Act CLIV of 1997 on Health

Parliament,
− inspired by its responsibility for the population’s health status,
− guided by the conviction that the interest of the individual in his health and well-being must take priority, and that the achievements of the development of medical science should be utilized to ensure positive benefit for present and future generations;
− being aware that health as a prerequisite for the individual's quality of life and self- realization has a major impact upon the family, work and, as a result, the entire nation;
− in consideration of the fact that the system of means and resources available to health services cannot serve the promotion, maintenance and restoration of health unless completed by a social welfare system, the protection of the natural and man-made environment, together with the social and economic environment, as well as by health promoting public policies and practices;
− with regard to recent scientific, technical, ethical, and social changes as well as to amendments and changes affecting the legal system, furthermore to our international obligations,
hereby creates the following Act setting out the complex system of conditions for the promotion and improvement of health.

Chapter VIII

BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Section 157

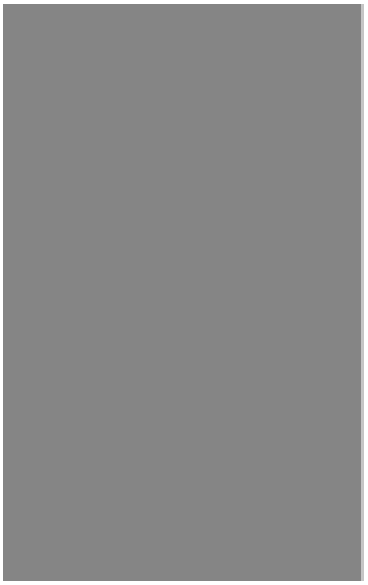
The objective of biomedical research involving human subjects (hereinafter: research) is to improve detection of the causes and origins of diseases and to facilitate treatment, prevention, and rehabilitation, and shall include interventions and modes of observation that deviate from the ones applied in usual healthcare services, or ones that apply factors (active ingredients, materials, implements, procedures, methods, circumstances, conditions) that have not yet become fully known or completely investigated.

Section 158

(1) Research may be conducted within the framework set forth in this Act, with the differences as set forth under separate statute with regard to clinical research on pharmaceuticals.

(2) The professional conditions and detailed rules for research shall be set forth by the Minister of Health, who shall consider the opinion of the MRC.

[38] Established by Section 13, Act LXXI of 1999. In force as of 1 July 1999 [39] Inserted by Section 13, Act LXXI of 1999. In force as of 1 July 1999
[40] Numbering amended by Section 13, Act LXXI of 1999.



e)
provided written consent to the research.

70

Section 159

(1) Research on persons with full disposing capacities shall be conducted exclusively for proposes of perfecting diagnostic, therapeutic, preventive, and rehabilitation procedures, of elaborating new procedures, and of gaining a better understanding of the etiology and pathogenesis of disease, and shall be conducted by a healthcare services provider with the appropriate professional conditions to meet the requirements of the nature and risks of the research, but only if all of the following conditions are met:

a)

b)

c)

d) of

the research plan has been approved for implementation;

preliminary investigations have certified the effectiveness and safety of the research;

there is no other procedure similar in effectiveness to research involving human subjects;

the risks of conducting the research on a person are proportionate to the expected benefit the research, or to the significance of the research goal;

the research subject, after being fully informed in accordance with Subsection (3), has

(2) Researchshallnotbeconductedifitpresentsadisproportionatelyhighrisktothelife,or physical or emotional well-being of the research subject.

(3) Prior to obtaining the consent of the research subject, he shall be informed orally and in written form of

a) the voluntary nature of participation in research, as well as of the fact that his consent may be withdrawn at any time without specifying cause or suffering any prejudicial consequences;

b) the experimental nature of the planned examination or intervention, of its objectives, and of its duration;

c) the nature, duration, and possible risks and consequences of the examinations or other interventions performed as part of the research, as well as of all the discomfort involved;

4. d) expected benefits of the research to the subject or to others;
5. e) possible other examinations or interventions that are available instead of participating in

the research;

f) the nature and treatment of any damage to health sustained in conjunction with the research, and of damages or compensation available;

g) the names of the person(s) responsible for the research.

(4) Research involving a person with impaired or limited disposing capacity may be conducted only if all of the following conditions are met:

1. a) the conditions set forth under Paragraphs a) - d) of Subsection (1) are met;
2. b) the results of the research can have an immediate beneficial effect on the health of the

research subject;

c) the research cannot be conducted effectively on a person who possesses full decision- making capacities;

d) the person set forth in Subsections (1) - (2) of Section 16 has consented to the research, in keeping with the provisions of Subsection (5) of Section 16.

(5) Under exceptional circumstances, the condition set forth under Paragraph b) of Subsection (4) may be waived if all of the following conditions are met:

a) the objective of the research is to enhance scientific knowledge related to the condition or disease of the research subject in a manner that is useful to said research subject or to other

persons who are similar in age and suffering the same disease, or who demonstrate similar characteristics and are in a similar state of health;

b) the risk of the research on the subject does not significantly exceed minimum, and the strain is mild;

c) the Minister of Health has granted permission for the research after hearing the opinion of the MRC.

(6) The research plan shall be approved for implementation by the executive of the healthcare institution, or in the case of another health service provider, by the executive of the regionally responsible Budapest or county inpatient institution, after receipt of the opinion of an independent professional and ethics committee made up of specialists in medicine, law, theology, ethics, and psychology, as defined in the Minister of Health Decree, in keeping with said opinion. If the committee rejects the proposal, the executive of the healthcare institution may submit a request to the MRC to revisit the opinion.

Section 160

In the case of an emergency, if the consent of the research subject or the person set forth in Subsections (1) - (2) of Section 16 cannot be obtained, exclusively an emergency experimental treatment expected to directly benefit the health of the research subject may be applied, if the research treatment can be applied within the framework of a research plan that has been granted previous approval.

Section 161

(1) An expectant or breast-feeding woman only may be used as a research subject if the research is expected to be of direct benefit to her or her child, or to the health of women and children in a similar phase of life, and if there is no procedure that would make it possible to conduct research with a similar outcome on women who are not expectant or breast-feeding.

(2) Noresearchshallbeconductedonpersonsorgroupsofpersonswhoarenotinaposition to freely consent to said research, because of considerations that put said persons in a state of financial or moral dependence on factors connected to the research or researchers, or if they are dependent on them for services.

(3) Research shall not be conducted on any person restricted in liberty or performing mandatory military service, even if they should consent to same. A person restricted in liberty but in possession of full disposing capacities may only, under this Act, be used as a subject for research if said research is of immediate and significant benefit to the person’s own health or to the health of an immediate family member or to that of a person in a similar situation, and if similar research results cannot be expected if conducting said research with persons who are not restricted in liberty as set forth in this Act.

(4) The Minister of Health, who shall consider the opinion of the MRC, shall grant permission to conduct research set forth under Subsections (1) - (3) .

Section 162

Research or interventions aimed at or resulting in modifications in the human genome shall be conducted only for preventive, diagnostic or therapeutic purposes and, with the exception of the provisions set forth under Subsections (1)-(2) of Section 182, shall be conducted only when the objective is not to alter the genetic complement of progeny or to bring about a new individual.

Section 163

In the course of research, the interests of the individual shall always have priority over the interests of science and society; therefore, the risk to the research subject shall be restricted to the lowest level possible.

Section 164

(1) In the event a research subject participating in research conducted in accordance with professional rules and the approved research plan suffers injuries or dies during the research, the state shall provide compensation to the subject or to his dependants.

(2)[41]Prior to beginning the research, the institution conducting the research shall have contracted for liability insurance specific to the research, in an amount corresponding to the risks involved.

Chapter IX

SPECIAL PROCEDURES TARGETED AT HUMAN REPRODUCTION, RESEARCH CONDUCTED USING EMBRYOS AND REPRODUCTIVE CELLS, STERILIZATION PROCEDURES

Section 165

For the purposes of this chapter

a) embryo: all live human embryos from the conclusion of fertilization until the 12th week of gestation,

b) fetus: all intra-uterine humans from the 12th week of gestation.
General Conditions of Special Procedures Targeted at Human Reproduction

Section 166

(1) Special methods that may be applied to human reproduction (hereinafter: reproduction procedures) are

1. a) in vitro fertilization and embryo implantation,
2. b) artificial in vivo fertilization using the sperm of the spouse or common-law spouse, or

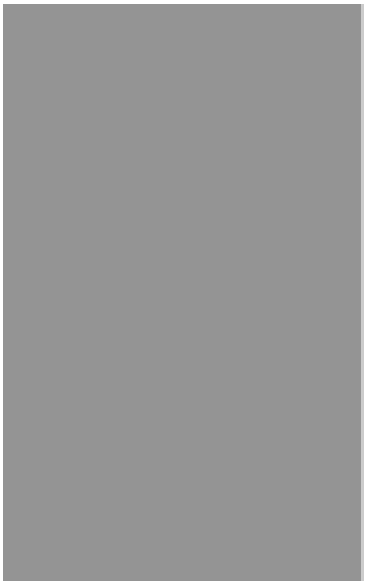
donor sperm,

c) in vitro fertilization using donor sperm and embryo implantation, d) implantation of donated embryos e)[42]

f) other methods to promote fertilization of female reproductive cells, to enhance the ability of said cells to become fertilized, and to promote the adhesion and development of fertilized reproductive cells.

(2) Only human reproductive cells or human embryos shall be used in fertilization and in embryo implants in the course of reproduction procedures.

[41] Amended by Paragraph f), Subsection (3), Section 24, Act LXXI of 1999. [42] Repealed by Subsection (1), Section 32, Act CXIX of 1999.



(3) Reproductive cells from deceased parties, including from persons who are brain-dead, or from dead fetuses, shall not be used in reproduction procedures.

(4) TheprovisionsofSections170-174,and/orSections175-179shalltakeprecedenceinthe donation of reproductive cells and/or embryos.

(5)[43] Only the methods set forth in Subsection (1) shall be applied as reproduction procedures.

Section 167

(1) Reproduction procedures may be performed on married couples or on two persons of opposing genders living together as common-law spouses if, for reasons of health existing among either party (infertility), it is highly probable that a healthy child cannot be produced through natural means. Among common-law spouses, the procedures only may be conducted if neither of the partners is married to another person.

(2) If the female reproductive cell already has been fertilized, the reproduction procedure may be continued by a woman who has become single by termination of the marriage (common-law) relationship. If, however, the fertilization was in vitro and the embryo has not yet been implanted, prior to the beginning of the reproduction procedure the married (common-law) couple may expressly preclude continuation of the procedure for the event of the death of the spouse (common-law spouse) by submitting a joint request focused on this eventuality as per Subsection (1) of Section 168.

(3) The reproduction procedures set forth in Subsections (1) - (2) only shall be performed when other methods of treating infertility have proven unsuccessful and when there is a medically founded chance that a healthy child will be conceived and born as a result of the procedure.

(4) Reproduction procedures may be conducted on recommendation of a competent specialist physician, and by a health service provider authorized to conduct said procedures in its operation license.

Section 168

(1)[44] A reproduction procedure, or in the case of a single woman, continuation of said procedure, shall occur at the joint written request of the married or common-law couple or of the single woman, in absence of a declaration of preclusion as set forth in Subsection (2) of Section 167, and within the framework of the law on disposition over an embryo that has been deposited. The request shall be formulated as a private legal document of full evidentiary validity. Common-law spouses shall submit a statement of their common-law relationship in the form of an official document.

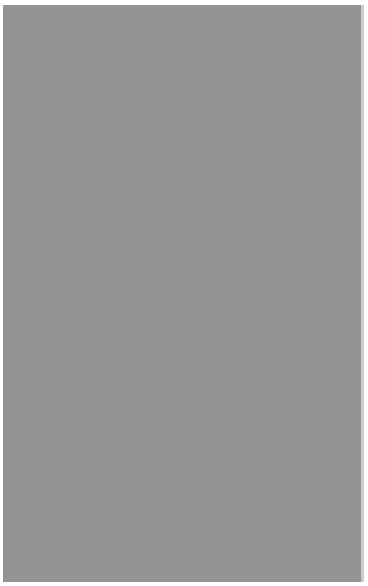
(2) Prior to beginning the procedure, the physician conducting the procedure or a member of the medical team shall meet with the applicants, who shall appear together and in person, and provide oral and written information on the reproduction procedures that can be conducted in their given case. The information shall include, in particular:

1. a) the medical indications for the procedure;
2. b) the nature of the procedure that can be performed, possible further and additional medical

interventions that may become necessary during execution;

c) the effects of drug treatment necessary prior to performing the intervention;

[43] Inserted by Section 16, Act CXIX of 1999. In force as of 1 January 2000.
[44] Established by Section 14, Act LXXI of 1999. Amended by Subsection (1), Section 32, Act CXIX of 1999.



4. d) the effects and possible risks to the unborn child and/or the subjects of the intervention;
5. e) the expected results of the procedure;
6. f) the expected costs of submitting to the procedure;
7. g) the statutes regulating execution of the procedure.

(3) When informing the patient as set forth under Subsection (2), general rules on providing information to patients as set forth in this Act shall have precedence, however, the spouse or common-law spouse not participating directly in the intervention also shall be entitled to the legal status of patient. If several of the reproduction procedures set forth in Subsection (1) of Section 166 may be applied, the information shall cover all procedures that can be conducted and shall also include a concrete medical recommendation for one of the procedures.

(4) The reproduction procedure only shall be begun on receipt of a joint written statement of consent written after they have been informed, or - in the case of a single woman - shall only be continued after a written statement of consent from the applicant has been received.

(5) Only a person in full possession of his disposing capacity shall be entitled to make the legal declarations set forth in Subsections (1) and (4).

Section 169

(1) A Minister of Health Decree shall set forth the professional conditions for the operation of healthcare providers authorized to conduct reproduction procedures, the set of health indications serving as the basis for the various interventions, and the detailed professional rules for performing the healthcare interventions.

(2) Operation license to perform reproduction procedures shall be awarded only to health service providers which can simultaneously meet the professional requirements set forth under separate statute for the frozen storage of reproductive cells and embryos.

Donating and Depositing Reproductive Cells Section 170

(1) Reproductive cells may be donated for use in reproduction procedures or for medical research, and shall be used only for the purpose specified by the donor.

(2) When conducting a reproductive procedure, the reproductive cells used shall all come from the same donor.

(3) Remuneration for donating reproductive cells shall not be requested or provided. Donation-related necessary and certified costs of a donor, including loss of income, shall be reimbursed, within the sphere and under the conditions set forth by Minister of Health Decree.

Section 171

(1) Reproductive cells may be donated by any person in full possession of his disposing capacity, when cells are donated for a reproductive procedure, by persons under the age of 35 years, who meets the conditions set forth under separate statute.

(2) Reproductive cells for reproduction procedures or for reproductive cell research can be donated directly to healthcare providers and/or research facilities authorized to conduct reproduction procedures or reproductive cell research. Natural persons, legal entities, or unincorporated organizations that are not authorized to conduct reproduction procedures or

research shall not accept human reproductive cells or materials containing said cells as donations, and cannot claim ownership to same.

(3) The donation set forth under Subsection (2) shall occur by providing a written declaration of donation to the health service provider or research facility authorized to accept reproductive cells and by appearing in person at the institution for harvesting the substance containing the reproductive cells. When donating the cells for a reproduction procedure, the donor's declaration shall contain the name of the donor (family and given name, maiden name), mother's maiden name, address, date of birth, gender, physical description, and all illnesses of which the donor is aware.

(4) The health service provider to which a donation has been offered, prior to harvesting the reproductive cells being donated for reproductive procedures, shall see to it that the donor, who has appeared in person, undergoes a preliminary medical examination, and shall orally inform the donor of the purpose and conditions of the donation. When appearing in person, the donor shall credibly certify the correctness of the personal data submitted.

(5) A donor declaration and preliminary medical examination as set forth in Subsections (3) and (4) are necessary only prior to the first harvesting of reproductive cells, if the donations of reproductive cells are made repeatedly, on an ongoing basis. The ongoing nature of the donations does not exempt the donor from providing information on any known illnesses.

(6) The health service provider or research facility authorized to accept donations of reproductive cells may reject the donation without specifying cause. Donations offered for reproductive procedures shall be rejected if

1. a) the donor has a disease which precludes donation;
2. b) the donor refuses to provide the personal and special data set forth in Subsection (3) and

if the data cannot be learned in another credible manner;

c) the donation is made in a manner other than by harvesting of substance containing reproductive cells during a personal appearance before the health service provider that is competent by the place of donation.

(7) All persons and bodies shall be obliged to take measures resulting in the immediate destruction of reproductive cells or substances containing reproductive cells coming into their possession through donations made in an unauthorized manner or coming into their possession through donations made in an authorized manner but rejected on the basis of Subsection (6).

Section 172

(1) All personal and special data learned by the health service provider or the research facility through the provisions of Subsection (3) of Section 171 or the personal appearance and examination of the donor, shall be managed in accordance with the provisions of Act 63 of 1992 on the Protection of Personal Data and the Publicity of Data of Public Interest, and of Act 47 of 1997 on the Handling and Protection of Health Data and Related Personal Data, with due consideration for Subsections (2) - (4).

(2) The health service provider shall handle only the personal and special data listed under Subsection (3) of Section 171 in relation to donations of reproductive cells. In the course of data management, with

respect to personal data, information on name and address shall not be transferred but all other data, treated so that it cannot be used to identify a person, may be transferred to the bodies or persons defined in Subsection (3). A reproductive service provider learning of data that is outside the scope of lawful data management shall take immediate measures to destroy said data.

(3) In the course of data management as set forth under Subsection (2), personal and special data may be provided to other healthcare providers authorized to conduct reproduction procedures, or to persons authorized to make use of reproduction procedures, with the restrictions set forth in Subsection (2).

(4) Of the data learned in connection with the donation of reproductive cells, research facilities may manage only data specific to the state of health, and the illnesses of the donor. The right to manage data includes maintaining records of the data that are authorized to manage in a manner that prevents personal identification, and transferring or disclosing said data only as it relates to the objectives and/or results of medical research.

Section 173

(1) A health service provider only may provide reproductive cells donated for reproductive procedures in order to conduct said procedure and only to the extent made necessary by the procedure, under the restrictions set forth in Subsection (2), either for procedures that it shall conduct or for procedures conducted by another healthcare provider authorized to conduct reproductive procedures.

(2) When providing reproductive cells, it shall be ensured that the number of progeny from one and the same reproductive cell donor shall not exceed four, even when reproductive procedures are performed on different persons. Reproductive cells used in a single reproductive procedure shall all come from the same donor.

(3) Prior to issuing donated reproductive cells, when the reproductive procedure is being performed by another health service provider, using the data made available by the institution conducting the intervention, the health service provider storing the reproductive cells shall ascertain that the reproductive cells can be used for the given reproduction procedure, and determine the absence of any possible biological incompatibility. The persons applying for the reproductive procedure shall provide data suitable for identification to the facility conducting the investigation, if this is necessary to complete the investigation.

(4) The health service provider handling the storage of the reproductive cells shall provide no information on the circumstances under which the reproductive cells were transferred or on the data of persons involved in their use, and shall not transfer any such data, or disclose any of it.

(5) Aresearchfacilityonlymaytransferreproductivecellsforpurposesofmedicalresearch, and only to a healthcare provider or research facility authorized to receive reproductive cells.

Section 174

(1) The health service provider shall store donated and accepted reproductive cells by freezing them. Storage of reproductive cells can be precluded or limited in duration by the provisions of separate statute. On expiration of the limited duration, the stored reproductive cells shall be destroyed.

(2) On medical grounds and on recommendation of a specialist physician or when otherwise requested for cause, facilities may accept deposits of reproductive cells from persons in possession of full disposing capacities for frozen storage to be used by the depositor at a later date (reproductive cell deposits). Only reproductive cells coming from the depositor and personally harvested from depositor shall be accepted for storage.

(3) Reproductive cells that have been deposited may be provided to health service providers conducting reproduction procedures on the written request of the depositor. On the written

request of the depositor, the reproductive cells shall be destroyed before expiration of the storage time limit.

(4) Inthecourseofstoringreproductivecells,cellsfromdifferentdonors,cellsfromoneand the same donor harvested at different times, cells donated for different purposes, and various samples of cells provided for deposit, shall not be mixed.

(5) Continuousrecordsshallbekeptonreproductivecellsstored,andontheissuance,useor destruction of said cells. To maintain these records, the reproductive cells shall be stored in a manner enabling identification of the donor, or when stored for purposes of research, in a manner that does not enable identification of the donor, and each storage unit shall be affixed with an identification code.

Embryo Donations and Deposits Section 175

(1) The married (common-law) couple shall jointly exercise the right of disposal over an embryo brought about in vitro for reproductive purposes until the death of one of the partners, irrespectively of any subsequent change in the spousal (common-law spousal) relationship, but either of the parties shall have the right to renounce the right of disposal in an official document or a private document with full evidentiary authority. When there is a difference of opinion, the rules of embryo deposit shall be appropriately applied.

(2) The married (common-law) couple participating in a reproduction procedure involving their own reproductive cells shall be jointly entitled to the right of disposal of an in vitro embryo brought about through reproductive cell donation, also in keeping with the provisions of Subsection (1).

(3) The right of disposal over an embryo set forth in Subsections (1)-(2) shall include the right to deposit it for possible later use (embryo deposit), or to donate it to other persons for use in a reproduction procedure, or to offer it to research. In the absence of proper provisions, or knowledge of said provisions, it shall be assumed that the intention was to deposit a healthy embryo.

(4) Embryos coming from identical persons shall be used in reproduction procedures on a maximum of two other persons.

Section 176

(1) An embryo can be offered through a written declaration by the persons authorized to decide upon its disposal, which shall include the objective of the offer and, when offered as an embryo donation, the ages and physical characteristics of the persons contributing to the embryo, and any illnesses known to the persons making the declaration.

(2) When offering and/or rejecting an embryo, the provisions of Subsection (2) of Section 171 shall be applied, as appropriate.

(3) Thehealthserviceproviderorresearchfacilityofferedtheembryomayrejecttheembryo offered if it is probable that it will not be able to use it for the purpose specified within the time frame under which it can be used, however, it shall be mandated to safeguard it and store it until use under Subsection (4). An offer of an embryo donation shall be rejected if it is not probable that a healthy child can develop from said embryo.

(4) Any body or person gaining possession of an embryo without the authority to do so, or with the authority to do so, but when the offer of the embryo has been rejected in accordance

with Subsection (3), shall be obliged to transfer the embryo to an authorized health service provider or research facility. A damaged embryo may only be transferred to a research facility. The possessor of the embryo must safeguard an embryo not transferred to another authorized facility, or to destroy a damaged embryo, pursuant to the provisions of Subsection (5).

(5) All healthcare providers and research facilities shall accept transfer of a viable embryo from a person or body clearly unauthorized to possess said embryo, and treat disposal of the embryo in keeping with the intent or assumed intent of the parties authorized to decide upon its disposal in keeping with Subsection (3) of Section 175.

Section 177

(1) Personalandspecialdatalearnedbythehealthcareproviderortheresearchfacilitythatis related to donations of embryos or donations for purposes of research shall be treated in accordance with data management for the donation of reproductive cells contained in this Act, with the constraint that in embryo donation procedures, only the data set forth under Subsection (1) of Section 176 shall be managed.

(2) In procedures involving embryo donations, management of data related to embryos and to the donation of reproductive cells learned in an authorized manner by healthcare providers and which is connected to personal and special data that can be managed in at least one of the procedures shall not be considered unauthorized management.

Section 178

(1) Release of embryos that have been donated or offered for research, storage of embryos by health service providers, and deposits of embryos shall be governed by the provisions of Subsections (1), and (4) -(5) of Section 173 and by Subsections (1) - (3), and (5) of Section 174 with the difference set forth in Subsections (2) - (3).

(2) Anembryoshallbedepositeduponmeasurestakenbytheperson(s)authorizedtodecide upon its disposal, or on the basis of the assumed intention of that person (those persons) as set forth by this Act. Stipulation of the medical ground or other cause for depositing the embryo shall not be necessary.

(3) An embryo that has been deposited shall be released only on the basis of a written declaration expressing the agreement of both parties with the right to decide on disposal, except in the case of the death of one party, or a renunciation of said rights.

(4) An embryo shall be released to a single woman with the right to decide upon disposal following the death of her spouse (common-law spouse) for purposes of implanting, in the absence of a declaration precluding this as set forth in Subsection (2) of Section 167. If such a declaration of preclusion exists, the declaration of the person authorized to decide on disposal of the deposited embryo shall have precedence; in lieu of such a declaration the stipulations set forth for embryo donation shall be properly applied, and in doing so the healthcare provider at which the embryo was deposited shall be considered the healthcare provider making the donation.

(5) An embryo offered for donation shall be stored for a maximum of 5 years, which can be extended for one additional 5 year period. The maximum length of time during which a deposited embryo shall be stored is 10 years. An embryo that remains unused shall not be destroyed before expiration of the duration of the permitted storage period, unless it is probable that it is damaged. After expiration of the permitted storage period, the healthcare provider shall destroy the embryo or may use it for scientific research, precluding the

possibility that it may be used for reproductive purposes, or may transfer it to a research institute authorized to use it for such purposes.

Section 179

(1) It shall be the right of a child conceived and born as the result of donated reproductive cells and/or embryos to learn of the circumstances of his conception and birth upon reaching his majority, which shall include making available the data set forth in Subsections (2) - (3) of Section 172.

(2) The birth parent of the child, or immediately prior to the attainment of his majority, the legal guardian of the child shall be authorized to provide the information set forth in Subsection (1).

(3) When a child is conceived and born in accordance with Subsection (1) the persons requesting use of the reproductive cell or the reproduction procedure involving implantation of the embryo shall be considered the birth parents. An embryo conceived through in vitro fertilization shall be legally considered a viable fetus from the date of implantation.

(4) In the course of a procedure to determine the legal status of a child within the family, on request of an authority conducting proceedings, or of either of the members of the married couple (common-law couple) participating in the reproduction procedure, the healthcare provider performing the intervention shall certify to the fact of conducting the reproduction procedure and to its result.

Research, Investigations, and Interventions
that May Be Conducted with Embryos and Reproductive Cells

Section 180

(1) Research with embryos or reproductive cells may be conducted on the basis of a permit issued by the Human Reproduction Committee as set forth in Section 186, in keeping with the order of documentation set forth in the permit and in accordance with the research plan approved simultaneously, by a healthcare provider or other research facility that has the professional conditions available to meet the objectives of the research.

(2) Embryos and reproductive cells shall be used for research, only for the research objectives set forth in Subsection (1) of Section 159.

(3) Embryos shall not be brought into existence for research purposes; research shall be conducted only on embryos brought about for reproductive purposes when this is authorized by the persons authorized to decide upon its disposal, or when the embryo is damaged.

(4) Human embryos shall not be implanted into the body of an animal, and human and animal reproductive cells shall not be used to fertilize one another.

(5) During reproductive procedures or other healthcare services, or during medical research, an embryo shall not be turned into multiple embryos or, with the exception of the provisions of Subsection (1) - (2) of Section 182, shall not be manipulated by changing its characteristics from those existing at the time of conception or by introducing new characteristics when the embryo is intended for viability; multiple individuals that conform to one another genetically shall not be brought about.

Section 181

(1) An embryo on which research has been conducted must not be implanted into the human body, and reproductive cells that have been used for research must not be used in

reproductive procedures. An embryo used for research shall be kept viable for a maximum of 14 days, not counting the time it was frozen for storage, even considering the duration of the research.

(2) Examinations for purposes of diagnostics or therapy, or to determine the suitability of an embryo for replanting or implanting, shall not qualify as embryo research for purposes of applying this Act.

Section 182

(1) Procedures to select the gender of progeny prior to birth may be conducted to identify heritable diseases linked to gender or to prevent the occurrence of said diseases.

(2) Various genetic specifics of an embryo may be altered, as opposed to the provisions of Subsection (1), to prevent or treat diseases expected to occur in the child that will be born, to the extent and in the manner considered absolutely necessary to achieve the purpose.

(3) Separation of the cells in an embryo only shall be done to diagnose diseases considered probable to occur in the child once born, and to determine damage to an embryo.

(4) The married couple (common-law couple) bringing about the embryo shall give awritten statement of consent, after receiving proper information, prior to completing the procedures set forth in Subsections (1) - (3), which shall be executed by a healthcare provider authorized to conduct reproduction procedures.

Sections 183-184[45]

Reducing the Number of Embryos or Fetuses in Multiple Pregnancies

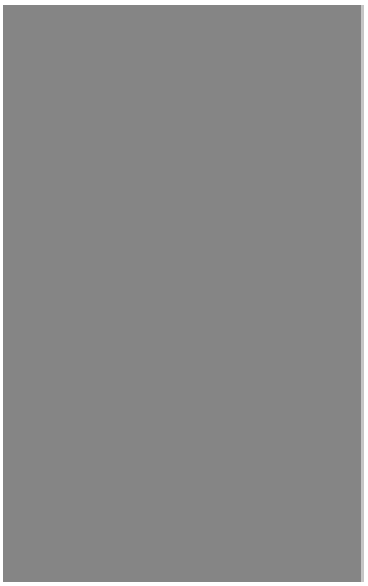
Section 185

(1) When a multiple pregnancy exists, intrauterine intervention may be conducted when it is considered medically probable that certain embryos (fetuses) have development disorders rendering them non-viable or, while viable, have suffered damage resulting in serious and untreatable disabilities, to reduce the embryos (fetuses) carried to term to the healthy ones.

(2) In order to carry the pregnancy to term, to bring healthy children into the world, or to ensure a safe pregnancy that does not endanger the life and well-being of the embryos (fetuses) or the mother, the number of embryos (fetuses) in a multiple pregnancy can be reduced even when all embryos (fetuses) are healthy.

(3) In the case set forth under Subsection (1), on recommendation of the responsible genetic counselor, the number of intra-uterine fetuses can be reduced up until the 20th week of gestation, or, if the diagnostic process is prolonged, until the 24th week. With respect to a multiple pregnancy set forth under Subsection (2), on recommendation of a specialist physician, the number of fetuses can be reduced until the 12th week of gestation, or if there is an obstacle to diagnosing the multiple pregnancy at an earlier time, until the 14th week of gestation.

(4) In procedures to reduce the number of intra-uterine embryos (fetuses), the provisions of Act 79 of 1992 on Protection of Fetal Life (hereinafter: Fetal Protection Act) shall have precedence in issues not regulated by this Act. The provisions of this Act do not effect the



[45] Repealed together with the subtitle preceding Section 183, by Subsection (1), Section 32 of CXIX of 1999

opportunity to reduce the number of fetuses for other reasons set forth by the Fetal Protection Act as cause for premature termination of a pregnancy (abortion).

The Human Reproduction Committee Section 186

(1) The MRC's Human Reproduction Committee (hereinafter: Committee) shall operate as the Minister of Health's advisory, decision-making and supervisory body in the area of reproduction procedures and medical research conducted with embryos.

2. (2) TheCommitteeshallconductthetaskssetforthinthis Actandbyseparatestatute.
3. (3) Inparticular,thetasksofthecommitteeshallbeto

a) provide preliminary opinions on granting operation licenses to healthcare providers to conduct reproduction procedures and/or so store reproductive cells (embryos) in frozen form, to continuously monitor operations, and when necessary to make recommendations on specific measures to be taken by the health service providers, the bodies maintaining them, and by the health authority responsible for professional supervision;

b) grant permits for medical research with embryos and/or reproductive cells, based on the research plan documentation presented to it;

c) render opinions of statutes and professional rules affecting reproduction processes, and to propose the establishment or amendment of statutes;

d) continuously evaluate domestic and international practices related to reproduction procedures, and to research with embryos.

(4) InconductingthetaskssetforthunderParagrapha)ofSubsection(3),anymemberofthe Committee shall be authorized to enter the premises of a healthcare provider being monitored, to access documentation on the various interventions, and to request additional information on the activity being studied.

(5) One portion of the Committee members shall be appointed by the Minister of Health from among board-certified obstetricians/gynecologists with satisfactory experience in the profession, and from among persons with legal qualifications, while the other portion shall be delegated directly by social organizations and scientific bodies affected by the conduction of reproduction procedures.

(6) The detailed rules governing the tasks, operation, and composition of the Committee shall be regulated by a Minister of Health Decree.

Sterilization Section 187

(1) Sterilization, which shall render either gender incapable of reproduction may be performed for purposes of family planning, or for medical reasons, based on a written application from the woman or man affected, on a satisfactory specialist medical opinion, or on recommendation of the latter.

(2) Sterilization for purposes of family planning may be performed on a person over the age of 35 years, or a person who has three birth children of his own. To validate an application by the persons set forth in Subsections (1)-(2) of Section 16, the agreement of the public guardianship authority is necessary.

(3) Sterilization for purposes of family planning shall be performed only on Hungarian citizens with an address or place of residence in Hungary.

(4)[46] Sterilization may be performed only after three months have elapsed after the date on which the application was submitted, except when

a) a delivery or other surgical event makes it possible to complete the intervention as a priority case, or

b) a pregnancy that might occur in the interim would directly endanger the life, physical well-being or the health of the woman, or when it is highly probable that a child born of the pregnancy would not be healthy.

(5)[47] Prior to beginning the intervention, a physician appointed by the healthcare provider that will conduct the intervention shall provide information to the applicant, and if married or living in a common law marriage, to the spouse or common-law spouse as well, on other opportunities for contraception, as well as on the nature of the intervention, and the possible risks and consequences.