

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](#), as amended by Act [VIII of 2026](#).

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

2. (1) This Act shall apply without prejudice to the Human Blood and Transplants Act and any subsidiary legislation made thereunder. Applicability.
Cap. 483.

(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.

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

"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;

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. 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.

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.

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.

De-registration.

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.

Registration
following choice
not to be a donor.

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.

Donation of human organs, tissues and cells from a cadaver.

Substituted by:
[VIII.2026.2.](#)

12. (1) Deceased organ, tissue and cell donation shall be considered in persons who are certified dead using neurological or circulatory criteria by a clinician.

(2) The Superintendent shall maintain updated and peer reviewed guidelines, which shall be published on the Ministry's website, for the diagnosis of death using neurological and circulatory criteria 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.

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.