SUBSIDIARY LEGISLATION 483.01

TISSUES AND CELLS (QUALITY AND SAFETY) REGULATIONS

10th November, 2006

LEGAL NOTICE 271 of 2006, as amended by Legal Notice 222 of 2014.

Citation and scope. *Amended by: L.N. 222 of 2014.*

1. (1) The title of these regulations is the Tissues and Cells (Quality and Safety) Regulations.

(2) The scope of these regulations is to transpose Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, and Directive 2006/17/EC of the European Parliament and of the Council of the 8th February 2006 as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

(3) The scope of these regulations is also to transpose Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells.

Interpretation. *Amended by: L.N. 222 of 2014.* Cap. 483.

2. In these regulations unless the context otherwise requires:

"the Act" means the Human Blood and Transplants Act;

"allogeneic use" means cells or tissues removed from one person and applied to another;

"autologous use" means cells or tissues removed from and applied in the same person;

"cells" means individual human cells or a collection of human cells when not bound by any form of connective tissue;

"Directive 2004/23/EC" means the Dirctive of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;

"Directive 2006/17/EC" means the Directive of the European Parliament and of the Council of the 8th February 2006 as regards certain technical requirements for the donation, procurement and testing of human tissues and cells as amended by Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells;

"direct use" means any procedure where cells are donated and used without any banking;

"distribution" means transportation and delivery of tissues or cells intended for human applications;

"donation" means donating human tissues or cells intended for

human applications;

"donor" means every human source, whether living or deceased, of human cells or tissues;

"human application" means the use of tissues or cells on or in a human recipient and extracorporal applications;

"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;

"partner donation" means the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship;

"preservation" means the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues;

"processing" means all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications;

"procurement" means a process by which tissue or cells are made available;

"procurement organisation" means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells and that may not be accredited, designated, authorised or licensed as a tissue establishment;

"quality system" means the organisational structure, defined responsibilities, procedures, processes, and resources for implementing quality management and includes all activities which contribute to quality, directly or indirectly;

"quarantine" means the status of retrieved tissue or cells, or tissue isolated physically or by other effective means, whilst awaiting a decision on their acceptance or rejection;

"reproductive cells" means all tissues and cells intended to be used for the purpose of assisted reproduction;

"serious adverse event" means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity;

"standard operating procedures" (SOPs) means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product;

"storage" means maintaining the product under appropriate controlled conditions until distribution;

"tissue" means all constituent parts of the human body formed by cells;

"tissue establishment" means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells;

"traceability" means the ability to locate and identify the tissue or cell during any step from procurement, through processing, testing and storage, to distribution to the recipient or disposal, which also implies the ability to identify the donor and the tissue establishment or the manufacturing facility receiving, processing or storing the tissue or cells, and the ability to identify any recipient at the medical facility or facilities applying the tissue or cells to any recipient< traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with those tissues or cells;

"validation" (or "qualification" in the case of equipment or environments) means establishing documented evidence that provides a high degree of assurance that a specific process, SOP, piece of equipment or environment will consistently produce a product meeting its predetermined specifications and quality attributes; a process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use.

Responsible person.
Amended by: L.N. 222 of 2014.

3. (1) A tissue and cell establishment, hereinafter referred to as "establishment", shall designate a person who shall be responsible for the following tasks:

(*a*) ensuring that human tissues and cells intended for human applications in the establishment for which that person is responsible are procured, tested, processed, stored and distributed in accordance with these regulations and with the laws in force in Malta;

(*b*) providing information to the competent authority or authorities as required in regulation 6;

(*c*) ensuring that appropriate control measures are in place within the tissue establishment and implementing the requirements of regulations 4, 5, 7, 8, 11, 12, 13, 14, 15 within the tissue establishment; and

(*d*) ensure that the Authority is notified of any serious adverse events and reactions and is provided with a report analysing the cause and the ensuing outcome.

(2) An establishment shall only designate a person as a responsible person if such person is in possession of:

(*a*) a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Authority; and

(*b*) at least two yearsí practical experience in the relevant fields.

(3) The responsible person may delegate any of the tasks specified in sub-regulation (1) to other persons who shall be qualified by training and experience to perform them.

(4) The establishments shall notify the Licensing Authority, hereinafter referred to as "the Authority" of the name of any persons to whom tasks have been delegated by the responsible person and the specific tasks which have been delegated to such persons.

(5) Where the responsible person or a person to whom tasks have been delegated is permanently or temporarily replaced, the establishment shall immediately provide the Authority with the name of the replacement, details of his qualifications and the date on which the replacement began his duties.

(6) If the Authority considers that the responsible person does not meet the requirements of sub-regulation (2), it may serve a notice to that effect on the establishment.

(7) If, within fourteen days of receiving a notice in accordance with sub-regulation (6), a establishment is not able to demonstrate to the reasonable satisfaction of the Authority that the responsible person does meet the requirements of sub-regulation (2), the establishment shall, without delay -

(*a*) relieve him of the duties of responsible person in respect of the establishment;

(*b*) appoint a new responsible person in his place; and

(*c*) notify the Authority that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed.

Duties of establishments. *Amended by: L.N. 222 of 2014.*

4. An establishment shall -

(*a*) ensure that the personnel directly involved in the procurement, processing, preservation, storage and distribution of tissues and cells are qualified to perform such tasks and are provided with timely, relevant and regularly updated training;

(*b*) ensure that all donations of human tissues and cells are subjected to tests in accordance with the requirements referred to in these regulations and any schedules and any amendments thereto and that the selection and acceptance of tissues and cells comply with the requirements referred to in these regulations and any schedules and any amendments thereto;

(*c*) ensure that human tissue and cells and associated documentation comply with the requirements referred to in these regulations and any schedules and any amendments thereto;

(*d*) verify and record the fact that the packaging of human tissue and cells received complies with the

requirements referred to in these regulations and any schedules and any amendments thereto;

(*e*) discard all tissues and cells that do not comply with those requirements;

(*f*) document the acceptance or rejection of received tissues or cells;

(*g*) ensure that human tissues and cells are correctly identified at all times by assigning an identifying code to each delivery or batch of tissues or cells in accordance with regulation 6;

(*h*) hold tissue and cells in quarantine until such time as the requirements relating to donor testing and information have been met in accordance with article 15 of the Act;

(*i*) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection;

(*j*) include in their standard operating procedures all processes that affect quality and safety and shall ensure that they are carried out under controlled conditions;

(*k*) ensure that the equipment used, the working environment and process design, validation and control conditions are in compliance with the requirements referred to in these regulations and any schedules and any amendments thereto;

(*l*) ensure that any modifications to the processes used in the preparation of tissues and cells shall also meet the criteria laid down in the preceeding paragraph;

(*m*) include in their standard operating procedures special provisions for the handling of tissues and cells to be discarded, in order to prevent the contamination of other tissues or cells, the processing environment or personnel;

(*n*) ensure that all procedures associated with the storage of tissues and cells are documented in the standard operating procedures and that the storage conditions comply with the requirements referred to in these regulations and any schedules and any amendments thereto;

(*o*) ensure that all storage processes are carried out under controlled conditions;

(*p*) establish and apply procedures for the control of packaging and storage areas, in order to prevent any situation arising that might adversely affect the functioning or integrity of tissues and cells;

(*q*) not to distribute processed tissues and cells until all the requirements laid down in these regulations and

any schedules and any amendments thereto have been met;

(*r*) have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored tissues and cells shall be transferred to other tissue establishment or establishments licensed by the Authority;

(*s*) ensure that labelling and documentation and packaging conform to the requirements set by these regulations and any schedules and any amendments thereto; and

(*t*) ensure that the quality of tissues and cells during distribution and that the distribution conditions comply with the requirements set by these regulations and any schedules and any amendments thereto.

Relations between tissue establishment and third parties. *Amended by: L.N. 222 of 2014.*

5. (1) Tissue establishments shall:

(*a*) establish written agreements with a third party each time an external activity takes place which influences the quality and safety of tissues and cells processed in cooperation with a third party, and in particular in the following circumstances:

(i) where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party;

(ii) where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution;

(iii) where a tissue establishment provides services to a tissue establishment which is not accredited;

(iv) where a tissue establishment distributes tissue or cells processed by third parties;

(*b*) evaluate and select third parties on the basis of their ability to meet the standards laid down in these regulations and any schedules and any amendments thereto;

(*c*) keep a complete list of the agreements referred to in paragraph (*a*) which they have established with third parties; and

(*d*) provide copies of agreements with third parties at the request of the competent authority or authorities.

(2) Agreements between tissue establishments and third parties shall specify the responsibilities of the third parties and detailed procedures.

Traceability. *Amended by: L.N. 222 of 2014.*

6. An establishment shall ensure that:

(*a*) all tissues and cells procured, processed, stored or distributed on their territory can be traced from the donor to the recipient and vice versa. This traceability shall also apply to all relevant data relating to products and materials coming into contact with these tissues

and cells;

(*b*) by means of a donor identification system a unique code is assigned to each donation and to each of the products associated with it;

(*c*) all tissues and cells are identified with a label that contains the information or references allowing a link to the information referred to in the schedules to these regulations and any amendments thereto; and

(*d*) the data necessary to ensure traceability at all stages is kept for a minimum of thirty years after clinical use. Data storage may also be in electronic form.

Keeping of records and reporting obligations. *Amended by: L.N. 222 of 2014.*

7. (1) Tissue establishments shall keep a record of their activities, including the types and quantities of tissues and, or cells procured, tested, preserved, processed, stored and distributed, or otherwise disposed of, and on the origin and destination of the tissues and cells intended for human applications, in accordance with the requirements referred to in these regulations and any schedules and any amendments thereto.

(2) Such establishments shall submit to the Authority an annual report on these activities which shall be publicly accessible.

Notification of serious adverse events and reactions.

8. An establishment shall:

(*a*) establish and maintain a system to report, investigate, register and transmit information about serious adverse events and reactions which may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells, as well as any serious adverse reaction observed during or after clinical application which may be linked to the quality and safety of tissues and cells;

(*b*) report any relevant information to establishments engaged in the donation, procurement, testing, processing, storage and distribution of human tissues and cells in order to facilitate traceability and ensure quality and safety control; and

(*c*) ensure that an accurate, rapid and verifiable procedure is in place which will enable such establishment to recall from distribution any product which may be related to an adverse event or reaction.

Consent. *Amended by: L.N. 222 of 2014.*

9. An establishment shall, in relation to the procurement of human tissues or cells:

(*a*) give all prospective donors of tissues or cells, their relatives or any other person granting consent on behalf of donors, information in accordance with guidelines and authorization requirements as established by the Authority;

(*b*) obtain from all persons who are willing to donate tissues or cells, their relatives or any other person

granting consent on behalf of donors, information in accordance with guidelines and authorization requirements established by the Authority;

(*c*) put and keep in place procedures for the evaluation of donors in accordance with the requirements set by these regulations and schedules and any amendments thereto;

(*d*) apply eligibility criteria for all donors of tissues and cells;

(*e*) maintain records of the results of donor evaluations and report to donors any relevant abnormal findings from the evaluations;

(*f*) ensure that:

(i) an examination of the donor, including an interview, is carried out before any donation of tissues or cells,

(ii) a qualified health professional is responsible for giving to and gathering from donors the information which is necessary to assess their eligibility to donate, and

(iii) on the basis of that information, a qualified health professional assesses the eligibility of all donors to donate;

(*g*) encourage voluntary and unpaid tissue and cell donations with a view to ensuring that tissues and cells are, in so far as possible, provided from such donations; and

(*h*) the tissues and cells are procured, packaged and transported in accordance with the requirements set by these regulations and any schedules and any amendments thereto.

Data protection and confidentiality. *Amended by: L.N. 222 of 2014.*

10. (1) An establishment shall ensure that all data, including genetic information, collated within the scope of the Act and any regulations made thereunder and to which third parties have access, have been rendered anonymous so that neither donors nor recipients remain identifiable.

(2) For that purpose, the establishment shall ensure that:

(*a*) data security measures are in place, as well as safeguards against any unauthorised data additions, deletions or modifications to donor files or deferral records, and transfer of information;

(*b*) procedures are in place to resolve data discrepancies;

(*c*) no unauthorised disclosure of information occurs, whilst guaranteeing the traceability of donations;

(*d*) the identity of any recipient is not disclosed to the donor or his family and vice versa, without prejudice to any legislation in force on the conditions for disclosure, notably in the case of gametes donation;

(*e*) the information which is collected for the purposes of these regulations is held securely so that it is -

(i) available for the purpose of, tracing donations;

(ii) not disclosed except in accordance with one or more of the requirements of sub-regulation (3).

(3) The requirements referred to under sub-regulation (2)(*e*)(ii) are that the disclosure:

(*a*) shall be in accordance with an order of a court, or as may otherwise be required by law;

(*b*) is made to an inspector appointed by the Authority.

(4) The responsible person of the establishment shall ensure that the results of the donor evaluation and testing procedures are documented and any major anomalies are reported to the Authority in accordance with the requirements referred to in Schedule I and any amendments thereto.

Quality management.

11. (1) Each tissue establishment shall put in place and update a quality system based on the principles of good practice.

(2) Such quality system shall include at least the following documentation:

(*a*) standard operating procedures,

(*b*) guidelines,

(*c*) training and reference manuals,

(*d*) reporting forms,

(*e*) donor records,

(*f*) information on the final destination of tissues or cells.

(3) The documentation referred to in sub-regualtion (2) shall be available for inspection by an authorised officer.

(4) Tissue establishments shall keep the data necessary to ensure traceability in accordance with regulation 4.

Requirements for the procurement of human tissues and cells.
Amended by: L.N. 222 of 2014.

12. (1) Procurement of human tissues and cells shall be carried out by persons who have successfully completed a training programme specified by a clinical team specialising in the tissues and cells to be procured or a tissue establishment authorised for procurement.

(2) The establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for donor selection, unless they are employed by the same organisation or establishment, specifying the procedures to be followed to assure compliance with the selection criteria for donors set out in Schedule II.

(3) The establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for tissue or cell procurement, unless they are employed by the same establishment or organisation, specifying any type of tissues and, or cells and, or test samples to be procured and the protocols to be followed.

(4) (*a*) There shall be standard operating procedures (SOPs) for the verification of:

(i) donor identity;

(ii) the details of donor or donor family consent or authorisation;

(iii) the assessment of the selection criteria for donors as detailed in regulation 13;

(iv) the assessment of the laboratory tests required for donors as detailed in regulation 14.

(*b*) There shall also be SOPs describing the procedures for procurement, packaging, labelling and transportation of the tissues and cells to the point of arrival at the tissue establishment or, in the case of direct distribution of tissues and cells, to the clinical team responsible for their application or, in the case of tissue or cell samples, to the laboratory for testing, in accordance with regulation 15.

(5) Procurement shall take place in appropriate facilities, following procedures that minimise bacterial or other contamination of procured tissues and cells, in accordance with regulation 15.

(6) Procurement materials and equipment shall be managed in accordance with the standards and specifications laid down in section 1.3 of Schedule V, and with due regard to relevant national and international regulation, standards and guidelines covering the sterilisation of medicines and medical devices. Qualified, sterile instruments and procurement devices shall be used for tissue and cell procurement.

(7) Procurement of tissues and cells from living donors shall take place in an environment that ensures their health, safety and privacy.

(8) Where appropriate, the staff and equipment necessary for body reconstruction of deceased donors shall be provided. Such reconstruction shall be completed effectively.

(9) The procedures for the procurement of tissues and cells shall be carried out in accordance with the requirements specified in regulation 15.

(10) A unique identifying code shall be allocated to the donor and to the donated tissues and cells, during procurement or at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material. The coded data shall be entered in a register maintained for the purpose.

(11) Donor documentation shall be maintained in accordance with section 1.4 of Schedule V.

Selection criteria for donors of tissues and cells. *Substituted by: L.N. 222 of 2014.*

13. Tissue and cells establishments shall in respect of donors adopt the selection criteria set out in these regulations namely:

(*a*) Schedule II for donors of tissues and cells, except donors of reproductive cells;

(*b*) Schedule IV for donors of reproductive cells.

Laboratory tests required for donors. *Substituted by: L.N. 222 of 2014.*

14. It shall be the duty of the establishment to ensure that:

(*a*) donors of tissues and cells, except donors of reproductive cells, undergo the biological tests set out in point 1 of Schedule III;

(*b*) such tests are carried out in compliance with the general requirements set out in point 2 of Schedule III;

(*c*) donors of reproductive cells undergo the biological tests set out in points 1, 2 and 3 of Schedule IV;

(*d*) such tests are carried out in compliance with the general requirements set out in point 4 of Schedule IV.

Tissue and, or cell donation and procurement procedures and reception at the tissue establishment. *Amended by: L.N. 222 of 2014.*

15. The establishment shall ensure that the tissue and, or cell donation and procurement procedures and the reception of tissues and, or cells at the tissue establishment comply with the requirements set out in Schedule IV.

Requirements for direct distribution to the recipient of specific tissues and cells.

16. The Authority may authorise the direct distribution of specific tissues and cells from where the procurement is carried out to a health care establishment for immediate transplantation.

Added by: L.N. 222 of 2014.

SCHEDULE I

Information to be provided on the Donation of Cells and/or Tissues

A. Living donors

1. The person in charge of the donation process shall ensure that the donor has been properly informed of at least those aspects relating to the donation and procurement process outlined in paragraph 3. Information must be given prior to the procurement.

2. The information must be given by a trained person able to transmit it in an appropriate and clear manner, using terms that are easily understood by the donor.

3. The information must cover: the purpose and nature of the procurement, its consequences and risks; analytical tests, if they are performed; recording and protection of donor data, medical confidentiality; therapeutic purpose and potential benefits and information on the applicable safeguards intended to protect the donor.

4. The donor must be informed that he/she has the right to receive the confirmed results of the analytical tests, clearly explained.

5. Information must be given on the necessity for requiring the applicable mandatory consent, certification and authorisation in order that the tissue and/or cell procurement can be carried out.

B. Deceased donors

1. All information must be given and all necessary consents and authorisations must be obtained in accordance with the National legislation in force.

2. The confirmed results of the donor's evaluation must be communicated and clearly explained to the relevant persons in accordance with the relevant national legislation.

Added by: L.N. 222 of 2014.

SCHEDULE II

Selection Criteria for Donors of Tissues and/or Cells (except Donors of Reproductive Cells) as referred to in paragraph (a) of regulation 13.

Selection criteria for donors are based on an analysis of the risks related to the application of the specific cells/tissues.

Indicators of these risks must be identified by physical examination, review of the medical and behavioural history, biological testing, post-mortem examination (for deceased donors) and any other appropriate investigation. Unless justified on the basis of a documented risk assessment approved by the responsible person as defined in regulation 3, donors must be excluded from donation if any of the following criteria applies:

1. Deceased Donors

1.1. General criteria for exclusion

1.1.1. Cause of death unknown, unless autopsy provides information on the cause of death after procurement and none of the general criteria for exclusion set out in the present section applies.

1.1.2. History of a disease of unknown aetiology.

1.1.3. Presence, or previous history, of malignant disease, except for primary basal cell carcinoma, carcinoma *in situ* of the uterine cervix, and some primary tumours of the central nervous system that have to be evaluated according to scientific evidence. Donors with malignant diseases can be evaluated and considered for cornea donation, except for those with retinoblastoma, haematological neoplasm, and malignant tumours of the anterior segment of the eye.

1.1.4. Risk of transmission of diseases caused by prions. This risk applies, for example, to:

(*a*) people diagnosed with Creutzfeldt-Jakob disease, or variant Creutzfeldt-Jacob disease, or having a family history of non-iatrogenic Creutzfeldt-Jakob disease;

(*b*) people with a history of rapid progressive dementia or degenerative neurological disease, including those of unknown origin;

(*c*) recipients of hormones derived from the human pituitary gland (such as growth hormones) and

recipients of grafts of cornea, sclera and dura mater, and persons that have undergone undocumented neurosurgery (where dura mater may have been used).

For variant Creutzfeldt-Jakob disease, further precautionary measures may be recommended.

1.1.5. Systemic infection which is not controlled at the time of donation, including bacterial diseases, systemic viral, fungal or parasitic infections, or significant local infection in the tissues and cells to be donated. Donors with bacterial septicaemia may be evaluated and considered for eye donation but only where the corneas are to be stored by organ culture to allow detection of any bacterial contamination of the tissue.

1.1.6. History, clinical evidence, or laboratory evidence of HIV, acute or chronic hepatitis B (except in the case of persons with a proven immune status), hepatitis C and HTLV I/II, transmission risk or evidence of risk factors for these infections.

1.1.7. History of chronic, systemic autoimmune disease that could have a detrimental effect on the quality of the tissue to be retrieved.

1.1.8. Indications that test results of donor blood samples will be invalid due to:

(*a*) the occurrence of haemodilution, according to the specifications in Schedule III, section 2, where a pre-transfusion sample is not available; or

(*b*) treatment with immunosuppressive agents.

1.1.9. Evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration donor travel and exposure history and local infectious disease prevalence.

1.1.10. Presence on the donor's body of physical signs implying a risk of transmissible disease(s) as described in Schedule V, point 1.2.3.

1.1.11. Ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health.

1.1.12. Recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist.

1.1.13. Transplantation with xenografts.

1.2. Additional exclusion criteria for deceased child donors

1.2.1. Any children born from mothers with HIV infection or that meet any of the exclusion criteria described in section 1.1 must be excluded as donors until the risk of transmission of infection can be definitely ruled out.

(*a*) Children aged less than 18 months born from mothers with HIV, hepatitis B, hepatitis C or HTLV infection, or at risk of such infection, and who have been breastfed by their mothers during the previous 12

months, cannot be considered as donors regardless of the results of the analytical tests.

(*b*) Children of mothers with HIV, hepatitis B, hepatitis C or HTLV infection, or at risk of such infection, and who have not been breastfed by their mothers during the previous 12 months and for whom analytical tests, physical examinations, and reviews of medical records do not provide evidence of HIV, hepatitis B, hepatitis C or HTLV infection, can be accepted as donors.

2. Living donors

2.1. Autologous living donor

2.1.1. If the removed tissues and cells are to be stored or cultured, the same minimum set of biological testing requirements must apply as for an allogeneic living donor. Positive test results will not necessarily prevent the tissues or cells or any product derived from them being stored, processed and reimplanted, if appropriate isolated storage facilities are available to ensure no risk of cross-contamination with other grafts and/or no risk of contamination with adventitious agents and/or mix-ups.

2.2. Allogeneic living donor

2.2.1. Allogeneic living donors must be selected on the basis of their health and medical history, provided on a questionnaire and through an interview performed by a qualified and trained healthcare professional with the donor, in compliance with point 2.2.2. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases or health risks to themselves. For any donation, the collection process must not interfere with or compromise the health or care of the donor. In the case of cord blood or amniotic membrane donation, this applies to both mother and baby.

2.2.2. Selection criteria for allogeneic living donors must be established and documented by the tissue establishment (and the transplanting clinician in the case of direct distribution to the recipient), based on the specific tissue or cells to be donated, together with the donor's physical status and medical and behavioural history and the results of clinical investigations and laboratory tests establishing the donor's state of health.

2.2.3. The same exclusion criteria must be applied as for deceased donors with the exception of point 1.1.1. Depending on the tissue or cell to be donated, other specific exclusion criteria may need to be added, such as:

(*a*) pregnancy (except for donors of umbilical cord blood cells and amniotic membrane and sibling donors of haematopoietic progenitors);

(*b*) breastfeeding;

(*c*) in the case of haematopoietic progenitor cells, the potential for transmission of inherited conditions.

SCHEDULE III

Added by: L.N. 222 of 2014.

Laboratory Tests required for Donors (except Donors of Reproductive Cells) as referred to in paragraph (*a*) of regulation 13.

1. Biological tests required for donors

1.1. The following biological tests must be performed for all donors as a minimum requirement:

HIV 1 and 2	Anti-HIV-1,2
Hepatitis B	HBsAg Anti HBc
Hepatitis C	Anti-HCV-Ab
Syphilis	See 1.4 (below)

1.2. HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.

1.3. When anti-HBc is positive and HBsAg is negative, further investigations are necessary with a risk assessment to determine eligibility for clinical use.

1.4. A validated testing algorithm must be applied to exclude the presence of active infection with Treponema pallidum. A non-reactive test, specific or non-specific, can allow tissues and cells to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific Treponema confirmatory test is non-reactive. A donor whose specimen tests reactive on a Treponema-specific test will require a thorough risk assessment to determine eligibility for clinical use.

1.5. In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, HLA, malaria, CMV, toxoplasma, EBV, Trypanosoma cruzi).

1.6. For autologous donors, Schedule II, point 2.1.1, applies.

2. General requirements to be met for determining biological markers

2.1. The tests must be carried out by a qualified laboratory, authorised as a testing centre by the Licensing Authority, using EC-marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge.

2.2. The biological tests will be carried out on the donor's serum or plasma; they must not be performed on other fluids or secretions such as the aqueous or vitreous humour unless specifically justified clinically using a validated test for such a fluid.

2.3. When potential donors have lost blood and have recently received donated blood, blood components, colloids or crystalloids, blood testing may not be valid due to haemodilution of the sample. An algorithm must be applied to assess the degree of haemodilution in the following circumstances:

(*a*) ante-mortem blood sampling: if blood, blood components and/or colloids were infused in the 48 hours preceding blood sampling or if crystalloids were infused in the hour preceding blood sampling;

(*b*) post-mortem blood sampling: if blood, blood components and/or colloids were infused in the 48 hours preceding death or if crystalloids were infused in the hour preceding death.

Tissue establishments may accept tissues and cells from donors with plasma dilution of more than 50% only if the testing procedures used are validated for such plasma or if a pre-transfusion sample is available.

2.4. In the case of a deceased donor, blood samples must have been obtained just prior to death or, if not possible, the time of sampling must be as soon as possible after death and in any case within 24 hours after death.

2.5. (*a*) In the case of living donors (except allogeneic bone marrow stem-cell and peripheral blood stem-cell donors, for practical reasons), blood samples must be obtained at the time of donation or, if not possible, within seven days post donation (this is the 'donation sample').

(*b*) Where tissues and cells of allogeneic living donors can be stored for long periods, repeat sampling and testing is required after an interval of 180 days. In these circumstances of repeat testing, the donation sample can be taken up to 30 days prior to and 7 days post donation.

(*c*) Where tissues and cells of allogeneic living donors cannot be stored for long periods and repeat sampling is therefore not possible, point 2(5)(*a*) above applies.

2.6. If in a living donor (except bone marrow stem-cell and peripheral blood stem-cell donors) the 'donation sample', as defined in point 2(5)(*a*) above, is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

2.7. In the case of bone marrow and peripheral blood stem-cell collection, blood samples must be taken for testing within 30 days prior to donation.

2.8. In the case of neonatal donors, the biological tests may be carried out on the donor's mother to avoid medically unnecessary procedures upon the infant.

SCHEDULE IV

Added by: L.N. 222 of 2014.

Selection Criteria and Laboratory Tests required for Donors of Reproductive Cells as referred to in regulation 13(*b*) and regulation 14(*c*)

1. Partner donation for direct use

Donor selection criteria and laboratory testing do not need to be applied in the case of partner donation of reproductive cells for direct use.

2. Partner donation (not direct use)

Reproductive cells that are processed and/or stored and reproductive cells that will result in the cryopreservation of embryos must meet the following criteria:

2.1. the clinician responsible for the donor must determine and document, based on the patient's medical history and therapeutic indications, the justification for the donation and its safety for the recipient and any child(ren) that might result;

2.2. the following biological tests must be carried out to assess the risk of cross-contamination:

HIV 1 and 2	Anti-HIV-1,2
Hepatitis B	HBsAg Anti-HBc
Hepatitis C	Anti-HCV-Ab

In case of sperm processed for intrauterine insemination and not to be stored, if the tissue establishment can demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated processes, biological testing may not be required;

2.3. where HIV 1 and 2, hepatitis B or hepatitis C test results are positive or unavailable, or where the donor is known to be a source of infection risk, a system of separate storage must be devised;

2.4. HTLV-I antibody testing must be performed for donors living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;

2.5. in certain circumstances, additional testing may be required depending on the donor's travel and exposure history and the characteristics of the tissue or cells donated (e.g. Rh D, malaria, CMV, T. cruzi);

2.6. positive results will not necessarily prevent partner donation in accordance with national rules.

3. Donations other than by partners

The use of reproductive cells other than for partner donation must meet the following criteria:

3.1. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare

professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases (such as sexually transmitted infections), or health risks to themselves (e.g. superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor);

3.2. the donors must be negative for HIV 1 and 2, HCV, HBV and syphilis on a serum or plasma sample, tested in accordance with Schedule III, point 1.1, and sperm donors must additionally be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT);

3.3. HTLV-I antibody testing must be performed for donors living in or originating from high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;

3.4. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, malaria, CMV, T. cruzi).

3.5. for autologous donors, SCHEDULE II, point 2.1.1 applies;

3.6. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information must be provided, in accordance with the requirements in force in Member States. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

4. General requirements to be met for determining biological markers

4.1. The tests must be carried out in accordance with Schedule III, points 2.1 and 2.2.

4.2. (a) For donations other than by partners, blood samples must be obtained at the time of each donation.

(*b*) For donation by partners (not for direct use), blood samples must be obtained within three months before the first donation. For further partner donations by the same donor, further blood samples must be obtained according to these regulations, but no later than 24 months from the previous sampling.

4.3. Sperm donations other than by partners will be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

SCHEDULE V

Added by: L.N. 222 of 2014.

Cell and/or Tissue Donation and Procurement Procedures and Reception at the Tissue Establishment as referred to in regulation 15

1. Donation and procurement procedures

1.1. Consent and donor identification

1.1.1. Before the procurement of tissues and cells proceeds, an authorised person must confirm and record:

(*a*) that consent for the procurement has been obtained in accordance with regulation 9(*a*) and (*b*); and

(*b*) how and by whom the donor has been reliably identified.

1.1.2. In the case of living donors, the health professional responsible for obtaining the health history must ensure that the donor has:

(*a*) understood the information provided;

(*b*) had an opportunity to ask questions and been provided with satisfactory responses;

(*c*) confirmed that all the information provided is true to the best of his/her knowledge.

1.2. Donor evaluation (this section does not apply to partner donation of reproductive cells or to autologous donors)

1.2.1. An authorised person must collect and record the donor's relevant medical and behavioural information according to the requirements described in section 1.4.

1.2.2. In order to acquire the appropriate information, different relevant sources must be used, including at least an interview with the donor, for living donors, and the following when appropriate:

(*a*) the medical records of the donor;

(*b*) an interview with a person who knew the donor well, for deceased donors;

(*c*) an interview with the treating physician;

(*d*) an interview with the general practitioner;

(*e*) the autopsy report.

1.2.3. In addition, in the case of a deceased donor, and in the case of a living donor when justified, a physical examination of the body must be performed to detect any signs that may be sufficient in themselves to exclude the donor or which must be assessed in the light of the donor's medical and personal history.

1.2.4. The complete donor records must be reviewed and assessed for suitability and signed by a qualified health professional.

1.3. Procurement procedures for tissues and cells

1.3.1. The procurement procedures must be appropriate for the type of donor and the type of tissue/cells donated.

There must be procedures in place to protect the safety of the living donor.

1.3.2. The procurement procedures must protect those properties of the tissue/cells that are required for their ultimate clinical use, and at the same time minimise the risk of microbiological contamination during the process, particularly when tissues and cells cannot subsequently be sterilised.

1.3.3. For deceased donation, the area of access must be restricted. A local sterile field using sterile drapes must be used.

Staff conducting procurement must be clothed appropriately for the type of procurement. Usually, this will extend to being scrubbed, gowned in sterile clothing and wearing sterile gloves, face shields and protective masks.

1.3.4. In the case of a deceased donor, the place of procurement must be recorded and the time interval from death to procurement must be specified so as to ensure that the required biological and/or physical properties of the tissues/cells are retained.

1.3.5. Once the tissues and cells have been retrieved from a deceased donor body, it must be reconstructed so that it is as similar as possible to its original anatomical appearance.

1.3.6. Any adverse event occurring during procurement that has or may have resulted in harm to a living donor and the outcome of any investigation to determine the cause must be recorded and reviewed.

1.3.7. Policies and procedures must be in place to minimise the risk of tissue or cell contamination by staff who might be infected with transmissible diseases.

1.3.8. Sterile instruments and devices must be used for tissue and cell procurement. Instruments or devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.

1.3.9. When reusable instruments must be used, a validated cleaning and sterilisation procedure for removal of infectious agents has to be in place.

1.3.10. Wherever possible, only CE marked medical devices must be used and all concerned staff must have received appropriate training on the use of such devices.

1.4. Donor documentation

1.4.1. For each donor, there must be a record containing:

(*a*) the donor identification (first name, family name and date of birth - if a mother and child are involved in the donation, both the name and date of birth of the mother and the name, if known, and date of birth of the child);

(*b*) age, sex, medical and behavioural history (the information collected must be sufficient to allow application of the exclusion criteria, where required);

(*c*) outcome of body examination, where applicable;

(*d*) haemodilution formula, where applicable;

(*e*) the consent/authorisation form, where applicable;

(*f*) clinical data, laboratory test results, and the results of other tests carried out;

(*g*) if an autopsy was performed, the results must be included in the record (for tissues and cells that cannot be stored for extended periods, a preliminary verbal report of the autopsy must be recorded);

(*h*) for haematopoietic progenitor cell donors, the donor's suitability for the chosen recipient must be documented.

For unrelated donations, when the organisation responsible for procurement has limited access to recipient data, the transplanting organisation must be provided with donor data relevant for confirming suitability.

1.4.2. The organisation performing the procurement must produce a procurement report, which is passed on to the tissue establishment. This report must contain at least:

(*a*) the identification, name and address of the tissue establishment to receive the cells/tissues;

(*b*) donor identification data (including how and by whom the donor was identified);

(*c*) description and identification of procured tissues and cells (including samples for testing);

(*d*) identification of the person who is responsible for the procurement session, including signing;

(*e*) date, time (where relevant, start and end) and location of procurement and procedure (SOP) used, including any incidents that occurred; where relevant, environmental conditions at the procurement facility (description of the physical area where procurement took place);

(*f*) for deceased donors, conditions under which the cadaver is kept: refrigerated (or not), time of start and end of refrigeration;

(*g*) ID/batch numbers of reagents and transport solutions used.

The report must also contain the date and time of death where possible.

Where sperm is procured at home, the procurement report must state this and must contain only:

(*a*) the name and address of the tissue establishment to receive the cells/tissues;

(*b*) the donor identification.

The date and time of procurement may be included, where possible.

1.4.3. All the records must be clear and readable, protected

from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation.

1.4.4. Donor records required for full traceability must be kept for a minimum of 30 years after clinical use, or the expiry date, in an appropriate archive acceptable to the Licensing Authority.

1.5. Packaging

1.5.1. Following procurement, all recovered tissues and cells must be packaged in a manner which minimises the risk of contamination and must be stored at temperatures that preserve the required characteristics and biological function of the cells/tissues. The packaging must also prevent contamination of those responsible for packaging and transportation of the tissues and cells.

1.5.2. The packaged cells/tissues must be shipped in a container which is suitable for the transport of biological materials and which maintains the safety and quality of the contained tissue or cells.

1.5.3. Any accompanying tissue or blood samples for testing must be accurately labelled to ensure identification with the donor, and must include a record of the time and place the specimen was taken.

1.6. Labelling of the procured tissues/cells

At the time of procurement, every package containing tissues and cells must be labelled. The primary tissue/cell container must indicate the donation identification or code and the type of tissues and cells. Where the size of the package permits, the following information must also be provided:

(*a*) date (and time where possible) of donation;

(*b*) hazard warnings;

(*c*) nature of any additives (if used);

(*d*) in the case of autologous donations, the label must state 'for autologous use only';

(*e*) in the case of directed donations, the label must identify the intended recipient.

If any of the information under points (*a*) to (*e*) above cannot be included on the primary package label, it must be provided on a separate sheet accompanying the primary package.

1.7. Labelling of the shipping container

When tissues/cells are shipped by an intermediary, every shipping container must be labelled at least with:

(*a*) TISSUES AND CELLS and HANDLE WITH CARE;

(*b*) the identification of the establishment from which the package is being transported (address and phone number) and a contact person in the event of problems;

(*c*) the identification of the tissue establishment of destination (address and phone number) and the person to be contacted to take delivery of the container;

(*d*) the date and time of the start of transportation;

(*e*) specifications concerning conditions of transport relevant to the quality and safety of the tissues and cells;

(*f*) in the case of all cellular products, the following indication: DO NOT IRRADIATE;

(*g*) when a product is known to be positive for a relevant infectious disease marker, the following indication: BIOLOGICAL HAZARD;

(*h*) in the case of autologous donors, the following indication: 'FOR AUTOLOGOUS USE ONLY';

(*i*) specifications concerning storage conditions (such as DO NOT FREEZE).

2. Reception of the tissue/cells at the tissue establishment

2.1. When the retrieved tissues/cells arrive at the tissue establishment, there must be documented verification that the consignment, including the transport conditions, packaging, labelling and associated documentation and samples, meet the requirements of this Schedule and the specifications of the receiving establishment.

2.2. Each establishment must ensure that the tissue and cells received are quarantined until they, along with the associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant donor/ procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.

2.3. Each tissue establishment must have a documented policy and specifications against which each consignment of tissues and cells, including samples, are verified. These must include the technical requirements and other criteria considered by the tissue establishment to be essential for the maintenance of acceptable quality. The tissue establishment must have documented procedures for the management and segregation of non-conforming consignments, or those with incomplete test results, to ensure that there is no risk of contamination of other tissues and cells being processed, preserved or stored.

2.4. The data that must be registered at the tissue establishment (except for donors of reproductive cells intended for partner donation) include:

(*a*) consent/authorisation; including the purpose(s) for which the tissues and cells may be used (i.e. therapeutic or research, or both therapeutic use and research) and any specific instructions for disposal if the tissue or cells are not used for the purpose for which consent was obtained;

(*b*) all required records relating to the procurement and the taking of the donor history, as described in the donor documentation section;

(*c*) results of physical examination, of laboratory tests and

of other tests (such as the autopsy report, if used in accordance with point 1.2.2.);

(*d*) for allogeneic donors, a properly documented review of the complete donor evaluation against the selection criteria by an authorised and trained person;

(*e*) in the case of cell cultures intended for autologous use, documentation of the possibility of medicinal allergies (such as to antibiotics) of the recipient.

2.5. In the case of reproductive cells intended for partner donation, the data to be registered at the tissue establishment include:

(*a*) consent; including the purpose(s) for which the tissues and cells may be used (such as reproductive only and/or for research) and any specific instructions for disposal if the tissue or cells are not used for the purpose for which consent was obtained;

(*b*) donor identification and characteristics: type of donor, age, sex, presence of risk factors and, in the case of a deceased donor, the cause of death;

(*c*) partner identification;

(*d*) place of procurement;

(*e*) tissues and cells obtained and relevant characteristics.

CHAPTER 558

HUMAN ORGANS, TISSUES AND CELL DONATION ACT

To provide for human organs, tissues and cell donation and transplantation in Malta and to provide for matters ancillary or consequential thereto.

16th December, 2016*

ACT XXVIII of 2016.

Short title.

1. The short title of this Act is the Human Organs, Tissues and Cell Donation Act.

Applicability. Cap. 483.

2. (1) This Act shall apply without prejudice to the Human Blood and Transplants Act and any subsidiary legislation made thereunder.

(2) This Act shall apply to all human organ, tissue and cell donations by persons residing in Malta.

(3) Human organ, tissue and cell donation for research and autologous organ, tissue and cell donation as well as embryo donations fall outside the scope of this Act.

Interpretation.

3. In this Act, unless the context otherwise requires:

"autologous use" means cells or tissues removed from and applied to the same person;

"cells" means individual diploid human cells or a collection of diploid human cells when not bound by any form of connective tissue;

"clinician" means a health professional being a doctor or consultant whose practice is based on direct observation and treatment of a patient;

"donation" means the act of giving human organs, tissues or cells intended for human transplantation;

"donor" means a person who donates one or several organs, tissues or cells, whether donation occurs during lifetime or after death;

"donor coordinator" means a person who confirms that the donor has the medical characteristics that ensures a successful transplantation;

"guardian" means a person appointed by a court to make decisions regarding the support, care, education, health, or welfare of an individual and includes a person who has been appointed in guardianship of a person in terms of the Civil Code; Cap.16.

*see article 1(2) of this Act as originally promulgated, and Legal Notice 421 of 2016.

"health care professional" shall have the same meaning assigned to it under the Health Care Professions Act; Cap. 464.

"human organ" and "organ" means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy:

Provided that a part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation;

"Minister" means the Minister responsible for Health;

"parent" means a person having parental authority;

"parental authority" shall have the same meaning assigned to the term under the Civil Code; Cap.16.

"procurement organization" means a health care establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of organs, and is authorised to do so by the Superintendent;

"recipient coordinator" means a person who ensures that the patient is in a suitable state to accept a successful transplant;

"register" shall refer to the National Human Organ and Tissue Donation Register defined in article 4;

"Superintendent" means the Superintendent of Public Health in terms of the Health Act; Cap. 528.

"tissue" means all constituent parts of the human body formed by cells;

"transplant co-ordinator" means a health care professional who coordinates activities related to organ donation and transplantation. A transplant coordinator can either be a donor coordinator or a recipient coordinator;

"transplantation centre" means a health care establishment, a team or a unit of a hospital or any other body which undertakes the transplantation of organs, tissues and cells and which is authorised to undertake such transplantation by the Superintendent.

Human Organ and Tissues Donation Register.

4. (1) There shall be a National Human Organ and Tissue Donation Register which shall be maintained by the Superintendent in physical or electronic form as may be determined by the Minister.

(2) The Register shall record information in accordance with this article and other provisions of this Act and in such manner as may be prescribed from time to time. In accordance with this sub-article, the Superintendent shall record the following in the Register:

(*a*) details of persons residing in Malta who wish to donate their organs, tissues or cells following their demise;

(*b*) details of persons residing in Malta who expressly

declare that they do not wish to donate their organs, tissues or cells following their demise;

(*c*) any particular organ, tissue and cell a person chooses to donate; and

(*d*) any particular organ, tissue and cell a person chooses not to donate.

(3) The Register shall be the only organs, tissues and cells register having legal validity for purposes of a donation under this Act.

Registration and role of Superintendent.

5. (1) The Superintendent shall only register a person requesting to become a donor under this Act after having satisfied himself that the said person:

(*a*) has attained the age of sixteen years;

(*b*) is not suffering from any mental disorder which renders him incapable of taking care of his own affairs;

(*c*) has done so voluntarily, out of his own free will;

(*d*) has had adequate information on the meaning and consequences of registration as a donor under this Act and has been certified under article 14.

(2) The Superintendent shall amend the said Register, whenever it appears to him necessary or appropriate to do so for giving effect to the provisions of this Act, and in particular for ensuring the accuracy of information contained in the Register, or for bringing up to date, or otherwise correcting any information entered into the Register.

(3) It shall be the duty of the Superintendent to ensure that the processing of the information contained in the Register is carried out in compliance with the Data Protection Act: Cap. 586.

Provided that the information shall, for purposes of this Act upon a potential donation taking place, be accessed solely to determine whether a person is a registered donor or a person who has registered his intention of not being a donor.

Eligibility for registration.

6. (1) Any person who has attained the age of sixteen may register to donate his organs and, or tissues and, or cells. Registration shall be made in such forms as the Minister may so establish, by regulations made under this Act. All registrations shall be recorded in the Register.

(2) A person who chooses to donate his organs, tissues or cells shall specify which organs, tissues or cells he would wish to donate and if he wishes to exclude particular organs, tissues or cells from being donated.

De-registration.

7. A person having registered as a donor under this Act shall be entitled to retract his choice of becoming a donor and to apply for de-registration with the Superintendent who shall forthwith record this information and de-register the said person.

Registration following choice not to be a donor.

8. A person who has expressly declared that he does not wish to donate his organs, tissues or cells may at any time thereafter register as a donor under this Act.

Death of a minor under sixteen years of age.

9. Upon the death of a minor who, at the time of death, is still under the age of sixteen, the parents or legal guardians shall be consulted with regards to an organ, tissue or cell donation taking place.

Death of an unregistered person.

10. (1) The next of kin of a deceased person who is not a registered donor may be approached by a transplant coordinator or a clinician to declare whether they consent to the donation taking place:

Provided that this sub-article shall not apply where the deceased has registered his wish not to be a donor.

(2) In the event where consent is given under this article the donation shall take place and the said person shall be deemed to have been a registered donor for purposes of this Act.

(3) In the event of a donation under this article taking place, this shall be annotated by the Superintendent in the Register.

Unfit organ.

11. Notwithstanding that a deceased person may have been a registered donor, a clinician shall have the right to decide that the organ or tissue object of the donation is unfit or unsuitable for transplantation.

Cadaveric organ.

12. (1) Cadaveric organ, tissue and cell donation shall be considered in patients who are certified brain dead by a clinician.

(2) The Superintendent shall maintain updated and peer reviewed guidelines for the diagnosis of brain death for the purposes of organ, tissue and cell donation.

Living organ donation.

13. Procurement organisations and transplantation centres shall be bound to have in place a framework approved by the Superintendent to assess all potential live organ donors and to decide whether the transplant should be approved, based on the following criteria:

(*a*) in the case of donation between blood relatives and family members who are not blood relatives, an organ must be donated to an identified recipient;

(*b*) in other non-related donations a pre-existent close emotional link has to be present between the donor and the recipient for such a donation to be acceptable; and

(*c*) in the case of non-directed altruistic organ donation the principle of distributive justice shall be adopted by which a donated organ shall be allocated to a recipient according to his medical needs. Such a decision shall be taken by the Superintendent.

Duties of clinician and certification.

14. (1) A clinician involved in the donation process must ascertain and certify that the donor fully understands the nature and consequences of the donation.

(2) A clinician shall not certify any donor who due to mental incompetence cannot understand the nature and consequences of the donation.

(3) In the case of a living minor under the age of sixteen a clinician shall only approve the donation and transplantation of regenerative hematopoietic stem cells for blood relatives.

Regulations.

15. The Minister may make regulations to implement and to give better effect to the provisions of this Act and without prejudice to the generality of the foregoing may, by such regulations, prescribe anything that is to be or which may be prescribed and provide for any matter consequential, incidental to or connected with the provisions of this Act.