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WEDNESDAY 26TH JANUARY, 2022

THE OFFICIAL GAZETTE 26TH JANUARY, 2022
LEGAL SUPPLEMENT — A

GUYANA

ACT NO. 1 OF 2022

HUMAN ORGAN AND TISSUE TRANSPLANT ACT 2022

I assent.

Mohamed Irfaan Ali,
President.
26th January, 2022

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AN ACT to make provision for the donation and removal of human organs, tissues, cells and biofluids for transplantation and blood for transfusion, for their use for regenerative medicine including cell therapy, gene therapy and stem cell therapy, and other therapeutic purposes, for medical education and for scientific research purposes including stem cell research, cell explant research and cell line research, and for connected matters.

A.D. 2022 Enacted by the Parliament of Guyana:-

PART I
PRELIMINARY

Short title. 1. This Act may be cited as the Human Organ and Tissue Transplant Act 2022.

Interpretation. 2. In this Act –

"adult" means a person who is at least eighteen years and includes a person who is under eighteen years but is married or a parent;

"Agency" means the Human Organ and Tissue Transplant Agency established under section 4;

"biofluid" means a human fluid and includes cerebrospinal fluid, urine, saliva, sweat, and any substance derived from a biofluid;

"blood" means human blood and includes –

(a) any substance derived from blood; and

(b) any part of the body which can be used as a source from which to derive a constituent of blood for therapeutic, diagnostic, prognostic and analytical use or for the preparation of a substance for that use;

"blood transfusion" means the transfusion of blood, or any of the constituents of blood, into a person and includes the operation of removing all or part of the blood of a person and replacing it with blood taken from another person;

"cell" means a human cell taken from an organ, a tissue, biofluid or other substance of a human body, and includes any substance derived from scientific procedures involving cells such as a cell explant or cell line;

"cell explant" means a cell that is taken from a human tissue, organ or biofluid and organotypically cultured using explant culture;

"cell line" means a cell culture developed from a single cell and therefore consisting of cells with a uniform genetic makeup that is specific to a given organ or disease state;

Cap. 4:03

"coroner" has the same meaning as in the Coroners Act;

"Department" means the National Blood Transfusion Department of the Ministry of Health referred to in section 33;

"donor" means a person whose organ, tissue, cell, cell explant, cell line, blood or biofluid is being considered for donation or in respect of whom a consent has been given;

"Donor Registry" means the National Donor and Transplant Registry established under section 13;

"designated officer" means a person appointed under section 18 to be the designated officer of a designated hospital;

"designated hospital" or "designated facility" means any hospital, including a private hospital, a clinic, healthcare provider, laboratory or any other facility designated by the Minister, by Order, under section 17;

"Director of Medical Services" or by whatever designation called, means a medical practitioner who is in charge of a designated hospital or having the control and management of the affairs of a designated hospital;

"guardian" means a person appointed by deed or will in accordance with any law, or by a Court of competent jurisdiction to be the guardian of a child;

Cap. 32:02 "medical practitioner" has the same meaning as in the Medical Practitioners Act;

"Minister" means the Minister with responsibility for health;

"minor" means a person under eighteen years of age, but does not include a person who is married or a parent;

"nearest relative" means, in strict order of priority –

(a) a spouse;

(b) a child who is not a minor;

(c) a parent or guardian;

(d) a brother or sister over eighteen years of age; or

(e) any other adult relative;

(f) any individual who may be a legally defined relative of non-genetic lineage;

"non-regenerative organ, tissue, cell or biofluid" means an organ, a tissue, cell or biofluid other than a regenerative organ, tissue, cell or biofluid, and includes a kidney and lung;

"organ" means a human organ, whether whole or in sections;

"regenerative organ, tissue, cell or biofluid" means an organ, a tissue, cell or biofluid that, after injury within or after removal from the body of a living person, is replaced in the person's body by natural processes, and includes a liver and bone marrow;

"serious adverse events" means any undesired and unexpected or toxic occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life threatening, disabling or incapacitating conditions for patients or which results in or prolong, hospitalisation or morbidity;

"spouse" means, in strict order of priority –

(a) a wife or husband; or

(b) a single woman or a single man of a common law union, in which the single woman and the single man have been living together for five years immediately preceding the hospitalisation

or death of the single woman or single man, but only one such union shall be considered;

"therapeutic purposes" includes transplantation purposes, cell therapy, gene therapy, stem cell therapy, and other regenerative medicine;

"tissue" means human tissue or substance extracted from the human body or a part of the human body, excluding an organ;

"scientific research" includes stem cell research, cell explant research, cell line research, and biotechnology; and

"transplantation" means the removal of an organ, a tissue, cell or biofluid from a human body, whether living or dead (as provided for under section 48), and –

(a) its implantation into a living human body;

(b) the implantation of any substance derived from any scientific procedure involving the organ, tissue, cell or biofluid, into a living body or the living body from which it was removed; or

(c) the implantation of the regenerated organ, tissue, cell or biofluid into a living body or the living body from which it was removed.

Non-application of Act.

3. This Act does not apply to –

(a) spermatozoa, semen or ova;

(b) an embryo or a foetus or a part of an embryo or a foetus;

(c) zygotes or oocytes;

(d) the removal of an organ or tissue from the body of a deceased person during the course of a post-mortem examination;

(e) the embalming of the body of a deceased person; and

(f) the preparation, including the restoration of any disfigurement or mutilation, of the body of a deceased person for the purpose of interment or cremation.

PART II
HUMAN ORGAN AND TISSUE TRANSPLANT AGENCY

Establishment and constitution of the Human Organ and Tissue Transplant Agency.

4. (1) There is established an agency known as the Human Organ and Tissue Transplant Agency to be the national organisation for human organ, tissue, cell and biofluid donation and transplantation.

Schedule I

(2) The constitution of the Agency and related matters are provided in the Schedule I.

Functions of the Agency.

5. The functions of the Agency shall be to –

(a) facilitate, coordinate and manage the donation process for organs, tissues, cells and biofluids for transplantation;

(b) implement a donation process involving close collaboration of the Agency's transplant coordinators with the designated officers of the designated hospitals to increase the supply of donated organs, tissues, cells and biofluids;

(c) plan, promote, co-ordinate and support activities relating to the donation of organs, tissues, cells and biofluids for transplantation, and activities relating to education, scientific research or scientific experimental procedures in connection with the donation of organs, tissues, cells and biofluids;

(d) co-ordinate and support the work of the designated hospitals in connection with the donation and transplantation of organs, tissues, cells and biofluids;

(e) facilitate, coordinate and manage the procurement, storage, preservation, distribution and delivery of organs, tissues, cells and biofluids;

(f) make reasonable efforts to ensure that patients and their nearest relatives have appropriate information and opportunities to consider whether to consent to the donation of organs, tissues, cells or biofluids and to facilitate the provision of that information;

(g) provide education to the public and to the health care community about matters relating to the donation and use of organs, tissues, cells and biofluids and to facilitate the provision of such education by others;

(h) collect, analyse and publish information relating to the donation and use of organs, tissues, cells and biofluids;

(i) to implement quality assurance programmes, including a donor quality assurance programme, with

regular audits for ongoing monitoring and evaluation of the programme;

(j) provide training for staff and transplant coordinators in organ, tissue, cell and biofluid donation management;

(k) advise the Minister on matters relating to the donation, storage and preservation of organs, tissues, cells and biofluids; and

(l) perform any other function in relation to the donation, transplantation, storage or preservation of organs, tissues, cells or biofluids that is entrusted to it by the Minister.

Directives of the Minister.

6. The Minister may give to the Agency any general or special policy directives with respect to the carrying out of its functions under this Act as the Minister considers necessary or expedient and the Agency shall give effect to the directives.

Establishment of facilities for storage and preservation of organs, tissues, cells and biofluids.

7. The Agency shall establish facilities for the storage and preservation of organs, tissues, cells and biofluids for –

(a) the transplantation of any of the organs, tissues, cells or biofluids to the body of a living person; or

(b) the use of the organs, tissues, cells or biofluids for other therapeutic purposes or for medical education or scientific research purposes.

Procedure for the management of serious adverse events and reactions.

8. The Agency shall, in collaboration with the designated hospitals, establish an operating procedure for the management of serious adverse events and reactions under a framework for quality and safety.

Mechanism to ensure traceability of donor and recipient.

9. (1) To safeguard the health of donors and recipients, the Agency shall establish a mechanism to ensure traceability of donor and recipient of an organ, tissue, cell or biofluid from donation to transplantation or disposal.

(2) All information required to ensure traceability at all stages of the chain from donation to transplantation or disposal, or donation to transfusion shall be kept for at least thirty years after the donation.

International cooperation and exchange.

10. (1) The Agency, with the approval of the Minister, may collaborate, coordinate, negotiate, or join with counterpart organisations of the Caribbean Community or other international counterpart organisations for exchange of organs, tissues, cells, biofluids and information, and sharing of expertise.

(2) Organs, tissues or cells exchange shall only be permitted if the organs, tissues or cells can be traced from the donor to the recipient and vice versa and if the organs, tissues or cells meet quality and safety requirements and any other requirement determined by the Minister.

Principles, standards and guidelines of international bodies.

11. Principles, guidelines, standards including ethical standards, and best practices of international institutions such as the World Health Organisation and scientific societies such as the International Transplantation Society or World Medical Association may be referred to for guidance in the application of this Act.

Advisory Board.

12. The Minister may establish an Advisory Board comprising local and international expertise for advising the Minister, or the Agency, in consultation with the Minister, on matters that may be

necessary for the successful implementation of this Act including matters in relation to transplantation, biobanking, immunology, systems biology and biotechnology.

PART III
NATIONAL DONOR AND TRANSPLANT REGISTRY

Establishment of the National Donor and Transplant Registry.

13. (1) The Minister shall establish a registry known as the National Donor and Transplant Registry in which shall be registered –

(a) consents, and amendments and revocation of consents of adults respecting the donation of their –

(i) organs, tissues, cells or biofluids; and

(ii) cell explants or cell lines.

(b) patients awaiting transplantation of organs, tissues, cells and biofluids; and

(c) recipients of organs, tissues, cells and biofluids.

(2) The Agency shall manage, operate and maintain the Donor Registry.

(3) The Agency shall keep proper records of all its dealings in relation to its functions under this Act which shall include annotations and inventories of organs, tissues, cells, cell explants, cell lines and biofluids and other substances available and those used and how used.

Public education programme.

14. The Agency shall establish a public education programme, including public awareness campaigns, to increase awareness about organ, tissue, cell and biofluid donation, the need to provide for an adequate rate or increase of the donations, and the benefits of organ, tissue, cell and biofluid transplantation and the therapeutic benefits

that may be derived from scientific procedures involving an organ, a tissue, cell and biofluid.

In-person and online registration for donors.

15. (1) The Registry shall have facility for both in-person and online registration of donors.

(2) The Agency shall establish an online system of registration that ensures security and confidentiality of information of donors.

(3) The Agency shall make available online printable registration forms and donor-cards.

Form A Schedule II

(4) The donor-card shall be in almost the manner and form of Form A of Schedule II.

Patients awaiting transplantation.

16. The Agency shall establish and manage –

(a) a register of patients waiting for the transplantation of organs, tissues, cells and biofluids;

(b) medical criteria for allocating organs, tissues, cells and biofluids, and substances derived from scientific procedures involving organs, tissues, cells and biofluids; and

(c) a system to fairly and equitably allocate available organs, tissues, cells, biofluids, and substances derived from any scientific procedures involving organs, tissues, cells and biofluids.

PART IV
DESIGNATED HOSPITALS, FACILITIES AND OFFICERS

Designated hospitals and facilities.

17. (1) The Minister may by Order designate any hospital, including a private hospital, clinic, healthcare provider, laboratory or any other facility to be a designated hospital or designated facility for the purposes of this Act.

(2) A clinic, healthcare provider, laboratory or any other facility referred to in subsection (1), with the appropriate facilities, may be a designated facility approved to render services relating to transplantation of organs, tissues, cells or biofluids, or relating to their use for regenerative medicine or other therapeutic purposes, or scientific research purposes, including testing, diagnostic, prognostic and analytical services, or services in relation to biobanking, systems biology and biotechnology.

Designated officers.

18. (1) The Chief Medical Officer or the Director of Medical Services may in writing nominate one or more medical practitioners, who have been in practice for a period of not less than three years, as the designated officers of a designated hospital for a period not exceeding two years for the purposes of this Act.

(2) The Chief Medical Officer or the Director of Medical Services shall submit nominations under subsection (1) to the Minister and on being satisfied, the Minister shall appoint the persons as designated officers for the designated hospital concerned.

(3) The designated officers may exercise the powers conferred and shall be subject to the duties imposed on designated officers by this Act.

(4) The Minister, on the advice of the Chief Medical Officer or the Director of Medical Services or in the Minister's own discretion,

may revoke the appointment of a person as a designated officer for a designated hospital by serving on that person a notice of revocation.

(5) A designated officer shall not participate in any of the medical procedures involved in the removal of any organ, tissue, cell or biofluid from or transplantation of any organ, tissue, cell or biofluid to the body of a person to which Parts V, VI and VII relate.

PART V
DONATION OF ORGAN, TISSUE, CELL AND BIOFLUID BY ADULTS

Donation of regenerative organ, tissue, cell or biofluid by adults.

19. (1) A person who qualifies under subsection (2) may, in writing signed by the person in the presence of a designated officer, consent to the removal from that person's body of a regenerative organ, tissue, cell or biofluid specified in that person's consent for any of the purposes set out in subsection (3).

(2) A person may consent to the removal from that person's body of a regenerative organ, tissue, cell or biofluid where the person –

(a) is an adult;

(b) is of sound mind; and

(c) in light of the medical advice given by a medical practitioner, agrees with the removal.

(3) The removal from the body of the person of a regenerative organ or tissue, cell or biofluid may be for –

(a) the transplantation of the organ, tissue, cell or biofluid to the body of another living person;

(b) the transplantation of any substance derived from any scientific procedure involving the organ, tissue, cell or

biofluid, into the same living body from which it was removed or another living body;

(c) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body from which it was removed or another living body;

(d) use for other therapeutic purposes; or

(e) medical education or scientific research purposes.

(4) A person who has given consent under subsection (1), may, at any time before the removal of the regenerative organ, tissue, cell or biofluid to which the consent applies, revoke the consent to the removal, orally or in writing and, where given orally, shall be confirmed in writing as soon as possible.

(5) The designated officer shall, before removal of the regenerative organ, tissue, cell or biofluid, certify in writing, that –

(a) all the requirements referred to in subsections (1), (2) and (3) have been complied with;

(b) the officer explained to the donor the implications of removal of the regenerative organ, tissue, cell or biofluid from the body; and

(c) the donor understood the implications of removal of the regenerative organ, tissue, cell or biofluid from the body.

Form B
Schedule II

(6) The certification referred to in subsection (5), shall be in the manner set out in Form B of Schedule II.

Consent under section 19.

20. A subsisting consent and certification under section 19, shall be sufficient authority for a medical practitioner who is a surgeon qualified to remove the regenerative organ, tissue, cell or biofluid other than the designated officer and the medical practitioner referred to in section 19(2)(c), to remove the regenerative organ, tissue, cell or biofluid referred to in the consent.

Donation of non-regenerative organ, tissue, cell or biofluid by adults.

21. (1) A person who qualifies under subsection (2) may, in writing signed by the person in the presence of a designated officer, consent to the removal of non-regenerative organ, tissue, cell, or biofluid from the person's body after the expiration of a period of at least twenty-four hours from the time at which the consent is signed, for any of the purposes set out in subsection (3).

(2) A person may give consent to the removal from the person's body of the non-regenerative organ, tissue, cell or biofluid where the person –

(a) is an adult;

(b) is of sound mind; and

(c) in light of the medical advice given by a medical practitioner, agrees with the removal.

(3) The removal from the body of the person of a non-regenerative organ, tissue, cell or biofluid may be for –

(a) the transplantation of the organ, tissue, cell or biofluid to the body of another living person;

(b) the transplantation of any substance derived from any scientific procedure involving the organ, tissue, cell or

biofluid into the same living body from which it was removed or another living body; or

(c) regenerative treatment of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body from which it was removed or another living body.

(d) use for other therapeutic purposes; or

(e) medical education or scientific research purposes.

(4) A person who has given consent under subsection (1), may, at any time before the removal of the non-regenerative organ, tissue, cell, or biofluid to which the consent applies, revoke the consent to the removal, orally or in writing and, where given orally, shall be confirmed in writing as soon as possible.

(5) The designated officer shall, before removal of non-regenerative organ, tissue, cell or biofluid, certify in writing, that –

(a) all the requirements referred to in subsections (1) and (2) have been complied with;

(b) the designated officer explained to the donor the implications of removal of the non-regenerative organ, tissue, cell or biofluid from the body; and

(c) the donor understood the implications of removal of the non-regenerative organ, tissue, cell or biofluid from the body.

Form C
Schedule II

(6) The certification referred to in subsection (5), shall be in the manner set out in Form C of Schedule II.

Consent under section 21.

22. A subsisting consent and certification under section 21, shall be sufficient authority for a medical practitioner, other than the designated officer and the medical practitioner referred to in section 21(2)(c), to remove, after the expiration of a period of at least twenty-four hours from the time at which the consent was given, the non-regenerative organ, tissue, cell or biofluid referred to in the consent.

Agency to record every removal and transplantation from adults.

23. The designated officer shall notify the Agency of every certification, removal and transplantation or other purpose for a removal under this Part and the Agency shall record every removal and transplantation or other purpose which record shall form part of the record of the Donor Registry.

PART VI
DONATION OF ORGAN, TISSUE, CELL AND BIOFLUID BY MINORS

Establishment of an Independent Assessment Committee.

24. (1) For the purposes of approving a donation by a minor under this Part, an Independent Assessment Committee shall be established by the Chief Medical Officer or Director of Medical Services of the designated hospital where the donated organ, tissue, cell or biofluid shall be procured for transplantation.

(2) The Independent Assessment Committee shall have a minimum of three members, one of whom shall be a designated officer and one of whom shall be a psychologist or psychiatrist.

(3) A person who has had any association with the donor or the proposed recipient that might influence the person's judgment shall not be a member of the Independent Assessment Committee.

Prohibition of removal of non-regenerative organ, tissue or cell.

25. A person shall not remove or consent to the removal of a non-regenerative organ, tissue or cell, from the body of a living minor for the purpose of transplantation of the non-regenerated organ, tissue or cell to the body of another living person or for use for other

therapeutic purposes, medical education or scientific research purposes.

Removal of regenerative organ, tissue, cell or biofluid where minor understands.

26. (1) Subject to subsection (2), a parent or guardian of a minor may consent in writing to the removal of a regenerative organ, a regenerative tissue, cell or biofluid specified in the consent from the body of the living minor for any of the purposes set out in subsection (2), so long as –

(a) the parent or guardian has obtained advice from a medical practitioner, other than the medical practitioner due to transplant the organ, tissue, cell or biofluid, regarding the nature and effect of the removal of the organ, tissue, cell or biofluid and the nature of the transplantation; and

(b) the donation is approved by an Independent Assessment Committee.

(2) The removal from the body of a minor of a regenerative organ, tissue, cell or biofluid may be for –

(a) the transplantation of the organ, tissue, cell or biofluid to the body of a living natural brother, sister or parent of the minor;

(b) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body of the minor from whom it was removed or the body of a living natural brother, sister or parent of the minor; or

(c) the transplantation of any substance derived from any scientific procedure involving the regenerative organ, tissue, cell or biofluid, into the same living body of the minor from whom it was removed or the body of a living natural brother, sister or parent of the minor.

(3) A parent or guardian shall not give a consent under subsection (1) if the parent or guardian –

(a) has personal knowledge that another parent or guardian would refuse to give a consent; or

(b) lacks the authority to make medical decisions in respect of the minor.

(4) Before approving a removal of any regenerative organ, tissue, cell or biofluid under this section, the Independent Assessment Committee shall ensure that –

(a) the parent or guardian understands the nature and effect of the removal of the organ, tissue, cell or biofluid and the nature of the transplantation;

(b) the minor, to the extent possible considering the minor's age, consents to the removal without coercion or inducement and understands the nature and consequences of the removal;

(c) the removal poses minimal risk to the minor; and

(d) all adult members of the immediate family of the recipient have been eliminated, for medical or other reasons, as donors.

(5) An Independent Assessment Committee shall not approve a removal of the regenerative organ, tissue, cell or biofluid if all the members of the Committee are not in agreement.

(6) The Independent Assessment Committee shall provide to the minor and the parent or guardian who gave a consent for the removal of the regenerative organ, tissue, cell or biofluid written notice, with reasons, of a decision to approve or disapprove a removal.

Forms D and E Schedule II

(7) The consent of the parent or guardian and the consent of the minor shall be in the manner set out in Form D and Form E of Schedule II.

(8) A person who has given consent or approval under subsection (1) may, at any time before the removal of the regenerative organ, tissue, cell or biofluid to which the consent applies, revoke the consent or approval to the removal, orally or in writing and, where given orally, shall be confirmed in writing as soon as possible.

(9) In this section a reference to a parent of the minor does not include a person standing in *loco parentis* to the minor.

(10) The Independent Assessment Committee shall, before the removal of the organ, tissue, cell or biofluid by a medical practitioner, certify in writing, that –

(a) all the requirements referred to in subsection (4) have been complied with;

(b) the Committee explained to the parent or guardian and minor the implications of removal of the regenerative organ, tissue, cell or biofluid from the body of the minor; and

(c) the parent or guardian and minor understood the implications of the removal of the regenerative organ, tissue, cell or biofluid from the body of the minor and the minor has agreed to the removal.

Form F
Schedule II

(11) The certification referred to in subsection (10) shall be in the manner set out in Form F of Schedule II.

Authority to remove organ, tissue, cell or biofluid under section 26.

27. The consent given by the parent or guardian, the approval of the committee under section 26(1) and the certification given under section 26(10) shall be sufficient authority for a medical practitioner who is a surgeon qualified to remove the regenerative organ, tissue, cell or biofluid from the body of the minor, to remove the organ, tissue, cell or biofluid, unless the consent or approval has been revoked under section 26(8) at any time prior to the removal.

Removal of regenerative organ, tissue, cell or biofluid where minor does not understand.

28. (1) A parent or guardian of a minor may consent in writing to the removal of a regenerative organ, tissue, cell or biofluid specified in the consent from the body of that living minor for any of the purposes set out in subsection (2), so long as –

(a) the parent or guardian has obtained advice from a medical practitioner, other than the medical practitioner due to transplant the organ, tissue, cell or biofluid, regarding the nature and effect of the removal of the organ, tissue, cell or biofluid and the nature of the transplantation;

(b) a medical practitioner, other than the medical practitioner due to transplant the organ, tissue, cell or biofluid, certifies in writing that unless the organ, tissue, cell or biofluid, specified in the consent, is removed for the purpose specified in the consent, and

transplanted to the minor, or the said brother, sister or parent, as the case may be, such person would die; and

(c) the donation is approved by an Independent Assessment Committee.

(2) The removal from the body of a minor of a regenerative organ, tissue, cell or biofluid may be for –

(a) the transplantation of the organ, tissue, cell, biofluid to the body of a living natural brother, sister or parent of the minor;

(b) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body of the minor from whom it was removed or the body of a living natural brother, sister or parent of the minor; or

(c) the transplantation of any substance derived from any scientific procedure involving the regenerative organ, tissue, cell or biofluid, into the same living body of the minor from whom it was removed or the body of a living natural brother, sister or parent of the minor.

(3) A parent or guardian shall not give a consent under subsection (1) if the parent or guardian –

(a) has personal knowledge that another parent or guardian would refuse to give a consent; or

(b) lacks the authority to make medical decisions in respect of the minor.

(4) Before approving a removal under this section, the Independent Assessment Committee shall ensure that –

(a) the parent or guardian understands the nature and effect of the removal of the organ, tissue cell or biofluid and the nature of the transplantation;

(b) the minor is not capable of understanding the nature and effect of the removal of the organ, tissue cell or biofluid and the nature of transplantation;

(c) the removal poses minimal risk to the minor;

(d) all adult members of the immediate family of the recipient have been eliminated, for medical or other reasons, as donors; and

(e) unless the organ, tissue cell or biofluid specified in the consent is transplanted to the said brother or sister or parent, as the case may be, such person would die.

(5) An Independent Assessment Committee shall not approve a removal if all the members of the Committee are not in agreement.

(6) The Independent Assessment Committee shall provide to the parent or guardian who gave a consent for the removal written notice, with reasons, of a decision to approve or disapprove a removal.

Form G
Form H
Schedule II

(7) The consent of the parent or guardian and the certificate of the medical practitioner under subsection (1)(b) shall be in the manner set out in Form G and Form H of Schedule II.

(8) A person who has given consent or approval under subsection (1) may, at any time before the removal of the regenerative organ, tissue cell or biofluid to which the consent applies, revoke the

consent or approval to the removal, orally or in writing and, where given orally, shall be confirmed in writing as soon as possible.

(9) In this section a reference to a parent of the minor does not include a person standing in *loco parentis* to the minor.

(10) The Independent Assessment Committee shall, before the removal of the organ, tissue cell or biofluid by a medical practitioner, certify in writing, that –

(a) all the requirements referred to in subsection (4) have been complied with;

(b) the Committee explained to the parent or guardian and the minor the implications of the removal of the regenerative organ, tissue cell or biofluid from the body of the minor;

(c) the parent or guardian understood the implications of the removal of the regenerative organ, tissue cell or biofluid from the body of the minor and the minor has agreed to the removal; and

(d) the minor is not capable of understanding the nature and effect of the removal of the organ, tissue cell or biofluid and the nature of transplantation.

Form I
Schedule II

(11) The certification referred to in subsection (10) shall be in the manner set out in Form I of Schedule II.

Authority to remove organ, tissue, cell or biofluid under section 28.

29. The consent given by the parent or guardian, the approval of the committee under section 28(1) and the certification given under section 28(10) shall be sufficient authority for a medical practitioner who is a surgeon qualified to remove the regenerative organ, tissue cell

or biofluid from the body of the minor, unless the consent or approval has been revoked under section 28(8) at any time prior to the removal.

Agency to record every removal and transplantation from minor.

30. The Independent Assessment Committee shall notify the Agency of every certification, removal and transplantation or other purpose for a removal under this Part and the Agency shall record every removal and transplantation or other purpose which record shall form part of the record of the Donor Registry.

PART VII
HUMAN ORGAN OR TISSUE PAIRED DONATION

Human organ or tissue paired donation.

31. Human organs or tissues may be donated or received under the following circumstances –

(a) an individual (referred to in this section as the 'first donor') desires to make a living donation of an organ or a tissue specifically to a particular patient (referred to in this section as the 'first patient'), but the donor is biologically incompatible as a donor for the patient;

(b) a second individual (referred to in this section as the 'second donor') desires to make a living donation of an organ, a tissue specifically to a second particular patient (referred to in this section as the 'second patient'), but the donor is biologically incompatible as a donor for the patient;

(c) subject to paragraph (d), the first donor is biologically compatible as a donor of an organ or a tissue for the second patient, and the second donor is biologically compatible as a donor of an organ or a tissue for the first patient;

(d) if there is any additional donor-patient pair as described in paragraph (a) or (b), each donor in the group of donor-patient pairs is biologically compatible as a donor of an organ or a tissue for a patient in the group;

(e) all donors and patients in the group of donor-patient pairs (whether two pairs or more than two pairs) enter into a single agreement to donate and receive the organs or tissues, respectively, according to such biological compatibility in the group;

(f) other than as described in paragraph (e), no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the organs or tissues referred to in the paragraph.

Agency to record every agreement, removal and transplantation.

32. The Agency shall be notified of every agreement, removal and transplantation under this Part and the Agency shall record every agreement, removal and transplantation which record shall form part of the record of the Donor Registry.

PART VIII
BLOOD DONATION AND TRANSFUSION

National Blood Transfusion Services Department.

33. (1) The National Blood Transfusion Services Department of the Ministry of Health shall be responsible for the donation and transfusion of blood and all other functions in relation to blood under this Act.

(2) The National Blood Transfusion Services Department shall continue as constituted at the commencement of this Act with the Director as head of the Department and staff of the Department

(3) The Department shall consist of such number of staff as may be necessary for the performance of the functions of the Department.

(4) The Department may have offices in and extend its services to other parts of the country.

Functions of the Department.

34. (1) In addition to the functions being performed by the Department at the commencement of this Act, the functions of the Department shall be to –

(a) facilitate, coordinate and manage the donation process for blood for transfusion;

(b) plan, promote, co-ordinate and support activities relating to the donation of blood for transfusion, and activities relating to education, scientific research or scientific experimental procedures in connection with the donation of blood;

(c) facilitate, coordinate and manage the procurement, storage, preservation, distribution and delivery of blood;

(d) make reasonable efforts to ensure that donors and recipients and their nearest relatives have appropriate information and opportunities to consider whether to consent to the donation or transfusion of blood and facilitate the provision of that information;

(e) provide education to the public and to the health care community about matters relating to the donation and use of blood and to facilitate the provision of such education by others;

(f) publish information relating to the donation and transfusion of blood;

(g) to implement quality assurance programmes, including a donor and recipient quality assurance programme, with regular audits for ongoing monitoring and evaluation of the programme;

(h) advise the Minister on matters relating to the donation, storage, preservation and transfusion of blood; and

(i) perform any other function in relation to the donation, storage, preservation of or transfusion of blood that is entrusted to it by the Minister.

(2) The Minister may give to the Department any general or special policy directives with respect to the carrying out of its functions under this Act as the Minister considers necessary or expedient and the Department shall give effect to the directives.

System of registration.

35. (1) The Department shall establish a system to keep records of persons who are interested in donating blood and persons who are in need of transfusion of blood and the Department may facilitate the registration of consents to donations in-person and on-line.

(2) Any consent given under this Part may be revoked at any time before it is acted upon.

(3) The Director shall establish a system to fairly and equitably allocate available blood.

Report.

36. The Director of the Department shall report on the performance of the Department in writing annually to the Minister.

Consent by adult to removal of blood.

37. (1) A person may consent to the removal of blood from the person's body for transfusion to another person or for use of the blood for medical education, therapeutic purposes or scientific research purposes where the person –

(a) is an adult; and

(b) is of sound mind.

(2) An adult may register the adult's consent to donate blood at the Department.

Removal of blood from minor.

38. (1) The parent or guardian of a minor may consent to the removal of blood from the body of the minor for transfusion to another person or for use of the blood for medical education, therapeutic purposes or scientific research purposes if –

(a) a medical practitioner advises that the removal will not be prejudicial to the health of the minor; and

(b) the minor, to the extent possible considering the minor's age, agrees in writing to the removal without coercion or inducement and understands the nature and consequences of the removal.

(2) Consent under this section shall be registered at the Department.

Consent to be sufficient authority for removal of blood.

39. Consent under section 37 or section 38, and the agreement under section 38(1)(b), shall be sufficient authority for the removal of blood from the body of the person who has given the consent or from the body of the person on whose behalf consent was given.

Department to record every removal and transfusion.

40. The Department shall record every removal and transfusion of blood or other purpose for the removal under this Part which record shall from part of the record of the Department.

PART IX
DONATION OF ORGAN, TISSUE, CELL AND BIOFLUID AFTER DEATH

Deceased donor.

41. (1) A person's organs, tissues, cells or biofluids may be donated after the person's death for the purposes set out in subsection (2) if a consent is given –

(a) where that person is an adult, by the adult –

(i) when the adult is alive, by any of the ways provided under section 42 (at the Donor Registry) or 43 (by will, statement or other form); or

(ii) when the adult is alive and capable of doing so, under section 44(1)(b) and (5) (when death is imminent); or

(b) by the nearest relative of the person, to the designated officer under section 44, in the case of a minor or an adult who is incapable of giving consent by virtue of the injury or disease.

(2) Where consent is given in accordance with subsection (1), a deceased person's organs, tissues, cells or biofluids may be donated after the person's death for –

(a) the transplantation of any of the organs, tissues, cells or biofluids to the body of a living person; or

(b) the use of the organs, tissues, cells or biofluids for other therapeutic purposes or for medical education or scientific research purposes.

Consent to donation at the Donor Registry.

42. (1) An adult may give consent to the donation of the adult's organs, tissues, cells or biofluids after the adult's death by registering the consent at the Donor Registry, in-person or using the online facility provided by the Registry.

(2) The Registry shall issue a donor-card to the in-person donor and the online donor may access a printable donor-card available online or attend the Registry to obtain a donor-card.

(3) If the donor is physically unable to sign a registration form, the form may be signed by another individual at the direction of the donor, in the presence of the donor and witnessed by at least two adults, at least one of whom is a disinterested witness, who have signed at the request of the donor.

(4) A donor may amend or revoke a consent given under this section, in-person, at the Registry, orally or in writing and, where given orally, shall be confirmed in writing as soon as possible; or using the online facility provided by the Registry.

Consent to donation in a will or statement, or by any other form.

43. (1) An adult may give consent to the donation of the adult's organs, tissues, cells or biofluids after the adult's death in a will, which consent may be amended or revoked in the manner provided for amendment or revocation of wills.

(2) A consent to the donation of an organ, tissue, cell or biofluid given by an adult in a will takes effect upon the donor's death

whether or not the will is probated, and invalidation of the will after the donor's death does not invalidate the consent to the donation.

(3) Consent to the donation of an adult's organs, tissues, cells or biofluids after the adult's death may be given by the adult in a signed statement by the adult donor, witnessed by at least two adults, at least one of whom is a disinterested witness, who have signed at the request of the donor.

(4) Consent to the donation of an adult's organs, tissues, cells or biofluids after the adult's death may be given by an adult during terminal illness or injury of the adult, by any form of communication addressed to at least two adults, at least one of whom is a disinterested witness.

(5) A donor may amend or revoke a consent given under subsection (3) or (4), orally or in writing and, where given orally, shall be confirmed in writing as soon as possible.

Mandatory referral by designated hospital to Agency in respect of a consent.

44. (1) A designated hospital shall notify the Agency as soon as possible when –

(a) a patient at the hospital has died;

(b) a medical practitioner is of the opinion that the death of a patient at the hospital is imminent by reason of injury or disease; or

(c) a dead body has been brought into the hospital.

(2) The Agency may establish requirements which the notice by the designated hospital is required to satisfy and the designated hospital shall give a notice in accordance with the requirements.

(3) The notice shall include the information as to whether the patient can be a prospective donor, on the medical and social history of the patient or person's whose dead body was brought into the hospital, to assist in determining the medical suitability of the organs, tissues, cells or biofluid for donation for any of the reasons set out in section 41(2), and any other information required by the Agency.

(4) When the designated hospital gives notice to the Agency, the Agency shall ascertain whether the patient is registered as a donor in the Donor Registry, and if the patient is not so registered, the Agency in consultation with the designated hospital shall determine whether the hospital is required to contact the patient or the patient's nearest relative, if the nearest relative has not already contacted the hospital on the relative's own motion, concerning consent for organ, tissue, cell or biofluid donation including whether there is consent by will, statement or any other form known to the nearest relative.

(5) If the Agency advises the designated hospital that it is required to contact the patient or the patient's nearest relative, the hospital shall make reasonable efforts to ensure that –

(a) the patient or the patient's nearest relative is contacted by a designated officer to determine whether the patient or nearest relative consents to the donation of the organs, tissues, cells or biofluids for any of the reasons set out in section 41(2); and

(b) the contact is made in a manner that meets the requirements of the Agency.

(6) The designated officer who contacts the patient or the patient's nearest relative shall inform the patient or nearest relative of the information required by the Agency and shall make reasonable

efforts to obtain from the patient or nearest relative the information required by the Agency.

(7) Where a consent is made known to the designated officer, the designated officer shall inform the Agency of the indication of the consent and the circumstances under which it was given, but if the patient recovers consciousness the designated person shall so inform the Agency.

(8) The designated hospital shall perform screening, tests and any other necessary procedures to determine medical suitability of the organs, tissues, cells or biofluids for any of the reasons set out in section 41(2).

Authority to remove organ, tissue, cell or biofluid donated under this Part.

45. (1) The designated officer, may authorise the removal of an organ, tissue, cell or biofluid donated under this Part –

(a) for the transplantation of the organ, tissue, cell or biofluid to the body of a living person; or

(b) for the use of organ, tissue, cell or biofluid for other therapeutic purposes or for medical education or scientific research purposes.

Form J
Schedule II

(2) The authorisation, referred to in subsection (1), shall be in the manner set out in Form J of Schedule II and given only where, after consultation with the Agency and making inquiries as are reasonable in the circumstances, the designated officer –

(a) is satisfied that the deceased donor during the donor's lifetime expressed the wish for, or consented to, in any of the ways provided for in section 42, 43 or 44(1)(b) and (5), the donation of the person's organs, tissues, cells or biofluids after the deceased person's death,

for the purpose or a use referred to in subsection (1) and had not withdrawn the wish or revoked the consent; or

(b) (i) has no reason to believe that the deceased donor has expressed an objection to the donation of the donor's organ, tissue, cell or biofluid after the donor's death for the purpose or a use referred to in subsection (1); and

(ii) is satisfied that the nearest relative of the deceased donor consents to the donation of the organ, tissue, cell or biofluid of the donor for the purpose or a use referred to in subsection (1).

(3) The authorisation of the designated officer to remove the organ, tissue, cell or biofluid under subsection (1) shall be restricted by the expressed terms of the wishes or consent of the deceased donor, or the consent of the nearest relative of the deceased donor, as the case may be, as to the organ, tissue, cell or biofluid which may be removed and the purpose or use of the organ, tissue, cell or biofluid.

(4) Where the nearest relative of a person made it known to the designated officer at any time when the person is unconscious and before death that the nearest relative consents to the donation, after death of the person, of the organs, tissues, cells or biofluids of the person for the purpose or a use referred to in subsection (1), the designated person shall not act on the indication if the person recovers consciousness and shall so inform the Agency.

(5) The designated officer shall not give the authorisation under subsection (1) nor the nearest relative give a consent under this Part

where the officer or the nearest relative has personal knowledge that –

(a) a person in a higher priority class is readily available to provide consent;

(b) a person in the same class would refuse to give a consent; or

(c) the donor would have refused to give consent.

(6) A person who contravenes subsection (5) commits an offence and is liable on summary conviction to a fine of five million dollars and to imprisonment for five years.

Respect for corpse and concern for the feelings of the family.

46. (1) The removal of the organs, tissues, cells or biofluids and the closing of the body shall be done with respect for the corpse and concern for the feelings of the family.

(2) Laying out shall be done as soon as possible so that the family can greet the deceased as soon as possible.

Removal or authority to remove organ, tissue, cell or biofluid only after death.

47. A person shall not remove or authorise the removal of the organ, tissue, cell or biofluid from the body of the donor under this Part until death has occurred in accordance with section 48.

When death occurs.

48. (1) A person is considered dead when there has occurred –

(a) irreversible cessation of circulatory and respiratory functions of that person; or

(b) irreversible cessation of all functions of the entire brain, including the brain stem of that person.

(2) Death shall be determined by two medical practitioners on the staff of the designated hospital, except, that –

(a) a medical practitioner who has a familial or professional relationship with the proposed recipient shall not take any part in the determination of the fact of the death of the donor of the organ, tissue, cell or fluid;

(b) a medical practitioner who had taken part in the determination of death under paragraph (a) shall not participate in the transplantation of the organ, tissue, cell or fluid to the recipient; and

(c) where the organ, tissue, cell or fluid is to be removed to be used for therapeutic purposes, medical education or scientific research, a medical practitioner who is due to remove or transplant the organ, tissue, cell or fluid shall not determine the occurrence of death nor be a part of any team or process by whom or which death is determined.

(3) The Minister shall, by regulations, prescribe the criteria for determining the irreversible cessation of all functions of the entire brain, including the brain stem of a person referred to in subsection (1).

Concurrence of coroner.

49. (1) Where a designated officer has reason to believe that the circumstances applicable to the death of a person are such that a coroner has jurisdiction to hold an inquiry or inquest into the manner and cause of death of the person under the provisions of the Coroners Act, the designated officer shall not, under section 45, authorise the removal of an organ, tissue, cell or fluid from the body of the deceased

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donor for any purpose or use referred to in that section 45(1) unless the coroner has stated that the coroner has no objection to the removal.

(2) A coroner may give a statement after the death of a person that the coroner has no objection to the removal of any organ, tissue, cell or fluid from the body of the person and, in that event, subsection (1) does not apply to or in relation to the removal of the organ, tissue, cell or fluid from the body of the person for any purpose or use referred to in section 45(1).

(3) A statement by a coroner under this section may be given orally or in writing and, where given orally, shall be confirmed in writing and shall be subject to the conditions as are specified in the statement.

Agency to record every removal and transplantation after death.

50. The designated officer shall notify the Agency of every donation, removal, transplantation and other purpose for removal under this Part and the Agency shall record every donation, removal, transplantation and other purpose for removal, which shall form part of the record of the Donor Registry.

PART X
PROHIBITION ON TRADING IN HUMAN ORGAN, TISSUE, CELL AND BIOFLUID

Trade in organ, tissue, cell and biofluid.

51. (1) A person shall not remove or cause to be removed any organ, tissue, cell, or blood or other biofluid from the body of a donor for the purposes of trading that organ, tissue, cell, or blood or other biofluid for valuable consideration.

(2) Any contract or arrangement is void under which a person agrees, for valuable consideration, whether given or to be given to the person or to another person –

(a) to the sale or supply of any organ, tissue, cell, or blood or other biofluid from the person's body or from the body of another person; or

(b) to the sale or supply of blood whether before or after the person's death or the death of the other person.

(3) A person who contravenes subsection (1) or enters into a contract or arrangement of the kind referred to in subsection (2), commits an offence and is liable on conviction to a fine of five million dollars and to imprisonment for five years.

Advertisement relating to buying or selling of organ, tissue, cell or biofluid prohibited.

52. (1) A person shall not advertise, issue or cause to be issued any advertisement relating to the buying or selling of any organ, tissue, cell, or blood or other biofluid from the body of a person.

(2) In this section, "advertisement" includes advertising –

(a) in a publication;

(b) by the display of any notice or signboard;

(c) by means of any catalogue, price list, letter (whether circular or addressed to a particular person) or other documents;

(d) by words inscribed on any article;

(e) by the exhibition of a photograph or a cinematograph film;

(f) by way of sound or audio recording or broadcasting by a television, computer system or telephone; or

(g) in any other way.

(3) Any reference to the issue of an advertisement shall be construed according to subsection (2).

(4) Any person who contravenes or fails to comply with subsection (1) or (2) commits an offence and is liable on summary conviction to a fine of five million dollars and to imprisonment for five years.

PART XI
MISCELLANEOUS

Exemption from liability.

53. No personal liability shall attach to any medical practitioner or other person given any function under this Act, for anything done, permitted or omitted to be done in good faith in the exercise of any authority under this Act, or done by reason of, or as a result of a consent, agreement or authority given or purported to have been given under this Act.

Offences in relation to removal of organ, tissue, cell or biofluid.

54. (1) A person shall not remove or cause to be removed any organ, tissue, cell, blood or biofluid from the body of a deceased person except in accordance with this Act.

(2) A person shall not remove or cause to be removed any organ, tissue, cell, blood or biofluid from the body of a living person, for any purpose except in accordance with this Act.

(3) Any person who contravenes or fails to comply with subsection (1) or (2) commits an offence and is liable on summary conviction to a fine of five million dollars and to imprisonment for five years.

Other offences.

55. (1) A person commits an offence who fails to comply with the requirements, which by this Act required compliance before certification.

(2) A person commits an offence who offers, gives or receives any reward or benefit for any organ, tissue, cell, blood or biofluid for use in transplantation, therapeutic purposes, medical education or scientific research.

(3) A person commits an offence who offers, gives or receives any reward or benefit for any blood for use in transfusion, therapeutic purposes, medical education or scientific research.

(4) A person commits an offence who uses, procures, transfers or processes any organ, tissue, cell or biofluid for transplantation, or blood for transfusion except in accordance with this Act or regulations made under it.

(5) A person shall not perform a transplantation unless the person is a registered medical practitioner who is qualified to perform the transplantation and the transplantation is performed in a designated hospital.

(6) A person who commits an offence under this section is liable on summary conviction to a fine of five million dollars and to imprisonment for five years.

University or laboratory to use organ, tissue, cell or biofluid for education or research.

56. (1) Only a university with a medical, dental or related health programme or a laboratory designated by the Minister by Order may use any organ, tissue, cell, blood or biofluid donated under this Act for medical education or scientific research purposes.

(2) A person commits an offence who contravenes subsection (1) and is liable on summary conviction to a fine of five million dollars and to imprisonment for five years.

Disclosure of information.

57. (1) A person shall not disclose or give to any other person, including a donor or recipient, any information or document which may –

(a) reveal the identity of the donor to the recipient and the family of the recipient or the identity of the recipient to the donor and the family of the donor; and

(b) make public the identity of a person –

(i) from whose body any organ, tissue, cell or biofluid has been removed for the purpose of transplantation;

(ii) from whose body any blood has been removed for the purpose of transfusion;

(iii) with respect to whom a consent or authority has been given under this Act;

(iv) into whose body any organ, tissue, cell or biofluid has been, or is being transplanted; or

(v) into whose body any blood has been, or is being transfused.

(2) Subsection (1), shall not apply to or in relation to any information disclosed –

(a) in pursuance of an order of a Court;

(b) for the purposes of continued care or *bona fide* medical education, therapeutic purposes or scientific research; or

(c) with the consent of the persons or both the donor and recipient, to whom the information relates.

(3) Any person who contravenes or fails to comply with subsection (1), commits an offence and is liable on summary conviction to a fine of five million dollars and to imprisonment for five years.

Regulations.

58. (1) The Minister may make Regulations for matters that are required or permitted by this Act to be prescribed and for matters that are necessary or convenient for carrying out or giving effect to this Act, and in particular –

(a) the screening and testing of organs, tissues, cells, blood or biofluid before and after removal from a body;

(b) the transportation, storage and handling of organs, tissues, cells, blood and biofluids;

(c) the conditions subject to which transplantation of organs, tissues, cells and biofluids shall be carried out;

(d) the criteria for determining the permanent cessation of all functions of the entire brain, including the brain stem of a person;

(e) the allocation of organs, tissues, cells, blood and biofluids;

(f) the use of organs, tissues, cells, blood and biofluids for medical education, therapeutic purposes and scientific research purposes; and

(g) the establishment of ethical standards to be referred to for guidance in the application of this Act.

(2) Regulations made under this Act may provide for offences for breach of the regulations, and for penalties not exceeding five million dollars and for imprisonment not exceeding five years.

SCHEDULE I

s. 4

CONSTITUTION AND RELATED MATTERS OF THE HUMAN ORGAN AND TISSUE TRANSPLANT AGENCY

Constitution of the Agency.

1. The Agency shall comprise the following members –

(a) a Chairperson appointed by the Minister;

(b) the Chief Executive Officer, appointed under paragraph 6;

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(c) the Chief Medical Officer, appointed under the Ministry of Health Act;

(d) the Director of Medical Services of each designated hospital;

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(e) the Chairperson of the Medical Council, appointed under the Medical Practitioners Act;

(f) two specialist medical practitioners, one a pediatrician and the other a general surgeon, appointed by the Minister; and

(g) two persons, one of whom has expertise in area of hematology, and the other, a blood bank specialist, appointed by the Minister.

Names of members to be published.

2. The names of the members of the Agency as first constituted and every change in the membership shall be published in the *Gazette*.

Tenure of office.

3. (1) The terms and conditions of appointment of the members other than the *ex officio* members shall be such as the Minister may determine, subject to subparagraph (2).

(2) Appointment of members other than the *ex officio* members shall be for a term not exceeding three years and members may be re-appointed for such further period as may be determined by the Minister.

(3) A member, other than an *ex officio* member may resign on giving one month's notice in writing to the Minister.

(4) The office of a member shall become vacant if –

(a) the member is absent without reasonable excuse from three consecutive meetings of the Agency of which the member has had notice; or

(b) the member is for any reason unable or unfit to carry out the functions of the office of member.

Co-opt other persons to participate in meetings.

4. (1) The Agency may invite any person whose presence is in its opinion desirable to attend and participate in the deliberations of a meeting of the Agency but such person shall have no vote.

Remuneration.

5. The Agency shall pay a member of the Agency such remuneration and allowances as the Minister may determine.

Chief Executive Officer.

6. (1) There shall be a Chief Executive Officer of the Agency who shall be appointed by the Minister on such terms and conditions as shall be specified in the instrument of appointment.

(2) The Chief Executive Officer, subject to the general supervision and control of the Agency, shall be responsible for the –

(a) day-to-day operation of the Agency;

(b) management of the funds and affairs and activities of the Agency; and

(c) administration, organisation and control of the staff of the Agency.

Secretary and other staff of the Agency.

7. (1) There shall be a Secretary to the Agency who shall be appointed by the Agency.

(2) The Secretary shall be responsible for the administration of the day-to-day affairs of the Agency under the general supervision of the Chief Executive Officer.

(3) The Chief Executive Officer, shall subject to the approval of the Agency, appoint other staff, including persons as transplant coordinators, as may be required by the Agency for the efficient discharge of its functions.

(4) Terms and conditions of all persons employed by the Agency shall be determined by the Agency.

(5) The Agency shall provide training to staff to enable them to perform their duties efficiently.

Proceedings and quorum.

8. (1) The Agency shall meet at any time as may be necessary or expedient for the transaction of business and its meetings shall be held at the place and time and on the days as the Agency may determine.

(2) A quorum shall be four members including the Chairperson and in the Chairperson's absence a member elected by the other members present shall preside over the meeting.

(3) Every *ex officio* member may vote.

(4) A person who has had any association with a donor or a recipient or proposed recipient that might influence the person's judgment may attend but shall not participate in the deliberation nor vote at a meeting concerning a decision to be made on the donor or recipient.

Finance.

9. (1) The Minister may out of money provided by Parliament make payments to the Agency of such amounts, at such times and on such conditions (if any) as the Minister considers appropriate.

(2) Funds of the Agency shall consist of –

(a) such amounts as may be appropriated by Parliament for the purpose of the Agency; and

(b) any grants, gifts, donations or other endowments given to the Agency and which shall be disclosed to the National Assembly and made public before use.

(3) The funds of the Agency shall be applied in meeting the expenses of the Agency including the remuneration and allowances of the Chairperson and other members and staff.

Annual estimates.

10. The Agency shall before the date specified by the Minister in any year submit to the Minister for his approval estimates of revenue and expenditure of the Agency for the ensuing financial year.

Accounts and audit.

11. (1) The Agency shall keep proper accounts and proper records in relation to its accounts.

(2) The Auditor-General shall audit the accounts of the Agency annually.

(3) The report of the auditor on the audit of accounts prepared under this section shall be transmitted to the Minister responsible for finance who shall lay the report before the National Assembly on or before 31st December of the following year.

Seal of the Agency.

12. The application of the seal of the Agency shall be authenticated by the signature of the Chairperson or any member of the Agency in the Chairperson's absence who has been authorised for the purpose by the Agency, and the secretary to the Agency, whether generally or specially.

SCHEDULE II

FORM A

section 15(4)

DONOR-CARD

HUMAN ORGAN OR TISSUE TRANSPLANT AGENCY

Name:

Age:

Blood Group:

After my death:

(A) Any organ, tissue, cell, cell explant, cell line, biofluid of my body or (B) [name of specific organ, tissue, cell or biofluid]

May be used for (A) transplantation to or treatment of others or (B) therapeutic use, medical education or scientific research

.....Date:.....

Signature/thumb print

In emergency, contact:.....

Tel:.....or

the Human Organ or Tissue Transplant Agency or a designated hospital.

Keep this card with you at all times. Please inform your relatives/family about your wish/consent.

FORM B section 19(6)

REGENERATIVE ORGAN, TISSUE, CELL OR BIOFLUID REMOVAL DESIGNATED OFFICER CERTIFICATE

I, ... *(Name of designated officer)* certify that ....., *(Name of donor)* being an adult of sound mind, and who has been given relevant medical advice by a medical practitioner, with which advice he/she agrees, has consented in writing to the removal from his/her body of the following regenerative organ, tissue, cell or biofluid for the purpose of –

(a) the transplantation of the organ, tissue, cell or biofluid to the body of another living person;

(b) the transplantation of any substance derived from any scientific procedure involving the organ, tissue, cell or biofluid, into the same living body from which it was removed or another living body;

(c) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body from which it was removed or another living body; or

(d) therapeutic/medical education/scientific research purposes:

.....

.....

I further certify that I have explained to ..... *(Name of donor)* the implications of the removal of the regenerative organ, tissue, cell or biofluid from his/her body and I am of the opinion that he/she understood the implications of the removal.

Date..... .....

Signature of designated officer

FORM C section 21(6)

NON-REGENERATIVE ORGAN, TISSUE, CELL OR BIOFLUID REMOVAL DESIGNATED OFFICER CERTIFICATE

I, ... *(Name of designated officer)* certify that ..... *(Name of donor)* being an adult of sound mind, and who has been given relevant medical advice by a medical practitioner, with which advice he/she agrees, has consented in writing to the removal from his/her body of the following non-regenerative organ, tissue, cell or biofluid for the purpose of –

(a) the transplantation of the organ, tissue, cell or biofluid to the body of another living person;

(b) the transplantation of any substance derived from any scientific procedure involving the organ, tissue, cell or biofluid into the same living body from which it was removed or another living body;

(c) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body from which it was removed or another living body; or

(d) therapeutic/medical education/scientific research purposes:

.....

.....

I further certify that I have explained to..... (Name of donor) the implications of the removal of the non-regenerative organ, tissue, cell or biofluid from his/her body and I am of the opinion that he/she understood the implications of the removal.

Date.....

.....

Signature of designated officer

FORM D section 26(7)

REMOVAL OF REGENERATIVE ORGAN, TISSUE, CELL OR BIOFLUID FROM MINOR WHO UNDERSTANDS

CONSENT FORM FOR PARENT/ GUARDIAN

I, ... parent/guardian of ..... *(Name of donor)* (a minor), consent to the removal of the undermentioned regenerative organ, tissue, cell or biofluid from his/her body for the purpose of:

(a) transplantation to the body of..... *(name of the natural brother/sister/parent of the minor)*; or

(b) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body of .....*(name of the minor from whom it was removed)* or ..... *(name of the natural brother/sister/parent of the minor)*; or

(c) the transplantation of any substance derived from any scientific procedure involving the regenerative organ, tissue, cell or biofluid, into the same living body of.....*(name of the minor from whom it was removed)* or.....*(name of the natural brother/sister/parent of the minor)*.

.....

.....

I certify that:

I have obtained advice from a medical practitioner, other than the practitioner due to transplant the organ, tissue, cell or biofluid, regarding the nature and effect of the removal of the organ, tissue, cell or biofluid and the nature of the transplantation/ regenerative treatment/substance to be transplanted;

..... *(Name of donor)* has the mental capacity to understand the nature and effect of the removal and the nature of the transplantation / regenerative treatment/substance to be transplanted.

..... *(Name of donor)* has consented to removal of the regenerative organ, tissue, cell or biofluid for the purpose of:

(a) transplantation to the body of..... *(name of the natural brother/sister/parent of the minor)*; or

(b) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body of ……*(name of the minor from whom it was removed)* or ..... *(name of the natural brother/sister/parent of the minor)*; or

(c) the transplantation of any substance derived from any scientific procedure involving the regenerative organ, tissue, cell or biofluid, into the same living body of……*(name of the minor from whom it was removed) or*……*(name of the natural brother/sister/parent of the minor)*.

Date ....

Signature of parent/guardian

FORM E section 26(7)

REMOVAL OF REGENERATIVE ORGAN, TISSUE, CELL OR BIOFLUID FROM MINOR WHO UNDERSTANDS

CONSENT FORM FOR MINOR

I, ... *(Name of donor)* (a minor), voluntarily consent to the removal of the undermentioned regenerative organ, tissue, cell or biofluid from my body for the purpose of:

(a) transplantation to the body of..... *(name of the natural brother/sister/parent of the minor)*; or

(b) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body of .....*(name of the minor from whom it was removed)* or ..... *(name of the natural brother/sister/parent of the minor)*; or

(c) the transplantation of any substance derived from any scientific procedure involving the regenerative organ, tissue, cell or biofluid, into the same living body of.....*(name of the minor from whom it was removed)* or.....*(name of the natural brother/sister/parent of the minor)*.

.....

.....

I certify that:

I have obtained advice from a medical practitioner, other than the practitioner due to transplant the organ, tissue, cell or biofluid regarding the nature and effect of the removal of the organ, tissue, cell or biofluid and the nature of the transplantation/ regenerative treatment/substance to be transplanted;

I, ... *(Name of donor) (a minor)* have the mental capacity to understand the nature and effect of the removal and the nature of the transplantation/regenerative treatment/substance to be transplanted.

I, ... *(Name of donor)* have agreed to removal of the regenerative organ, tissue, cell or biofluid for the purpose of

(a) transplantation to the body of..... *(name of the natural brother/sister/parent of the minor)*; or

(b) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body of ……*(name of the minor from whom it was removed)* or ..... *(name of the natural brother/sister/parent of the minor)*; or

(c) the transplantation of any substance derived from any scientific procedure involving the regenerative organ, tissue, cell or biofluid, into the same living body of.....*(name of the minor from whom it was removed)* or……*(name of the natural brother/sister/parent of the minor)*.

Date ....

Signature of donor (a minor)

FORM F section 26(11)

REMOVAL OF REGENERATIVE ORGAN, TISSUE, CELL OR BIOFLUID FROM MINOR WHO UNDERSTANDS

INDEPENDENT ASSESSMENT COMMITTEE CERTIFICATE

The Independent Assessment Committee certifies that..... parent/guardian of ....., a minor, has consented to the removal of the undermentioned regenerative organ, tissue, cell or biofluid from the body of the minor for the purpose of:

(a) transplantation to the body of..... *(name of the natural brother/sister/parent of the minor)*; or

(b) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body of .....*(name of the minor from whom it was removed)* or ..... *(name of the natural brother/sister/parent of the minor)*; or

(c) the transplantation of any substance derived from any scientific procedure involving the regenerative organ, tissue, cell or biofluid, into the same living body of.....*(name of the minor from whom it was removed)* or.....*(name of the natural brother/sister/parent of the minor):*

.....

.....

The Independent Assessment Committee further certifies that:

- the parent/guardian of the minor has obtained medical advice from a medical practitioner, other than the practitioner due to transplant the organ, tissue, cell or biofluid, regarding the nature and effect of the removal of the organ, tissue, cell or biofluid, and the nature of the transplantation/regenerative treatment/substance to be transplanted.
- the minor has the mental capacity to understand the nature and effect of the removal and the nature of the transplantation /regenerative treatment/substance to be transplanted, and has agreed to the removal of the regenerative organ, tissue, cell or biofluid for the purpose of:

(a) transplantation to the body of..... [name of the natural brother/sister/parent of the minor]; or

(b) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body of .....*(name of the minor from whom it was removed)* or ..... *(name of the natural brother/sister/parent of the minor);* or

(c) the transplantation of any substance derived from any scientific procedure involving the regenerative organ, tissue, cell or biofluid, into the same living body of.....*(name of the minor from whom it was removed)* or.....*(name of the natural brother/sister/parent of the minor).*

- The Independent Assessment Committee explained to the parent/guardian and minor the implications of the removal of the regenerative organ, tissue, cell or biofluid from the body of the minor and the parent/ guardian and minor appeared to understand the implications of the removal.

Date .....

.....

.....

.....

Signatures of all the members of the Independent Assessment Committee

FORM G section 28(7)

REMOVAL OF REGENERATIVE ORGAN, TISSUE, CELL OR BIOFLUID FROM MINOR WHO DOES NOT UNDERSTAND

CONSENT FORM FOR PARENT/ GUARDIAN

I, ... parent/guardian of ..... *(Name of donor)* (a minor), consent to the removal of the undermentioned regenerative organ, tissue, cell or biofluid from his/her body for the purpose of:

(a) transplantation to the body of..... *(name of the natural brother/sister/parent of the minor)*; or

(b) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body of .....*(name of the minor from whom it was removed)* or ..... *(name of the natural brother/sister/parent of the minor);* or

(c) the transplantation of any substance derived from any scientific procedure involving the regenerative organ, tissue, cell or biofluid, into the same living body of.....*(name of the minor from whom it was removed)* or.....*(name of the natural brother/sister/parent of the minor).*

.....

.....

I certify that:

I have obtained advice from a medical practitioner, other than the practitioner due to transplant the organ, tissue, cell or biofluid regarding the nature and effect of the removal of the organ, tissue, cell or biofluid and the nature of the transplantation/regenerative treatment/substance to be transplanted.

..... *(Name of donor)* does not have the mental capacity to understand the nature and effect of the removal and the nature of the transplantation/regenerative treatment/substance to be transplanted. A medical practitioner, other than the medical practitioner due to transplant the organ, tissue, cell or biofluid has certified in writing that unless:

(a) the above-mentioned organ, tissue, cell or biofluid is transplanted; or (b) the regenerated organ, tissue, cell or biofluid transplanted or (c) the substance derived from scientific procedure involving the organ, tissue, cell or biofluid:

to the body of ..... *(Name of recipient)*, he/she (the recipient) would die.

Date .....

.....

Signature of parent/guardian

FORM H section 28(7)

REMOVAL OF REGENERATIVE ORGAN, TISSUE, CELL OR BIOFLUID FROM MINOR WHO DOES NOT UNDERSTAND

MEDICAL PRACTITIONERS CERTIFICATE

I, ... medical practitioner, hereby certify that unless the undermentioned organ, tissue, cell or biofluid which is the same organ or tissue specified in the consent of ..... parent/guardian of....., a minor:

(a) is transplanted; or (b) the regenerated organ, tissue, cell or biofluid is transplanted; or (c) the substance derived from scientific procedure involving the organ, tissue, cell or biofluid is transplanted:

to the body of ..... *(Name of recipient)*, he/she ..... *(Name of recipient)* the minor/ the natural brother/sister/mother/father of the minor would die.

I further certify that I will not participate in any of the medical procedures involved in transplantation of the organ, tissue, cell or biofluid/regenerated organ, tissue, cell or biofluid/ substance derived from scientific procedure involving the organ, tissue, cell or biofluid.

Date ....

Signature of medical practitioner

FORM I section 28(11)

REMOVAL OF REGENERATIVE ORGAN, TISSUE, CELL OR BIOFLUID FROM MINOR WHO DOES NOT UNDERSTAND

INDEPENDENT ASSESSMENT COMMITTEE CERTIFICATE

The Independent Assessment Committee certifies that..... parent/guardian of ....., a minor, has consented to the removal of the undermentioned regenerative organ, tissue, cell or biofluid from the body of the minor for the purpose of:

(a) transplantation to the body of..... *(name of the natural brother/sister/parent of the minor)*; or

(b) regenerative treatment or therapy of the organ, tissue, cell or biofluid and the transplantation of the regenerated organ, tissue, cell or biofluid into the same living body of .....*(name of the minor from whom it was removed)* or ..... *(name of the natural brother/sister/parent of the minor);* or

(c) the transplantation of any substance derived from any scientific procedure involving the regenerative organ, tissue, cell or biofluid, into the same living body of.....*(name of the minor from whom it was removed)* or.....*(name of the natural brother/sister/parent of the minor):*

.....

.....

The Independent Assessment Committee further certifies that:

- the parent/guardian of the minor has obtained medical advice from a medical practitioner, other than the practitioner due to transplant the organ, tissue, cell or biofluid, regarding the nature and effect of the removal of the organ, tissue, cell or biofluid, and the nature of the transplantation/regenerative treatment/substance to be transplanted.
- the minor does not have the mental capacity to understand the nature and effect of the removal and the nature of the transplantation /regenerative treatment/substance to be transplanted.
- a medical practitioner, other than the medical practitioner due to transplant the organ, tissue, cell or biofluid, has certified in writing that unless the organ, tissue, cell or biofluid which is the same organ,

tissue, cell or biofluid specified in the consent of ..... parent/guardian of....., a minor, is:

(a) transplanted; or (b) the regenerated organ, tissue, cell or biofluid transplanted; or (c) the substance derived from scientific procedure involving the organ, tissue, cell or biofluid is transplanted:

to the body of ..... *(Name of recipient)*, he/she ..... *(Name of recipient)* the minor/ the natural brother/sister/mother/father of the minor would die.

Date .....

.....

.....

.....

Signatures of all the Members of the Independent Assessment Committee

FORM J section 45(2)

AUTHORITY TO REMOVE ORGAN, TISSUE, CELL OR BIOFLUID AFTER DEATH

The Designated Officer hereby authorises the removal of the undermentioned organ, tissue, cell or biofluid from the body of ..... *(Name of donor)*, deceased, for transplantation to the body of a living person/use for therapeutic/medical education/scientific research purposes:

.....

.....

The Designated Officer certifies that the designated officer has consulted with the Human Organ and Tissue Transplant Agency and made enquiries as are reasonable in the circumstances and

(delete as appropriate):

the Designated Officer is satisfied that the deceased during his/her lifetime expressed the wish for, or consented, in the register of the National Donor and Transplant Registry/will/statement/[other form], to, the removal of organ, tissue, cell or biofluid from his/her body after death for any purpose or use referred to above and had not withdrawn the wish or revoked the consent;

OR

The Designated Officer has no reason to believe that the deceased had expressed an objection to the removal of organ, tissue, cell or biofluid from his/her body after death for any purpose or use referred to above and the Designated Officer is satisfied that the nearest relative of the deceased consents to the removal of organ or tissue from the body of the deceased for any such purpose or use.

Date .....

.....

Signature of designated officer

Passed by the National Assembly on the 24th January, 2022.

S.E. Isaacs,

Clerk of the National Assembly.

(BILL No. 19/2021)