# Ordinance on Research involving Embryonic Stem Cells

## (Stem Cell Research Ordinance, SCRO)

of 2 February 2005 (Status as of 1 November 2024)

*The Swiss Federal Council,*

on the basis of Article 17 of the Stem Cell Research Act of 19 December 2003[1] (StRA),[2]

*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 StRA[3], 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.[4] about the nature, purpose and expected starting date of the research project concerned;

AS **2005** 959

1 SR **810.31**

2 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

3 Term in accordance with No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325). This change has been made throughout the text.

4 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

b.[5] about the couple's rights under Article 5 paragraph 3 StRA and under paragraph 3 of this Article and under Article 3 paragraph 2;

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

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

e.[6] that third parties may acquire rights to stem cells or products derived therefrom, 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 StRA, the stem cells derived may be passed on for other research projects; and

h.[7] about the content of the declaration of consent under Article 3 paragraph 1.

[2] The physician shall provide the couple with an information sheet and a form for the declaration of consent, made available by the person responsible for the research project (project leader).

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

[4] …[8]

**Art. 3**[9] Consent

[1] By signing the declaration of consent, 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.

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

**Art. 4**[10] Consequences of refusal or revocation of consent

If consent is withheld or revoked by the couple concerned, or by one member thereof, this must not prejudice the couple's subsequent treatment in the assisted reproduction procedure.

5 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
6 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
7 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
8 Repealed by No I of the O of 7 June 2024, with effect from 1 Nov. 2024 (AS **2024** 325).
9 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
10 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

## Section 2
## Licence Procedure for the Derivation of Embryonic Stem Cells[11]

### Art. 5 Application

When a licence is sought for stem cell derivation with a view to conducting a research project (Art. 7 StRA), the following documents must be submitted to the Federal Office of Public Health (FOPH[12]) for review:

a.[13] complete documentation of the stem cell derivation process, including evidence of the suitability of the laboratory facilities;

b.[14] complete documentation for the research project involving embryonic stem cells, as submitted to the competent ethics committee in accordance with Article 17 or with the Human Research Act of 30 September 2011[15] (HRA);

c.[16] the decision of the competent ethics committee concerning the approval of the research project;

d. a statement, based on an extract from the register specified in Article 18 StRA, of the reasons why embryonic stem cells available in Switzerland 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 FOPH shall review whether:

a. the documents are complete;

b. the licensing conditions specified in the StRA are met.

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

### Art. 7 Period

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

[2] If the FOPH requests additional documents from the project leader, the period shall begin as soon as the documents have arrived.[17]

[3] The FOPH shall notify the project leader of the beginning of the period.[18]

11 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
12 Term in accordance with No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325). This change has been made throughout the text.
13 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
14 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
15 SR **810.30**
16 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
17 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
18 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

## Section 3
## Licensing Procedure for Research Projects aimed at improving Derivation Methods[19]

### Art. 8 Application

When a licence is sought for a research project aimed at improving derivation methods (Art. 8 StRA), the following documents must be submitted to the FOPH 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.[20] a statement of the reasons why equivalent findings could not also be obtained in a different way, in particular through research projects involving induced pluripotent stem cells (iPSC);

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

e. the information sheet and the form for the declaration of consent.

### Art. 9 Review of the application

[1] The FOPH shall review whether:

a. the documents are complete;

b. the information sheet and the form for the declaration of consent are complete and comprehensible;

c. the licensing conditions specified in the StRA are met.

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

### Art. 10 Period

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

[2] If the FOPH requests additional documents from the project leader, the period shall begin as soon as the documents have arrived.[21]

[3] The FOPH shall notify the project leader of the beginning of the period.[22]

19 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
20 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
21 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
22 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

## Section 4 Licensing Procedure for the Storage of Surplus Embryos[23]

### Art. 11 Application

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

a. the licence granted under Article 7 or 8 StRA;

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 FOPH shall review whether:

a. the documents are complete;

b. the licensing conditions specified in the StRA are met.

## Section 5 Licensing Procedure for the Import of Embryonic Stem Cells[24]

### Art. 13 Application

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

a.[25] complete documentation for the research project involving embryonic stem cells, as submitted to the competent ethics committee in accordance with Article 17 or with the HRA[26];

b.[27] the decision of the competent ethics committee concerning the approval of the research project;

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 that:[28]

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.

23 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
24 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
25 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
26 SR **810.30**
27 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
28 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

**Art. 14** Review of the application

The FOPH shall review whether:

a. the documents are complete;

b. the licensing conditions specified in the StRA are met.

## Section 6
## Licensing Procedure for the Export of Embryonic Stem Cells[29]

**Art. 15** Application

When a licence is sought for the export of embryonic stem cells (Art. 15 StRA), the following documents must be submitted to the FOPH 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 leader;

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 that:[30]

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 leader.

**Art. 16** Review of the application

The FOPH shall review whether:

a. the documents are complete;

b. the licensing conditions specified in the StRA are met.

29 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
30 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

## Section 7
## Approval Procedure for the Competent Ethics Committee and Licensing Procedure for Initiation of the Research Project[31]

### Art. 17 Application

When approval is sought for the conduct of a research project involving embryonic stem cells (Art. 11 StRA), the following documents must be submitted to the competent ethics committee for review:[32]

a. complete documentation for the research project;

b.[33] a statement of the reasons why equivalent findings could not also be obtained in a different way, in particular through the use of iPSC;

c. the information sheet and the form for the declaration of consent, if embryonic stem cells have to be derived for the research project.

### Art. 18 Review of the application

[1] The ethics committee shall review whether:

a. the documents are complete;

b. the conditions specified in the StRA for the conduct of a research project involving embryonic stem cells are met.

[2] If the research project is to be conducted at several centres, it shall suffice if approval is granted under the regular procedure by the competent ethics committee at the first centre; decisions may be reached by the other ethics committees concerned under a simplified procedure. The project leader must submit the approval granted by the competent ethics committee at the first centre.[34]

[3] For the evaluation of the research project, the ethics committee may consult experts and request additional documents from the project leader.

### Art. 19[35] Period

[1] The ethics committee shall issue its decision within 30 days.

[2] If the ethics committee consults experts or requests additional documents from the project leader, the period shall begin as soon as the experts' comments or the documents have arrived.

[3] The ethics committee shall notify the project leader of the beginning of the period.

31 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
32 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
33 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
34 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
35 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

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

1 Prior to the initiation of the research project, the project leader shall notify the FOPH thereof and submit:

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

b.[36] 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 Switzerland are to be used for the project.

2 The FOPH may request additional documents from the project leader.

3 Within 15 days of receipt of the notification or the necessary documents, the FOPH shall assign a reference number to the research project, provided that it has no objections. It shall inform the project leader of the number.

4 After the communication of the reference number, the research project may be initiated.

**Art. 21** Re-evaluation and withdrawal of approval[37]

1 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.[38]

2 It shall notify the project leader and the FOPH immediately of the withdrawal of its approval.[39]

3 It shall inform the FOPH immediately of any irregularities in the conduct of the research project.

## Section 8 Modifications to the Project

**Art. 22**

1 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 FOPH of any planned substantial modifications to the project concerned.

2 Any person who carries out a research project involving embryonic stem cells must notify the ethics committee and the FOPH of any planned substantial modifications to the protocol.

36 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
37 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
38 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
39 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

3 The FOPH, or the ethics committee and the FOPH, shall issue a response within 30 days of receipt of such notification.

4 A project of the type specified in paragraph 1 may only be continued with the proposed modifications if the FOPH grants a new licence.

5 A research project of the type specified in paragraph 2 may only be continued in accordance with the modified protocol if the ethics committee renews its approval and the FOPH allows the reinitiating of the project.[40]

## Section 9 Notification and Reporting Duties

### Art. 23 Notification after discontinuation or completion of the project or the derivation of embryonic stem cells[41]

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

2 Any person who carries out a research project involving embryonic stem cells must notify the FOPH and the ethics committee of the discontinuation or completion of the project within 15 days.

3 If a project is discontinued, the reasons must be indicated in the notification.

### Art. 24 Final report

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

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

3 The FOPH may specify a shorter period if there is good cause for doing so; in response to a justified request from the project leader, it may in exceptional cases extend the period.

### Art. 25 Content of the final report

1 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.

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

a. the number of embryos used; and

40 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
41 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

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.

3 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;

c.[42] a summary of the results obtained.

4 The final report on a research project involving embryonic stem cells must also include a summary of the results obtained.[43]

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

Any person who stores embryonic stem cells must notify the FOPH 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**

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

2 The clinic performing the IVF procedure shall pseudonymise 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.[44]

3 It shall retain the data of the couple concerned, the information sheet, the original signed declaration of consent and the code key for 10 years. The data security measures must conform to the current technical standards.

## Section 11 Public Register

**Art. 28** Purpose of the register

The register specified in Article 18 StRA is intended in particular:

a. to enable embryonic stem cells to be passed on for research projects carried out in Switzerland, as specified in Article 9 paragraph 1 letter c StRA;

42 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
43 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).
44 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

b. to permit assessment of whether embryonic stem cells suitable for a research project are available in Switzerland;

c. to provide an overview of ongoing and completed research projects in Switzerland.

**Art. 29** Content of the register

[1] 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 FOPH:

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.[45] name and address of the licence holder,
   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.

[2] The FOPH shall include in the register 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.

[3] It shall publish in the register the summaries specified in Article 25 paragraphs 3 letter c and 4.

[4] It may request clarification of the information submitted.

## Section 12 Charges

**Art. 30** Calculation of charges

[1] 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.

[2] 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 FOPH shall levy the following charges in particular:

45 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 325).

| | | Swiss francs |
|---|---|---|
| a.[46] | Licence for derivation of embryonic stem cells from surplus embryos: grant, renewal, suspension, revocation | 500–10 000 |
| b.[47] | Licence for a research project aimed at improving derivation methods: grant, renewal, suspension, revocation | 500– 10 000 |
| c.[48] | Licence for the storage of surplus embryos: grant, renewal, suspension, revocation | 250–5 000 |
| d.[49] | 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 |

**Art. 32** Surcharge

The FOPH 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 FOPH.

46 Amended by No I of the O of 2 March 2012, in force since 1 April 2012 (AS **2012** 1201).
47 Amended by No I of the O of 2 March 2012, in force since 1 April 2012 (AS **2012** 1201).
48 Amended by No I of the O of 2 March 2012, in force since 1 April 2012 (AS **2012** 1201).
49 Amended by No I of the O of 2 March 2012, in force since 1 April 2012 (AS **2012** 1201).

## Section 13 Forms

**Art. 34**

The FOPH 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 register.

## Section 14 Commencement

**Art. 35**

This Ordinance comes into force on 1 March 2005.