# Federal Act on Research Involving Embryonic Stem Cells

**(Stem Cell Research Act, StRA)**

of 19 December 2003 (Status as of 1 January 2014)

*The Federal Assembly of the Swiss Confederation,*

on the basis of Article 119 of the Federal Constitution[1],
and having considered a dispatch of the Federal Council dated 20 November 2002[2],

*decrees:*

## Section 1 General Provisions

### Art. 1 Subject, purpose and scope

[1] This Act specifies the conditions under which it is permissible for human embryonic stem cells to be derived from surplus embryos and used for research purposes.

[2] It is intended to prevent the misuse of surplus embryos and embryonic stem cells, and to protect human dignity.

[3] It is not applicable to the use of embryonic stem cells for transplantation purposes in clinical trials.

### Art. 2 Definitions

In this Act:

a. *embryo* means the offspring, from the fusion of the cell nuclei (karyogamy) to the completion of organ development;

b. *surplus embryo* means an embryo produced in the course of an *in vitro* fertilization (IVF) procedure that cannot be used to establish a pregnancy and therefore has no prospect of survival;

c. *embryonic stem cell* means a cell from an IVF embryo with the ability to differentiate into the various cell types, but not to develop into a human being, and the cell line derived therefrom;

d. *parthenote* means an organism derived from an unfertilized oocyte.

AS **2005** 947
1 SR **101**
2 BBl **2003** 1163

**Art. 3** Prohibited acts

[1] It is prohibited:

a. to create an embryo for research purposes (Art. 29 para. 1 of the Reproductive Medicine Act of 18 December 1998[3]), to derive stem cells from such an embryo, or to use such cells;

b. to modify the genetic material in a germ cell (Art. 35 para. 1 of the Reproductive Medicine Act of 18 December 1998), to derive embryonic stem cells from an embryo that has undergone germ line modification, or to use such cells;

c. to create a clone, a chimera or a hybrid (Art. 36 para. 1 of the Reproductive Medicine Act of 18 December 1998), to derive embryonic stem cells from such an organism, or to use such cells;

d. to develop a parthenote, to derive embryonic stem cells therefrom, or to use such cells;

e. to import or export an embryo of the kind specified under Item a or b, or a clone, chimera, hybrid or parthenote.

[2] It is further prohibited:

a. to use surplus embryos for any purpose other than the derivation of embryonic stem cells;

b. to import or export surplus embryos;

c. to derive stem cells from a surplus embryo after the seventh day of its development;

d. to place in a woman a surplus embryo used for stem cell derivation.

**Art. 4** Non-commercialism

[1] Surplus embryos or embryonic stem cells must not be disposed of or acquired in exchange for payment.

[2] It is not permissible to use surplus embryos or embryonic stem cells acquired in exchange for payment.

[3] The acceptance or provision of non-financial benefits is also deemed to constitute payment.

[4] Reimbursement may be made of costs incurred for:

a. the storage or passing-on of surplus embryos;

b. the derivation, processing, storage or passing-on of embryonic stem cells.

3 SR **810.11**

## Section 2
## Derivation of Embryonic Stem Cells from Surplus Embryos

### Art. 5 Informed consent

1 A surplus embryo may only be used for the derivation of embryonic stem cells if written consent has been freely given by the couple concerned. Before such consent is given, the couple must be provided with adequate information, verbally and in writing, in a comprehensible form, concerning the use of the embryo.

2 A request may only be made to the couple after the determination of the surplus status of the embryo.

3 Consent may be revoked by the couple, or by the woman or man, at any time, without any statement of reasons, up until the initiation of stem cell derivation.

4 If consent is refused or revoked, the embryo must be destroyed immediately.

5 In the event of one partner's death, the decision concerning the use of the embryo for stem cell derivation shall be taken by the surviving partner; he or she must have regard to the declared or presumed wishes of the deceased.

### Art. 6 Independence of participants

It is not permissible for persons involved in the derivation of stem cells either to participate in the assisted reproduction procedure of the couple concerned or to have the authority to issue instructions to persons involved in this procedure.

### Art. 7 Licensing requirement for stem cell derivation

1 Any person wishing to derive embryonic stem cells from surplus embryos with a view to conducting a research project shall require a licence from the Federal Office of Public Health (Federal Office).

2 A licence shall be granted if:

a.[4] the research project has received the approval of the ethics committee, as specified in Article 11;

b. no suitable embryonic stem cells are available in this country;

c. no more surplus embryos are used than are essential for the derivation of embryonic stem cells; and

d. the technical and operational requirements are met.

4 Amended by Annex No 5 of the Human Research Act of 30 Sept. 2011, in force since 1 Jan. 2014 (AS **2013** 3215; BBl **2009** 8045).

**Art. 8** Licensing requirement for research projects aimed at improving derivation methods

1 Any person wishing to derive embryonic stem cells from surplus embryos in connection with a research project aimed at improving derivation methods shall require a licence from the Federal Office.

2 A licence shall be granted if:

a. the project meets the scientific and ethical requirements specified in Paragraph 3;

b. no more surplus embryos are used than are essential for the attainment of the research objective; and

c. the technical and operational requirements are met.

3 The research project may only be carried out if:

a. the project is designed to yield significant insights for the improvement of derivation methods;

b. equivalent insights cannot also be gained in a different way;

c. the project satisfies the scientific quality requirements; and

d. the project is ethically acceptable.

4 For the scientific and ethical assessment of the project, the Federal Office shall consult independent experts.

**Art. 9** Duties of the licensee

1 The holder of a licence granted under Article 7 or 8 is required:

a. to destroy the embryo immediately after the derivation of embryonic stem cells;

b. to report on the derivation of stem cells to the Federal Office;

c.[5] to pass on embryonic stem cells, with reimbursement possibly being provided as specified in Article 4, for research projects carried out in this country that have received the approval of an ethics committee as specified in Article 11.

2 In the case of a research project aimed at improving derivation methods, the licensee is additionally required:

a. to notify the Federal Office of the completion or discontinuation of the project;

b. within an appropriate period after the completion or discontinuation of the project, to make a summary of the results publicly available.

5 Amended by Annex No 5 of the Human Research Act of 30 Sept. 2011, in force since 1 Jan. 2014 (AS **2013** 3215; BBl **2009** 8045).

**Art. 10** Licensing requirement for the storage of surplus embryos

1 Any person wishing to store surplus embryos shall require a licence from the Federal Office.

2 A licence shall be granted if:

a. stem cell derivation is licensed under Article 7 or 8;

b. storage is essential for the purpose of stem cell derivation; and

c. the technical and operational requirements for storage are met.

## Section 3 Management of Embryonic Stem Cells

**Art. 11**[6] Mandatory approval for research projects

1 A research project involving embryonic stem cells may only be initiated when approval has been received from the ethics committee responsible.

2 The responsibility of the ethics committee and the approval procedure are governed by the Human Research Act of 30 September 2011[7].

**Art. 12** Scientific and ethical requirements for research projects

A research project involving embryonic stem cells may only be carried out if:

a. the project is designed to yield significant insights:

1. with regard to the detection, treatment or prevention of serious human diseases, or

2. concerning human developmental biology;

b. equivalent insights cannot also be gained in a different way;

c. the project satisfies the scientific quality requirements; and

d. the project is ethically acceptable.

**Art. 13** Duties of the project manager

1 The project manager must notify the Federal Office of the research project involving embryonic stem cells before it is carried out.

2 The project manager is required:

a. to notify the Federal Office and the competent ethics committee of the completion or discontinuation of the project;

b. within an appropriate period after the completion or discontinuation of the project:

6 Amended by Annex No 5 of the Human Research Act of 30 Sept. 2011, in force since 1 Jan. 2014 (AS **2013** 3215; BBl **2009** 8045).

7 SR **810.30**