Government of Iceland
Ministry of Health

[Act on Artificial Fertilisation and use of Human Gametes and Embryos for Stem-Cell Research][1)] No. 55/1996

[1)] Act No. 27/2008, Article 9

as amended by Act No. 65/2006, 27/2008, 54/2008, 55/2010, 65/2010, 153/2020, 107/2021 and 69/2023.

Where mention is made in this Act of 'the minister' or 'the ministry' without further definition, the reference intended is to the Minister of Health or to the Ministry of Health, which is responsible for the implementation of this Act. Information on the division of responsibilities between ministries according to a presidential decree may be found here.

Definitions.

Article 1

Artificial fertilisation: Conception resulting from artificial insemination or *in vitro* fertilisation.

Artificial insemination: Process whereby sperm are placed in or near the reproductive organs of a woman, other than by sexual intercourse.

In vitro fertilisation: Process whereby an ovum, which has been removed from a woman's body, is fertilised by sperm outside the body.

Gametes: Ova and sperm.

Embryo: Fertilised ovum at all stages of development, from fertilisation [with a sperm][1)] until the foetal stage.

Donor: Individual who provides another with gametes.

Surrogacy: Artificial fertilisation performed on a woman who intends to carry a child for another woman, and has agreed before the pregnancy to give up the child immediately after the birth.

[*Excess embryo*: Embryo created by *in vitro* fertilisation for reproductive purposes but not used for that purpose.

Nuclear transfer: Procedure whereby the nucleus is removed from a woman's ovum and replaced by the nucleus of a somatic cell.][1)]

[1)] Act No. 27/2008, Article 1.

General provisions.

Article 2

Artificial fertilisation may only be carried out at a health institution which has obtained a licence from the Minister for that purpose and under the supervision of specialists in gynaecology and obstetrics. [The Minister may impose special conditions upon such licences, *inter alia* with respect to the competence and knowledge of a laboratory's staff, monitoring by health authorities, provision of information and facilities.][1)]

[The use of excess embryos for stem-cell research under Article 12 and nuclear transfer under Article 13 are permitted only at research laboratories which have been granted the appropriate licence by the Minister. Conditions for the granting of such a licence are: compliance with the provisions of this Act, and of regulations which may be issued on the basis of the Act; that the laboratory be located in Iceland; and that it have satisfactory facilities for storage of embryos. The Minister may impose special conditions upon such a licence, *inter alia* with respect to the competence and knowledge of a laboratory's staff, monitoring by health authorities, provision of information and facilities. Before the Minister makes a decision upon the granting of a licence under this provision, he/she shall elicit the views of the Medical Director of Health. Should the licensee violate the provisions of this Act or rules issued on the basis of the Act, or the conditions of the licence, the Minister may, as appropriate, after having issued a reprimand, revoke the licence temporarily pending rectification, or permanently.][1)]

A health institution granted a licence under the first paragraph must offer [those][2)] who apply for artificial fertilisation, and prospective donors, professional counselling by specialists, such as social workers or psychologists.

[What this Act say about women also applies to individuals with uterus who have changed their gender registration.][3)]

[1)] Act No. 27/2008, Article 2. [2)] Act No. 54/2008, Article 1. [3)] Act No. 153/2020, Article 15.

Article 3

[Artificial fertilisation may only be carried out if:

a. the written and witnessed consent of the woman has been given. If the woman is married [or in cohabitation][1)], the witnessed written consent of the other party must also have been given,
b. the child to be conceived by the procedure may be deemed to be ensured good conditions in which to grow up,
c. the woman is of natural child-bearing age and has the physical capability and sufficiently good health to cope with the strain of the treatment, pregnancy and birth of the child. A factor to be taken into account is that the pregnancy and birth not be expected to entail damaging consequences for mother or child, on the basis of normal medical and obstetric standards,
d. the mental health and social circumstances of the couple or woman are good.

Before artificial fertilisation is carried out, and consent is given under item a of the first paragraph, information shall be provided on the treatment and its potential medical, social and legal implications.

Artificial fertilisation may only be performed if the conditions of the first paragraph are met. A physician assesses whether the conditions are met, before deciding whether the artificial fertilisation will take place. A refusal of artificial fertilisation by a physician may be appealed to the Medical Director of Health. The decision of the Medical Director of Health may be appealed to the Ministry. The procedure of appeals to the Medical Director of Health and the Ministry is as provided by the Administrative Procedures Act.

The Minister issues more detailed rules on the implementation of this provision, *inter alia* on the authority or obligation to seek the opinion of a social worker or other professional or, as appropriate, [a child protection service],[2)] on the social circumstances of the couple or woman.][3)]

[1)] Act No. 65/2010, Article 50. [2)] Act No. 107/2021, Article 44. [3)] Act No. 54/2008, Article 2.

Article 4

The physician providing treatment shall choose a suitable donor.

Should a donor request anonymity, health workers must ensure that this wish be respected. In such cases information may not be provided to the donor on the couple receiving donor gametes, nor about the child, nor may the couple or the child receive information on the donor.

Should the donor not request anonymity, the institution shall keep information on the donor in a special file. Should the donation of gametes result in the birth of a child, data on the child and on the couple who received the donated gametes shall be kept in the same file.

A child conceived as a result of a donation of gametes, where the donor did not request anonymity, may at the age of 18 request access to the records under the third paragraph, in order to acquire information on the name of the donor. Should a child receive information on the gamete donor from the institution, the institution shall, as soon as possible, inform the donor that the information has been provided.

[Artificial fertilisation treatment.][1)]

[1)] *Act No. 54/2008, Article 3.*

Article 5

[Artificial fertilisation may be carried out by artificial insemination or by *in vitro* fertilisation.

Artificial fertilisation with donor gametes may only be carried out if fertility is impaired, or in the case of a serious hereditary disease, or if other medical reasons indicate use of donor gametes. [If fertility of both spouses or a single woman is impaired, it is permitted to use both donor ova and donor sperm with *in vitro* fertilisation. [It is always permitted to use donor sperm in case of a single individual or an individual in marriage or in a registered cohabitation in cases where the spouse is unable to provide sperm.][1)]][2)] [Couple in a marriage or in a registered cohabitation may give each other gametes.][1)]

Donation of embryos is prohibited.

Surrogacy is prohibited.][3)]

[1)] *Act No. 153/2020, Article 16.* [2)] *Act No. 55/2010, Article 1.* [3)] *Act No. 54/2008, Article 3.*

...[1)]

[1)] *Act No. 54/2008, Article 4.*

Article 6

...[1)]

[1)] *Act No. 54/2008, Article 4.*

Storage of gametes and embryos.

Article 7

Storage of gametes and embryos is only permitted at a health institution licensed by the Minister to carry out artificial fertilisation, *cf.* Article 2.

Article 8

Gametes may only be stored for the purpose of:

a. the party‘s/parties‘ own use at a later time,
b. donation for research purposes, or
c. donation of gametes for use in artificial fertilisation.

The person who provides gametes shall give written consent for their storage in accord with the purpose of storage, after having been provided with information on the effect of storage on the gametes, and on the general rules applying to storage of gametes in this Act and in rules issued on the basis of the Act.

[The person who donates gametes can give written and certified consent for the use by the surviving spouse in artificial fertilisation, provided that the surviving spouse can use the gametes in his/her own body. The same applies to consent for the use by former spouse after a divorce or separation, as long as he/she can use the gametes in his/her own body and written and certified consent is available concurrently as the application for artificial fertilisation.][1)]

[1)] *Act No. 69/2023, Article 1.*

Article 9

Embryos may be stored for the purpose of transplanting them into the woman who provided the ova [or received them as a gift for use in *in vitro* fertilisation].[1)] The storage of embryos for other purposes is prohibited.

[Storage of embryos is subject to the condition that the individuals who provided the gametes or received them as a gift for use *in vitro* fertilisation, whether they are a married couple or in a registered cohabitation or a single individual, give written consent for storage in accordance with its purpose, having previously been provided with information on how the storage affects the embryos and on the general conditions regarding the storage of the gametes and embryos laid down in this Act and rules based on the Act.][2)]

Embryos may only be used in accord with the consent of those providing the gametes [or received the as a gift for use in *in vitro* fertilisation].[1)] [An individual who has consented to the storage of embryos according to the second paragraph may give written and certified consent for the surviving spouse to use the for artificial fertilisation, provided that the surviving spouse can use the embryo in their own body. The same applies to consent for the use by former spouse after a divorce or separation, as long as he/she can use the embryos in his/her own body and written and certified consent is available concurrently as the application for artificial fertilisation.][3)]

[1)] Act No. 55/2010, Article 2. [2)] Act No. 153/2020, Article 17. [3)] Act No. 69/2023, Article 2.

Article 10

The Minister shall issue rules on how long gametes and embryos may be stored, in accord with the best medical knowledge at the time.

At the end of the maximum storage period, unused gametes and embryos shall be destroyed. [If the maximum storage time has not passed, but the person who consented the storage of gametes or embryos withdraws his/her consent, the gametes or embryos shall be destroyed.][1)]

Should the person who provided gametes die before the expiry of the maximum storage period, unused gametes shall be destroyed, unless the purpose of the storage was to donate gametes for use in artificial fertilisation [or written and certified consent of the deceased has been given to the surviving spouse to use by them for artificial fertilisation according to the first sentence of the third paragraph of Article 8.][1)]

[If the maximum storage period of the embryos has not expired, but the person who has consented to the storage of the embryos dies, then the embryos shall be destroyed unless the deceased has given a written and certified consent for the surviving spouse to use them for artificial fertilisation according to the second sentence of the third paragraph of Article 9.][1)]

[Notwithstanding the provisions of the second, third and fourth paragraphs, it is permissible, after the expiry of the maximum storage period, or after the embryos must be destroyed under the third and fourth paragraphs, to pass the embryos to a body which has been granted permission to use embryos in stem-cell research, provided that the informed consent of both gamete donors has been given. In provision of embryos under this provision, information on their origin shall be encrypted, and the code shall be kept by the responsible party for the licensee. If the interests of the gamete donors, or exigent research interests, so require, the information on the origins of the embryo may be decoded, by permission of the Bioethics Committee. In such decoding it shall be ensured that access to the information be restricted to members of the licensee's staff for whom access is necessary.

A gamete donor may at any time revoke his/her consent under the fifth paragraph, in which case the responsible party of the licensee shall ensure that gametes of the relevant donor are not used in research, and are destroyed without undue delay.

The licensee is absolutely prohibited from passing on to other parties embryos which have been provided to it.

A fee may be charged to the licensee for provision of excess embryos under the fifth paragraph, reflecting the costs of the arrangements. All other fees are prohibited.][4)]

[1)] Act No. 69/2023, Article 3. [2)] Act No. 27/2008, Article 3.

[Research on embryos in connection with in vitro fertilisation treatment.][1)]

[1)] Act No. 27/2008, Article 4.

Article 11

[A health institution which has been granted a licence under the first paragraph of Article 2 may, with the informed consent of the gamete donors, perform research, experiments and procedures on embryos which have been created by *in vitro* treatment, and are a part of that, or have been created in order to diagnose hereditary diseases in the embryos themselves. The same applies to research which aims to advance treatment for infertility, or to enhance understanding of the causes of congenital diseases and miscarriages.][1)]

[1)] Act No. 27/2008, Article 4.

[Use of excess embryos for stem-cell research.][1)]

[1)] Act No. 27/2008, Article 5.

Article 12

[By permission of the Bioethics Committee, those who have been granted licences under the second paragraph of Article 2 may use excess embryos provided to them under the fifth paragraph of Article 10 to create stem-cell lines which may be useful to gain biological and medical knowledge, or to enhance health and cure disease. The Bioethics Committee judges whether the above-mentioned conditions and other mandated conditions for scientific research are met.][1)]

[1)] Act No. 27/2008, Article 5.

[Article 13

Licensees under the second paragraph of Article 2 may, with the consent of the Bioethics Committee, the ovum donor and the person who is the source of genetic material, perform nuclear transfer for the purpose of creating a stem-cell line which may be used for medical purposes, or to gain biological and medical knowledge, if it is deemed impossible to achieve the same results or acquire the same knowledge by use of stem-cell lines made using excess embryos or by other means. The Bioethics Committee judges whether the above-mentioned conditions and other mandated conditions for scientific research are met. An ovum on which nuclear transfer has been carried out may not be grown for more than 14 days or once the primitive streak has appeared. It is prohibited at all stages to implant in a woman‘s uterus an ovum on which nuclear transfer has been performed.][1)]

[1)] Act No. 27/2008, Article 6.

[Article 14

It is prohibited to:

a. cultivate or produce embryos solely for research purposes,
b. cultivate embryos for more than 14 days outside the body or once the primitive streak has appeared,
c. transplant human embryos into animals,
d. perform nuclear transfer for reproductive purposes (cloning).][1)]

[1)] Act No. 27/2008, Article 6.

Final provisions.

[Article 15][1)]

The Minister issues more detailed rules[2)] on the implementation of this Act. These shall cover, *inter alia*:

[a. general conditions for granting of licences under Article 2],[3)]
[b.][3)] preparation of prospective parents for the treatment, *inter alia* their access to counselling,
[c.][3)] use of donor gametes, including use of donor gametes within the family,
[d.][3)] storage period of embryos,
[e. provision of embryos under the fifth paragraph of Article 10, arrangements for acquiring informed consent of gamete donors, and the content of such informed consent, maximum storage period of embryos and of ova on which nuclear transfer has been performed by a research body, encryption of information on the origins of embryos, and when such information may be decoded],[3)]
[f.][3)] [research on embryos and use of excess embryos to create stem-cell lines under Articles 11 and 12],[3)]
[g. nuclear transfer under Article 13],[3)]
[h. maximum number of embryos that it shall normally be permissible to implant in artificial fertilisation procedures,
i. maximum age of gamete donors.][4)]

[1)] Act No. 27/2008, Article 6. [2)] Regulation No. 144/2009, cf. 1107/2019 and 670/2023. [3)] Act No. 27/2008, Article 7. [4)] Act No. 54/2008, Article 6.

[Article 16

The Medical Director of Health monitors that artificial fertilisation treatments carried out in Iceland are consistent with the provisions of this Act and regulations issued on the basis of the Act. Monitoring by the Medical Director of Health, and his/her monitoring sanctions, are as provided in the Medical Director of Health Act.][1)]

[1)] Act No. 54/2008, Article 7.

[Article 17][1)]

Violation of the provisions of this Act or of rules based on it entails fines or imprisonment of up to three months.

[A violation against the provisions of Article 13 or item d of Article 14 entails fines or imprisonment for up to one year.][2)]

Complicity in such a violation shall entail the same penalties, unless more severe penalties apply under other legislation.

[1)] Act No. 54/2008, Article 7. [2)] Act No. 27/2008, Article 8.

[Article 18][1)]

This Act takes effect on 1 June 1996, and at that time rules shall have been formulated as provided in Article 13 on the practice of artificial fertilisation, issued by the Minister.

[1)] Act No. 54/2008, Article 7.

Temporary Provisions.

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[*This translation is published for information only.*
The original Icelandic text is published in the Law Gazette.
In case of a possible discrepancy, the original Icelandic text applies.]