Ordinance on Organisational Aspects of the Human Research Act

(HRA Organisation Ordinance, OrgO-HRA)

of 20 September 2013 (Status as of 26 May 2021)

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 persons possessing expertise in the following disciplines:

a. medicine;
b. psychology;
c. nursing;
d. pharmaceutics or pharmaceutical medicine;
e. biology;
f. biostatistics;
g. ethics; and
h. law, including data protection.

[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**

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 letters a–c must have experience in the conduct of research projects.

Art. 3 Scientific secretariat

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

a. a degree in medicine, pharmaceutics, natural sciences, psychology or law;

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 Withdrawal from participation

[1] Members of the ethics committee shall withdraw from participation in cases where:

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] 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.[2] 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[3] on Clinical Trials (ClinO), provided that the trial does not raise any particular ethical, scientific or legal issues;

a[bis].[4] clinical trials of devices in Subcategory A1 as referred to in Article 6 paragraph 1 of the Ordinance of 1 July 2020[5] on Clinical Trials with 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[6];

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. significant changes to authorised research projects, if they raise particular ethical, scientific or legal issues.

[2] The group of three must comprise members from different disciplines specified in Article 1.[7]

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

[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:

2 Amended by Annex No 3 of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
3 SR **810.305**
4 Inserted by Annex 2 No 3 of the O of 1 July 2020 on Clinical Trials with Medical Devices, in force since 26 May 2021 (AS **2020** 3033).
5 SR **812.213.3**
6 SR **810.301**
7 Amended by Annex 2 No 3 of the O of 1 July 2020 on Clinical Trials with Medical Devices, in force since 26 May 2021 (AS **2020** 3033).