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I assent.

(L.S.)

**MARIE-LOUISE
COLEIRO PRECA
President**

10th June, 2016

ACT No. XXVIII of 2016

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

BE IT ENACTED by the President, by and with the advice and consent of the House of Representatives, in this present Parliament assembled, and by the authority of the same as follows:-

Short title and
commencement.

1. (1) The short title of this Act is the Human Organs, Tissues and Cell Donation Act, 2016.

(2) The provisions of this Act shall come into force on such a date as the Minister responsible for Health may by notice in the Gazette establish, and different dates may be so established for different provisions or different purposes of this 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.

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

Interpretation.

"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.

"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;

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

"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;

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

"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.

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:

Registration and
role of
Superintendent.

- (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. 440.

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.

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.

Eligibility for
registration.

(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.

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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.

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. Duties of clinician and certification.

(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.

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. Regulations.

16. The Criminal Code shall be amended as follows:

(a) article 248C thereof shall be re-numbered as sub-article (1) thereof, and immediately thereafter there shall be added the following new sub-article:

Consequential amendments to the Criminal Code. Cap. 9.

"(2) For purposes of this article, the removal of organs, tissues and cells shall include the conduct referred to in article 248CA(1).".

(b) immediately following article 248C thereof, there shall be added the following new article:

"Trafficking in human organs.

248CA. (1) Whosoever removes a human organ, tissue or cell from living or deceased donors in any of the following circumstances -

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(a) where the removal is not performed under the Act with the free, informed and specific consent of the living or deceased donor, or, in the case of the deceased donor, without the removal being authorised under the Act;

(b) where, in exchange for the removal of organs, tissues or cells the living donor, or a third party, has been offered or has received a financial gain or comparable advantage;

(c) where, in exchange for the removal of organs, tissues or cells from a deceased donor, a third party has been offered or has received a financial gain or comparable advantage,

shall be guilty of an offence and shall be liable on conviction to the punishment of imprisonment for a term from six to twelve years.

(2) A person who does any of the following acts shall be guilty of an offence against this article -

(a) makes use of illicitly removed organs, tissues or cells as described in sub-article (1), for purposes of implantation or other purposes than implantation;

(b) the implantation of human organs, tissues or cells from living or deceased donors where the implantation is not performed under the Act or where the implantation is, in any manner, performed in breach of the Act;

(c) solicits or recruits an organ donor or a recipient for financial gain or comparable advantage;

(d) prepares, preserves or stores illicitly removed human organs, tissues or cells as described in sub-article (1);

(e) transports, transfers, receives, imports or exports illicitly removed human organs, tissues or cells as described in sub-article (1),

and shall be liable on conviction to the punishment laid down in sub-article (1).

(3) The provisions of articles 115 and 121(3) shall, *mutatis mutandis*, apply to an offence under this article.

(4) For purposes of this article -

"Act" means the Human Organs, Tissues and Cell Donation Act;

"human 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;

"financial gain or comparable advantage" shall not include compensation for loss of earnings and any other justifiable expenses caused by the removal or by the related medical examinations, or compensation in case of damage which is not inherent to the removal of organs.";

(c) in article 248D thereof, for the words "to 248C" there shall be substituted the words "to 248CA";

(d) in article 248DA thereof, for the words "to 248C" there shall be substituted the words "to 248CA"; and

(e) sub-article (2) of article 248E thereof shall be amended as follows:

(i) in paragraph (a) thereof, for the words "has caused grievous bodily harm" there shall be substituted the words "or has resulted in harm to the physical or psychological health of the victim";

(ii) in paragraph (e) thereof, for the words "article 208A(2);" there shall be substituted the words "article 208AC(2)"; and

(iii) in paragraph (f) thereof, for the word "trafficked," there shall be substituted the words "trafficked; or" and immediately thereafter there shall be

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added the following new paragraphs:

"(g) when the offender has been previously convicted of an offence under this article; or

(h) is committed by a member of the child's family, a person cohabiting with the child or a person who has abused a recognised position of trust or authority,".

Passed by the House of Representatives at Sitting No. 399 of the 6th June, 2016.

ANĠLU FARRUGIA
Speaker

RAYMOND SCICLUNA
Clerk of the House of Representatives

