

CHAPTER 524

EMBRYO PROTECTION ACT

To provide for the protection of human embryos and other ancillary matters.

1st January, 2013*

ACT XXI of 2012, as amended by Acts XXIV of 2018 and XI of 2022.

1. The short title of this Act is the Embryo Protection Act.

Short title.

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

Interpretation.
Amended by:
XXIV.2018.2;
XI.2022.3.

"Authority" means the Embryo Protection Authority established by article 3;

"the Council" means the Medical Council established by article 9 of the [Health Care Professions Act](#);

Cap. 464.

"Directive" means the [Commission 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;

"donor" means a third party who donates germ line cells to be used in medically assisted procreation:

Provided that donations by an ascendant to a descendant, descendant to an ascendant, from sibling to sibling, whether of the full or half-blood, shall not be permissible;

"embryo" means the human organism that results from the fertilisation of a human egg cell by a human sperm cell which is capable of developing and shall further include each totipotent cell removed from a human embryo or otherwise produced, that is assumed to be able to divide and to develop as a human being under the appropriate conditions;

"embryo adoption" means that process established in this Act whereby embryos that are not transferred are gratuitously donated to the prospective parent or prospective parents:

Provided that this term does not have the same meaning and shall not produce the same effects of "adoption" under the [Civil Code](#) and the term "adoptive" shall be construed accordingly;

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"embryo donation" means the transfer of an embryo resulting from gametes (spermatozoa and oocytes) that did not originate from the prospective parent or prospective parents;

"germ line cells" means all egg and sperm cells which may lead to the resultant human being;

"health care professional" shall have the same meaning assigned to it by article 2 of the [Health Care Professions Act](#);

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"medically assisted procreation" means all treatments or procedures that include the in vitro handling of human oocytes,

*see article 1(2) as originally enacted, and Legal Notice [455 of 2012](#).

spermatozoa or embryos for establishing a pregnancy. This includes, but is not limited to, intra-uterine insemination, in vitro fertilisation, intracytoplasmic sperm injection, embryo transfer, gamete, germinal tissue and embryo cryo-preservation, oocyte and embryo donation;

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"medical practitioner" means a person licensed under the [Health Care Professions Act](#) to practice as a medical practitioner;

"Minister" means the Minister responsible for health;

"prospective parent" means any person regardless of gender or sexual orientation, who has attained the age of majority and is a receiver or user of the medically assisted procreation techniques regulated under this Act;

"Protocol" means the Protocol established in writing by the Authority and brought into force by regulations made by the Minister under this Act, as published in the Gazette;

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

Establishment and composition of the Embryo Protection Authority.

3. (1) There shall be a body, to be known as the Embryo Protection Authority, which shall consist of a Chairman and such number of other members not being less than four who shall be appointed by the Minister.

(2) The Chairman shall be a person in possession of a warrant to exercise the profession of Advocate and who has exercised that profession for at least twelve years or a retired Judge or a retired Magistrate.

(3) A person shall not be qualified to hold office as a member of the Authority if he:

- (a) is a Minister or Parliamentary Secretary;
- (b) is a member of, or a candidate for election to, the House; or
- (c) is a member of a local government authority; or
- (d) has a financial or other interest in any enterprise or activity which is likely to affect the discharge of his functions as a member of the Authority.

(4) Subject to the provisions of this article, the office of a member of the Authority shall become vacant -

- (a) at the expiration of five years from the date of his appointment or at such earlier time as may be specified in the instrument by which he was appointed; or
- (b) if any circumstances arise that, if he were not a member of the Authority, would cause him to be disqualified for appointment as such.

(5) A member of the Authority may be removed from office by the Minister if, in the opinion of the Minister, such member is unfit

to continue in office or has become incapable of properly performing his duties as a member, whether arising from infirmity of mind or body or any other cause, or for misbehaviour.

(6) If the office of a member of the Authority is vacant or if a member is for any reason unable to perform the functions of his office, the Minister may appoint another person as a temporary member of the Authority until the member who was unable to perform the functions of his office resumes those functions.

(7) The members of the Authority, in the exercise of their functions, shall act on their own individual judgement and shall not be subject to the direction or control of any person or authority.

4. (1) The functions and powers of the Authority shall be the following:

Functions and
powers of the
Authority.
Amended by:
XXIV.2018.3;
XI.2022.4.

- (a) to ensure that high standards of ethics are maintained by all medical practitioners, paramedics and other personnel involved in procedures of medically assisted procreation and gamete donation;
- (b) to request and obtain, in cases of reasonable suspicion that the provisions of this Act and any regulations made thereunder are not being followed, information and copies, in any form, of documents required by the Directive to ensure traceability of human cells;
- (c) to carry out inspections in order to ensure that the standards of best practice are being respected and implemented and that all information and documentation required under this Act and any regulations made thereunder are being kept appropriately and for this purpose to access clinics and any other places as necessary;
- (d) to maintain a statement of the general principles which, in its opinion, should be followed:
 - (i) in carrying out its activities under this Act; and
 - (ii) in carrying out its functions in relation to such activities under this Act;
- (e) to ensure, in relation to activities under this Act, compliance with:
 - (i) the obligations and requirements imposed by or under this Act and any regulations made thereunder; and
 - (ii) the codes of practice established under paragraph (a);
- (f) to determine the eligibility and suitability or otherwise of a prospective adoptive parent in terms of the Protocol in those cases where it may give for adoption the embryos in terms of this Act and keep a register thereof;
- (g) to keep a register of every medically assisted

procreation procedure, germ line cell donation, cryo-preservation of germ line cells, cryo-preservation of embryos and embryo donation and adoption in terms of this Act which shall in all cases remain confidential;

- (h) to perform such other functions as may, from time to time, be prescribed by regulations made under this Act;
- (i) to establish and maintain a Protocol in writing, which shall consist of the regulatory principles that shall be followed in carrying out its functions under this Act:

Provided that such Protocol shall be discussed in the Standing Committee on Health within four (4) weeks from the date of publication of the regulations referred to in the definition "Protocol" in article 2.

(2) Notwithstanding the provisions of any other law and notwithstanding the provisions of article 7 but subject to the provisions of article 18, the Authority may give for adoption the embryos to a third party who qualifies for medically assisted procreation procedures, in those cases where:

- (a) after the fertilization of the egg cells but before the implantation of the embryos into the womb has taken place death of the woman ensues; or
- (b) for any other reason the implantation of the embryos into the womb of the prospective parent cannot take place including those cases where the prospective parent refuses said implantation or has reached the maximum permissible age for the implantation thereof or fails to renew the contract with the licensee where the cryo-preserved embryos are being stored for future use:

Provided that the Authority shall give for adoption the embryos when the prospective parent has reached the maximum permissible age for the implantation thereof.

(3) The adoption of an embryo may only take place if the Authority, on the application of a prospective parent or prospective parents, so decides:

Provided that the Authority shall only issue its authorisation if the prospective parent or prospective parents have been declared as physically fit by a medical practitioner for the transfer of an embryo and following a favourable recommendation issued by the Adoption Board in accordance with the [Adoption Administration Act](#) determining the eligibility and suitability or otherwise of the prospective parent or prospective parents:

Provided further that the Authority shall make all reasonable efforts to match prospective adoptive parents with the embryos who require an adoption placement:

Provided further that, without prejudice to the provisions of sub-article (4) of article 9, the identity of the adopter or adopters and the

persons from whom the germ line cells originated shall in all cases remain anonymous and the prospective parents shall only be entitled to such generic information as specified in the Protocol:

Provided further that the Authority shall be obliged to provide the prospective parent or prospective parents with medical and, or diagnostic information concerning the embryo as specified in the Protocol defined in article 2:

Provided further that the simultaneous implantation of embryos originating from different persons in a prospective parent during the same cycle is prohibited.

(4) Nothing in this article shall prejudice the authority or the exercise of any function or power of the Licencing Authority under the [Human Blood and Transplants Act](#):

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Provided that in the exceptional case when the embryo has not yet been adopted by the prospective parent or prospective parents during the period from the day in which the implantation of the fertilized embryo into the womb of the prospective parent cannot take place for the reasons mentioned in this article until the day of giving the embryo for adoption, the Authority shall be deemed to be curator of the embryo for all intents and purposes of the law and the Authority shall immediately and during the duration of the curatorship inform and consult with the prospective parent or parents, or in their absence their legal heir, on the decisions which need to be taken on the embryo. In the case that both prospective parents can still be consulted, the Authority shall, in so far as it is possible, respect the wishes of the prospective parents within the parameters of this Act:

Provided that any person having a juridical interest, or in their absence their legal heir, within twenty days from the date of decision of the Authority for giving for adoption the embryos may file a sworn application in the Civil Court (Family Section) to enquire into the validity of the decision of the Authority and there shall be a right of appeal therefrom to the Civil Court (Family Section) before the Court of Appeal by means of an application filed within twenty days from the date of the decision of the Civil Court (Family Section). Where no application is filed before the Civil Court (Family Section) according to the provisions of this article, or where the judicial proceedings are withdrawn or discontinued, or where the judicial proceedings become *res judicata*, the decision of the Authority or the court becomes final:

Provided further that the embryo shall remain cryo-preserved until the decision of the Authority or the court becomes final.

(5) When the decision of the Authority or the court giving an embryo for adoption becomes final, that embryo shall be considered as the embryo of the adopter or adopters and the persons from whom the embryo originated shall lose all rights and shall be freed from all obligations with respect thereto.

(6) Save as otherwise provided in this article, once the decision of the Authority giving an embryo for adoption becomes final, it shall be

irrevocable.

Entitlement to
medically assisted
procreation
procedures.

5. (1) Any prospective parent shall have access to medically assisted procreation procedures:

Provided that these procedures may only be resorted to where there is a reasonable chance of success and the procedures do not entail any known undue risk to the health of the woman or the child, beyond those already well known as inherently associated with the procedure itself.

(2) Any person who provides, or assists in, any medically assisted procreation procedure to a person other than a prospective parent shall be guilty of an offence and shall, on conviction, be liable to a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment:

Provided that where the person is a medical practitioner, who performs the said procedure, the medical practitioner shall be exempt from criminal liability where he shows that he took reasonable care to determine that the person on whom the procedure was performed or attempted was entitled to access to such procedure.

Unlawful
procedures.
Amended by:
XXIV.2018.4;
XI.2022.5.

6. Whosoever -

- (a) artificially fertilizes any egg cell for any purpose other than that of bringing about the pregnancy of the prospective parent;
- (b) intentionally fertilizes more egg cells than the maximum amount established by the Protocol from one woman in one cycle of treatment:

Provided that the medical practitioner in charge of the medically assisted procreation may, in consultation with the multidisciplinary team and with the permission of the Authority, decide to fertilize more than two egg cells within one (1) treatment cycle provided that this is done in accordance with the Protocol:

Provided further that no more egg cells can be fertilized until all the cryo-preserved embryos have been implanted in the prospective parent from whom they originate from any prior medically assisted procreation treatments except in those instances which may be specified in the Protocol and with the prior authorisation of the Authority, in which case, the fertilisation of more egg cells shall be permissible:

Provided further that where the prospective parent or prospective parents undergoing medically assisted procreation procedures do not expressly give their consent to the cryo-preservation of embryos and to the donation of fertilized eggs if necessary, in terms of article 18, it shall not be lawful to fertilize more than two (2) eggs within each treatment cycle.

- (c) transfers more than two embryos into the prospective parent within each treatment cycle;

- (d) removes an embryo from a woman before the completion of implantation in the womb in order to transfer the embryo to another woman;
- (e) selects or discards an embryo for eugenic purposes:
 Provided that the Protocol may specify that certain exceptional circumstances shall not constitute selection of embryos for eugenic purposes; provided, however, also that the medical experts as listed in the Protocol shall provide information and explanations relating to the testing of human egg cells (oocytes) and other testing which is available to the prospective parent or prospective parents and the said prospective parent or prospective parents shall decide which testing shall be carried out after consulting with the medical experts;
- (f) carries out an artificial fertilization of, or transfers a human embryo into, a woman who is prepared to give up her child permanently after birth (surrogate mother),

shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment:

Provided that -

- (i) the prospective parent in respect of the conduct referred to in paragraphs (a) and (d); and, or
- (ii) the woman into whom the egg cell or embryo will be transferred, in respect of the conduct referred to in paragraph (f);

shall have the punishment decreased by one or two degrees.

7. (1) Sperm cells may be cryo-preserved in authorized tissue establishments during the lifetime of the person from whom they originate.

(2) Oocytes may be cryo-preserved in authorized tissue establishments up to the maximum permissible age for the fertilization and transfer thereof into the prospective parent unless they are donated in terms of this Act:

Provided that, in any case, it shall not be lawful to extract and commence cryo-preservation of oocytes after the death of the person from whom they originate.

(3) Embryos which cannot be transferred into the prospective parent within a treatment cycle shall be cryo-preserved in licensed tissue establishments for future use by that prospective parent:

Provided that the cryo-preservation of embryos shall be regulated by an agreement between the prospective parent or prospective parents and the licensee subject to the prior authorisation

Cryo-preservation
of germ line cells
and embryos.
Substituted by:
XXIV.2018.5.
Amended by:
XI.2022.6.

of the Authority and shall have a maximum term of validity of five years renewable up to a maximum permissible age for the transfer thereof into the prospective parent in terms of the Protocol:

Provided further that when the maximum permissible age for the transfer of the embryo into the prospective parent is reached, the Authority shall authorize the donation of the cryo-preserved embryo.

(4) Subject to the foregoing sub-articles, all other forms of preservation, of germ line cells and embryos are prohibited and whosoever contravenes this article shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment:

Provided that when there has been a breach of any provision of this Act, the Authority may order the cryo-preservation of any embryo.

(5) A prospective parent or prospective parents who have cryo-preserved embryos in tissue establishments abroad may apply to be granted an authorisation by the Authority to bring two cryo-preserved embryos to be transferred locally into the prospective parent or prospective parents for each cycle:

Provided that the Authority shall not authorise the transfer of more than two embryos for each cycle.

Improper use of
human embryos.
Amended by:
XXIV.2018.6.

8. (1) Whosoever, other than for the purpose of implantation in a prospective parent as may be authorized by the provisions of this Act, disposes of, hands over or acquires a human embryo produced outside the body, or removes such embryo from a prospective parent before the completion of implantation in the womb, shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment.

(2) Whosoever causes a human fertilised egg to develop further outside the body for any purpose other than in order to bring about a pregnancy, shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment.

Donation and use
of germ line cells.
Substituted by:
XXIV.2018.7.
Amended by:
XI.2022.7.

9. (1) The donation of germ line cells for the purpose of medically assisted procreation shall be a confidential agreement between the donor and the licensee:

Provided that prior to entering into such an agreement, the licensee shall duly inform the donor of the consequences thereof in terms of this Act:

Provided further that where the donor has donated the germ line cells in a tissue establishment abroad in accordance with the [Human Blood and Transplants Act](#) and these germ line cells are to be distributed and, or imported to a tissue establishment in Malta, there shall be a third-party agreement signed between the Maltese licensee and the licensee of the foreign tissue establishment:

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Provided further that there shall be no link of filiation in accordance with the provisions of the Civil Code between the embryo fertilised using donated germ line cells and the donor.

(2) A donor must be over eighteen (18) years of age, have the legal capacity to contract and of good mental and physical health and further satisfies the criteria specified in the Protocol.

(3) A donor must not have attained the age of thirty-six (36) years on day of donation:

Provided that the Authority may authorise a donor above this age limit in exceptional circumstances specified in the Protocol.

(4) Except in cases of a direct donation, the prospective parents or prospective parent shall only be entitled to obtain such generic information as specified in the Protocol about the donor whose identity shall in all cases remain confidential:

Provided that the medical records that may affect the health of the child and the identity of the donor or of the persons from whom an adopted embryo originated shall be accessible to the child conceived from the germ line cells of such donor upon the child reaching eighteen (18) years of age and, subject to the consent of the Authority, the medical records that may affect the health of the child shall be accessible to the parent or parents at any earlier stage in exceptional circumstances in which the life or health of the child born from such germ line cells is at risk:

Provided further that the Authority shall keep the records traceable to the identity of the donor for a period of sixty-five (65) years:

Provided further that if the Authority becomes aware of serious illness it shall be obliged to disclose the information to the parent or parents and, in the case that the child has attained majority, to the child.

(5) The donation of germ line cells for the purpose of medically assisted procreation shall be limited to one donation only and such donation shall be used in one prospective parent only.

(5A) Cryo-preserved germ line cells which have not been used in Malta may be exported and, or distributed to tissue establishments abroad:

Provided further that the exportation and, or distribution of germ line cells to tissue establishments abroad shall be recorded in

such a way as to ensure their traceability and such record shall be forwarded to the Authority without delay.

(6) It shall be the responsibility of every licensee receiving donor germ line cells to verify the eligibility and suitability of the donor and the prospective parent to whom the germ line cells are donated in terms of the foregoing provisions, to keep a register with updated records thereof, including the records traceable to the donors and to inform the Authority without delay the full details of every donation.

(7) Whosoever uses, transfers or fertilises any germ line cells in contravention of this article shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment:

Provided that where the person is a medical practitioner he shall be exempt from criminal liability where he shows that he took reasonable care to determine that the person from whom the germ line cells originated was a prospective parent or an eligible donor within the meaning of this Act.

(8) No person shall pay consideration to a donor or to any other person to arrange for the services of a donor or offer to pay such consideration:

Provided that oocytes donors may be compensated for the costs and expenses of the stimulation treatments.

Prohibition of
selection of sex.

10. (1) Whosoever artificially fertilizes a human egg cell with a sperm cell that is selected for the sex chromosome contained in it, shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than four thousand euro (€4,000) and not exceeding ten thousand euro (€10,000).

(2) Nothing contained in sub-article (1) shall be understood as preventing the selection of a sperm cell by a medical practitioner in order to prevent the child from falling ill with a sex-linked genetic illness.

Prohibition of
cloning.

11. (1) Any intervention seeking to create a human being genetically identical to another embryo, *foetus*, or human being, whether living or dead, is prohibited and for the purpose of this article, the term "genetically identical" means a human being sharing with another the same nuclear gene set.

(2) Whosoever intervenes or participates in any artificial intervention as referred to in sub-article (1) shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment.

(3) Whosoever transfers into a woman an embryo as referred to

in sub-article (1) shall be liable to the same punishment laid down in sub-article (2).

12. (1) Whosoever -

- (a) artificially fertilizes an egg cell without the consent of the woman, whose egg cell is to be fertilized, or without the consent of the man, whose sperm cell will be used for fertilization;
- (b) transfers an embryo into a woman without her consent;
- (c) knowingly artificially fertilizes an egg cell with the sperm of a man before or after his death, except in the case where the deceased has donated his sperm;
- (d) knowingly artificially fertilizes an egg cell of a woman before or after her death, except in the case where the deceased has donated her egg cells,

Unauthorised fertilisation, embryo transfer, and artificial fertilisation after death.

Amended by:
XXIV.2018.8.

shall be guilty of an offence and shall, on conviction, be liable to a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-five thousand euro (€25,000):

Provided that the punishment shall be decreased by one or two degrees -

- (i) as regards the woman whose egg has been fertilized, in respect of paragraph (c); and
- (ii) as regards the man whose sperm was used for fertilisation in respect of paragraph (d).

(2) Nothing in this Act shall be construed or interpreted in a way as to impede, for medical reasons and according to accepted medical norms, the taking and freezing of sperm or egg of a person with the aim of making use of that same sperm or egg at a later stage for the generation of an embryo.

13. (1) Subject to the provisions of sub-article (3), whosoever shall willfully alter in an artificial way the genetic information of a human germ line cell shall be guilty of an offence and, on conviction, shall liable to the punishment of a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment.

Prohibition of artificial alteration of human germ line cells.

(2) Whosoever knowingly uses a human germ line cell with artificially altered genetic information for fertilization shall be guilty of an offence and shall be liable to the same punishment laid down in sub-article (1).

(3) No offence shall arise, against the medical practitioner carrying out the medically assisted procedure, under sub-article (1) where the alteration of the genetic information of a germ line cell is the unintended consequence of inoculation, radiation or chemotherapeutic or treatment.

14. (1) Whosoever-

- (a) unites embryos with different genetic material to a cell

Prohibition of formation of chimerae and hybrids.

conglomerate using at least one human embryo; or

- (b) joins a human embryo with a cell that contains genetic information different from the embryo cells and induces them to develop further; or
- (c) fertilizes a human egg cell with the sperm of an animal or fertilizes an animal's egg cell with the sperm of a man, with the intention of generating an embryo capable of development,

shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) not less than ten thousand euro (€10,000) and not exceeding seventy thousand euro (€70,000) or to imprisonment not exceeding seven years or to both such fine and imprisonment.

(2) Whosoever transfers to a woman or an animal an embryo arising out of a procedure described in sub-article (1) or transfers to an animal a human embryo shall be guilty of an offence and shall be liable to the same punishment laid down in sub-article (1).

Prohibition of
experimentation on
human embryos.
Amended by:
XI.2022.8.

15. (1) Any experimentation on human embryos is prohibited and whosoever contravenes this sub-article shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) not exceeding seventy thousand euro (€70,000) and to imprisonment not exceeding seven years.

(2) The creation of human embryos for the purpose of research or experimentation or for any other purpose not permitted under this Act is prohibited and whosoever contravenes this sub-article shall be guilty of an offence and shall be liable to the same punishment laid down in sub-article (1).

(3) Clinical interventions on a human embryo are allowed on condition that said interventions pursue an exclusively diagnostic and, or therapeutic purpose related to the embryo and are in the interests of the health and development of the embryo itself:

Provided that nothing in this sub-article shall in any way be construed as prohibiting clinical interventions deemed permissible in terms of the Protocol, nor prohibiting the prospective parent and, or prospective parents from opting for the cryopreservation of the human embryo after the carrying out of any such intervention wherever such an option is deemed permissible in terms of the Protocol.

Wilful cause of
death of embryos.

16. (1) Whosoever wilfully causes the death of any embryo shall be guilty of an offence and shall, on conviction, be liable to a fine (*multa*) not exceeding twelve thousand euro (€12,000) or to imprisonment not exceeding two years or to both such fine and imprisonment.

(2) This article shall also apply to any human clone created in breach of article 11.

Application of
articles 121D and
248E(3) of the
Criminal Code.
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17. The provisions of articles 121D and 248E(4) of the [Criminal Code](#) shall, *mutatis mutandis*, apply to persons found guilty of an offence under this Act.

18. (1) The consent of the prospective parent or parents who are to have access to medically assisted procreation procedures is to be expressed in writing in such form, as may be prescribed by regulations under this Act also specifying whether they consent to cryo-preservation of any supernumerary embryos and whether they consent to the donation of embryos, if necessary, to and in the presence of the medical practitioner in charge of the procedure:

Informed consent.
Amended by:
XXIV.2018.9.

Provided that where the prospective parents are married or in a stable relationship, their consent shall be expressed jointly in writing in the prescribed form:

Provided further that when the prospective parent or prospective parents give their consent to cryo-preservation of any supernumerary embryos and for the donation of embryos if necessary, the medical practitioner in charge of the procedure shall implant up to a maximum of two embryos:

Provided further that when the prospective parent or prospective parents do not give their consent to the cryo-preservation of any supernumerary embryos and to the donation of fertilised eggs if necessary, the medical practitioner in charge of the procedure shall only fertilize up to a maximum of two eggs:

Provided further that consent to cryo-preservation may only be withdrawn in writing by the prospective parent or prospective parents before fertilisation.

(2) For the purposes of informed consent and before applying any procedure leading to medically assisted procreation, the medical practitioner in charge of the procedure shall inform in detail and in writing the prospective parent or prospective parents on:

- (a) the methods and treatment of any procedure to be employed;
- (b) the complications that may arise for the woman and potential offspring;
- (c) the probable chances of success of the said procedure;
- (d) all the risks involved to both prospective parents and the offspring;
- (e) the possible psychological effects as a result of the application of the said procedure to both prospective parents and offspring;
- (f) the bioethical issues, including the cryo-preservation process involved as referred to in article 4 and article 7;
- (g) where applicable, on the cost of the entire procedure;
- (h) the circumstances in which the Authority may give for adoption embryos to a third party in terms of this Act.

(3) The medical practitioner in charge of the procedure shall ensure that the prospective parents respectively receive independent clinical counselling before, throughout and after the procedure.

(4) Every medical practitioner responsible for a procedure of

medically assisted procreation shall ensure that a copy is kept of all the documentation required under this Act, including such documentation certifying that the informed consent required under this article was obtained after the same medical practitioner gave the prospective parents all the information and after ensuring that the prospective parent or prospective parents received the required counselling.

Status of child
born.
*Substituted by:
XXIV.2018.10.*

19. (1) Any child born as a result of any medically assisted procreation procedure, including cases where the child was born from donated germ line cells or a donated embryo, shall be considered to be the child of the prospective parent or prospective parents who have expressed their consent in writing as provided in article 18 and shall for all intents and purposes of law be deemed to have been naturally born of the same prospective parent or prospective parents without the intervention of any procedure as aforesaid; and notwithstanding the provision of any other law, any such child shall be registered in any act of civil status as the direct descendant of such prospective parent or prospective parents who shall enjoy such rights and bear such duties according to law in respect of such child.

(2) There shall be no link of filiation between the child born from donated germ line cells or adopted embryos and the persons from whom donated germ line cells or adopted embryos originated.

Conscientious
objection.

20. (1) A health care professional is under no obligation to participate in any procedure for the application of any technique of medically assisted procreation regulated by this Act when such professional considers such participation objectionable as a matter of conscience and declares his objection beforehand. Such a declaration shall be communicated within three months from the coming into force of this Act, to the Authority and to the director of the hospital or medical establishment with whom the health care professional is employed.

(2) The objection declared as provided in sub-article (1) may be revoked or the said objection may be declared even after the lapse of the period referred to in sub-article (1) but in such a case the declaration raising the objection shall only come into effect after the lapse of a month from the date of its communication as provided in sub-article (1).

(3) The objection declared as provided in sub-articles (1) or (2) shall have the effect of exempting the health care professional who makes the declaration from any participation in any procedure or activity specifically and necessarily directed towards the implementation of the technique or procedure leading to a medically assisted procreation but does not exempt him from providing assistance before or after the said procedure or activity.

Additional
penalties.

21. Without prejudice to any punishment as may be prescribed by this Act or by any other law, where the person convicted of an offence under this Act is a medical practitioner or a health care professional, the Court shall order that a copy of the judgment be served upon the competent council under the [Health Care Professions Act](#) and on the Minister.

Cap. 464.

22. (1) No premises may be used for any activity related to medically assisted procreation unless the premises are licensed for the purpose by the Licensing Authority according to the [Human Blood and Transplants Act](#) and any regulations made thereunder.

Licence for premises.
Substituted by:
XXIV.2018.11.
Cap. 483.

(2) It shall be the duty of every licensee to keep a confidential register with full details of every medically assisted procreation procedure, germ line cell donation, cryo-preservation of germ line cells and cryo-preservation of embryos in terms of this Act and to pass on this information to the Authority without delay.

23. (1) The Minister shall, with the concurrence of the Minister responsible for justice, have power to make regulations to:

Power to make regulations.
Amended by:
XI.2022.9.

- (a) prescribe anything which may be prescribed for the implementation and execution of the provisions of this Act;
- (b) regulate the licensing of any premises used for the execution of any procedure of medically assisted procreation including the conditions required for a medical practitioner to practice any such procedure in such premises;
- (c) lay down any conditions for the execution of such procedures of medically assisted procreation;
- (d) enact or to bring into force any Protocol referred to in this Act and to revoke, amend or vary the same.

(2) The Protocol issued in terms of this Act may be published in the English language only.
