

Uganda

Uganda Human Organ Donation and Transplant Act Chapter 311

Legislation as at 31 December 2023

Note: This Act has not yet come into force in full. See the commencements table for more information.

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Uganda

Uganda Human Organ Donation and Transplant Act Chapter 311

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There are multiple commencements

Provisions	Status
Part II (in part); Part III, section 19–24, section 25(1)–(4); Part XI, section 84(1)–(7), section 85–90; Part XII, section 94(1)–(2), (3)–(4), section 95(1)–(2), (3)–(5), section 96	commenced on 20 November 2023.
Part IV (in part)	commenced on 22 December 2023.
Part I (section 1–4); Part II, section 5–18; Part III, section 25(4)26; Part IV, section 27–36; Part V (section 37–38); Part VI (section 39–43); Part VII (section 44–50); Part VIII (section 51–76); Part IX (section 77); Part X (section 78–83); Part XI, section 84(7)(a)–(b); Part XII, section 91–93, section 94(1), section 95(1)	not yet commenced.

[This is the version of this document at 31 December 2023.]

[Note: This legislation was revised and consolidated as at 31 December 2000 and 31 December 2023 by the Law Reform Commission of Uganda. All subsequent amendments have been researched and applied by Laws.Africa for ULII.]

[Act 9/2023; S.I. 109/2023; S.I. 111/2023]

An Act to provide for the regulation of the removal, storage and transplantation of human organs, tissues and cells for therapeutic purposes; to establish the Uganda Human Organ Donation and Transplant Council; to provide for the accreditation and designation of hospitals as transplant centres; to provide for the establishment and 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; to provide for 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.

1. Commencement

This Act shall come into force on a day to be appointed by the Minister by statutory instrument; and different days may be appointed for the commencement of different provisions.

2. Purpose of Act

The purpose of this Act is—

- (a) to establish a legal framework for the donation of human organs, tissues and cells for therapeutic purposes;
- (b) to regulate the practice of organ, tissue and cell donations;
- (c) to provide for the accreditation and designation of hospitals as organ, tissue and cell transplant centres;
- (d) 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 donation and transplantation of organs, tissues and cells of human origin;
- (e) to regulate the transplantation of organs, tissues and cells of human origin for therapeutic purposes;
- (f) to provide for the establishment and approval of banks for human organs, tissues and cells;
- (g) to provide for a system to ensure equitable access to transplantation services by patients; and
- (h) to prohibit and eliminate illicit trade in human organs, tissues and cells.

3. Application of Act

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

- (a) kidneys;
- (b) heart;
- (c) lungs;
- (d) liver;
- (e) pancreas;
- (f) intestines;
- (g) thymus;
- (h) bone marrow;
- (i) bones;
- (j) tendons;
- (k) ligaments;
- (l) corneas;
- (m) hair;
- (n) skin;
- (o) amniotic membrane;
- (p) penile;
- (q) uterus; and
- (r) any other organ, tissue or cell for the purpose of donation and transplantation.

4. Interpretation

In this Act, unless the context otherwise requires—

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

“**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;

“**allograft**” means tissue that is transplanted from one person to another;

“**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, written standards of operation and other relevant standards;

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

“**autograft**” means tissue which is transplanted within the same person;

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

“**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, tissues or cells;

“**bone marrow**” means the soft, spongy, gelatinous tissue that fills the medullary cavities or the centers of the bones, which is responsible for the production of red blood cells, white blood cells and platelets;

“**brain dead**” means a condition where a person is on an artificial life support machine, with irreversible cessation of all functions of the entire brain, including the brainstem, confirmed by an electroencephalogram and independent team, and the person has no chance of revival;

“**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 a spouse, son, daughter, father, mother, brother or sister;

“**Council**” means the Uganda Human Organ Donation and Transplant Council appointed under section 6;

“**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;

“**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;

“**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;

“**container**” means a receptacle used to contain human organs, tissues or cells and which 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;

“**currency point**” has the value assigned to it in Schedule 1 to this Act;

“**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 an 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, organ, tissue, cell, 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;

“**harvest**” means obtaining an organ that is still receiving perfusion;

“**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;

“**human organ, tissue or cell acquisition**” means the process by which the donated organs, tissues or cells are removed from a donor for transplantation, research or education;

“**living donor recipient**” means a transplant recipient that receives a living donor organ, tissue or cell;

“**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, which 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 meaning assigned to it in the Children Act;

“**parental rights**” has the meaning assigned to it 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 or any material derived from any 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 programme**” means a programme 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 programme of a bank, hospital or designated transplant centre to be performed to monitor retrieval, processing, preservation and storage of organ,

tissue or cell 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 organs, tissues or cells that have not yet been characterised 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 organ, tissue or cell 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 organ, tissue or cell;

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

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

“registered medical practitioner” means a medical practitioner who is registered under the Medical and Dental Practitioners 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 organ, tissue or cell in humans as determined by the Minister;

“retrieval team” means an intensive care team that is capable of handling a patient on life support;

“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 organ, tissue or cell 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;

“stem cells” means undifferentiated cells originating from adult or embryonic tissue that can turn into specific cells, as the body needs them;

“stem cell transplant” means a medical procedure performed to replace bone marrow that has been damaged or destroyed by disease, infection, or chemotherapy;

“**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 analysis of tissue for viability, abnormality, contaminants, compatibility and microorganisms to determine its fitness for purpose;

“**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 action designed to produce results within the acceptable range in future tests;

“**traceability**” means the act or ability to locate an organ, tissue or cell 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 organ, tissue or cell;

“**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 centre**” means a hospital designated by the Minister under section [27](#);

“**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 organ, tissue or cell into the person; and
- (b) by so doing, necessitates the removal of an organ or part of an organ, tissue or cell from the person, which in turn is intended to be used for transplantation in respect of another living person;

“**transplant programme**” 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;

“**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 – Minister and Uganda Human Organ Donation and Transplant Council

Minister

5. Powers and functions of 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) The 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, tissues or cells for donation or transplantation;
 - (b) take any necessary measures or make any directives relating to the quality, safety, storage and use of any human organ, 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.

Uganda Human Organ Donation and Transplant Council

6. Uganda Human Organ Donation and Transplant Council

- (1) There is established the Uganda Human Organ Donation and Transplant Council to oversee and regulate organ, tissue or cell 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 movable 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 18.
- (4) The Council established under subsection (1) shall consist of seven technical members appointed by the Minister.
- (5) The Council shall be independent but shall work in collaboration with the relevant health professional councils, 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.

7. Qualifications of members of Council

The members of the council shall be persons of high moral character and proven integrity who are qualified and have experience in specified fields such as medicine, surgery, intensive care, law, anaesthesia, financial management, bioethics, investigative specialist, sociology, pharmacy or information and communications technology.

8. Disqualification for appointment to 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;
- (d) is serving on any other Council or Board; or
- (e) is directly involved in the organ, cell or tissue transplant service.

9. Tenure of office of members of Council

A member of the Council shall hold office for three years and is eligible for re-appointment.

10. Termination of appointment

- (1) A member of the Council may, at any time, resign his or her office by giving 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 misbehaviour 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 11.

11. Remuneration of members of Council

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.

12. Filling of vacancies on 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), 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.

13. Functions of Council

- (1) The Council is responsible for the regulation, organisation and supervision of all national human organ, tissue and cell 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 organ, tissue and cell acquisition and donation;
 - (f) oversee the national waiting list;
 - (g) regulate the allocation of organs, and if required, tissues and cells;
 - (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 the 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, tissue and cell donation and transplantation; and
 - (o) perform such other functions as may be prescribed by the Minister.

14. Meetings of Council

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

15. Committees of 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) inquire into and advise the Council on any matter concerning the functions of the Council as the Council may refer to the technical committee; and
 - (b) exercise such powers or perform such functions of the Council as the Council may delegate or refer to the technical committee.
- (3) A technical 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 technical committee appointed under this section.
- (5) Members of a technical committee appointed under this section shall be paid such allowances as the Council may determine.
- (6) The Council may require a technical committee appointed under this section to act jointly or in cooperation with any other technical committee.
- (7) A technical 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 technical committee appointed under this section may regulate its own procedure.

16. 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.

17. Protection from liability of members of Council

A member of the Council or of a technical 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.

18. 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

19. Funds of Council

The funds of the Council shall consist of—

- (a) moneys 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 moneys 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; and
- (e) money from any other source as may be approved by the Minister and the Minister responsible for finance.

20. 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) ensure its revenue is sufficient for meeting all charges, including interest on capital and loans properly chargeable to revenue account;
- (b) ensure sufficient provision is made to provide for depreciation of assets; and
- (c) ensure that 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.

21. 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 bank account of the Council without the authority of the Council.

22. 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.

23. 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 account shall include—
 - (a) a balance sheet, an income and expenditure account and a source and application of the funds of the Council; 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.

24. 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.
- (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.

25. 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 of 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 report of the Auditor General 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.

26. Compliance with Public Finance Management Act

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

Part IV – Designation of transplant centres and establishment and approval of banks

Designation of transplant centres

27. Designation of transplant centres

The Minister may, by statutory instrument, in consultation with the Council, designate a hospital as an organ, tissue or cell donation and transplant centre.

28. Application for designation as transplant centre

- (1) A hospital seeking to be designated as a transplant centre under section 27 shall apply to the Council for accreditation and designation.
- (2) The Council shall, before recommending a hospital to the Minister for designation under section 27, carry out due diligence and satisfy itself that the applicant has complied with all the requirements of this Act, regulations made under this Act and internationally acceptable standards.
- (3) Where, after the due diligence carried out under subsection (2) 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 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.
- (5) A hospital designated as a transplant centre by the Council shall be accredited annually for suitability to offer services and the Council shall issue an accreditation certificate which shall expire on the 31st day of December of every calendar year.
- (6) A person aggrieved by the decision of the Council made under subsection (3) may appeal to the Minister within thirty days from the date of decision of the Council.
- (7) The Minister shall dispose of the appeal within thirty days from the date of receipt of the appeal.

29. Qualification for designation as transplant centre

A hospital shall not be designated as a transplant centre under section 27 unless the hospital is a fully-fledged hospital with a full range of services including routine surgeries, emergency care and other services and has the following—

- (a) an Intensive Care Unit 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, clinical pharmacist, 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) at least 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 forty-eight hours turn over;
- (g) a valid operating licence of the facility from the Uganda Medical and Dental Practitioners Council; and
- (h) any other requirement that the Minister may prescribe by regulations, or standards issued by the Minister.

30. 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 to operate specific transplant services for which the hospital is qualified.

- (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 as a transplant centre 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 as a transplant centre 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.

31. Existing centres

- (1) A hospital shall not commence any activity relating to the removal, storage or transplantation of any human organ, tissue or 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 shall—
 - (a) apply to the Council for accreditation and 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).

32. Regulation of conduct of donation and transplant activities

- (1) On the commencement of this Act—
 - (a) a hospital shall not conduct, associate with or assist in the removal, storage or transplantation of any human organ, tissue or cell unless the hospital is designated as a transplant centre under this Act;
 - (b) a medical practitioner or other person shall not 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 a human organ, tissue or cell at a place other than a designated transplant centre; and
 - (c) a person shall not use or cause to be used a place, including a hospital designated as a transplant centre under this Act, for the removal, storage or transplantation of any human organ, tissue or cell, except for therapeutic purposes.

- (2) A hospital designated as a transplant centre 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.
- (3) Approval under subsection (2) shall be based on readiness of the country and a designated transplant centre and institutional readiness.
- (4) 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.
- (5) The Council shall, in a manner prescribed by regulations, approve local and expatriate transplant surgeons before they can undertake transplantation activities under this Act.
- (6) A transplant surgeon shall not be approved under subsection (5) unless he or she is registered by the relevant professional body.

Establishment and approval of human organ, tissue and cell banks

33. Establishment and approval of banks

- (1) A designated transplant centre shall establish and maintain banks for the purposes of this Act.
- (2) The Minister shall, on the recommendation of the Council, annually, by notice in the *Gazette*, approve banks established under subsection (1) for the purposes of this Act.
- (3) All organ, tissue and cell banks shall be operated by and located within the designated transplant centres.
- (4) A bank shall not be approved or gazetted under subsection (2) unless it has the following—
 - (a) the facilities specified in Part V;
 - (b) qualified professionals; and
 - (c) any other requirement that the Minister may deem necessary.
- (5) The Minister may, in approving a bank under subsection (2), attach such terms and conditions as the Minister may deem necessary.
- (6) 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.
- (7) 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 (4).

Policies and procedures for designated transplant centres and approved banks

34. Policies and procedures for designated transplant centres and approved banks

- (1) Designated transplant centres and approved banks shall maintain policies and procedures and shall conform to regulations made under this Act which shall detail all aspects of retrieval, processing, testing, 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) Any modifications to the standard procedures referred to under subsection (1), or the development of new procedures shall be approved by a registered medical practitioner of the designated transplant centre, in consultation with the Council.
- (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 technical 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 a designated transplant centre shall be available to the Council or an authorised officer for inspection, upon request.
- (7) The procedures contained in the policies shall be detailed, simple and unambiguous.

35. Ethical standards

- (1) Each designated transplant centre and approved bank shall have measures in place to avoid conflict 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.

36. Educational services to the public

- (1) A designated transplant centre shall assist hospitals and health centres in establishing and implementing guidelines for making routine inquiries regarding organ, cell and tissue donations by potential donors.
- (2) A designated transplant centre shall maintain documentation that shall be available for review by the Council or an authorised officer relating to education services provided to the community, health care professionals and hospitals in the service area of the designated transplant centre.
- (3) A designated transplant centre shall ensure that—
 - (a) documentation of education qualifications 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 centres, to document the activities referred to in paragraphs (a) and (b) are entered into.

- (4) A 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 as may be approved by the Council.
- (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

37. 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 33.
- (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 inspected by the Council, an authorised person or an independent qualified person authorised by the Council at least every two years to ensure that they comply with this Act, regulations made under this Act and international standards.
- (5) The Minister shall, by regulations, prescribe detailed requirements for approved banks.

38. 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

39. Organ donation and transplant 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 the 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.

40. 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;
 - (l) tissue evaluation;
 - (m) access control; and
 - (n) internal audit or risk management.
- (2) A designated transplant centre shall perform an investigation and report any adverse reaction information within thirty days to the Council for review in a manner prescribed by regulations.

41. Recall procedures

- (1) A 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 policies and procedures of the designated transplant centre.
- (3) The Minister may, in consultation with the Council, by regulation, prescribe additional requirements for recall procedures.

42. Look back procedures

- (1) Each bank shall establish procedures for notifying a designated transplant centre or registered medical practitioner that it 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 registered medical practitioner that it may have received infected organs, cells or tissues.
- (3) Documentation of look back procedures shall be included in the policies and procedures of the bank and designated transplant centre.

43. 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

44. 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.

45. 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 an approved bank shall ensure that the facilities and equipment of the designated transplant centre and approved bank comply with the regulations made by the Minister and standards prescribed under subsection (1).

46. 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

47. 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.

48. 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.

49. Returned organs, tissues and 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.

50. Fraudulent activities

- (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 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 ten 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 or bank shall ensure that the Council is copied in all correspondence relating to the fraudulent activity during their follow up.

Part VIII – Transplant of organs, tissues and cells

51. 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.

52. 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 another recognised national or international transplant organisation with which the Council has an agreement.
- (3) The Council may also authorise the sharing 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, tissues and cells shall be provided without regard to the recipient's sex, age, religion, race, creed, color or financial standing or any other discriminatory ground.

53. Transplantation activities

- (1) The harvesting, retrieval, preservation and transplantation of human organs, tissues and cells shall only be performed by a registered health professional 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 the criteria of 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 as may be prescribed by the respective professional bodies.
- (5) When a person has been confirmed brain dead by the team in care, the Council shall immediately be notified to send an independent 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 contraindicated or inappropriate.
- (8) The independent team referred to in subsection (5) shall consist of a neurosurgeon, neurophysician and an anesthesiologist or intensivist.
- (9) Where a person has been declared and confirmed brain dead in accordance with subsection (5), in an Intensive Care Unit of a hospital which is not a designated transplant centre, a retrieval team shall be dispatched by the Council to retrieve the potential donor to a designated transplant centre.
- (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.

54. 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 to 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 to imprisonment for a term not exceeding ten years, or both.

55. 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 [53\(10\)](#).
- (2) No authority for the removal of any human organ, tissue or cell 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 to imprisonment for a term not exceeding seven years, or both.

56. 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 shall 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.

57. Organ, tissue and cell sampling

- (1) A registered medical practitioner may, in accordance with this Act and with the relevant consent, remove any organ, tissue 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 made under this Act, standards issued by the Minister and internationally recognised standards.

58. Testing requirements

- (1) A designated transplant centre shall, before harvesting an organ, tissue or cell 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, tissue or cell donation shall be determined in accordance with this Act and regulations made under this Act.

59. 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 seven hours after receipt of the body, notify the Council.

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

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

61. 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 and cells from deceased donors

62. 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) the location of the donor;
 - (b) the age of the donor; and
 - (c) the cause and time of death.
- (3) The Minister may, by regulations, prescribe additional requirements for retrieval and recovery of human organs, tissues and cells for purposes of this Act.

63. 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 close relation 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

64. Minimum information to be retained

- (1) A designated transplant centre shall ensure that the forms for retaining donor and recipient or consignee information are established and readily accessible for inspection by the Council or an authorised officer.
- (2) The forms referred to under subsection (1) shall, at a minimum, contain the following—
 - (a) the designated transplant centre identification number unique to each organ, tissue or cell;
 - (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 registered medical practitioner or consignee receiving organ, tissue or cell;
 - (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 registered medical practitioner has been requested.

65. Recipient follow-up information

- (1) A designated transplant centre and, where applicable a bank, shall obtain a 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 the following information—
 - (a) the patient's name; if allowed by law;
 - (b) the 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 registered medical practitioner receiving transplanting organ, tissue or cell;
 - (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 the transplant from the consignee concerning possible adverse reactions on all organs, tissues or cells that are distributed.

Transplantation of organ, tissue or cell from living donors

66. 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 of the organ, tissue or cell;
 - (e) understands that he or she may be compensated for justifiable expenses which should be declared to and cleared by the Council within reasonable time;
 - (f) understands that he or she is not in any way being coerced to donate the organ, tissue or cell; 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 the prior authorisation of the Council commits an offence and is liable, on conviction, to a fine not exceeding one hundred fifty thousand currency points or to imprisonment for a term not exceeding twelve years, or both.

Transplant of organs harvested from cadavers

67. 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 a 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 [61](#).

68. 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 [53](#) 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 the purposes of this Act, brain death shall be confirmed in a person with irreversible damage to the vital centres in the brain, while cardiorespiratory function is artificially maintained, by specific testing criteria approved by the Council.

69. Procedure after determination of brain death

- (1) After a person has been determined and certified to be brain dead under section [68](#), a registered medical professional shall inform the close relation 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 practitioner determines that no consent was given by the brain dead person prior to his or her death, the registered medical practitioner shall inquire from the close relation of the deceased person whether the close relation has any objection to the donation.
- (3) After obtaining consent under subsection [\(1\)](#) or [\(2\)](#), the registered medical practitioner 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

70. 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 is a 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 relation of that person to obtain his or her consent for 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 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 occurs and is certified in accordance with this Act, any close relation 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.

71. Prohibition of donation from living child

- (1) Donation from a living child is prohibited save for exceptional circumstances approved by the Council, with the consent of a parent or a legal guardian.
- (2) A person who contravenes this section commits an offence and is liable, on conviction, to imprisonment for life.
- (3) For the purpose of this section, “exceptional circumstances” means haematopoietic stem cell, allograft and autograft to a twin or sibling.

72. Appropriate consent for donation from brain dead or dead child

- (1) Where a child is brain dead or has died “appropriate consent” means—
 - (a) the consent of a person who, immediately before the death of a child, had parental responsibility for a child, witnessed by two adults with mental capacity; or
 - (b) where no person had parental responsibility for the child immediately before the death of the child, the consent of a person who had a close relation with the child at the time, witnessed by two adults with mental capacity.
- (2) For the avoidance of doubt, donation from a brain dead or dead child shall only be in accordance with section 71.

73. 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 with mental capacity, 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 adult.

74. 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.
- (1) 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 75, witnessed by at least two adults of sound mind.
- (2) 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.

75. 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 it is made in the presence of at least three witnesses present at the same time, one of whom shall 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 to the signature, one of whom shall 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 to 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, the persons shall be regarded as appointed to act jointly and severally unless the appointment provides that the persons 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 has mental incapacity.

76. Persons harvesting or using human organs, tissues and cells 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 relation 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 relations of donors shall be informed of the testing required to ascertain donor suitability and 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

77. 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 from a body under this Act, shall—
 - (a) do so in a manner that avoids unnecessary mutilation of the body; and
 - (b) conduct the examination or collection in an orderly and decent manner.

Part X – Human organ and tissue database and reporting requirements

78. 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) the type and number of human organs, tissues and cells harvested or transplanted;
 - (d) demographic details of donors and recipients;
 - (e) information on successful transplants;
 - (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, information contained on the database may be made available to the public in a manner prescribed by regulations.

79. Data collection

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

- (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) the 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.

80. Records and 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, tissues and cells collected;
 - (b) the human organs, tissues and cells transplanted;
 - (c) the names and addresses of donors;
 - (d) the names of 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 to imprisonment for a term not exceeding four years, or both.

81. Additional records

- (1) Subject to [the Constitution](#) and the Access to Information Act, 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 the suitability of the donated organ, tissue or cell 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 organs, tissues or cells recorded in accordance with the policies and procedures of the 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, tissue or cell 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, tissue or cell 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, 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, 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 of 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 the 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;
 - (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.

82. 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 relation or recipient can understand.
- (2) Donor and recipient screening forms and copies of relevant medical records reviewed shall be completed and retained for 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 a potential recipient shall be informed about the implications of testing required to ascertain donor suitability and the nature and consequences of the donation.

83. Confidentiality

- (1) Subject to [the Constitution](#) and the Access to Information Act, 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

84. Prohibition of commercial dealings in human material for transplantation

- (1) Monetary or any other form of compensation for organs, tissues or cells is prohibited, except justifiable expenses approved by the Council.
- (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 who—
 - (a) gives or receives a reward for the supply of, or for an offer to supply, a human organ, tissue or cell;
 - (b) seeks to find a person willing to supply for payment, any human organ, tissue or cell;
 - (c) offers to supply any human organ, tissue or cell 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, tissue or cell;
 - (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, tissue or cell;
 - (ii) offering to supply any human organ, tissue or cell for payment; or

- (iii) indicating that the advertiser is willing to initiate or negotiate any arrangement referred to in paragraph (d),
commits an offence.
- (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 to imprisonment for a term 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, 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 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—
“advertisement” includes any form of advertising whether to the public generally, to any section of the public or individually to selected persons; and
“reward” means any description of financial or other material advantage.

85. Removal of human organ, tissue or cell 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, tissue or cell 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 to imprisonment for a term 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 professional body for necessary action, including the removal of his or her name from the register of the Council for a period of ten years for a 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, tissue or cell without authority and contrary to this Act commits an offence and is liable, on conviction, to imprisonment for life.

86. Prevention of organ, tissue and cell trafficking

- (1) The following activities are prohibited—
 - (a) trade in human organs, tissues and cells;
 - (b) trafficking in human organs, tissues and cells;
 - (c) obtaining unjustifiable financial gain or comparable advantage from the medical and scientific use of the 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 compensation for living donors and any other justifiable expenses caused by the removal of human organs, tissues or cells or by related medical examinations, as may be approved by the Council.
- (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 donation of organs, tissues or cells is prohibited.
- (6) A person who contravenes this section commits an offence and is liable, on conviction, to life imprisonment.

87. 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.

88. 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 to imprisonment for a term not exceeding seven years, or both.

89. 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) A reference to the director, manager or secretary of a 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, under this Act.
- (5) A body corporate which commits an offence under subsection (1) is liable, on conviction, to a fine not exceeding five hundred thousand currency points.

90. General penalty

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

Part XII – Miscellaneous

91. Counselling for donors and recipients

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

92. 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 for the return of an organ, tissue or cell after the harvesting or transplantation has taken place.

93. 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 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 the 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 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 with the request.

- (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.

94. Regulations

- (1) The Minister shall, by statutory instrument, make regulations generally for the better carrying into effect of the provisions of this Act and shall lay the regulations before Parliament.
- (2) Notwithstanding the general effect of subsection (1), regulations made under this section may provide for—
 - (a) the criteria for accreditation and designation of transplant centres;
 - (b) transplant quality control systems;
 - (c) transplantation activities;
 - (d) the transplantation of organs, tissues and cells;
 - (e) the harvesting and use of human organs, tissues and cells;
 - (f) the national waiting list;
 - (g) the donor list;
 - (h) donor screening;
 - (i) tissue and cell banking;
 - (j) preservation of organs for transplantation;
 - (k) application procedures;
 - (l) organ donations;
 - (m) consent;
 - (n) cadaveric donations;
 - (o) post-mortem examinations;
 - (p) fees to be charged by the Council;
 - (q) recall procedures;
 - (r) look back procedures;
 - (s) procedures for sharing of organs;
 - (t) the manner in which, and the conditions subject to which, any donor may authorise removal, before his or her death, of any human organ, tissue or cell of his or her body under this Act;
 - (u) 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;
 - (v) 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, tissue or cell under this Act;

- (w) 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;
 - (x) 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, tissue or cell under this Act;
 - (y) 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;
 - (z) giving any notice required under this Act;
 - (aa) the organ, tissue and cell database;
 - (ab) confidentiality of information;
 - (ac) records and documentation;
 - (ad) reporting mechanisms; and
 - (ae) 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 to imprisonment for a term 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.
- (4) For the purposes of this section, “sharing of organs” means medically sanctioned movement of body organs, tissues or cells from one bank to another.

95. 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 a 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 a 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 the 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) The code of practice issued under this section shall come into effect on the date of its publication in the *Gazette*.

96. Power to amend 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.

Schedule 1 (Sections 4, 96(1))

Currency point

A currency point is equivalent to twenty thousand shillings.

Schedule 2 (Sections 4, 54(1), 96(2))

Authorised transplantation activities

- (1) Donation
- (2) Transplantation
- (3) Harvesting organs, tissues and cells
- (4) Storage

Schedule 3 (Sections 14, 96(2))

Meetings of Council

1. Meetings of Council

- (1) The Council shall meet as often as required for the performance of the functions of the Council under the 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.
- (3) 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 five 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 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 the purposes of determining whether there is 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.