

BILLS SUPPLEMENT

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Bill No. 35

*Uganda Human Organ Donation and
Transplant Bill*

2021**THE UGANDA HUMAN ORGAN DONATION AND
TRANSPLANT BILL, 2021****MEMORANDUM****1. POLICY AND PRINCIPLES**

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

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

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

2. DEFECTS IN THE EXISTING LAW

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

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

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

3. REMEDIES PROPOSED TO DEAL WITH THE DEFECTS

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

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

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

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

DR. JANE RUTH ACENG OCERO,
Minister of Health.

THE UGANDA HUMAN ORGAN DONATION AND TRANSPLANT
BILL, 2021

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ENTITLED

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

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

BE IT ENACTED by Parliament as follows:

PART I—PRELIMINARY

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 the 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, cells and tissue donations;
- (c) to designate Mulago National Referral Hospital as the pioneer transplant centre;
- (d) to provide for the designation of hospitals as organ, tissue and cell transplant centres;
- (e) 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;
- (f) to regulate the transplantation of organs, tissues and cells of human origin for therapeutic purposes;
- (g) to provide for the approval of banks for human organs, tissues and cells;
- (h) to provide for a system to ensure equitable access to transplantation services by patients; and

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

3. Application.

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

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

4. Interpretation.

In this Act, unless the context otherwise requires—

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

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

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

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

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

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

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

“cells” means individual cells or collections of cells when not bound by any form of connective tissue;

“child” means a person under the age of eighteen years;

“close relation” means spouse, son, daughter, father, mother, brother or sister;

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

“complaint” means any written or oral communication concerning dissatisfaction with the identity, quality, packaging, durability, reliability, safety, effectiveness or performance of a human organ, tissue or cell transplanted in accordance with this Act;

“competency” means the ability of an employee to acceptably perform tasks related with his or her educational level for which he or she has been trained;

“competency assessment” means the evaluation of the ability of an employee to acceptably perform tasks that are expected of the employee for the duties and responsibilities assigned to him or her;

“consent” means the process by which approval for donation is obtained from the donor or the donor’s close relation or any other legal representative;

“consignee” means any bank, banking intermediary, designated transplant centre or transplanting surgeon whether an individual, bank or designated transplant centre, institution, or organisation, that receives a human organ, tissue or cell and assumes responsibility for any step in the processing, storage, distribution or use of such organ, tissue or cell or;

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

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

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

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

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

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

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

“distribution” means the process of allocation of tissues, cells or organs for transplant and includes receipt of request, selection, inspection and release of the tissue, cell or organ to a consignee which is responsible for maintaining the principles of tracking, traceability and adverse reaction reporting throughout the process of distribution;

“donated material” means the body of a brain-dead person or relevant material which has come from a human body, which is, or has been, the subject of donation;

“donor” means a living or deceased person who provides the source of organ, tissue or cell for transplantation;

“donor eligibility determination” means the evaluation of all available information about a potential donor to assess whether the donor meets the qualifications specified in the Standard Operating Procedures and any other standards and includes, medical, social and sexual histories, laboratory test results, physical assessment or physical examination and autopsy findings, if performed;

“evaluation” means the assessment of an entity, tissue, cell, organ equipment, personnel and performance in relation to predetermined expectations or standards;

“expiration date” means the date after which instruments, supplies, organs, tissues and cells are deemed to be no longer suitable for use;

“graft failure” means where an organ is removed, a recipient dies, or a recipient is placed on a chronic allograft support system;

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

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

“human organ” means any part of the human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body;

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

“medical record” means a chronological account of a patient’s examination and treatment that includes the patient’s medical history and complaints, the physician’s physical findings, the results of diagnostic tests and procedures, and medications and therapeutic procedures;

“Minister” means the minister responsible for health;

“national waiting list” means the list created under section 51;

“non-domino therapeutic donor” means an individual who has a tissue, cell or organ removed as a component of medical treatment and whose organ is transplanted into another person, but the donor does not receive a replacement organ;

“organ” means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;

“organ transplant” means the procedure for transplantation of organs including solid organ transplants and islet infusions and begins at the start of organ anastomosis or the start

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

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

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

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

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

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

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

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

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

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

“quality assurance program” means a program that—

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

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

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

“qualifying purpose” means—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PART II—THE MINISTER AND THE HUMAN ORGAN
TRANSPLANT COUNCIL

The Minister

5. Powers and functions of the Minister.

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

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

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

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

(4) The Minister shall--

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

6. Assistance and support.

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

Uganda Organ Donation Transplant Council

7. Uganda Organ Donation and Transplant Council.

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

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

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

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

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

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

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

8. Qualifications of members of the Council.

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

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

9. Disqualification for appointment to the Council.

A person shall not be appointed to the Council who--

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

10. Tenure of office of members of the Council.

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

11. Termination of appointment.

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

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

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

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

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

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

12. Remuneration of Council members.

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

13. Filling of vacancies on the Council.

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

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

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

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

14. Functions of the Council.

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

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

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

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

15. Meetings of the Council.

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

16. Committees of the Council.

- (1) The Council shall work through technical committees.
- (2) The Council may appoint technical committees as it deems necessary to provide advice to enable the Council to fulfil its responsibilities and—
 - (a) to inquire into and advise the Council on any matter concerning the functions of the Council as the Council may refer to the committee; and
 - (b) to exercise such powers or perform such functions of the Council as the Council may delegate or refer to the technical committee.
- (3) A committee appointed under subsection (1) shall consist of a chairperson who shall be a member of the Council, and other persons, whether members of the Council or not, as the Council may determine.
- (4) The Council shall, in writing, specify the terms and conditions of service of members of a committee appointed under this section.
- (5) Members of a committee appointed under this section shall be paid such allowances as the Council may determine.
- (6) The Council may require a committee appointed under this section to act jointly or in co-operation with any other committee.
- (7) A committee is subject to the control of the Council and may be discharged or reconstituted at any time by the Council.
- (8) Subject to any direction given by the Council, a committee appointed under this section may regulate its own procedure.

17. Power to engage consultants.

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

18. Protection from liability of members of Council.

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

19. Secretariat of Council.

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

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

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

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

PART III—FINANCES OF COUNCIL

20. Funds of the Council.

The funds of the Council shall consist of—

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

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

21. Duty to operate on sound financial principles.

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

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

22. Power to open and operate bank accounts.

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

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

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

23. Estimates.

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

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

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

24. Accounts.

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

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

(3) The statement of accounts shall include—

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

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

25. Audit.

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

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

26. Annual report.

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

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

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

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

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

27. Compliance with Public Finance Management Act, 2015.

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

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

Designation of Transplant Centres

28. Designation of transplant centres.

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

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

29. Application for designation as transplant centre.

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

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

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

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

30. Qualification for designation as transplant centre.

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

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

31. Designation by Minister.

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

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

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

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

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

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

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

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

32. Existing centres.

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