

Act containing rules relating to the use
of gametes and embryos
(Embryos Act)

Greetings to all who shall see or hear these presents! Be it known:

Whereas We have considered that it is desirable out of respect for human life to prohibit certain uses of human gametes and embryos, to regulate the conditions under which other uses of human gametes and embryos with a view to improving medical care may be permitted, and to lay down rules regarding control over gametes and embryos;

We, therefore, having heard the Council of State, and in consultation with the States General, have approved and decreed as we hereby approve and decree:

Division 1. General provisions

Section 1

In this Act the following words shall have the following meanings:

- a. Our Minister: Our Minister of Health, Welfare and Sport;
- b. gametes: human spermatozoa and oocytes;
- c. embryo: a cell or a complex of cells with the capacity to develop into a human being;
- d. foetus: an embryo in the human body;
- e. Central Committee: the committee referred to in Section 14 of the Medical Research (Human Subjects) Act;
- f. the person who commissions the research: the person who commissions the organisation or performance of a research project;
- g. the person carrying out the research: the person who is charged with the actual performance of the research. If the research is actually carried out by an employee or some other assistant, the person who makes use of that person shall be regarded as the person carrying out the research.

Section 2

1. The managing board of an establishment where embryos are created outside the human body, or other procedures involving embryos are carried out, shall draw up a protocol regarding the use of gametes and embryos after receiving recommendations from the committee which, pursuant to the Medical Research (Human Subjects) Act, is charged with the assessment of research proposals for medical research in the establishment. Any changes and additions to the protocol shall likewise require prior recommendations from the aforementioned committee.
2. Taking into consideration Sections 5 to 9, rules shall be laid down in the protocol regarding control over gametes and embryos, the creation of embryos outside the human body, inducing a pregnancy with those embryos and the use of gametes and embryos for other purposes, in so far as this is relevant to the establishment in question.

3. The protocol shall contain in any event rules relating to:
 - a. the manner in which ovary stimulation takes place;
 - b. the manner in which gametes are obtained;
 - c. the procedure for fertilisation and for the development and implantation of embryos;
 - d. the manner in which gametes and embryos are stored and how the origin of the embryos and their storage is entered in the establishment's records;
 - e. the period for which gametes and embryos may be stored and what happens once this period has elapsed;
 - f. the procedure with respect to making gametes and embryos available for other purposes and for posthumous use.
4. Together with the recommendations referred to in subsection 1, the protocol and any changes thereto shall be brought to the notice of the Central Committee and Our Minister, as shall any plans to perform in the establishment procedures with gametes and embryos which will lead to a change or an addition to the protocol.

Section 3

1. Research involving embryos, including research involving gametes leading to the creation of embryos, shall be performed in accordance with a specially drafted research protocol which contains a full description of the intended research.
2. The research shall be permitted only if a favourable recommendation on the research protocol is received from the Central Committee.

Section 4

1. The Central Committee shall submit an annual report to Our Minister regarding the application of this Act, giving particular consideration to new developments regarding the use of gametes and embryos.
2. Our Minister shall send this report to both the House of Representatives and the Senate, together with his view of the new developments identified by the Central Committee.
3. Rules may be laid down by order in council with regard to the manner in which Our Minister prepares the view referred to in subsection 2.

Division 2. Rules governing control over gametes and embryos

Section 5

1. Adults who are capable of making a reasonable assessment of their interests in this regard may make their gametes available in order to induce pregnancy in another person or for research purposes, without prejudice to cases in which the gametes are intended for the said adults' own medical use and without prejudice to Section 9.
2. Gametes may be made available as referred to above only by means of a written donation and without consideration, and only after a person as referred to in subsection 1 has been informed by the person storing the gametes regarding the nature and the purpose thereof. The person concerned may revoke his/her decision at any time before the gametes are used, without giving reasons.
3. If an invasive procedure is required in order to obtain gametes from the person concerned, the latter shall also be informed by the person

who performs the procedure of the attendant risks and draw-backs. In that case, consent shall also be required from the committee referred to in Section 2, subsection 1, which shall determine whether the interests served by making the gametes available are in proportion to the risks and drawbacks of the procedure, having regard to the circumstances of the person concerned. In so far as is necessary, Section 5 of the Medical Research (Human Subjects) Act shall not apply in such cases.

Section 6

1. The information shall be supplied in such a way that it is reasonably certain that the person concerned has understood it and in the case referred to in Section 5, subsection 3, shall be supplied in writing. The person concerned shall be given sufficient time for reflection to allow him/her to make a carefully considered decision on the basis of the information provided about making his/her gametes available .
2. When gametes are made available in this way, the purposes for which the gametes may be used and the period for which they will be kept shall be laid down in writing. The person storing the gametes and the person who has made them available may jointly change the purposes and extend the period.
3. When making his/her gametes available, the person concerned may stipulate that research may be performed using the gametes in question only after he/she has been informed about the purpose of the research and has given his/her express consent for such research.
4. If gametes are made available in order to induce pregnancy in another person, the person concerned shall be given the opportunity to stipulate that his/her consent is required for the use of embryos created using his/her gametes for any other purposes.

Section 7

If they were not made available for other purposes, the gametes shall in any event be destroyed upon expiry of the period for which they were made available and if the decision to make them available is revoked. Furthermore, the gametes shall be destroyed if it has come to the attention of the person storing them that the person concerned has died, unless the latter has expressly consented in writing to their being used after his/her death.

Section 8

1. Adults who are capable of making a reasonable assessment of their interests in this regard may make available for the following purposes embryos which have been created outside the body for their own pregnancy, but which will no longer be used for this purpose:
 - a. to induce pregnancy in another person;
 - b. to culture embryonic cells for medical purposes, medical and biological research and medical and biological education;
 - c. to carry out research that is permissible under this Act using those embryos.
2. Embryos may be made available only by means of a written donation and without consideration, and only after the persons concerned, including the person whose consent is required pursuant to Section 6, subsection 4, have been informed by the person storing the embryos

regarding the nature and the purpose thereof. Where a difference of opinion arises between the parties concerned, the embryos shall not be made available. Any of the persons concerned may revoke his/her decision at any time before the embryos have been used, without giving reasons.

3. Sections 6 and 7 shall apply *mutatis mutandis*.

Section 9

1. Adults who are capable of making a reasonable assessment of their interests in this regard may make their gametes available for the creation of embryos specifically for:
 - a. culturing embryonic cells intended for implantation in humans where this can only be achieved using cells from specially created embryos;
 - b. carrying out research using those embryos that is permissible under this Act.
2. Sections 5 (subsection 2 and 3), 6 and 7 shall apply *mutatis mutandis*.

Division 3. Rules governing research with embryos outside the human body which does not induce pregnancy

Section 10

The Central Committee shall deliver a favourable recommendation on a research protocol concerning research with embryos which does not induce pregnancy only if:

- a. it can reasonably be assumed that the research will lead to new insights in the field of medical science;
- b. it can reasonably be assumed that the insights referred to under a. cannot be achieved through any forms or methods of research other than research with the embryos in question or through a less invasive form of research;
- c. the research in question meets the standards of proper research methodology;
- d. the research is carried out by or under the direction of persons who are expert in the relevant research area;
- e. the research also satisfies requirements which might reasonably be imposed on it in other respects.

Section 11

Carrying out research with embryos created specifically for this purpose is prohibited. This prohibition shall not apply to research which is reasonably likely to lead to new insights in the fields of infertility, artificial reproduction techniques, hereditary or congenital diseases or transplant medicine, and which can only be performed by making use of embryos as referred to in the first sentence.

Section 12

1. Carrying out research with embryos is prohibited unless these embryos, or the gametes from which they were created, were made

available for that purpose and, if necessary, Section 6, subsections 3 and 4 have been applied (or applied *mutatis mutandis*).

2. If Section 6, subsection 3 is applied (or applied *mutatis mutandis*), Section 5, subsection 2 and Section 6, subsection 1 shall apply *mutatis mutandis*.

Section 13

The person who commissions the research is responsible for compliance with Section 3.

Section 14

The person carrying out the research is responsible for ensuring that the privacy of the individuals from whom the gametes originate and those who have made an embryo available is protected as far as possible.

Section 15

The person carrying out the research is responsible for ensuring that, before the research commences, those individuals whose professional cooperation is required in the performance of the research are informed about its nature and purpose.

Division 4. Rules governing research with embryos outside the human body which is intended to induce pregnancy

Section 16

The Central Committee shall deliver a favourable recommendation on a research protocol concerning research with embryos outside the human body which is intended to induce pregnancy only if:

- a. it can reasonably be assumed that the research will lead to new insights with regard to research or therapeutic methods that are aimed at inducing pregnancy and the birth of a healthy child;
- b. it can reasonably be assumed that the new insights referred to under a. cannot be achieved through any forms or methods of research other than research with embryos with which a pregnancy is intended to be induced or through a less invasive form of research;
- c. it can reasonably be assumed that the interests to be served by the research are proportional to the drawbacks and risks for the potential child and the woman in question and
- d. the requirements laid down in Section 10 c, d and e have been satisfied.

Section 17

1. Carrying out research as referred to in Section 16 without the written consent of the woman and her husband, registered partner or other life companion is prohibited. Consent may only be given by adults who are capable of making a reasonable assessment of their interests in this regard.
2. Before consent is requested, the person carrying out the research shall ensure that the persons from whom consent is required are informed

in writing about the purpose and nature of the research, the provisions of the third sentence of subsection 3 and the provisions of subsection 5 of this Section and the provisions of Section 14.

3. The information shall be supplied in such a way that it is reasonably certain that the persons from whom consent is required have understood it. If required, the information supplied shall be supplemented. The persons from whom consent is required shall be given sufficient time for reflection to enable them to make a carefully considered decision regarding consent.
4. The manner in which this Section is to be put into effect shall be established in the research protocol.
5. A person who has given consent may withdraw it at any time, without giving reasons. He/she shall not be obliged to pay any compensation in respect of the withdrawal.

Section 18

Sections 13, 14 and 15 shall apply *mutatis mutandis* to research as referred to in this Division.

Division 5. Rules governing research with fetuses

Section 19

The Central Committee shall deliver a favourable recommendation on a research protocol concerning research with fetuses only if:

- a. it can reasonably be assumed that the research will lead to new medical insights in relation to unborn and newborn children or regarding the continuation of pregnancies to term;
- b. it can reasonably be assumed that the objective referred to under a. cannot be achieved through any forms or methods of research other than research with fetuses or via a less invasive form of research;
- c. it can reasonably be assumed that the interests to be served by the research are proportional to the drawbacks and risks for the fetus and the woman in question and
- d. the requirements laid down in Section 10 c, d and e have been satisfied.

Section 20

Research using a fetus is permitted only if it might assist in the diagnosis, prevention or treatment of serious diseases in the fetus concerned and if it cannot be postponed until after the birth.

Section 21

1. Carrying out research using a fetus without the written consent of the pregnant woman is prohibited. If she is a minor and under sixteen years of age, written consent is also required from her parents or guardians.
2. If the pregnant woman in question is not capable of making a reasonable assessment of her interests in this regard, consent may be given by her parents or guardians or, if she is of age, by her legal representative or, in the absence of the latter, by her husband, registered part-

- ner or other life companion.
3. Before consent is requested, the person carrying out the research shall ensure that the persons from whom consent is required are informed in writing regarding:
 - a. the purpose, nature and duration of the research;
 - b. the risks which the research may entail for the health of the pregnant woman and the foetus;
 - c. the risks which premature termination of the research may entail for the health of the pregnant woman and the foetus and
 - d. the drawbacks which the research may entail for the pregnant woman and the foetus.
 4. Section 17, subsections 3 and 4 shall apply *mutatis mutandis*.
 5. The pregnant woman, or, if she is not competent to give consent under the terms of this Section, the person who is competent on her behalf, may withdraw consent at any time, without giving reasons. She shall not be obliged to pay any compensation in respect of the withdrawal.

Section 22

1. If the research should take a course which is significantly less favourable for the pregnant woman or the foetus than is foreseen in the research protocol, the person carrying out the research shall notify the person who has given consent and the Central Committee to this effect, requesting a further recommendation from the Committee. The research shall be suspended until such time as a further recommendation is given, unless the health of the pregnant woman or of the foetus does not permit immediate suspension.
2. If the further recommendation is unfavourable, the research shall be terminated, unless the health of the pregnant woman or of the foetus does not permit immediate termination.
3. The person carrying out the research shall also notify the Central Committee of the premature termination of a research project, giving the reasons.

Section 23

Sections 13, 14 and 15 shall apply *mutatis mutandis* to research using foetuses.

Division 6. Prohibited uses of gametes and embryos

Section 24

The following procedures are prohibited:

- a. creating an embryo specifically for research purposes or for purposes other than the induction of a pregnancy and using such an embryo in research or for purposes other than the induction of a pregnancy;
- b. creating an embryo specifically and using such an embryo for purposes other than the induction of a pregnancy or the purposes for which it may be made available pursuant to Section 9, subsection 1;

- c. using gametes and embryos other than those referred to under b. for purposes other than those for which they may be made available pursuant to this Act;
- d. using gametes and embryos for purposes permissible under the terms of this Act if they have not been made available for such purposes;
- e. allowing an embryo to develop outside the human body for longer than fourteen days;
- f. performing procedures with gametes or embryos with a view to the birth of genetically identical human individuals;
- g. intentionally modifying the genetic material of the nucleus of human germ-line cells with which a pregnancy is to be induced;
- h. using cells cultured from an embryo for purposes other than those for which it is permissible to make them available under the terms of Section 8, subsection 1 (b) and Section 9, subsection 1 (a), respectively.

Section 25

The following procedures are prohibited:

- a. combining a human and an animal gamete with a view to creating a multicellular hybrid;
- b. allowing a chimera created from human and animal (or exclusively human) embryonic cells to develop for longer than fourteen days or implanting said chimera into a human being or an animal;
- c. implanting an embryo into an animal;
- d. implanting an animal embryo into a human being.

Section 26

- 1. Performing procedures with gametes or embryos with a view to selecting the sex of a potential child is prohibited.
- 2. The prohibition referred to in subsection 1 shall not apply if, according to scientifically sound medical opinion, there is a risk of a serious sex-linked hereditary disease in the child and the procedures are intended to prevent that disease.
- 3. Offering services consisting of procedures prohibited under this Section is prohibited.

Section 27

It is prohibited to charge a fee for providing gametes and embryos made available pursuant to Sections 5, 8 and 9 of this Act to third parties if the said fee exceeds the costs directly incurred as a result of procedures carried out using the said gametes and embryos.

Division 7. Penalties

Section 28

- 1. Any person who acts in contravention of a prohibition contained in Section 12, 17, subsection 1, 21, subsection 1, 24, 25, 26 or 27, whether intentionally or unintentionally, shall be liable to a prison sentence not exceeding one year or a fourth-category fine.
- 2. Any person who acts in contravention of Section 2, 3, 5, 8, 14, 15, 20 or 22 shall be liable to a period of detention not exceeding six months or a fourth-category fine.

3. The offences specified in subsection 1 are serious offences; the offences specified in subsection 2 are minor offences.

Division 8. Final provisions

Section 29

1. The officers of the Public Health Supervisory Service shall be charged with supervision of compliance with provisions laid down by or pursuant to this Act.
2. The persons referred to in subsection 1 shall not enjoy the powers referred to in Section 5:19 of the General Administrative Law Act.

Section 30

The Medical Research (Human Subjects) Act shall be amended as follows:

- A. In Section I, subsection 3, "(Bulletin of Acts and Decrees 1992, 611)" shall be replaced by: "and, with the exception of Sections 7 and 9, and of Sections 8, 11 and 33 in so far as they relate to Section 7, to research for which the research protocol under the terms of the Embryo Act has received a favourable recommendation from the Central Committee referred to in Section 14".
- B. In the second sentence of Section 14, subsection 1, "thirteen" shall be replaced by: "fourteen".
- C. In Section 14, subsection 2, " embryology," shall be inserted after the words "in the field of".

Section 31

On the date referred to in Section 33, subsection 2, the phrase "Sections 12" in Section 28, subsection 1 shall be replaced by: "Section 11, 12" and in Section 28, subsection 2, "8, 14" shall be replaced by: "8, 9, 14".

Section 32

Within three years of this Act entering into force, and every four years thereafter, Our Minister shall send a report to Parliament concerning its effectiveness and impact in practice.

Section 33

1. This Act shall enter into force on a date to be determined by Royal Decree, which may differ for the different sections or parts thereof, on the understanding that Sections 9, 11 and 24 (b), shall enter into force on the date referred to in subsection 2.
2. Section 24 (a) shall lapse on a date to be determined by Royal Decree. The recommendation of this Decree shall take place at most five years after the date on which that part of the section enters into force. The recommendation of this Decree shall not take place any earlier than four weeks after the draft of the Decree has been submitted to both Houses of the States General, nor if, within that period, notice has been given by or on behalf of one of the Houses or by at least one-fifth of the constitutional number of Members of one of the Houses to

the effect that the date on which Section 24 (a) is to lapse will be regulated by Act of Parliament.

Section 34

This Act may be cited as the Embryo Act.

We order and command that this Act shall be published in the Bulletin of Acts and Decrees (*Staatsblad*), and that all ministerial departments, authorities, bodies and officials whom it may concern shall diligently implement it.

Done

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Minister of Health, Welfare and Sport

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Minister of Justice