Ordinance on Research involving Embryonic Stem Cells

(Stem Cell Research Ordinance, SCRO)

of 2 February 2005 (Status as of 1 April 2012)

The Swiss Federal Council,

on the basis of Article 17 of the Stem Cell Research Act of 19 December 2003[1] (the Act),

ordains:

Section 1: Informed Consent of the Couple Concerned

Art. 1 Determination of the surplus status of an embryo

If an embryo cannot be used to establish a pregnancy, the physician treating a couple in connection with an assisted reproduction procedure shall inform the couple:

a. that it is a surplus embryo;

b. why the embryo has become surplus; and

c. that the surplus embryo will be destroyed unless it is used, subject to the conditions specified in the Act, for the derivation of stem cells with a view to the conduct of a research project (stem cell derivation) or for a research project aimed at improving derivation methods.

Art. 2 Information to be provided for the couple concerned prior to consent

[1] If a licence has been obtained for stem cell derivation or for a research project aimed at improving derivation methods, the physician shall verbally inform the couple concerned, in a comprehensible manner:

a. about the nature, purpose and expected starting date of the intended research project;

b. about the couple's rights under Article 5 paragraph 3 of the Act and under paragraphs 3 and 4 of this Article;

c. about the non-commercialism specified in Article 4 of the Act;

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d. about the measures provided for in Article 27 to protect the couple's personal data;

e. that third parties may acquire rights to stem cells or products derived therefrom, for example in accordance with the Patent Act of 25 June 1954[2], without any entitlements accruing to the couple as a result;

f. that it is possible for stem cells or products derived therefrom to be used in clinical research and practice, without any entitlements accruing to the couple as a result;

g. that, under Article 9 paragraph 1 letter c of the Act, the stem cells derived may be passed on for other research projects; and

h. about the content of the written consent, as specified in Article 3.

[2] The physician shall provide the couple with an information sheet and an informed consent form made available by the person responsible for the research project (project manager).

[3] The couple have the right to put questions, or have questions put, to the project manager.

[4] The couple must be allowed an appropriate period for reflection on the decision concerning consent.

Art. 3 Content of informed consent form

By signing the informed consent form, the couple concerned certify that they have received the information specified in Article 2 and that they consent to the use of the surplus embryo for stem cell derivation or for a research project aimed at improving derivation methods.

Art. 4 Consequences of refusal or revocation of consent

If consent is refused or revoked by the couple concerned, or by the woman or the man, this may not prejudice the couple in relation to any subsequent treatment in the assisted reproduction procedure.

Section 2: Licence for the Derivation of Embryonic Stem Cells

Art. 5 Application

When a licence is sought for stem cell derivation with a view to conducting a research project (Art. 7 of the Act), the following documents must be submitted to the Federal Office of Public Health (Federal Office) for review:

a. complete documentation of the stem cell derivation project, including evidence of the suitability of the laboratory facilities;

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b. complete documentation for the research project involving embryonic stem cells, as submitted to the competent ethics committee in accordance with Article 17;

c. the approval of the research project granted by the competent ethics committee;

d. a statement, based on an extract from the registry specified in Article 18 of the Act, of the reasons why the embryonic stem cells available in this country are not suitable for the research project;

e. information on the number of surplus embryos expected to be required.

Art. 6 Review of the application

1 The Federal Office determines whether:

a. the documents are complete;

b. the licence conditions specified in the Act are met.

2 It may request additional documents from the project manager.

Art. 7 Review period

1 The Federal Office shall reach a decision within 60 days.

2 If the Federal Office requests additional documents from the project manager, the review period begins as soon as the documents have arrived; it shall notify the project manager of the beginning of the period.

Section 3: Licence for Research Projects aimed at improving Derivation Methods

Art. 8 Application

When a licence is sought for a research project aimed at improving derivation methods (Art. 8 of the Act), the following documents must be submitted to the Federal Office for review:

a. complete documentation for the research project, including evidence of the suitability of the laboratory facilities;

b. an account of the extent to which the research project is expected to yield important findings for the improvement of derivation methods;

c. a statement of the reasons why equivalent findings could not also be obtained in a different way, in particular through experiments involving animal embryos;

d. information on the number of surplus embryos expected to be required;

e. the information sheet and informed consent form.

Art. 9 Review of the application

[1] The Federal Office determines whether:

a. the documents are complete;

b. the information sheet and the informed consent form are complete and comprehensible;

c. the licence conditions specified in the Act are met.

[2] It may request additional documents from the project manager.

Art. 10 Review period

[1] The Federal Office shall reach a decision within 60 days.

[2] If the Federal Office requests additional documents from the project manager, the review period begins as soon as the documents have arrived; it shall notify the project manager of the beginning of the period.

Section 4: Licence for the Storage of Surplus Embryos

Art. 11 Application

When a licence is sought for the storage of surplus embryos (Art. 10 of the Act), the following documents must be submitted to the Federal Office for review:

a. the licence granted under Article 7 or 8 of the Act;

b. a statement of the reasons why storage of the surplus embryos is essential;

c. evidence of the qualifications of the staff;

d. evidence of the suitability of the laboratory facilities.

Art. 12 Review of the application

The Federal Office determines whether:

a. the documents are complete;

b. the licence conditions specified in the Act are met.

Section 5: Licence for the Import of Embryonic Stem Cells

Art. 13 Application

When a licence is sought for the import of embryonic stem cells (Art. 15 of the Act), the following documents must be submitted to the Federal Office for review:

a. complete documentation for the research project involving embryonic stem cells, as submitted to the competent ethics committee in accordance with Article 17;

b. the approval of the research project granted by the competent ethics committee;

c. details of the number of embryonic stem cells or stem cell lines required and a characterisation thereof, as specified in Article 29 paragraph 1 letter b;

d. evidence provided by the authority designated as competent under national legislation in the country concerned or recognised by that country to the effect that:

1. the stem cells have been derived from surplus embryos,
2. the couple concerned have freely given informed consent to the use of the embryo for research purposes, and
3. the couple concerned are receiving no payment in return.

Art. 14 Review of the application

The Federal Office determines whether:

a. the documents are complete;

b. the licence conditions specified in the Act are met.

Section 6: Licence for the Export of Embryonic Stem Cells

Art. 15 Application

When a licence is sought for the export of embryonic stem cells (Art. 15 of the Act), the following documents must be submitted to the Federal Office for review:

a. the title, objective and place of execution of the research project involving embryonic stem cells;

b. the name and address of the project manager;

c. the number of embryonic stem cells or stem cell lines to be exported and a characterisation thereof, as specified in Article 29 paragraph 1 letter b;

d. evidence provided by the authority designated as competent under national legislation in the country concerned or recognised by that country, to the effect that:

1. the project is designed to yield important findings with regard to the detection, treatment or prevention of serious human diseases or concerning human developmental biology, and
2. the project has received ethical approval from an authority independent of the project manager.

Art. 16 Review of the application

The Federal Office determines whether:

a. the documents are complete;