Ordinance on Organisational Aspects of the Human Research Act

(HRA Organisation Ordinance, OrgO-HRA)

of 20 September 2013 (Status as of 1 November 2024)

The Swiss Federal Council,

on the basis of Articles 49 paragraphs 1 and 2, 53 paragraph 3, 59 paragraph 6, 60 paragraph 2 and 65 of the Human Research Act of 30 September 2011[1] (HRA),

ordains:

Chapter 1 Research Ethics Committee

Art. 1 Composition

[1] The research ethics committee (ethics committee) shall be composed at least of:

a. persons possessing expertise in the following disciplines:
   1. medicine,
   2. psychology,
   3. nursing,
   4. pharmaceutics or pharmaceutical medicine,
   5. biology,
   6. biostatistics,
   7. ethics,
   8. law, including data protection,
   9. information technology in the health sector; and

b. one or more persons representing patients.[2]

[2] It shall be of balanced composition as regards gender and professional groups.

[3] The ethics committee must be able to draw on knowledge of local conditions in the various areas of responsibility.

[4] If the ethics committee lacks the expertise required for the assessment of a research project, it must call in external specialists.

AS **2013** 3455

1 SR **810.30**

2 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 324).

Art. 2 Requirements for members

[1] Members of the ethics committee must, on commencing their service, attend a course on the duties of the ethics committee and the fundamentals of the assessment of research projects, and must regularly undergo further training in this area.

[2] The members specified in Article 1 paragraph 1 letter a numbers 1–3 must have experience in the conduct of research projects.[3]

Art. 3 Scientific secretariat

[1] Persons working for the scientific secretariat must have:

a.[4] a higher education degree;

b. adequate training in Good Clinical Practice;

c. a knowledge of scientific methods for human research projects; and

d. a knowledge of the legal requirements governing human research.

[2] The scientific secretariat shall be staffed at a level that is sufficient:

a. to ensure its availability for the committee and for applicants; and

b. to guarantee that procedural deadlines are met.

Art. 4 Recusal

[1] Members of the ethics committee shall recuse themselves from cases in which:

a. they are personally involved, or otherwise have a personal interest, in the research project;

b. persons reporting to them, to whom they report, or with whom they have close personal ties, are involved in the research project; or

c. they are an interested party for other reasons.

[2] Members who are interested parties must not participate in deliberations or in decision-making on the matter in question.

Art. 5 Regular procedure

[1] The ethics committee shall make decisions under the regular procedure with the participation of at least seven members. The composition of this group shall be such as to guarantee an expert and interdisciplinary assessment of the application.

[2] Decisions shall be taken after oral deliberations. In justified exceptional cases, it is permissible for proceedings to be conducted in writing; a member may at any time request oral deliberations.

3 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 324).
4 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 324).

3 Decisions of the ethics committee shall be made by majority vote. In the event of a tie, the chair or vice-chair shall have a casting vote.

4 The provisions of Articles 6 and 7 are reserved.

Art. 6 Simplified procedure

1 The ethics committee shall make decisions with the participation of three members on:

a.[5] Category A clinical trials, as specified in Article 19 paragraph 1, Article 20 paragraph 1, Article 49 paragraph 1 and Article 61 paragraph 1 of the Ordinance of 20 September 2013[6] on Clinical Trials (ClinO), provided that the trial does not raise any particular ethical, scientific or legal issues;

a^{bis}.[7] clinical trials in Subcategory A1 as referred to in Article 6 paragraph 2 letter a and Article 6*a* paragraph 1 letter a of the Ordinance of 1 July 2020[8] on Clinical Trials of Medical Devices, provided the trial does not raise any particular specific ethical, scientific or legal issues;

b. Category A research projects involving persons, as specified in Article 7 paragraph 1 of the Human Research Ordinance of 20 September 2013[9];

b^{bis}.[10] research projects involving existing biological material and existing health-related personal data in accordance with Articles 32 and 33 HRA, if they raise particular ethical, scientific or legal issues;

c. the further use for research of biological material or health-related personal data in the absence of informed consent, in accordance with Article 34 HRA, provided that this does not raise any particular ethical, scientific or legal issues;

d. research projects involving deceased persons, with the exception of research projects involving deceased persons undergoing artificial respiration, as specified in Article 37 paragraph 2 HRA;

e.[11] substantial modifications to an approved research project, if they raise particular ethical, scientific or legal issues.

2 The group of three must be selected in such a way as to ensure an expert and interdisciplinary assessment of the application.[12]

3 The conduct of proceedings in writing is permissible if no members request oral deliberations.

5 Amended by Annex No 3 of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
6 SR **810.305**
7 Inserted by Annex 2 No 3 of the O of 1 July 2020 on Clinical Trials on Medical Devices (AS **2020** 3033). Amended by Annex 2 No 3 of the O of 4 May 2022, in force since 26 May 2022 (AS **2022** 294).
8 SR **812.213.3**
9 SR **810.301**
10 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 324).
11 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 324).
12 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 324).

4 The regular procedure shall be adopted if:

a. unanimous agreement is not reached; or

b. a request to this effect is made by a member of the group of three.

Art. 7 Decisions to be made by the chair

1 The chair or vice-chair of the ethics committee shall make decisions on:

a.[13] research projects involving existing biological material and existing health-related personal data in accordance with Articles 32 and 33 HRA if they do not raise any particular ethical, scientific or legal issues;

b.[14] substantial modifications to an approved research project if they do not raise any particular ethical, scientific or legal issues;

c. whether the requirements concerning local conditions in multicentre research projects are met;

d. refusal to consider incomplete applications;

e. the cancellation of applications which are no longer relevant or have been withdrawn;

f. the fulfilment of conditions imposed;

g. the ordering of official measures as specified in Article 48 HRA.

2 He or she may at any time order the adoption of the simplified or regular procedure.

Art. 8 Obligation to retain documents and right of inspection

1 Application documents submitted to the ethics committee, minutes of meetings and correspondence must be retained for ten years after the completion or premature termination of a research project.

2 The cantonal supervisory authority may inspect these documents.

Art. 9 Notification requirements

The cantonal supervisory authority shall notify the coordination office as specified in Article 10 of the responsible ethics committee.

Chapter 2[15] Coordination and Information

Art. 10 Duties of the Federal Office of Public Health and of the Coordination Office

1 The Federal Office of Public Health (FOPH) has, in particular, the following duties:

13 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 324).
14 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 324).
15 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 324).

a. it operates a Coordination Office to ensure coordination between ethics committees and other supervisory authorities, as specified in Article 55 paragraph 1 HRA;

b. it oversees the coordination responsibilities delegated to third parties under Article 10*a*;

c. it issues guidelines concerning the content of the reports to be submitted by the ethics committees in accordance with Article 55 paragraph 2 HRA;

d. it provides information for the public, preparing in particular a summary of the annual reports submitted by ethics committees and a statistical overview of the research projects approved.

2 The Coordination Office, in particular, ensures regular exchanges between the supervisory authorities concerned.

3 It may, in cooperation with the ethics committees and, where appropriate, other supervisory authorities concerned, issue recommendations on approval and notification procedures and on specific aspects of decision-making practice.

Art. 10*a* Delegation of coordination responsibilities to the Swiss Association of Research Ethics Committees

1 Coordination between the ethics committees shall be delegated to the Swiss Association of Research Ethics Committees (Swissethics). For its demonstrable efforts in this connection, Swissethics shall receive federal compensation.

2 The details of the delegation of responsibilities and the compensation shall be determined in a public law contract between the FOPH and Swissethics.

Chapter 3 Data Protection

Art. 11 Disclosure of personal data

1 Before the enforcement authority discloses personal data to the authorities responsible in accordance with Article 59 paragraphs 1 and 2 HRA, it shall solicit comments from the data subject, providing information at the same time on:

a. the purpose of the disclosure of data;

b. the nature of the data to be disclosed; and

c. the data recipient.

2 The obligations specified in paragraph 1 do not apply if:

a.[16] the data subject already has the relevant information;

16 Amended by Annex 2 No II 96 of the Data Protection Ordinance of 31 Aug. 2022, in force since 1 Sept. 2023 (AS **2022** 568).

b.[17] ...

c. there is an immediate risk of legal claims or important third-party interests being prejudiced, or the fulfilment of legal duties being prevented; or

d. the data subject cannot be traced.

3 If data are to be published under Article 59 paragraph 3 HRA, all items which, when combined, would enable the data subject to be identified without disproportionate effort, must be made unrecognisable or deleted. These include in particular the name, address, date of birth and unique identification numbers.

Art. 11*a*[18] Data transmission by the cantons

The cantons shall transmit to the FOPH the data from the cantonal information system which it requires for:

a. the provision of information for the public;

b. the evaluation of human research legislation;

c. the operation of the portal specified in Article 67 ClinO[19].

Art. 12[20] Exchange of data with foreign authorities and institutions

1 The following are authorised to exchange confidential data with foreign authorities and institutions or international bodies:

a. the responsible ethics committee;

b. the cantonal supervisory authority;

c. the Swiss Agency for Therapeutic Products; and

d. the FOPH.

2 Personal data may be disclosed abroad provided the Federal Council has established that the legislation in the State concerned or the international body guarantees an adequate level of protection in accordance with Article 16 paragraph 1 of the Data Protection Act of 25 September 2020[21] (FADP). If no assessment from the Federal Council is available, personal data may be disclosed abroad if there are sufficient guarantees, in particular contractual guarantees, to ensure an adequate level of protection in the State concerned.

3 In derogation from Article 16 paragraphs 1 and 2 FADP personal data may be disclosed abroad in the following cases:

17 Repealed by Annex 2 No II 96 of the Data Protection Ordinance of 31 Aug. 2022, with effect from 1 Sept. 2023 (AS **2022** 568).
18 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 324).
19 SR **810.305**
20 Amended by Annex 2 No II 96 of the Data Protection Ordinance of 31 Aug. 2022, in force since 1 Sept. 2023 (AS **2022** 568).
21 SR **235.1**

a. Disclosure is required in order to protect the life or the physical integrity of the data subject or a third party and it is not possible to obtain the consent of the data subject within a reasonable time.

b. Disclosure is essential in order to avert an imminent danger to public health.

c. The data subject has expressly consented to disclosure.

[4] If personal data are disclosed abroad, the enforcement authority shall notify the data subject of the State or the international body to which they have been disclosed and if applicable of the guarantees in accordance with Article 16 paragraph 2 FADP or of the application of an exception under Article 17 FADP.

Chapter 4 Commencement

Art. 13

This Ordinance shall come into force on 1 January 2014.