved banks, including ethical standards and educational services to the public;
- (f) establish a donation and transplant system which ensures equitable access to quality donation and transplantation services to donors and potential recipients;
- (g) establish standards for storage of harvested organs, tissues and cells;
- (h) establish a system of distribution of organs, tissues and cells;
- (i) provide for the transplant of organs, tissues and cells;
- (j) establish and maintain a national waiting list for potential organ, tissue and cell donors and recipients drawn from designated transplant centres and other hospitals and health centres;
- (k) create a database of information of donors and recipients to be retained by the transplant centers, hospitals and health facilities;
- (l) establish procedures for the transplantation of organs and tissue from living donors including due diligence;
- (m) establish the procedures for transplantation of organs and tissue harvested from cadavers;
- (n) prescribe the appropriate consent to be given by donors;
- (o) prescribe the requirements to be fulfilled before carrying out a post mortem examination of a confirmed brain dead donor;

- (p) establish a human organ and tissue data base and reporting requirements;
- (q) prescribe offences and penalties related to issues of organ and tissue donation and transplantation.

DR. JANE RUTH ACENG OCERO,
Minister of Health.

**THE UGANDA HUMAN ORGAN DONATION AND TRANSPLANT
BILL, 2021**

ARRANGEMENT OF CLAUSES

PART I—PRELIMINARY

Clause

1. Commencement.
2. Purpose of Act.
3. Application.
4. Interpretation.

**PART II—THE MINISTER AND THE HUMAN ORGAN
TRANSPLANT COUNCIL**

The Minister

5. Powers and functions of the Minister.
6. Assistance and support.

Uganda Organ Donation Transplant Council

7. Uganda Organ Donation and Transplant Council.
8. Qualifications of members of Council.
9. Disqualification for appointment to the Council.
10. Tenure of office of members of the Council.
11. Termination of appointment.
12. Remuneration of Council members.
13. Filling of vacancies on the Council.
14. Functions of the Council.
15. Meetings of the Council.
16. Committees of the Council.
17. Power to engage consultants.
18. Protection from liability of members of Council.
19. Secretariat of Council.

Clause

PART III—FINANCES OF COUNCIL

20. Funds of Council.
21. Duty to operate on sound financial principles.
22. Power to open and operate bank accounts.
23. Estimates.
24. Accounts.
25. Audit.
26. Annual report.
27. Compliance with Public Finance Management Act, 2015.

**PART IV—DESIGNATION OF TRANSPLANT CENTRES
AND APPROVAL OF BANKS**

Designation of Transplant Centres

28. Designation of transplant centres.
29. Application for designation as transplant centre.
30. Qualification for designation as transplant centre.
31. Designation by Minister.
32. Existing centres.
33. Regulation of conduct of donation and transplant activities.

Approval of Human Organ, Tissue and Cell Banks

34. Approval of Banks.

*Policies and Procedures for Designated Transplant
Centres and Approved Banks*

35. Policies and procedures for designated transplant centres and approved Banks.
36. Ethical standards.
37. Educational services to the public.

Clause

**PART V—ADDITIONAL REQUIREMENTS FOR ORGAN,
TISSUE AND CELL BANKS**

- 38. Organ, tissue and cell banking.
- 39. Minimum Standards for Banks.

PART VI—QUALITY ASSURANCE AND QUALITY CONTROL

- 40. Organ Donation and Transplant Quality Control System.
- 41. Quality assurance programmes.
- 42. Recall procedures.
- 43. Look back procedures.
- 44. Notification requirements.

**PART VII—STORAGE OF ORGANS, TISSUES AND
CELLS OUTSIDE THE BODY**

- 45. Preservation of organs, tissues and cells.
- 46. Storage of organs, tissues and cells outside body.
- 47. Packaging and labeling of storage containers.

Distribution of Organs, Tissues and Cells

- 48. Review of donor medical information.
- 49. Distribution compliance.
- 50. Returned tissue.
- 51. Fraudulent activity.

PART VIII—TRANSPLANT OF ORGANS, TISSUES AND CELLS

- 52. National waiting list.
- 53. Fair and equitable system.
- 54. Transplantation activity.
- 55. Authorised transplantation activities.
- 56. Council not to authorise transplant activities in certain cases.

Clause

- 57. Donor screening.
- 58. Organ, tissue or cell sampling.
- 59. Testing requirements.
- 60. Preservation for transplantation.
- 61. Harvesting of organs, tissues and cells.
- 62. Reconstruction.

Retrieval of Organs, Tissues or Cells from Deceased Donors

- 63. Retrieval of organs, tissues and cells from deceased donors.
- 64. Retrieval procedure.

Information of Donors and Recipients to be Retained

- 65. Minimum information to be retained.
- 66. Recipient follow-up information.

Transplantation of Organs from Living Donors

- 67. Donation and transplant of organs, tissues and cells removed from living donors.

Transplant of Organs Harvested from Cadavers

- 68. Cadaveric donation.
- 69. Determination of brain death.
- 70. Procedure after determination of brain death.

Appropriate Consent

- 71. Authority for removal of human organs, tissue and cells.
- 72. Prohibition of donation from living child.
- 73. Appropriate consent for donation from a brain dead or dead child.
- 74. Appropriate consent by living adult.
- 75. Appropriate consent from brain dead or dead adult.

Clause

- 76. Nominated representatives.
- 77. Persons harvesting or using tissue to take into account cultural and spiritual needs, values and beliefs.

**PART IX—POST MORTEM EXAMINATION OF CONFIRMED
BRAIN DEAD DONOR**

- 78. Requirements for carrying out post-mortem examination.
- 79. Authority for removal of human organ, cell or tissue from a body sent for postmortem examination for certain purposes.

**PART X—HUMAN ORGAN AND TISSUE DATA BASE
AND REPORTING REQUIREMENTS**

- 80. Establishment of human organ, tissue and cell database.
- 81. Data collection.
- 82. Records, information on harvest and use of parts of organs, tissues or cells for transplantation.
- 83. Additional records.
- 84. Information for donor, recipients and close relations.
- 85. Confidentiality.

PART XI—OFFENCES AND PENALTIES

- 86. Prohibition of commercial dealings in human material for transplantation.
- 87. Removal of human organ, cell or tissue without authority.
- 88. Prevention of organ, tissue or cell trafficking.
- 89. Removal of human organ, tissue or cell from living donor without consent or authorisation.
- 90. Restriction of activities in relation to donated material.
- 91. Offences by bodies corporate.
- 92. General penalty.

Clause

PART XII—MISCELLANEOUS

- 93. Counseling for donors and recipients.
- 94. Revocation of consent.
- 95. Power to inspect.
- 96. Regulations.
- 97. Code of practice.
- 98. Amendment of Schedules.

SCHEDULES

SCHEDULE 1 — CURRENCY POINT

SCHEDULE 2 — PURPOSES REQUIRING CONSENT

SCHEDULE 3 — MEETING OF THE COUNCIL

A BILL for an Act

ENTITLED

**THE UGANDA HUMAN ORGAN DONATION AND
TRANSPLANT ACT, 2021**

An Act to provide for the regulation of the removal, storage and transplantation of human organs, tissues and cells for therapeutic purpose; to establish the Uganda Organ Transplant Council; to provide for the designation of hospitals as transplant centres; to provide for the approval of human organ, tissue and cell banks; to provide for appropriate consent for purposes of human organ, tissue and cells donations and transplantation; to prohibit commercial dealings in human organs, tissues and cells; to protect the dignity and identity of every person and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to donations and transplantation of human organs, tissues and cells; to regulate the transplantation of organs, tissues and cells of human origin carried out for therapeutic purposes; to provide for a system to ensure equitable access to transplantation services to patients, traceability of organs, tissues and cells and recall procedures; to provide for offences and punitive penalties for illegal dealings in human organs, tissues and cells and for related matters.

- (i) to prohibit and eliminate illicit trade in human organs, tissues and cells.

3. Application.

This Act applies to the donation and transplantation of human organs, tissues and cells including—

- (a) kidneys;
- (b) heart;
- (c) blood;
- (d) lungs;
- (e) liver;
- (f) pancreas;
- (g) intestines;
- (h) thymus;
- (i) bone marrow;
- (j) bone;
- (k) tendon;
- (l) ligaments;
- (m) corneas;
- (n) cells;
- (o) skin;
- (p) amniotic membrane;
- (q) penile;
- (r) uterus; and
- (s) other organs, cells and tissues related to those in paragraphs (a) to (r).

4. Interpretation.

In this Act, unless the context otherwise requires—

“adverse reaction” means any biological dysfunction, communicable or other infectious disease that is possibly, reasonably likely or definite to have been transmitted by transplantation of donor organ, tissue or cells;

“adult” means a person who is 18 years of age or above;

“audit” means a documented review of procedures, records, personnel functions, equipment, materials, facilities or vendors to evaluate adherence to this Act, any other applicable law, the written standards of operation and other relevant standards;

“autologous use” means the implantation, transplantation, infusion or transfer of human organ, tissue or cell back into the individual from whom the organ, tissue or cell were recovered;

“authorised officer” means an officer or other person acting under the authority of the Minister or the Council under this Act;

“bank” means an entity within a designated transplant centre that provides or engages in one or more services involving the storage of organs, tissues or cells from living or deceased individuals for transplantation and assessing donor suitability; including screening, recovery, processing, evaluation, testing, quarantine, labeling, storage, distribution, tracking, disposition and recall of organs, tissue or cells including blood banks;

“Council” means the Uganda Organ Donation and Transplant Council appointed under section 7;

- “cells” means individual cells or collections of cells when not bound by any form of connective tissue;
- “child” means a person under the age of eighteen years;
- “close relation” means spouse, son, daughter, father, mother, brother or sister;
- “currency point” has the value assigned to it in Schedule 1 to this Act;
- “complaint” means any written or oral communication concerning dissatisfaction with the identity, quality, packaging, durability, reliability, safety, effectiveness or performance of a human organ, tissue or cell transplanted in accordance with this Act;
- “competency” means the ability of an employee to acceptably perform tasks related with his or her educational level for which he or she has been trained;
- “competency assessment” means the evaluation of the ability of an employee to acceptably perform tasks that are expected of the employee for the duties and responsibilities assigned to him or her;
- “consent” means the process by which approval for donation is obtained from the donor or the donor’s close relation or any other legal representative;
- “consignee” means any bank, banking intermediary, designated transplant centre or transplanting surgeon whether an individual, bank or designated transplant centre, institution, or organisation, that receives a human organ, tissue or cell and assumes responsibility for any step in the processing, storage, distribution or use of such organ, tissue or cell or;

“container” means a receptacle that is used to contain human organs, tissues or cells and is in direct contact with the organ, tissue or cell;

“cornea” means the transparent anterior part of the outer fibrous coat of the eye bounded by an outer stratified epithelium and an inner monolayer of endothelial cells which is the major refractive component of the eye;

“cryopreserved” means preservation by freezing or vitrification in the presence of a cryoprotectant and using a method validated to maintain cellular viability or preserve tissue matrix structure;

“deceased donor” means an individual from whom at least one organ, tissue or cell is recovered for the purpose of transplantation after determination and declaration of death in accordance with this Act;

“departure from procedure or accident” means a planned excursion from Standard Operating Procedure and where the Standard Operating Procedure is relevant to preventing risks of communicable disease transmission, a responsible person must determine that the departure does not increase the risks of communicable disease transmission and must document the decision;

“disposition” means the final destination of an organ, tissue or cell including use for transplantation or discarded;

“distributing bank” means an entity that is reimbursed for or billed for providing an organ, tissue or cell to the end user; and which shall be responsible for tracking recipient or consignee information, post operation follow-up and reporting any adverse reaction to the source bank or the designated transplant centre;

- “distribution” means the process of allocation of tissues, cells or organs for transplant and includes receipt of request, selection, inspection and release of the tissue, cell or organ to a consignee which is responsible for maintaining the principles of tracking, traceability and adverse reaction reporting throughout the process of distribution;
- “donated material” means the body of a brain-dead person or relevant material which has come from a human body, which is, or has been, the subject of donation;
- “donor” means a living or deceased person who provides the source of organ, tissue or cell for transplantation;
- “donor eligibility determination” means the evaluation of all available information about a potential donor to assess whether the donor meets the qualifications specified in the Standard Operating Procedures and any other standards and includes, medical, social and sexual histories, laboratory test results, physical assessment or physical examination and autopsy findings, if performed;
- “evaluation” means the assessment of an entity, tissue, cell, organ equipment, personnel and performance in relation to predetermined expectations or standards;
- “expiration date” means the date after which instruments, supplies, organs, tissues and cells are deemed to be no longer suitable for use;
- “graft failure” means where an organ is removed, a recipient dies, or a recipient is placed on a chronic allograft support system;
- “harvest” means obtaining an organ that is still receiving perfusion;

- “human cell, tissue and organ acquisition” means the process by which the donated organs, tissues or cells are removed from a donor for transplantation, research or education;
- “human organ” means any part of the human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body;
- “living donor recipient” means a transplant recipient that receives a living donor tissue, cell or organ;
- “medical record” means a chronological account of a patient’s examination and treatment that includes the patient’s medical history and complaints, the physician’s physical findings, the results of diagnostic tests and procedures, and medications and therapeutic procedures;
- “Minister” means the minister responsible for health;
- “national waiting list” means the list created under section 51;
- “non-domino therapeutic donor” means an individual who has a tissue, cell or organ removed as a component of medical treatment and whose organ is transplanted into another person, but the donor does not receive a replacement organ;
- “organ” means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;
- “organ transplant” means the procedure for transplantation of organs including solid organ transplants and islet infusions and begins at the start of organ anastomosis or the start

of an islet infusion; and an organ transplant procedure is complete when any of the following occurs—

- (a) the chest or abdominal cavity is closed and the final skin stitch or staple is applied;
- (b) the transplant recipient leaves the operating room, even if the chest or abdominal cavity cannot be closed; or
- (c) the islet infusion is complete;

“parental responsibilities” has the same meaning as in the Children Act;

“parental rights” has the same meaning as in the Children Act;

“payment” means payment in money or money’s worth but does not include any payment for defraying or reimbursing—

- (a) the cost of removing, transporting or preserving the human organ to be supplied; or
- (b) any expenses or loss of earnings incurred by a person so far as reasonably and directly attributable to his or her supplying any human organ from his or her body;

“post-mortem examination” means the examination of the body of a dead person; involving its dissection and the removal of organs, tissue sample, blood or any material derived from blood or other body fluid which is carried out for any or all of the following purposes—

- (a) providing information about or confirming the cause of death;

- (b) investigating the effect and efficacy of any medical or surgical intervention carried out on the dead person;
- (c) obtaining information which may be relevant to the health of any other person; or
- (d) determining suitability for donation and transplant;

“procurement” means the process of acquisition of human organs, tissues and cells but excludes trade in human organs, tissues or cells;

“quality assurance program” means a program that—

- (a) defines the policies and environment required to meet standards of quality and safety prescribed under this Act, regulations made under this Act, any other applicable law and standards issued by the Minister; and
- (b) provides confidence that the processes and tissue, cell or organ consistently conform to requirements for quality,

and the dimensions of quality assurance may include quality control, auditing and process control, standards for personnel, facilities, procedures, equipment, testing and record keeping activities;

“quality control” means specific tests defined by the quality program of a bank, hospital or designated transplant centre to be performed to monitor retrieval, processing, preservation and storage of tissue, cell or organ quality, and test accuracy including performance evaluations, inspection, testing and controls used to determine the accuracy and reliability of the equipment and operational procedures and the monitoring of supplies, reagents, equipment, and facilities;

“qualifying purpose” means—

- (a) a purpose specified in Schedule 2 to this Act;
- (b) the purpose of medical diagnosis or treatment;
- (c) the purpose of proper disposal; and
- (d) a purpose specified in regulations made by the Minister;

“quarantine” means the identification of a tissue, cell or organ as not currently eligible for transplantation, including ocular tissue, other tissues, cells or organs that has not yet been characterized as being eligible for transplantation and includes the storage of that tissue, cell or organ in an area clearly identified for such use or other procedures, such as automated designation, to prevent the premature release of the tissue, cell or organ for transplantation;

“recall” means an action taken to locate and retrieve tissue, cell or organ from distribution and dispensary inventories or the removal or correction of a marketed or distributed tissue, cell or organ that designated transplant centre considers to be in violation of this Act and any other applicable law and recalls may be conducted at the designated transplant centre’s own initiative or at the request or directive of the Council;

“recipient” means an individual who receives a donated human cell, tissue or organ transplant;

“recover” means the removal, acquisition, recovery, or collection of donor tissue, cell or organ;

“recovery establishment” means an entity that recovers tissue, cell or organ from a donor;

“registered medical practitioner” means a medical practitioner who is registered under the Medical and Dental

Practitioner's Act, duly qualified and certified by the Council to undertake organ, tissue and cell donation and transplantation activities;

“relevant communicable disease” means any communicable disease relevant to transplantation of tissues, cells or organ in humans as determined by the Minister;

“reward” means any description of financial or other material advantage, but does not include any payment in money or money's worth for defraying or reimbursing—

- (a) the cost of removing, transporting, preparing, preserving or storing the organ, tissue or cell;
- (b) any liability incurred in respect of expenses incurred by a third party in, or in connection with, any of the activities referred to in paragraph (a); or
- (c) any expenses or loss of earnings incurred by the person from whose body the organ, tissue or cell is harvested so far as reasonably and directly attributable to the donation;

“safety” means a level of quality of tissue, cell or organ that indicates handling according to acceptable standards and assures substantial freedom from the potential for harmful effects to recipients and includes the condition of being protected from risk or injury associated with occupational exposure;

“sedation” means the reduction of irritability or agitation by administration of sedative drugs, generally to facilitate a medical procedure or diagnostic procedure;

“therapeutic purposes” means systematic treatment of any disease or the measures to improve health according to any particular method or modality;

“tissue” means all constituent parts of a human organ formed by cells including; skin, cornea and bone marrow;

“tissue evaluation” means the performing of the following on tissue intended for transplant—

- (a) slit lamp examination;
- (b) endothelial cell density; and
- (c) pachymetry measurement;

“tolerance limits” means the limits that define a range of acceptable values established for each testing procedure that, when exceeded, require the implementation of corrective actions designed to produce results within the acceptable range in future tests;

“traceability” means the act or ability to locate a tissue, cell or organ during any step of its recovery, processing, evaluation, testing, quarantine, labeling, storage, distribution, disposition or recall and includes the capacity to identify the surgeon, consignee, or designated transplant centre receiving the tissue and the ability of the surgeon, consignee, or designated transplant centre to identify the storage, recipient or final disposition of the tissue, cell or organ;

“tracking” means the act or ability to locate individual organs, tissues or cells during any step of its recovery, processing, evaluation, testing, quarantine, labeling, storage, distribution, disposition and recalling and includes the capacity of the distributing Bank or designated transplant centre to identify the consignee and the consignee to identify the recipient;

“transplant” means the process of reconstituting a function by transferring equivalent organs, tissues or cells from a donor to a recipient and transplantation may be from one person to another (allogenic) or from a person to himself or herself (autologous);

“transplant operation” means an operation performed on a living person by a registered medical practitioner—

- (a) which is designed to safeguard or promote the physical health of the person by transplanting an organs, cells or tissue into the person; and
- (b) by so doing, necessitates the removal of an organ or part of an organ, cell or tissue from the person which in turn is intended to be used for transplantation in respect of another living person;

“transplant program” means an organisation of medical personnel and allied health care professionals, operating in one or more designated transplant centres, with the responsibility for the transplantation of one or more types of organs, tissues or cells;

“transplant centre” means a hospital designated by the Minister under section 28;

“withdrawal” means the removal or collection of a distributed organ, tissue or cell by a bank that involves a minor violation or that involves no violation and does not involve a communicable disease.

PART II—THE MINISTER AND THE HUMAN ORGAN TRANSPLANT COUNCIL

The Minister

5. Powers and functions of the Minister.

- (1) The Minister may give directions in writing to the Council with respect to the policy to be observed and implemented by the

Council under this Act, and the Council shall comply with those directions.

(2) Directions given by the Minister under subsection (1) shall not adversely affect or interfere with the independence of the Council or the performance of the functions and exercise of the powers of the Council under this Act.

(3) The Minister shall cause a copy of any directions given to the Council under subsection (1) to be published in the Gazette.

(4) The Minister shall—

- (a) promote, support and approve programmes of human organs, cells and tissue for donation or transplantation;
- (b) take any necessary measures or make any directives relating to the quality, safety, storage and use of any human organs, tissue or cell donated for transplantation;
- (c) provide information and increase awareness about organ, tissue or cell donation and transplantation;
- (d) prescribe the circumstances in which consent to organ, tissue or cell donation and transplantation activities is deemed to have been given in the absence of express consent; and
- (e) ensure that the resources available to the Council include the specialist skills and competencies required for the purposes of this Act.

6. Assistance and support.

The Minister may, on the recommendation of the Council, provide assistance and support to any person providing or proposing to provide a service relating to human organ, cell or tissue donation or transplantation.

*Uganda Organ Donation Transplant Council***7. Uganda Organ Donation and Transplant Council.**

(1) There is established the Uganda Organ and Transplant Council to oversee and regulate organ, cell and tissue donation and transplantation in Uganda.

(2) The Council shall be a body corporate with perpetual succession and an official seal and may, for the discharge of its functions under this Act—

- (a) acquire, hold and dispose of moveable and immovable property;
- (b) sue and be sued in its corporate name; and
- (c) do all acts and things as a body corporate may lawfully do.

(3) The Council shall be a full time Council with a Secretariat appointed in accordance with section 19.

(4) The Council established under subsection (1) shall consist of nine technical members appointed by the Minister.

(5) The Council shall be independent but shall work in collaboration with the Uganda Medical and Dental Practitioner's Council, especially in relation to disciplinary cases against registered medical practitioners certified by the Council under this Act to undertake organ, tissue and cell donation and transplant activities.

(6) The Council shall, in its operations, report to the Minister.

8. Qualifications of members of the Council.

The members of the Council shall be persons of high moral character and proven integrity who are qualified in and have had experience

and shown capacity in surgery, internal medicine, anesthesiology, bioethics, diagnostics, radiology, health sciences, law, management or financial management.

9. Disqualification for appointment to the Council.

A person shall not be appointed to the Council who—

- (a) has been convicted of an offence under this Act or of an offence involving dishonesty or fraud by a competent court in Uganda or outside Uganda;
- (b) has been convicted of an offence and sentenced to imprisonment for six months or more by a competent court in Uganda or outside Uganda without the option of a fine;
- (c) is an undischarged bankrupt or has made any assignment or arrangement with his or her creditors; or
- (d) is serving on any other Council or Board.

10. Tenure of office of members of the Council.

A member of the Council shall hold office for three years and is eligible for reappointment for one more term.

11. Termination of appointment.

(1) A member of the Council may, at any time, resign his or her office by thirty days' notice in writing delivered to the Minister.

(2) The Minister may, at any time, remove a member of the Council—

- (a) for incompetence;
- (b) for misbehavior or misconduct;

- (c) for failure to disclose, at a Council meeting, a matter in which he or she has conflict of interest;
- (d) for inability to perform the functions of his or her office arising from infirmity of body or mind;
- (e) who has been convicted of an offence and sentenced to a term of imprisonment for six months or more by a competent court in Uganda or outside Uganda;
- (f) for bankruptcy or insolvency; or
- (g) for absence, without prior permission of the Chairperson, or without reasonable cause to the satisfaction of the Minister, from more than four consecutive meetings of the Council, or absence from Uganda for more than six months.

(3) Where it appears to the Minister that there is cause to remove a member of the Council under subsection (2), the Minister shall notify the member concerned in writing and shall give the member an opportunity to submit his or her explanation to the Minister.

(4) A person removed under this section, except under subsection (2) (d), is not entitled to any benefits that may be payable to him or her under section 12.

12. Remuneration of Council members.

The Chairperson and members of the Council shall be paid such remuneration as the Minister may determine in consultation with the Minister responsible for finance and the Minister responsible for public service.

13. Filling of vacancies on the Council.

(1) Where a member of the Council resigns, dies, is removed from office or is for any other reason unable to act as a member of

the Council, the Chairperson shall notify the Minister of the vacancy within one month after the occurrence of the vacancy.

(2) The Minister shall, after being notified of the vacancy under subsection (1), in accordance with section 7, appoint another person to hold office for the remainder of the term of the previous member.

(3) Where the member of the Council referred to in subsection (1) is the Chairperson of the Council, the Secretary to the Council shall notify the Minister of the vacancy and the Minister shall appoint another person to the office of Chairperson for the unexpired portion of the Chairperson's term of office.

14. Functions of the Council.

(1) The Council is responsible for the regulation, organisation and supervision of all national human organ, tissue and cells donation and transplant activities.

(2) Without prejudice to the general effect of subsection (1), the Council shall—

- (a) regulate designated transplant centres and approved banks;
- (b) enforce such standards as may be prescribed by the Minister for designated transplant centres and approved banks;
- (c) investigate any complaint of breach of any of the provisions of this Act or any other applicable law;
- (d) inspect designated transplant centres and approved banks periodically for examination of the quality of transplantation and the follow-up medical care to persons who have undergone transplantation and persons from whom organs are removed;

- (e) regulate and coordinate cell, tissue and organ acquisition and donation;
- (f) oversee the national waiting list;
- (g) regulate the allocation of organs and if required, cells and tissues;
- (h) regulate the exchange and transportation of organs, tissues and cells both nationally and internationally for therapeutic benefit;
- (i) recommend transplant centres for designation by the Minister;
- (j) approve donated organs, tissues and cells for transplant;
- (k) ensure safety and quality of processes of acquisition, donation and transplantation of organs, tissues and cells;
- (l) ensure traceability of all organs, tissues and cells;
- (m) monitor and audit the results of donation and transplantation procedures;
- (n) promote the education of health professionals and the general public on human organ, cell and tissue donation and transplantation; and
- (o) undertake such other measures as may be prescribed by the Minister.

15. Meetings of the Council.

Schedule 3 has effect in relation to meetings of the Council and other matters provided for in that Schedule.

16. Committees of the Council.

(1) The Council shall work through technical committees.

(2) The Council may appoint technical committees as it deems necessary to provide advice to enable the Council to fulfil its responsibilities and—

(a) to inquire into and advise the Council on any matter concerning the functions of the Council as the Council may refer to the committee; and

(b) to exercise such powers or perform such functions of the Council as the Council may delegate or refer to the technical committee.

(3) A committee appointed under subsection (1) shall consist of a chairperson who shall be a member of the Council, and other persons, whether members of the Council or not, as the Council may determine.

(4) The Council shall, in writing, specify the terms and conditions of service of members of a committee appointed under this section.

(5) Members of a committee appointed under this section shall be paid such allowances as the Council may determine.

(6) The Council may require a committee appointed under this section to act jointly or in co-operation with any other committee.

(7) A committee is subject to the control of the Council and may be discharged or reconstituted at any time by the Council.

(8) Subject to any direction given by the Council, a committee appointed under this section may regulate its own procedure.

17. Power to engage consultants.

The Council may, in the performance of its functions under this Act, engage the services of or work in consultation with professional or technical experts or consultants, to enhance the performance of the functions of the Council.

18. Protection from liability of members of Council.

A member of the Council or of a committee of the Council, is not personally liable for any act or omission done or omitted to be done in good faith in the exercise of functions under this Act.

19. Secretariat of Council.

(1) The Council shall have a secretariat consisting of members appointed by the Council in consultation with the Minister.

(2) The secretariat shall have an Executive Secretary and such other staff as the Council may determine in consultation with the Minister.

(3) The Executive Secretary and other staff appointed under subsection (2) shall be paid such remuneration as the Council may determine in consultation with the Minister.

(4) The Executive Secretary shall be the accounting officer of the Council.

PART III—FINANCES OF COUNCIL**20. Funds of the Council.**

The funds of the Council shall consist of—

- (a) monies appropriated by Parliament for the purposes of the Council;
- (b) money that may accrue to the Council in the discharge of its functions;

- (c) grants or monies donated to the Council with the approval of the Minister and the Minister responsible for finance;
- (d) money borrowed by the Council in accordance with this Act and the Public Finance Management Act, 2015; and
- (e) money from any other source as may be approved by the Minister and the Minister responsible for finance.

21. Duty to operate on sound financial principles.

The Council shall, in the performance of its functions under this Act, have due regard to sound financial principles and shall conduct its business in such a manner that, taking one transaction with another, and taking one year with another—

- (a) its revenue is sufficient for meeting all charges, including interest on capital and loans properly chargeable to revenue account;
- (b) sufficient provision is made to provide for depreciation of assets; and
- (c) where any loss or bad debt arises in respect of any transaction, provision is made in respect of other transactions, whether of a similar nature or otherwise, to offset the amount of that loss or debt.

22. Power to open and operate bank accounts.

(1) The Council shall, with the authorisation of the Accountant General, open and maintain such bank accounts as are necessary for the performance of the functions of the Council.

(2) The Chairperson of the Council shall ensure that all money received by or on behalf of the Council is banked as soon as practicable after being received.

(3) The Chairperson of the Council shall ensure that no money is withdrawn from or paid out of any of the Council's bank accounts without the authority of the Council.

23. Estimates.

(1) The Executive Secretary shall, within three months before the end of each financial year, cause to be prepared and submitted to the Council for its approval, estimates of the income and expenditure of the Council.

(2) The Chairperson shall, within two months after receipt of the estimates referred to in subsection (1), cause to be submitted to the Minister for his or her approval, the estimates of income and expenditure as approved by the Council.

(3) The Minister shall submit the estimates of the Council to the Minister responsible for finance for approval of the budget containing estimates of income and expenditure of the Council for the next financial year in accordance with the Public Finance Management Act, 2015.

24. Accounts.

(1) The Chairperson shall cause to be kept, proper books of accounts and records of the transactions of the Council in accordance with accepted accounting principles.

(2) Subject to any direction given by the Council, the Chairperson shall cause to be prepared an annual financial statement stating the basis of accounting and shall identify any significant departure from it and the reasons for the departure.

(3) The statement of accounts shall include—

- (a) a balance sheet, an income and expenditure account and a source and application of the Council's funds; and

- (b) any other information in respect of the financial affairs of the Council as the Auditor General or an auditor appointed by the Auditor General may, in writing, require.

25. Audit.

(1) The Auditor General or an auditor appointed by the Auditor General shall, in each financial year, audit the accounts of the Council in accordance with the National Audit Act, 2008.

(2) The Council shall ensure that within three months after the end of each financial year, a statement of accounts is submitted to the Auditor General or to an auditor appointed by the Auditor General for auditing.

26. Annual report.

(1) The Council shall submit to the Minister, as soon as practicable and in any event not later than three months after the end of each financial year, a report dealing generally with the activities and operations of the Council during the year to which the report relates.

(2) The report referred to in subsection (1) shall contain—

- (a) the audited accounts of the Council and the Auditor General's report on the accounts of the Council; and
- (b) such other information as the Council may consider necessary.

(3) The Minister shall, within two months after the receipt of the annual report, submit the report to Parliament with any statement which he or she considers necessary.

(4) The Council shall cause to be published the annual report and audited accounts in a newspaper of national circulation within six months after the end of each financial year.

27. Compliance with Public Finance Management Act, 2015.

The Council shall at all times comply with the Public Finance Management Act, 2015.

**PART IV—DESIGNATION OF TRANSPLANT CENTRES
AND APPROVAL OF BANKS*****Designation of Transplant Centres*****28. Designation of transplant centres.**

(1) Mulago National Referral Hospital is designated as the pioneer transplant centre for purposes of this Act.

(2) Notwithstanding subsection (1), the Minister may, on the recommendation of the Council, by statutory instrument, designate a hospital as an organ, tissue or cell donation and transplant centre.

29. Application for designation as transplant centre.

(1) A hospital that wishes to be designated as a transplant centre under section 28 (2) shall apply to the Council in a manner prescribed by the Minister by regulations.

(2) The Council shall, before recommending a hospital to the Minister for designation under section 28(2), carry out due diligence and satisfy itself that the applicant has complied with all the requirements of this Act, the regulations made under this Act and internationally acceptable standards.

(3) Where, after the due diligence carried out under subsection (3) and after giving an opportunity to the applicant to be heard, the Council is satisfied that the applicant does not meet the requirements of this Act and the regulations made under this Act, the Council shall, reject the application giving reasons for the refusal in writing.

(4) A hospital whose application is rejected may, after fulfillment of the requirements under this Act, re-apply to the Council in accordance with this Act.

30. Qualification for designation as transplant centre.

A hospital shall not be designated as a transplant centre under section 29 unless it is a fully-fledged hospital with a full range of services including routine surgeries, emergency care and other services and has the following—

- (a) Intensive Care Unit and High Dependent Unit beds dedicated to the transplant programme connected to the theatre by a sterile corridor or interconnectivity with dialysis capability;
- (b) specialised medical professionals, including a transplant surgeon, physician, anaesthesiologist, intensivist and transplant nurse qualified and experienced in the type of organ, tissue or cells to be harvested and the transplant activities to be carried out;
- (c) two adjacent theatres; one for the donor and another for the recipient;
- (d) a fully-fledged specialised organ support unit for organ, tissue or cell donation or transplant;
- (e) radiology and imaging capability, as applicable;
- (f) 24-hour laboratory services covering the full range of tests necessary for transplant surgery but particularly the tests requiring less than 48 hours turn over; and
- (g) any other requirement that the Minister may prescribe by regulations or standards issued by the Minister.

31. Designation by Minister.

(1) The Council shall, after being satisfied that a hospital meets all the requirements of this Act, regulations made under this Act, standards issued by the Minister and any other applicable law, recommend the hospital to the Minister for designation as a transplant centre.

(2) The Minister may, on receipt of the recommendation from the Council under subsection (1), carry out additional investigations and due diligence on the recommended hospital.

(3) The Minister may, where he or she is not satisfied after carrying out additional investigations under subsection (2), refer the matter back to the Council with the concerns for consideration within a period specified by the Minister.

(4) The Minister shall, where he or she is satisfied that the hospital meets the criteria prescribed under this Act, designate a hospital as a transplant centre.

(5) The Minister may, in designating a hospital under subsection (1), attach such terms and conditions as the Minister may deem necessary.

(6) A hospital seeking to be designated to undertake cadaveric transplantation activities shall be required to get additional approval from the Minister in a manner prescribed by regulations.

(7) The Minister may, on recommendation of the Council, remove a hospital from the list of designated transplant centres where the facilities of the hospital cease to meet the requirements of this Act, regulations made under this Act, any other applicable law or standards issued by the Minister.

(8) A hospital designated under this section shall comply with this Act, regulations made under this Act, any other applicable law, standards issued by the Minister, directives of the Council and international best practice.

32. Existing centres.

(1) A hospital shall not commence any activity relating to the removal, storage or transplantation of any human organ, tissue

cell for transplantation after the commencement of this Act unless the hospital is designated as a transplant centre under this Act.

(2) Notwithstanding subsection (1), a hospital engaged, either partly or exclusively in any activity relating to the removal, storage or transplantation of any human organ, tissue or cell for transplantation immediately before the commencement of this Act—

- (a) shall apply to the Council for designation as a transplant centre within ninety days from the date of commencement of this Act; and
- (b) cease to engage in any activity relating to the removal, storage or transplantation of any human organ, tissue or cell for transplantation on the expiry of six months from the date of commencement of this Act and await the decision of the Minister on the application made under paragraph (a).

33. Regulation of conduct of donation and transplant activities.

(1) On the commencement of this Act—

- (a) no hospital, unless designated as a transplant centre under this Act, shall conduct, associate with or assist in the removal, storage or transplantation of any human organ, tissue or cell;
- (b) no medical practitioner or other person shall conduct, cause to be conducted or aid in conducting by himself or herself or through any other person, any activity relating to the removal, storage or transplantation of any human organ, tissue or cell at a place other than a designated transplant centre; and
- (c) no place, including a hospital designated under this Act, shall be used or cause to be used by any person for the removal, storage or transplantation of any human organ, cell or tissue, except for therapeutic purposes.

(2) A hospital designated under this Act shall, for the first five years or such other time as the Minister may by statutory instrument determine, after approval, only use human organs, tissues and cells from living donors and imported organs

(2) Approval under subsection (1) shall be based on readiness of the country and the designated transplant centres and institutional readiness.

(3) A designated transplant centre may, after the lapse of the period referred to in subsection (2), apply to the Council for approval to use for therapeutic purposes, human organs, tissues and cells from cadaveric donors.

(4) The Council shall, in a manner prescribed by regulations, approve local and expatriate transplant surgeons before they can undertake transplantation activities under this Act.

(5) A transplant surgeon shall not be approved under subsection (4) unless he or she is registered by the respective professional Councils.

Approval of Human Organ, Tissue and Cell Banks

34. Approval of Banks.

(1) The Minister shall, on the recommendation of the Council, annually, by notice in the Gazette, approve banks for the purposes of this Act.

(2) With the exception of blood banks provided for under subsection (7), all other organ, tissue and cell banks shall be operated by and located within the designated transplant centres.

(3) A bank shall not be approved or gazetted under subsection (1) unless it has the following—

(a) the facilities specified in Part V;

(b) qualified professionals; and

(c) any other requirement that Minister may deem necessary.

(4) The Minister may, in approving a bank under subsection (1), attach such terms and conditions as the Minister may deem necessary.

(5) A bank approved under this section shall comply with this Act, regulations made under this Act, any other applicable law, standards issued by the Minister, directives of the Council and international best practice.

(6) The Minister may, on the recommendation of the Council, cancel the approval of a bank and de-gazette the bank where it ceases to meet the requirements of subsection (2).

(7) The National Blood Bank shall be accredited by the Council but shall, in its day to day activities report to the Minister.

*Policies and Procedures for Designated Transplant Centres and
Approved Banks*

35. Policies and procedures for designated transplant centres and approved Banks.

(1) Designated transplant centres and approved banks shall maintain policies and procedures which shall detail all aspects of retrieval, processing, testing and storage and distribution practices for organs, tissues and cells.

(2) The policies and procedures referred to under subsection (1) shall be reviewed and affirmed annually in writing by the registered medical practitioner in charge of the designated transplant centre.

(3) Modifications of standard procedures and development of new procedures shall be approved by the registered medical practitioner.

(4) Obsolete revised procedures shall be retained separately to maintain a historical sequence.

(5) Copies of policies and procedures of a designated transplant centre shall be available to the staff at all times and the technical staff shall be required to state in writing that they have read and understood the manual containing the policies and procedures.

(6) Copies of the policies and procedures of designated transplant centre shall be available to Council or an authorised officer for inspection, upon request.

(7) The procedures contained in the policies shall be detailed, simple and unambiguous.

36. Ethical standards.

(1) Each designated transplant centre and approved bank shall have measures in place to avoid conflicts of interest.

(2) The measures referred to under subsection (1) shall ensure that no employee of the designated transplant centre shall—

- (a) have any interest, financial or otherwise, direct or indirect in relation to activities of the designated transplant centre;
- (b) engage in any business transaction or professional activity related to those of a bank or designated transplant centre; or
- (c) incur any obligation of any nature which is in substantial conflict with the full and competent performance of duties in the bank or designated transplant centre in which he or she is employed.

(3) Where services, other than obtaining referral or consent are provided to a procuring designated transplant centre, that procuring designated transplant centre may make arrangements to pay expenses incurred for services rendered.

(4) Reimbursement for expenses under subsection (3) to employees shall not be deemed conflict of interest with the personnel policies of the primary employer.

37. Educational services to the public.

(1) Each designated transplant centre shall assist hospitals and health centres in establishing and implementing protocols for making routine inquiries regarding organ, cell and tissue donations by potential donors.

(2) Every designated transplant centre shall maintain documentation that shall be available for review by the Council or an authorised officer relating to educational services provided to the community, health care professionals and hospitals in designated transplant centre's service area.

(3) Designated transplant centre shall ensure that—

- (a) documentation of education of professionals is maintained;
- (b) documentation of donor hospital policies, procedures, characteristics and donor related activities is kept; and
- (c) written agreements between hospitals, health centres and designated transplant centre to document the activities referred to in paragraphs (a) and (b) are entered into.

(4) Every designated transplant centre shall produce or have available literature and media items that provide education and awareness creation for donation of organs, tissues or cells.

(5) A designated transplant centre shall be responsible for establishing and assisting in the dissemination of the materials referred to in subsection (4).

**PART V—ADDITIONAL REQUIREMENTS FOR ORGAN, TISSUE
AND CELL BANKS**

38. Organ, tissue and cell banking.

(1) Where applicable, removed organs, tissues or cells which are not immediately used for transplantation shall be tested, preserved, processed, stored and distributed by banks approved by the Minister under section 34.

(2) Only organs, tissues and cells supplied by approved Banks shall be used for purposes of transplantation.

(3) A person shall not import into Uganda human organs, tissues or cells for transplantation without the authorisation of the Council.

(4) All approved banks shall be independently inspected by the Council, an authorised person or an independent qualified person authorised by the Council to ensure that they comply with this Act, regulations made under this Act and international standards at least every two years.

(5) The Minister shall, by regulations, prescribe detailed requirements for approved banks.

39. Minimum Standards for Banks.

(1) The Minister shall issue standards to be followed by banks.

(2) A bank approved under this Act shall comply with standards issued by the Minister in consultation with the Council.

PART VI—QUALITY ASSURANCE AND QUALITY CONTROL**40. Organ Donation and Transport Quality Control System.**

(1) The Council shall establish an organ donation and transplant quality control system which ensures equitable access to quality donation and transplantation services to donors and potential recipients.

(2) The system established under subsection (1) shall provide for—

- (a) quality control and testing of all donations, procurement, testing, processing, preservation, storage and distribution activities to ensure the quality and safety of organs, tissues and cells used in transplantation;
- (b) the identification, reporting, investigation and management of serious adverse events relating to donation or transplantation activity;
- (c) the waiting list of recipients;
- (d) the donor list;
- (e) a database for all potential recipients and donors;
- (f) measures for traceability of donated and transplanted organs, tissues and cells;
- (g) a system for recall of organs, tissues and cells; and
- (h) any other information that the Council may deem necessary.

(3) The Council shall ensure that information relating to adverse events is brought to the attention of all health professionals involved in transplantation and other transplant organisations.

(4) The Minister may, by regulations, prescribe additional requirements for the Organ Donation and Transplant Quality Control System.

41. Quality assurance programmes.

(1) A designated transplant centre shall put in place quality assurance programmes in a manner prescribed by regulations including requirements for—

- (a) facilities;
- (b) environmental control;
- (c) equipment;
- (d) supplies and reagents;
- (e) recovery;
- (f) processing and processing controls;
- (g) labeling controls;
- (h) transportation;
- (i) storage;
- (j) receipt, pre-distribution shipment and distribution;
- (k) donor eligibility determination, donor screening and donor testing; and
- (l) tissue evaluation;
- (m) access control; and
- (n) internal audit or risk management.

(2) A designated transplant centres shall perform an investigation and report any adverse reaction information within 30 days to the Council for review in a manner prescribed by regulations.

42. Recall procedures.

(1) Every designated transplant centre shall establish a written procedure for—

- (a) recall of organs, tissues or cells;
- (b) notification of recipient hospitals of the possibility of contamination, defects in processing, preparation or distribution; and
- (c) other factors affecting the suitability of the organs, tissues or cells.

(2) The procedure referred to in subsection (1) shall be included in the designated transplant centre's policies and procedures.

(3) The Minister may, by regulations, prescribe minimum requirements for recall procedures to be established by designated transplant centres under subsection (1).

43. Look back procedures.

(1) Each bank shall establish procedures for notifying a designated transplant centre or physician that they may have received infected organs, cells or tissues.

(2) Each designated transplant centre shall have procedures for notifying the transplanting bank or designated transplant centre or physician that they may have received infected organs, cells or tissues.

(3) Documentation of look back procedures shall be included in the bank and designated transplant centre's policies and procedures.

44. Notification requirements.

Notification of test results to donors and recipients of organs, tissues and cells shall be in a manner prescribed by regulations.

PART VII—STORAGE OF ORGANS, TISSUES AND CELLS
OUTSIDE THE BODY**45. Preservation of organs, tissues and cells.**

After the removal of any human organ, tissue or cell from the body of any person for transplantation, the registered medical practitioner shall take such steps as are necessary for the preservation of the human organ, tissues or cell removed in accordance with this Act, regulations made under this Act and standards issued by the Minister.

46. Storage of organs, tissues and cells outside the body.

(1) The Minister shall, in consultation with the Council, establish standards for storage of harvested organs, tissues and cells.

(2) A designated transplant centre and approved banks shall ensure that their facilities and equipment comply with the regulations made by the Minister and standards prescribed under subsection (1).

47. Packaging and labeling of storage containers.

(1) Approved banks and designated transplant centres shall ensure that human organs, tissues and cells are packaged in a manner prescribed by regulations and in accordance with standards issued by the Minister.

(2) Each tissue, cell or organ for distribution shipment shall be individually packaged and sealed with a tamper-evident seal or enclosed in a tamper-evident container.

(3) A bank or designated transplant centre shall ensure that each tissue, cell or organ storage container is clearly and indelibly labeled in a manner prescribed by regulations.

*Distribution of Organs, Tissues and Cells***48. Review of donor medical information.**

Prior to the distribution of any organ, tissue or cell for transplantation, the registered medical practitioner of a bank and the designated transplant centre shall review and document that the medical and laboratory information is in accordance with standards issued by the Minister, and that any departures from procedure does not increase the risk of transmission of communicable diseases.

49. Distribution compliance.

(1) A designated transplant centre or bank shall ensure that medical standards issued by the Minister are complied with throughout the distribution process.

(2) An approved bank or designated transplant centre performing the distribution shall inform the consignee, in writing, of the requirements for tracking and traceability, outcomes and adverse reaction reporting.

(3) The consignee shall comply with applicable laws, regulations and standards, after receipt of the organ, cell or tissue.

50. Returned organs, tissues or cells.

Where an organ, tissue or cell is returned and redistributed, transportation and storage information shall be documented and made available to the relevant bank, designated transplant centre and transplanting surgeon.

51. Fraudulent activity.

(1) Where a designated transplant centre or approved Bank discovers that a fraudulent activity has occurred in the distribution, shipping or labeling of any organ, tissue or cell imported or exported by the designated transplant centre or Bank, an investigation shall be conducted to identify the root cause of the fraudulent activity.

(2) A designated transplant centre or bank shall report the occurrence of a fraudulent activity and the findings of the investigation carried out under subsection (1) to the Council within 10 days after the identification of the fraudulent activity.

(3) The Council shall notify the appropriate regulatory bodies of a fraudulent activity reported to it under subsection (2).

(4) A designated transplant centre and bank shall ensure that the Council is copied on all correspondence relating to the fraudulent activity during their follow up.

PART VIII—TRANSPLANT OF ORGANS, TISSUES AND CELLS

52. National waiting list.

The Council shall establish and maintain a national waiting list for potential organ, tissue and cell donors and recipients drawn from designated transplant centres; hospitals and health centres.

53. Fair and equitable system.

(1) The Council shall ensure that organs, tissues and cells are allocated to patients on the national waiting list in a fair and equitable manner as shall be prescribed by the Minister by regulations.

(2) Where no suitable recipient is identified on the national waiting list, the Council may authorise the allocation of the organ, tissue or cells to any other recognised national or international transplant organisation with which the Council has an agreement.

(3) The Council may also authorise the importation of organs, tissues and cells from an international transplant organisation referred to in subsection (2).

(4) Documentation relating to the distribution of organs, tissues and cells including date of requests for, offer of, and delivery of organs, tissues and cells shall be available for examination by the Council or an authorised officer.

(5) Access to organs, cells and tissues shall be provided without regard to recipient sex, age, religion, race, creed, color or financial standing.

54. Transplantation activity.

(1) The retrieval and preservation of human organs, tissues and cells for transplantation shall only be performed by a registered health professionals approved by the Council and in accordance with this Act, regulations made under this Act, any other applicable law and standards issued by the Minister.

(2) The Council shall establish a criteria for identifying, at the appropriate stage, all brain-dead persons who are potential organ donors and their notification to the organ designated transplant centres.

(3) Transplantation of human organs, tissues or cells shall only be carried out in designated transplant centres.

(4) All transplant activity shall be performed to the highest professional and ethical standards.

(5) When a person has been confirmed brain dead by the team in care, the Council shall immediately be notified to send an independent neurological team to confirm the death for purposes of donation.

(6) The team that confirms the death of a brain-dead donor shall not be involved in the harvest or transplantation activity.

(7) The notification referred to in subsection (5) shall take place even if the attending clinical staff believe that donation, after death has been confirmed by an independent team might be contra-indicated or inappropriate.

(8) The independent team referred to in subsection (7) shall consist of a neurosurgeon, neurophysician and an anesthesiologist or intensivist.

(9) The independent team and organ retrieval team shall be self-sufficient and shall not require anesthetic, theatre or surgical staff from the donor hospital and shall be available 24 hours a day without other elective commitments during their time on call and able to respond appropriately if there is more than one donor on the same day.

(10) Where the brain death of a potential organ donor occurs in circumstances that require notification to the police, notification shall be done before donation takes place, even where a donor has explicitly stated a wish to donate.

(11) A patient who is a potential organ donor shall be provided with the best possible treatment, in the best interests of the patient, in the hope or expectation that the patient shall survive.

55. Authorised transplantation activities.

(1) The authorised activities for purposes of this Act are listed in Schedule 2 to this Act.

(2) A person shall not perform a transplantation activity without the prior authorisation of the Council.

(3) The authorisation under subsection (2) shall be given expeditiously.

(4) Notwithstanding subsection (3), the Council may, by statutory instrument exempt certain transplant processes from the prior authorisation of the Council including; tissue, bone marrow and emergency transplants.

(5) Any person and the designated transplant centre that performs a transplant under subsection (4) shall immediately, but in any case not later than twenty four hours after the transplant procedure, submit a report of the Council.

(6) A person who contravenes subsection (2) commits an offence and is liable on conviction to a fine not exceeding fifty thousand currency points or imprisonment not exceeding ten years or both.

56. Council not to authorise transplant activities in certain cases.

(1) The Council may not authorise the removal of an organ, tissue or cell from a dead person where the Council has reason to believe that the person's death is suspicious and may require police investigation, until the police investigation is completed and notification has been given in accordance with section 54 (10).

(2) No authority for the removal of any human organ, cell or tissue from the body of a deceased person shall be given by a person to whom the body has been entrusted solely for the purpose of interment, cremation or other disposal.

(3) A person who contravenes this section commits an offence and is liable, on conviction, to a fine not exceeding ten thousand currency points or imprisonment not exceeding seven years or both.

57. Donor screening.

(1) The removal of organs, tissues or cells from a potential donor person shall not be performed unless the donor has been examined and tested for evidence of transmittable diseases in accordance with this Act, regulations made under this Act, standards issued by the Minister and internationally recognised standards.

(2) Prior to making an eligibility determination, the donor must be screened and tissue evaluated for suitability in a manner prescribed by regulations and in accordance with standards issued by the Minister.

(3) A designated transplant centre shall have a consistent policy for conducting and documenting the examination and consistent operational procedures for examination and documentation of the prospective donor's available medical record and death investigation, where applicable.

58. Organ, tissue or cell sampling.

(1) A registered medical practitioner may, in accordance with this Act and with the relevant consent, remove any tissue, organ or cell from a potential donor for examination to determine the viability of the organ, tissue or cell for transplantation, including the safety of the transplant for the person who is to receive it.

(2) Organ, tissue or cell testing and sampling under subsection (1) shall be in accordance with this Act, regulations prescribed made under this Act, standards issued by the Minister and internationally recognised standards.

59. Testing requirements.

(1) A designated transplant centre shall, before harvesting an organ, cell or tissue from a donor, carry out tests in accordance with this Act and in a manner prescribed by regulations and according to standards issued by the Minister, to determine the suitability of the donor.

(2) The suitability of a specific individual for organ, cell and tissue donation shall be determined in accordance with this Act and regulations made under this Act.

60. Preservation for transplantation.

(1) Where part of the body of a brain-dead person in a hospital, nursing home or other institution is or may be suitable for use for transplantation, the hospital, nursing home or institution shall preserve the body and transfer it to a designated transplant centre for harvesting in accordance with this Act.

(2) A designated transplant centre receiving a preserved body under subsection (1) shall immediately, and in any case not later than 7 hours after receipt of the body, notify the Council.

(3) A designated transplant centre shall not harvest any tissue, cell or organ from a brain-dead person referred to under subsection (1) without the approval of the Council.

61. Harvesting of organs, tissues and cells.

(1) The registered medical practitioner in charge of a designated transplant centre shall ensure that, before the harvesting of any tissue, cell or organ from a donor, consent for donation is obtained in accordance with this Act and documented in writing.

(2) A designated transplant centre shall ensure that personnel are trained regarding obtaining and documenting consent for donation.

(3) The original signed consent form shall be kept as part of the patient's hospital medical record if signed at a hospital.

(4) A copy of the original signed consent form shall be retained in a designated transplant centre's donor record.

(5) The consent form shall state the organs, cell or tissues for which permission is granted such as bone from the upper, lower extremities, bone from below the waist, heart, liver kidney or skin.

(6) Information provided under this section shall be written or spoken in a language understandable to the donor or the donor's next of kin.

(7) Permission to retrieve organs, tissues or cells from non-living donors shall be sought from close relation in accordance with this Act, where the deceased did not give consent before his or her death.

62. Reconstruction.

(1) A designated transplant centre shall have a policy for the reconstruction of the body of the donor which is integral to maintaining the dignity of the donor.

(2) Notwithstanding subsection (1), the Minister may issue regulations for reconstruction of bodies after donation.

Retrieval of Organs, Tissues or Cells from Deceased Donors

63. Retrieval of organs, tissues and cells from deceased donors.

(1) A designated transplant centre shall ensure that only a registered medical practitioner trained in enucleation or excision is approved to retrieve organs, tissues or cells from a deceased donor with a written death certificate.

(2) A designated transplant centre shall before retrieving an organ, tissue or cell under subsection (1). ascertain the following—

- (a) location of the donor;
- (b) age of the donor; and
- (c) cause and time of death. in the case of a deceased donor.

(3) The Minister may, by regulations, prescribe additional requirements for retrieval and recovery of human organs, tissues and cells for purposes of this Act.

64. Retrieval procedure.

(1) The retrieval of organs, tissues and cells shall be in a manner prescribed by regulations.

(2) The bank or designated transplant centre shall ensure that consent has been obtained in accordance with this Act.

(3) The bank or designated transplant centre shall ensure that after obtaining consent, the donor is identified either through a tag or through the next of kin and the site is prepared in accordance with standards issued by the Minister.

(4) Physical examination of a donor shall be conducted with utmost respect for observations regarding build, whether average, healthy or emaciated and the team shall look out for needle marks on the arm and skin lesions.

Information of Donors and Recipients to be Retained

65. Minimum information to be retained.

(1) A designated transplant centre shall ensure that forms for retaining donor and recipient or consignee information is established and readily accessible for inspection by the Council or an authorised officer.

(2) The form referred to under subsection (1) shall, at a minimum, contain the following—

- (a) the designated transplant centre identification number unique to each tissue, cell or organ;

- (b) the name of the Bank and designated transplant centre;
- (c) the type of storage solution used;
- (d) storage solution lot numbers;
- (e) unique donor identification number;
- (f) name of donor or, if imported tissue, name of importing bank and its unique ID number;
- (g) age of donor;
- (h) cause of death, if applicable;
- (i) date and time of death, if applicable;
- (j) enucleation or in situ excision date and time;
- (k) preservation date and time;
- (l) the time that cooling of ocular tissues or refrigeration of the body was begun;
- (m) additional tissue processing date and time;
- (n) slit lamp report;
- (o) endothelial cell density, if applicable;
- (p) the name of enucleator, processor, evaluator or technician;
- (q) name of surgeon or consignee receiving tissue, cell or organ;
- (r) tissue, readily traceable from donor to consignee for each unique graft number;
- (s) date, time and method of transportation;
- (t) result of tests;

- (u) microbiologic screening results, if performed;
- (v) microbiologic reports of positive donor rim cultures from the receiving surgeon, if reported;
- (w) adverse reactions, if reported; and
- (x) documentation that post-operative outcome information from the transplanting surgeon has been requested.

66. Recipient follow-up information.

(1) A designated transplant centre and, where applicable a bank, shall obtain consignee name and address information for each organ, tissue or cell used for human transplantation distributed by the designated transplant centre or bank.

(2) Each distributing bank or designated transplant centre shall request information on—

- (a) patient's name; if allowed by law;
- (b) unique identification according to the following order of preference—
 - (i) National Identification Number;
 - (ii) driver's licence number;
 - (iii) hospital information number; or
 - (iv) passport number;
- (c) date of birth;
- (d) diagnosis;
- (e) name of surgeon receiving transplanting tissue, cell or organ;
- (f) date of surgery;

- (g) location of surgery;
- (h) post-operative complications; and
- (i) type of surgery performed.

(3) Each distributing bank or designated transplant centre shall request postoperative outcome information between three and six months after transplant from the consignee concerning possible adverse reactions on all tissues, cells or organs distributed.

Transplantation of Organs from Living Donors

67. Donation and transplant of organs, tissues and cells removed from living donors.

(1) The donation of organs, tissues or cells from living donors shall not take place without the prior authorisation of the Council.

(2) A person shall not remove any human organ, tissue or cell from any living person who does not have the capacity to give valid consent in accordance with this Act and any other applicable law.

(3) The Council may, in the following exceptional circumstances authorise the removal of regenerative cells or tissues from a living donor—

- (a) if the person concerned is willing to donate and consents to the donation;
- (b) the donation is for the benefit of a person with whom they have a close relation as defined under section 4; and
- (c) the procedure carries minimal risk and burden to the donor.

(4) The Council shall ensure that the donation is legal and justified by ensuring that the proposed donor—

- (a) meets the conditions under subsection (3):

- (b) has been given all the information he or she requires about the nature of the procedure and its implications and risks;
- (c) understands the procedure and its risks;
- (d) understands that it is illegal to accept any financial or other inducement for the donation but that he or she may have any expenses or loss of earnings reimbursed;
- (e) understands that he or she may be compensated for any unanticipated harm resulting from the donation;
- (f) understands that he or she is not in any way being coerced to donate the cells, tissue or organ; and
- (g) understands that he or she may freely withdraw his or her consent at any time before the organ, tissue or cell is harvested.

(5) The Council shall in addition ensure that the recipient—

- (a) understands the nature and risks of both the donor removal procedure and those of the transplant procedure;
- (b) understands that it is illegal to offer any inducement or use coercion to obtain a donation and that no such inducement has been offered or coercion used by the recipient; and
- (c) understands that the donor may freely withdraw his or her consent at any time before harvest.

(6) The Council may, where it is satisfied that the proposed donation is legally and ethically acceptable, authorise the procedure.

(7) The Council shall establish and publish the procedures required to allow authorisation of a living donor transplant and may issue simplified rules for low risk donations.

(8) All living organ donors shall be registered and offered lifelong follow up, where required.

(9) A person who transplants an organ, tissue or cell from a living donor without prior authorisation of the Council commits an offence and is liable, on conviction, to a fine not exceeding one fifty thousand currency points or imprisonment not exceeding twelve years or both.

Transplant of Organs Harvested from Cadavers

68. Cadaveric donation.

(1) Organs, tissues or cells shall not be removed from a brain dead person unless that person has been certified as dead in accordance with a nationally certified criteria approved by the Council.

(2) A registered medical practitioner certifying the death of a potential donor shall not participate directly in the removal of any organs, tissues or cells or subsequent transplant procedures or have care of a potential transplant recipient to avoid conflict of interest.

(3) Organs, tissues or cells shall not be removed from a brain dead person unless valid written consent has been obtained in accordance with this Act.

(4) The registered medical practitioner removing organs, tissues or cells from a brain dead donor has a responsibility for the physical reconstruction of the appearance of the body as required under section 62.

69. Determination of brain death.

(1) In the case of a potential organ, tissue or cell donation from a brain dead person, the brain death of the potential donor must be confirmed in accordance with section 54 before any procedure related to donation is commenced.

(2) Determination of brain death under subsection (1) shall be confirmed by a registered medical practitioner with appropriate qualifications and experience who is independent of the transplant team.

(3) An independent team of specialists sanctioned by the Council shall confirm brain death.

(4) For purposes of this Act, brain death shall be confirmed in a person with irreversible damage to the vital centres in the brain, while cardio-respiratory function is artificially maintained, by specific testing criteria approved by the Council.

70. Procedure after determination of brain death.

(1) After a person has been determined and certified to be brain dead under section 69, a registered medical professional shall inform the close relations of the brain dead person and ascertain whether or not the person consented to donate any of his or her organ, tissue or cell.

(2) Where the registered medical professional determines that no consent was given by the brain dead person prior to their death, the registered medical professional shall inquire from the close relation of the deceased person whether they have any objection to the donation.

(3) After obtaining consent under subsection (1) or (2), the registered medical professional shall immediately contact a designated transplant centre.

(4) The designated transplant centre shall, immediately, after being contacted under subsection (3), take over the body of the brain dead person, ensure that the body is well preserved and carry out further tests to determine suitability of the donor.

(5) A designated transplant centre shall, after determining the suitability of the donor, seek the approval of the Council prior to harvesting the organs, tissues or cells.

(6) The Council may, after being satisfied that the provisions of this Act, regulations made under this Act or standards issued by the Minister have been complied with, approve the harvesting of the organs, tissues or cells from the brain dead person.

Appropriate Consent

71. Authority for removal of human organs, tissues and cells.

(1) A person may, in such manner and subject to such conditions as may be prescribed, authorise before his or her death, the removal of any organ, tissue or cell from his or her body for therapeutic purposes.

(2) Where a donor had, in writing and in the presence of two or more witnesses, at least one of whom has close relation, unequivocally authorised at any time before his or her death, the removal of any human organ, tissue or cell from his or her body, after his or her death, for therapeutic purposes, the person lawfully in possession of the dead body of the donor shall, unless he or she has any reason to believe that the donor had subsequently revoked the authority, grant to a registered medical practitioner from a designated transplant centre all reasonable facilities for the removal, for therapeutic purposes, of an organ, tissue or cell from the dead body of the donor.

(3) Where no authority referred to in subsection (2) was made by a person before his or her death but no objection was also expressed by the person to any of his or her organs, tissues or cells being used after his or her death for therapeutic purposes, the person lawfully in possession of the dead body of the person may, contact the close relations of that person to obtain their consent for the removal of the removal of any human organ of the deceased person for use for therapeutic purposes.

(4) The authority given under subsection (1) or subsection (2) or, as the case may be, subsection (3) shall be sufficient warrant for the removal, for therapeutic purposes, of the human organ, tissue or cell but no such removal shall be made by any person other than a registered medical practitioner from a designated transplant centre.

(5) Where any human organ, tissue or cell is to be removed from the body of a deceased person, the registered medical practitioner shall satisfy himself or herself, before the removal, by personal examination of the body from which any human organ, tissue or cell is to be removed, that life is extinct in the body or, where it appears to be a case of brain death, that the death has been certified under subsection (6) and the removal approved by the Council.

(6) Where any human organ, tissue or cell is to be removed from the body of a person in the event of his or her brain-death, no the removal shall be undertaken unless the death has been certified in accordance with this Act or regulations made under this Act.

(7) Notwithstanding subsection (3), where brain-death of any person, below the age of eighteen years of age, occurs and is certified in accordance with this Act, any of the parents of the deceased person may give authority, in such form and in such manner as may be prescribed by the Minister by regulations, for the removal of any human organ, tissue or cell from the body of the deceased person.

72. Prohibition of donation from living child.

Donation from a living child is prohibited.

73. Appropriate consent for donation from a brain dead or dead child.

Where a child is brain dead or has died, "appropriate consent" means—

- (a) the express consent of the child in force immediately before the child died witnessed by at least one close relative or an authorised officer;

- (b) where the child died without giving express consent under paragraph (a), the consent of a person who had parental responsibility for the child immediately before he or she died, witnessed by two adults of sound mind; or
- (c) where no person had parental responsibility for the child immediately before he or she died, the consent of a person who has a close relation with him or her at that time, witnessed by two adults of sound mind.

74. Appropriate consent by living adult.

(1) Where an adult is alive, "appropriate consent" means his or her consent in writing witnessed by at least two adults of sound mind, one of whom is a close relation.

(2) Where the adult giving consent under subsection (1) is between the age of eighteen years and twenty one years, at least one of the witnesses shall be the person having parental rights over that person.

75. Appropriate consent from brain dead or dead adult.

(1) Where an adult is brain dead or has died "appropriate consent" means his or her consent in writing in force immediately before his or her death.

(2) Where an adult dies without giving express consent under subsection (1), consent may be given by a person who has a close relation with him or her at that time or a representative nominated by that person under section 76, witnessed by at least two adults of sound mind.

(3) Consent in writing for the purposes of subsection (1) is only valid if—

- (a) it is signed by the person concerned in the presence of at least two witnesses who attest to the signature of the deceased;

- (b) it is signed at the direction of the person concerned, in his or her presence and in the presence of at least one witness who attests to the signature; or
- (c) it is contained in a will made in accordance with the Succession Act.

(4) The Council may apply to court for consent where a person dies without express consent and does not have any close relations.

76. Nominated representatives.

(1) An adult may appoint one or more persons to represent him or her after his or her death in relation to consent under section 74.

(2) An appointment under subsection (1) may be general or limited to consent in relation to one or more organs, tissues or cells as may be specified in the appointment.

(3) An appointment under subsection (1) may be made orally or in writing.

(4) An oral appointment referred to in subsection (3) is only valid if made in the presence of at least three witnesses present at the same time, of which one should be a close relation.

(5) A written appointment referred to under subsection (3) is only valid if—

- (a) it is signed by the person making it in the presence of at least three witnesses who attest the signature, one of whom should be a close relation or a legal representative;
- (b) it is signed at the direction of the person making it, in his or her presence and in the presence of at least one witness who attests the signature; or

(c) it is made in accordance with the requirements of the Succession Act.

(6) Where a person appoints two or more persons under this section in relation to the same activity, they shall be regarded as appointed to act jointly and severally unless the appointment provides that they are appointed to act individually.

(7) An appointment under this section may be revoked at any time.

(8) Subsections (3) to (5) apply to the revocation of an appointment under this section as they apply to the making of the appointment.

(9) A person appointed under this section may at any time renounce his or her appointment.

(10) A person may not act under an appointment under this section if he or she is not an adult or is of unsound mind.

77. Persons harvesting or using tissue to take into account cultural and spiritual needs, values and beliefs.

(1) A person harvesting or using human organs, tissues or cells must take into account, so far as they are known to the person based on information available to the person in the circumstances, the cultural and spiritual needs, values and beliefs of the close relations of the individual whose organs, tissues or cells are collected or used after obtaining appropriate consent under this Act.

(2) The cultural and spiritual needs, values and beliefs shall not affect the safety of the procedure and the quality of the donated organs, tissues or cells.

(3) Living donors and close relation of donors shall be informed of the testing required to ascertain donor suitability, the

purpose and nature of the removal together with any consequences and risks.

(4) A recipient of an organ, tissue or cell shall be given full information about the nature of the procedure and its risks and consequences.

**PART IX—POST MORTEM EXAMINATION OF CONFIRMED
BRAIN DEAD DONOR**

78. Requirements for carrying out post-mortem examination.

(1) A post-mortem shall be carried out on all cadaveric donors and shall be conducted at the same time as the harvesting of the organs to determine the cause of death and the suitability of the donor.

(2) A person who performs a post-mortem or anatomical examination or collects tissue that is, or is collected from, a body, under this Act, shall—

- (a) do so in a manner that avoids unnecessary mutilation of the body that is being collected or examined, or from which the collection is being effected; and
- (b) conduct the examination or collection in an orderly and decent manner.

(3) Subject to subsection (4), any part of the body of a deceased person mentioned in subsection (6) may, under the authorisation for the post-mortem examination of the body, be removed from the body during the post-mortem examination for the purposes of the examination.

(4) Any part of the body of a deceased person other than an organ, tissue or cell which is removed from the body during the post-mortem examination under the authorisation referred to in subsection (3) forms part of the medical records of the dead person.

(5) Where an organ, tissue or cell is removed from the body of a brain-dead person during the post-mortem examination of the body, or under the authorisation referred to in subsection (3)—

- (a) samples may, under the authorisation, be taken from the organ, tissue or cell; and
- (b) samples taken under paragraph (a) shall form part of the medical records of the brain-dead person.
- (6) The parts of the body referred to in subsection (1) includ—
 - (a) an organ;
 - (b) tissue sample;
 - (c) cells;
 - (c) blood, or any material derived from blood; and
 - (d) other body fluid.

79. Authority for removal of human organ, cell or tissue from a body sent for postmortem examination for certain purposes.

(1) Where the body of a person has been sent for post-mortem examination—

- (a) for medico-legal purposes by reason of the death of that person having been caused by accident or any other unnatural cause; or
- (b) for pathological purposes,

the person competent under this Act to give authority for the removal of any human organ, cell or tissue from the dead body may, if he or she has reason to believe that the human organ, cell or tissue will not be required for the purpose for which the body has been sent for post-mortem examination, authorise the removal, for therapeutic purposes, of that human organ, cell or tissue of the deceased person.

(2) Subsection (1) shall only apply where the competent person is satisfied—

- (a) that the deceased person had not expressed, before his or her death, any objection to any of his or her organ, tissue or cell being used for therapeutic purposes after his or her death; or
- (b) that where the deceased had granted authority for the use of any of his or her organ, tissue or cell for therapeutic purposes after his or her death, the authority had not been revoked by him or her before his or her death.

**PART X—HUMAN ORGAN AND TISSUE DATA BASE
AND REPORTING REQUIREMENTS**

80. Establishment of human organ, tissue and cell database.

(1) The Council shall establish and maintain a human organ, tissue and cell database in a manner prescribed by regulations.

(2) The database referred to under subsection (1) shall contain—

- (a) a list of potential donors;
- (b) a list of potential recipients;
- (c) type and number human organs, tissues and cells harvested or transplanted;
- (d) demographic details of donors and recipients;
- (e) information on successful transplant;
- (f) information on failed transplants;
- (g) any complications or deaths registered; and
- (h) any other information as the Council may determine.

(3) Subject to the Constitution and the Access to Information Act, 2005, information contained on the database may be made available to the public in a manner prescribed by regulations.

81. Data collection.

Each designated transplant centre shall collect, maintain, and report the following data quarterly to the Council—

- (a) the number of donors received by age, sex and race;
- (b) the number of recipients received by age, sex and race;
- (c) the type of donations received;
- (d) the cause of death of donors, where applicable;
- (e) donor source hospital or designated transplant centre;
- (f) the number of organs retrieved;
- (g) the disposal of processed organs, tissues and cells;
- (h) the distribution of organs, tissues and cells;
- (i) revenues derived from retrieving, processing, storing or distributing organs, tissue and cells; and
- (j) expenses associated with retrieving, processing, storing or distributing organs, tissues and cells.

82. Records, information on harvest and use of parts of organs, tissues or cells for transplantation.

(1) A designated transplant centre involved in the harvesting or transplantation of human organs, tissues and cells shall keep records and information in a manner prescribed by regulations.

(2) The records and information referred to in subsection (1) shall include—

- (a) the human organs and tissues collected;
- (b) the human organs, cells and tissues transplanted;
- (c) the names and addresses of donors;
- (d) the names or recipients;
- (e) information on successful transplants;
- (f) information on failed transplants;
- (g) any complication or deaths registered; and
- (h) any other information as the Council may deem necessary.

(3) The records and information maintained under subsection (1) shall be submitted to the Council quarterly.

(4) The Council shall, annually, submit to the Minister a report on the activities of the Council under this Act.

(5) A person who contravenes this section commits an offence and is liable, on conviction, to a fine not exceeding twenty thousand currency points or imprisonment not exceeding four years or both.

83. Additional records.

(1) Subject to the Constitution and the Access to Information Act, 2005, every bank and designated transplant centre shall keep accurate, complete and confidential, records of donors and recipients in a manner prescribed by regulations.

(2) Donor medical records and a final hard copy of the results of all laboratory tests shall be reviewed and affirmed in writing by a registered medical professional to ensure suitability of the donated organ, cell or tissue for the intended application.

(3) Documentation shall be concurrent with the performance of each activity in the retrieval, preparation, testing, storage and distribution of organs, tissues and cells in such a manner that all activities can be clearly traced.

(4) All records kept under this section shall—

- (a) be legible and indelible and shall identify the person performing the procedures or tasks;
- (b) include dates of entries and test results with the expiration period assigned to specific categories of processed tissues, cells or organs recorded in accordance with policies and procedures of designated transplant centre;
- (c) be as detailed as necessary for a clear understanding of each activity and shall be available for inspection by the Council or an authorised officer, upon request;
- (d) assign each organ, cell, tissue and any components derived from the organ, tissue or cell, in addition to generic designation, one unique identification number which shall serve as a lot number to identify the material from retrieval through distribution and utilisation; and
- (e) identify the donor, document the pathological and microbiological evaluation of the donor, verify the conditions under which the organ or tissue is retrieved, processed and stored, if applicable and indicate disposition of the transplanted organ or tissue.

(5) Maintenance of records kept under this section shall, as applicable, be the responsibility of the designated transplant centre.

(6) Subject to the Constitution and the Access to Information Act, 2005, records concerning donor history and processing information shall be made available to the transplant surgeon, upon request.

(7) Subject to the Constitution and the Access to Information Act, 2005, all records and communication between the designated transplant centre and its donors and patient recipients shall be regarded as confidential and privileged.

(8) The Council or an authorised officer shall, subject to subsection (7), have access to records and communication upon request at the time of the inspection.

(9) Maintenance and certification records on facilities, instruments, and equipment, including their monitors, shall be maintained.

(10) The records kept under this section shall indicate dates of inspection the name of facility, and performance evaluations.

(11) A bank or designated transplant centre shall include in its procedures manual, the monitoring, inspection and cleaning procedures and schedules for each piece of equipment.

(12) Records of function checks requiring interpretation of findings shall include the interpretation of—

- (a) temperature of incubators when in use;
- (b) spore lot number and expiration date used for autoclave function check; and
- (c) control and test results; and
- (d) any other purpose approved by the Council.

(13) A designated transplant centre shall maintain a file on adverse reactions.

(14) The records kept under this section shall be retained in a manner prescribed by regulations.

84. Information for donor, recipients and close relations.

(1) A registered medical professional authorised to harvest or transplant organs, tissues or cells must provide accurate information in a form that the donor, close relations or the recipient can understand.

(2) Donor and recipient screening forms and copies of relevant medical records reviewed shall be completed and retained on all donated organs, tissues or cells.

(3) A unique donor and recipient identifying number including hospital medical record number, National Identification Number or driver's licence number, shall be obtained and recorded in the donor record.

(4) A close relation to a brain-dead donor and potential recipient shall be informed about the implications of testing required to ascertain donor suitability and the nature and consequences of the donation.

85. Confidentiality.

(1) Subject to the Constitution and the Access to Information Act, 2005, all data, including genetic data, collected in relation to activities under this Act is subject to internationally agreed rules on medical and personal data protection.

(2) Data to which third parties may have access shall be rendered anonymous to ensure confidentiality.

(3) Subsections (1) and (2) shall not prevent the transmission of medical information about the donor or recipient required for medical purposes and required for traceability.

(4) Information about a donor may be communicated to a recipient with the consent of both parties, after a period of at least five years from the date of donation and transplant and in a manner prescribed by regulations.

PART XI—OFFENCES AND PENALTIES

86. Prohibition of commercial dealings in human material for transplantation.

(1) Monetary or any other forms of compensation for organs, tissues or cells other than reimbursement of donation-related expenses is prohibited.

(2) The sale of one of a pair of organs such as an eye or kidney by a living donor for financial or any other form of compensation is prohibited.

(3) A person commits an offence who—

- (a) gives or receives a reward for the supply of, or for an offer to supply a human organ, cell or tissue;
- (b) seeks to find a person willing to supply for payment, any human organ, cell or tissue;
- (c) offers to supply any human organ, cell or tissue for reward;
- (d) initiates or negotiates any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any human organ, cell or tissue;
- (e) takes part in the management or control of a body of persons corporate or unincorporated whose activities consist of or include the initiation or negotiation of arrangements to seek or offer human organs, tissues or cells for reward;
- (f) takes part in the management or control of a body of persons, whether a society, firm or body corporate, whose activities consist of or include the initiation or negotiation of any arrangement referred to in paragraph (d); or
- (g) publishes or distributes or causes to be published or distributed any advertisement—

- (i) inviting persons to supply for payment any human organ, cell or tissue;
- (ii) offering to supply any human organ, cell or tissue for payment; or
- (iii) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in paragraph (d).

(4) A person who contravenes subsection (1) or (2) commits an offence and is liable, on conviction, to imprisonment for life.

(5) A person who commits an offence under subsection (3) is liable, on conviction, to a fine not exceeding one hundred thousand currency points or imprisonment not exceeding twenty years or both.

(6) A reference in this section to “reward”, in relation to the supply of any human organ, tissue or cell does not include payment in money or money’s worth for defraying or reimbursing—

- (a) any expenses incurred in, or in connection with, transporting, removing, preparing, preserving or storing any human organ, cell or tissue;
- (b) any liability incurred in respect of expenses incurred by a third party in, or in connection with, any of the activities mentioned in paragraph (a); or
- (c) any expenses or loss of earnings incurred by the person from whose body the organ, tissue or cell is removed so far as reasonably and directly attributable to his or her organ, tissue or cell, for a period of six months from the date of donation.

(7) In this section—

- (a) “advertisement” includes any form of advertising whether to the public generally, to any section of the public or individually to selected persons; and
- (b) “reward” means any description of financial or other material advantage.

87. Removal of human organ, cell or tissue without authority.

(1) A person who renders his or her services to or at any hospital and who, for purposes of transplantation, conducts, associates with, or helps in any manner, in the removal of any human organ, cell or tissue without authority and contrary to this Act commits an offence and is liable, on conviction, to a fine not exceeding one hundred thousand currency points or imprisonment not exceeding twelve years or both.

(2) Where a person convicted under subsection (1) is a registered health practitioner, he or she shall be referred to the appropriate Council for necessary action including the removal of his or her name from the register of the Council for a period of ten years for the first offence and permanently for a subsequent offence.

(3) A person who renders his or her services outside a hospital environment for purposes of transplantation, conducts, associates with, or helps in any manner, in the removal of any human organ, cell or tissue without authority and contrary to this Act commits an offence and is liable, on conviction to imprisonment for life.

88. Prevention of organ, tissue or cell trafficking.

- (1) The following activities are prohibited—
 - (a) trade in human organs, cells and tissues;
 - (b) trafficking in human organs, cells and tissues;

- (c) obtaining financial gain or comparable advantage from the medical and scientific use of human body and its parts.

(2) The prohibition under subsection (1) shall not prevent payments which do not constitute a financial gain or comparable advantage, in particular—

- (a) compensation for living donors of loss of earnings and any other justifiable expenses caused by the removal or by related medical examinations;
- (b) payment of a justifiable fee for legitimate medical or other related technical services rendered in connection with the transplantation; and
- (c) compensation in case of undue damage resulting from the removal of an organ, tissue or cell from a living person.

(3) Transplantation of organs, tissues or cells from a living or brain dead donor shall be carried out solely for the therapeutic benefit of the recipient where there is no alternative therapeutic method of comparable effectiveness.

(4) All publicity relating to transplantation activities shall be authorised by the Council.

(5) The use of force or any form of coercion to obtain a donation of organs, tissues or cells is prohibited.

(6) A person who contravenes this section commits an offence and is liable, on conviction, to a fine not exceeding one hundred thousand currency points or imprisonment not exceeding twelve years or both.

89. Removal of human organ, tissue or cell from living donor without consent or authorisation.

(1) A person commits an offence who, without authorisation and appropriate consent in accordance with this Act, removes an organ, tissue or cell from the body of any person intending that it be used for transplantation.

(2) A person who commits an offence under subsection (1) is liable, on conviction, to imprisonment for life.

90. Restriction of activities in relation to donated material.

(1) A person commits an offence who—

- (a) uses any donated organ, tissue or cell for a purpose which is not a qualifying purpose; or
- (b) stores donated material for use for a purpose which is not a qualifying purpose.

(2) A person who commits an offence under subsection (1) is liable, on conviction, to a fine not exceeding fifty thousand currency points or imprisonment not exceeding seven years or both.

91. Offences by bodies corporate.

(1) Where an offence under this Act is committed by a body corporate and is proven to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of—

- (a) any director, manager or secretary of the body corporate;
or
- (b) any officer who was purporting to act in that capacity,

he or she as well as the body corporate commits the offence and is liable to be prosecuted and punished for the offence under this Act.

(2) The reference to the director, manager or secretary of the body corporate includes a reference—

- (a) to any similar officer of the body; and
- (b) where the body is a body corporate whose affairs are managed by its members, to any officer or member of the body.

(3) For purposes of this section—

- (a) “body corporate” means any company and includes a firm or other association of individuals; and
- (b) “director”, in relation to a firm, means a partner in the firm.

(4) A person who commits an offence under subsection (1) is liable, on conviction, to a fine or imprisonment prescribed by the relevant section.

92. General penalty.

A person contravenes a provision of this Act or any regulations made under this Act, or any condition of the designation granted under this Act for which no punishment is separately provided in this Act is liable, on conviction, to a fine not exceeding ten thousand currency points or imprisonment not exceeding three years or both.

PART XII—MISCELLANEOUS

93. Counseling for donors and recipients.

A designated transplant centre shall ensure that donors, recipients and their families are given appropriate counseling in a manner prescribed by regulations.

94. Revocation of consent.

(1) A person who gives consent for any purpose under this Act may revoke the consent at any time before harvesting without giving any justification.

(2) For the avoidance of doubt, a person shall not revoke consent or demand back an organ, tissue or cell after the harvesting or transplantation has taken place.

95. Power to inspect.

(1) The Council or an authorised officer may, at any reasonable time, enter and inspect any premises carrying out any activity regulated under this Act.

(2) A person carrying out an inspection under subsection (1) may require a person to produce for inspection, any records which he or she is required to keep by, or under, this Act.

(3) Where records which a person is required to keep under this Act are stored in any electronic form, the power under subsection (2) includes power to require the records to be made available for inspection—

- (a) in a visible and legible form; or
- (b) in a form from which they can readily be produced in a visible and legible form.

(4) A person carrying out an inspection under subsection (1) may inspect and take copies of any records produced for inspection in pursuance of a requirement under this section.

(5) Entry and search shall be at a reasonable time unless the person carrying out the search or inspection thinks that the purpose of the search may be frustrated on an entry at a reasonable time.

(6) A person carrying out an inspection under subsection (1) may seize anything on the premises which he or she has reasonable grounds to believe may be required for purposes of the functions of the Council under this Act or which the person believes to have been used in contravention of this Act, regulations made under this Act or standards issued by the Minister.

(7) The Council may require any designated transplant centre or bank to make available for purposes of the Council, any facilities including laboratories, and the designated transplant centre or bank shall comply.

(8) Where a person has power under subsection (5) to seize anything, he or she may take such steps as appear to be necessary for preserving the thing or preventing interference with it.

(9) The power under subsection (5) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.

(10) Where, under this section, a person seizes anything, he or she shall leave on the premises from which the thing was seized, a statement giving particulars of what he or she has seized and stating that he or she has seized it.

96. Regulations.

(1) The Minister may, by statutory instrument, make regulations generally for the better carrying into effect of the provisions of this Act.

(2) Notwithstanding the general effect of subsection (1), regulations made under this section may provide for—

- (a) the criteria for designation of transplant centres;
- (b) transplant quality control systems;
- (c) transplantation activities;
- (d) the transplantation of organs, tissues or cells;
- (e) the harvesting and use of human organs, tissues or cells;

- (f) the waiting list;
- (g) the donor list;
- (h) donor screening;
- (i) tissue and cell banking;
- (j) preservation of organs for transplantation;
- (k) application procedure;
- (l) organ donations;
- (m) consent;
- (n) cadaveric donation;
- (o) post mortem examination;
- (p) the manner in which and the conditions subject to which any donor may authorise removal, before his or her death, of any human organ, cell or tissue of his or her body under this Act;
- (q) the form and the manner in which a brain-dead person is to be certified and the conditions and requirements which are to be satisfied for that purpose under this Act;
- (r) the form and the manner in which any of the parents may give authority, in the case of brain-death of a child, for the removal of any human organ, cell or tissue under this Act;
- (s) the form in which authority for the removal of any human organ, cell or tissue from an unclaimed dead body may be given by the person in charge of the management or control of the hospital or prison;

- (t) the manner in which all possible effects, complications and hazards connected with the removal and transplantation is to be explained by the registered medical practitioner to the donor and the recipient under this Act;
 - (u) the standards to be enforced by the Council for designated transplant centres and approved banks engaged in the removal, storage or transplantation of any human organ, cell or tissue under this Act;
 - (v) the specialised services and facilities to be provided, skilled manpower and the equipment to be possessed and the standards to be maintained by a designated transplant centre;
 - (w) giving any notice required under this Act;
 - (x) the organ, tissue and cell database;
 - (y) confidentiality of information;
 - (z) records and documentation;
 - (aa) reporting mechanisms; and
 - (ab) any other matter related or incidental to the functions under this Act.
- (3) Regulations made under subsection (1) may, in respect of any contravention of any of the regulations—
- (a) prescribe a penalty of a fine not exceeding thirty thousand currency points or imprisonment not exceeding twelve years, or both;

- (b) in the case of a continuing contravention, prescribe an additional penalty not exceeding one thousand currency points in respect of each day on which the offence continues; and
- (c) prescribe a higher penalty not exceeding thirty thousand currency points in respect of a second or subsequent contravention.

97. Code of practice.

(1) The Minister may, in consultation with the Council, issue a code of practice for the purpose of—

- (a) giving practical guidance to persons carrying out activities under this Act; and
- (b) laying down the standards expected in relation to the carrying-out of activities under this Act.

(2) The code of practice referred to under subsection (1) may provide for—

- (a) the carrying-out of anatomical examinations;
- (b) the storage of anatomical specimens;
- (c) the storage and disposal of former anatomical specimens;
- (d) the definition of death for the purposes of this Act;
- (e) communication with the family of the brain dead person in relation to the making of a post-mortem examination;
- (f) the making of post-mortem examinations;
- (g) communication with the family of the brain-dead person in relation to the removal from the body of the brain dead person, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains;

- (h) the removal from a human body, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains;
- (i) the storage for use for a scheduled purpose, and the use for such a purpose, of—
 - (i) the body of a brain-dead person, or
 - (ii) relevant material which has come from a human body;
- (j) the storage for use for a scheduled purpose;
- (k) the import or the export of the body of a brain-dead person or organ, tissue or cell from a human body for use for a scheduled purpose;
- (l) issues of consent; and
- (m) the disposal of relevant material which has been removed from a human body for use for a scheduled purpose.

(3) Before preparing a code of practice under this section, the Minister shall consult any other stakeholders as he or she deems necessary.

(4) The Minister shall publish the code of practice issued under this section in the Gazette.

(5) A code of practice issued under this section shall come into effect on the date of its publication in the Gazette.

98. Amendment of Schedules.

(1) The Minister may, by statutory instrument, with the approval of Cabinet, amend Schedule 1 to this Act.

(2) The Minister may, by statutory instrument, amend Schedules 2 and 3 to this Act

SCHEDULES

SCHEDULE 1

*Sections 4
and 98 (1)*

CURRENCY POINT

A currency point is equivalent to twenty thousand shillings

SCHEDULE 2

Sections 4, 55 and 98 (2).

AUTHORISED TRANSPLANTATION ACTIVITIES

1. Donation.
2. Transplantation.
3. Harvesting organs, tissues and cells.

SCHEDULE 3

Sections 15 and 98 (2)

MEETINGS OF THE COUNCIL

1. Meetings of the Council.

(1) The Council shall meet as often as required for the performance of the functions of the Council under this Act.

(2) The Chairperson shall convene every meeting of the Council at times and places as the Council may determine, and the Council shall meet for the discharge of business every working day.

(2) The Chairperson shall preside at every meeting of the Council and in the absence of the Chairperson, the members present shall appoint a member from among themselves to preside at that meeting.

2. Quorum.

(1) The quorum for a meeting of the Council is 5 members.

(2) All decisions at a meeting of the Council shall be by a majority of the votes of the members present and voting and in case of an equality of votes, the person presiding at the meeting shall have a casting vote in addition to his or her deliberative vote.

3. Minutes of meetings.

(1) The Council shall cause to be recorded and kept, minutes of all meetings of the Council in a form approved by the Council.

(2) The minutes recorded under this paragraph shall be submitted to the Council for confirmation at its next meeting following that to which the minutes relate and when so confirmed, shall be signed by the Chairperson and the Secretary to the Council, in the presence of the members present at the latter meeting.

4. Decision by circulation of papers.

(1) Subject to paragraph (2), decisions of the Council may be made by the circulation of the relevant papers among the members and the expression of their views in writing or electronically, but any member is entitled to request that any such decision shall be deferred until the subject matter has been considered at a meeting of the Council.

(2) A decision made by circulation of papers under this paragraph is not valid unless it is supported by not less than five members.

5. Power to co-opt.

(1) The Council may co-opt any person who, in the opinion of the Council, has expert knowledge concerning the functions of the Council, to attend and take part in the proceedings of the Council.

(2) A person co-opted under this paragraph may take part in any discussion at the meeting of the Council on which his or her advice is required but shall not have any right to vote at that meeting.

6. Validity of proceedings not affected by vacancy.

The validity of any proceedings of the Council shall not be affected by a vacancy in its membership or by any defect in the appointment or qualification of a member or by reason that a person not entitled, took part in its proceedings.

7. Disclosure of interest of members.

(1) A member of the Council who is in any way directly or indirectly interested in a contract made or proposed to be made by the Council, or in any other matter which falls to be considered by the Council, shall disclose the nature of his or her interest at a meeting of the Council.

(2) A disclosure made under subparagraph (1) shall be recorded in the minutes of that meeting.

(3) A member who makes a disclosure under subparagraph (1) shall not—

- (a) be present during any deliberation of the Council with respect to that matter; or
- (b) take part in any decision of the Council with respect to that matter.

(4) For purposes of determining whether there is a quorum, a member withdrawing from a meeting or who is not taking part in a meeting under subparagraph (3) shall be treated as being present.

8. Council may regulate its procedure.

Subject to this Act, the Council may regulate its own procedure or any other matter relating to its meetings.

Cross References

Constitution of the Republic of Uganda. 1995
Access to Information Act, 2005 Act 6 of 2005
Births and Deaths Registration Act, Cap. 309
Children Act, Cap. 59
Medical and Dental Practitioners Act, Cap 59
National Audit Act, 2008. Act 7 of 2008
Occupational Safety and Health Act, 2006. Act 9 of 2006
Public Finance Management Act, 2015, Act 3 of 2015
Succession Act, Cap. 162