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# 810.311

*English is not an official language of the Swiss Confederation. This translation is provided for information purposes only and has no legal force.*

## **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 (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

<sup>1</sup> 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;
- 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<sup>1</sup>, 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.

<sup>2</sup> 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).

<sup>3</sup> The couple have the right to put questions, or have questions put, to the project manager.

<sup>4</sup> The couple must be allowed an appropriate period for reflection on the decision concerning consent.

<sup>1</sup> SR 232.14

#### **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;

- 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

<sup>1</sup> The Federal Office determines whether:

- a. the documents are complete;
- b. the licence conditions specified in the Act are met.

<sup>2</sup> It may request additional documents from the project manager.

#### **Art. 7** Review period

<sup>1</sup> The Federal Office shall reach a decision within 60 days.

<sup>2</sup> 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

<sup>1</sup> 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.

<sup>2</sup> It may request additional documents from the project manager.

**Art. 10** Review period

<sup>1</sup> The Federal Office shall reach a decision within 60 days.

<sup>2</sup> 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;
- b. the licence conditions specified in the Act are met.

## **Section 7: Assessment by the competent Ethics Committee and Authorisation of the Research Project**

#### **Art. 17** Application

When an assessment is sought of a research project involving embryonic stem cells (Art. 11 of the Act), the following documents must be submitted to the competent ethics committee for review:

- a. complete documentation for the research project;
- b. a statement of the reasons why equivalent findings could not also be obtained in a different way;
- c. the information sheet and the informed consent form, if embryonic stem cells have to be derived for the research project.

#### **Art. 18** Review of the application

<sup>1</sup> The ethics committee determines whether:

- a. the documents are complete;
- b. the conditions specified in the Act for the conduct of a research project with embryonic stem cells are met.

<sup>2</sup> If the research project is to be conducted at several centres, it suffices if an assessment is given according to the standard procedure by the ethics committee that is competent at the first centre; decisions may be reached by the other ethics committees concerned according to a simplified procedure. The project manager must submit the approval granted by the ethics committee competent at the first centre.

<sup>3</sup> For the evaluation of the research project, the ethics committee may consult experts and request additional documents from the project manager.

#### **Art. 19** Assessment period

<sup>1</sup> The ethics committee shall issue its assessment within 30 days.

<sup>2</sup> If the ethics committee consults experts or requests additional documents from the project manager, the assessment period begins as soon as the experts' comments or the documents have arrived; the ethics committee shall notify the project manager of the beginning of the period.

**Art. 20** Authorisation of the research project

<sup>1</sup> Prior to the initiation of the research project, the project manager shall notify the Federal Office thereof and submit:

a.

the title of the research project, if the Federal Office has the project documents at its disposal in connection with the licensing procedure under Article 5 or 13;

b.

the complete documentation for the research project, as submitted to the competent ethics committee in accordance with Article 17, together with this committee's approval, if embryonic stem cells available in this country are to be used for the project.

<sup>2</sup> The Federal Office may request additional documents from the project manager.

<sup>3</sup> Within 15 days of receipt of the notification or the necessary documents, the Federal Office shall assign a reference number to the research project, provided that it has no objections. It shall inform the project manager of the number.

<sup>4</sup> After the communication of the reference number, the research project may be initiated.

**Art. 21** Re-evaluation and withdrawal of approval

<sup>1</sup> The ethics committee may re-evaluate a research project and if appropriate withdraw its approval, if this is necessitated by new scientific findings and a resultant change in the ethical assessment.

<sup>2</sup> It shall notify the project manager and the Federal Office immediately of the withdrawal of its approval.

<sup>3</sup> It shall inform the Federal Office immediately of any irregularities in the conduct of the research project.

## Section 8: Changes to the Project

**Art. 22**

<sup>1</sup> Any person who derives embryonic stem cells, carries out a research project aimed at improving derivation methods, stores surplus embryos, or imports or exports embryonic stem cells must notify the Federal Office of any significant planned changes to the project concerned.

<sup>2</sup> Any person who carries out a research project involving embryonic stem cells must notify the ethics committee and the Federal Office of any significant planned changes to the research protocol.

<sup>3</sup> The Federal Office, or the ethics committee and the Federal Office, shall issue a response within 30 days of receipt of such notification.

<sup>4</sup> A project of the type specified in paragraph 1 may only be continued with the proposed changes if the Federal Office grants a new licence.

<sup>5</sup> A research project of the type specified in paragraph 2 may only be continued in accordance with the modified research protocol if the ethics committee renews its approval and the Federal Office renews its authorisation of the project.

## Section 9: Notification and Reporting Duties

### Art. 23 Notification after discontinuation or completion of the project

<sup>1</sup> Any person who derives embryonic stem cells or carries out a research project aimed at improving derivation methods must notify the Federal Office of the discontinuation or completion of stem cell derivation or the research project within 15 days.

<sup>2</sup> Any person who carries out a research project involving embryonic stem cells must notify the Federal Office and the ethics committee of the discontinuation or completion of the project within 15 days.

<sup>3</sup> If a project is discontinued, the reasons must be indicated in the notification.

### Art. 24 Final report

<sup>1</sup> Any person who derives embryonic stem cells or carries out a research project aimed at improving derivation methods must submit a report to the Federal Office within six months of the discontinuation or completion of stem cell derivation or the research project.

<sup>2</sup> Any person who carries out a research project involving embryonic stem cells must submit a report to the Federal Office and the ethics committee within six months of the discontinuation or completion of the research project.

<sup>3</sup> The Federal Office may specify a shorter period if there is good cause for doing so; in response to a justified request from the project manager, it may in exceptional cases extend the period.

### Art. 25 Content of the final report

<sup>1</sup> The final report must document the course and results of the embryonic stem cell derivation, or of the research project aimed at improving derivation methods or involving embryonic stem cells.

<sup>2</sup> The final report on embryonic stem cell derivation must also include the following details:

- a. the number of embryos used; and
- b. the number of embryonic stem cells derived, or the number of stem cell lines and a characterisation thereof, as specified in Article 29 paragraph 1 letter b.

<sup>3</sup> The final report on a research project aimed at improving derivation methods must also include the following details:

- a. the number of embryos used;
- b. the number of embryonic stem cells derived, or the number of stem cell lines and a characterisation thereof, as specified in Article 29 paragraph 1 letter b, if stem cells are derived in connection with the project; and

c.

a summary of the positive and the negative results.

<sup>4</sup> The final report on a research project involving embryonic stem cells must also include a summary of the positive and the negative results.

#### **Art. 26** Storage of embryonic stem cells

Any person who stores embryonic stem cells must notify the Federal Office annually, as at 1 July, of the total numbers of deposits and withdrawals, and of the number of stem cell lines stored and the characterisation thereof, as specified in Article 29 paragraph 1 letter b.

## **Section 10: Data Protection**

#### **Art. 27**

<sup>1</sup> No data permitting identification of the couple concerned may be communicated to the persons involved in stem cell derivation or in research projects.

<sup>2</sup> The clinic performing the IVF procedure shall anonymise the data concerning the surplus embryo by the assignment of a code before passing on the embryo for stem cell derivation or for a research project aimed at improving derivation methods.

<sup>3</sup> It shall retain the data of the couple concerned, the information sheet, the original signed consent form and the code key for ten (10) years. The data security measures must conform to the current technical standards.

## **Section 11: Public Registry**

#### **Art. 28** Purpose of the registry

The registry specified in Article 18 of the Act is intended in particular:

a.

to enable embryonic stem cells to be passed on for research projects carried out in this country, as specified in Article 9 paragraph 1 letter c of the Act;

b.

to permit assessment of whether embryonic stem cells suitable for a research project are available in this country;

c.

to provide an overview of ongoing and completed research projects in this country.

#### **Art. 29** Content of the registry

<sup>1</sup> Any person who derives embryonic stem cells, carries out a research project aimed at improving derivation methods, or involving embryonic stem cells, or imports embryonic stem cells must submit the following information to the Federal Office:

a.

a description of the project in which the stem cells are derived or used, including the following details:

1.

title of the project,

2.

objective of the project,

3.

name and address of the project manager,

4.

starting date and expected duration of the project;

**b.**

a characterisation of the embryonic stem cells derived or used in the project, and of the stem cell lines used; stem cell lines are pluripotent cells derived from cells of an early embryo, which can be cultured in vitro and reproduced over generations, exhibiting a stable genotype and phenotype.

<sup>2</sup> The Federal Office shall include in the registry the information required by paragraph 1 letter a when a licence is granted under Articles 5, 8 or 13, or when a notification is received under Article 20.

<sup>3</sup> It shall publish in the registry the summaries specified in Article 25 paragraphs 3 letter c and 4.

<sup>4</sup> It may request clarification of the information submitted.

## Section 12: Charges

### Art. 30 Calculation of charges

<sup>1</sup> The charges are calculated according to the rates given in Article 31. Within the framework of these rates, the charges are set on the basis of the time required, taking account of the necessary expertise.

<sup>2</sup> For services not explicitly mentioned in Article 31, the level of the charge is based on the time required. The hourly rate, according to the expertise required and the functional level of the personnel involved, ranges from 90 to 200 Swiss francs.

### Art. 31 Rates of charges

The Federal Office levies the following charges in particular:

	Swiss francs
a. <sup>1</sup> Licence for derivation of embryonic stem cells from surplus embryos: grant, renewal, suspension, revocation	500 - 10 000
b. <sup>2</sup> Licence for a research project aimed at improving derivation methods: grant, renewal, suspension, revocation	500 - 10 000
c. <sup>3</sup> Licence for the storage of surplus embryos: grant, renewal, suspension, revocation	250 - 5 000
d. <sup>4</sup> Licence for the import or export of embryonic stem cells: grant, renewal, suspension, revocation	500 - 10 000
e. Inspection (excluding preparation and report) per day	1 000 - 20 000
f. Certificates, reports	200 - 2 000

<sup>1</sup> Amended by No I of the Ordinance of 2 March 2012, in force since 1 April 2012 (AS 2012 1201).

<sup>2</sup> Amended by No I of the Ordinance of 2 March 2012, in force since 1 April 2012 (AS 2012 1201).

<sup>3</sup> Amended by No I of the Ordinance of 2 March 2012, in force since 1 April 2012 (AS 2012 1201).

<sup>4</sup> Amended by No I of the Ordinance of 2 March 2012, in force since 1 April 2012 (AS 2012 1201).

#### **Art. 32 Surcharge**

The Federal Office may levy a surcharge of up to 50 per cent of the charge if the service:

- a. is provided, on request, urgently or outside normal working hours;
- b. is exceptionally time-consuming or involves particular difficulties.

#### **Art. 33 Expenses**

In addition to the charges levied, expenses relating to the individual service are invoiced. The following items are deemed to be expenses:

- a. fees for committee members, experts and representatives;
- b. costs occasioned by the collection of evidence, scientific studies, special investigations or the procurement of documents;
- c. travel and transport costs;
- d. costs of tests at internal or external laboratories;
- e. costs of work carried out by third parties on behalf of the Federal Office.

## **Section 13: Forms**

#### **Art. 34**

The Federal Office may prescribe forms:

- a. for the licensing procedures under Articles 5, 8, 11, 13 and 15;
- b. for the fulfilment of notification and reporting duties under Articles 20, 23 and 24;
- c. for the information to be collected for the public registry.

## **Section 14: Commencement**

#### **Art. 35**

This Ordinance comes into force on 1 March 2005.

**SR 810.31**

### Additional informations

This text is in force.

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<b>Decision</b>	2 February 2005
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<b>In force</b>	1 March 2005
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### All versions of this law

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■	01.04.2012	PDF
■	01.03.2005	

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### All editions of this law

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