Ordinance on Organisational Aspects of the Human Research Act

(HRA Organisation Ordinance, OrgO-HRA)

of 20 September 2013 (Status as of 1 January 2014)

The Swiss Federal Council,

on the basis of Article 49 paragraphs 1 and 2, Article 53 paragraph 3, Article 59 paragraph 6, Article 60 paragraph 2 and Article 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.

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

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 paragraph 1.

[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:

a. research projects involving existing biological material or existing health-related personal data, with the exception of further use in accordance with Article 34 HRA;

b. significant changes to authorised research projects which 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;

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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 discontinuation 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: Coordination Office

Art. 10

1 The Federal Office of Public Health (FOPH) shall manage the coordination office as specified in Article 55 HRA.

2 In particular, the coordination office has the following duties:

a. It ensures regular exchanges between the supervisory authorities concerned.

b. It ensures regular exchanges with research representatives and institutions.

c. In cooperation with the ethics committees and, where appropriate, other supervisory authorities concerned, it issues recommendations on authorisation and notification procedures and on specific aspects of decision-making practice.

d. It participates in the design and implementation of basic and further training for members of ethics committees.

e. 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 authorised.

3 It may, within the framework of the operation of the portal and the supplementary federal database in accordance with Article 67 ClinO[4], enable the electronic ex-

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change of documents relating to the authorisation and notification procedures between applicants and authorisation authorities.

4 It shall issue guidelines on the content of the reports to be submitted by ethics committees in accordance with Article 55 paragraph 2 HRA.

Chapter 3: Data Protection

Art. 11 Disclosure of personal data

1 Before the enforcement body 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. the data subject has already been adequately informed;

b. the disclosure of data is evident from the circumstances of the particular case;

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 is 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 masked or deleted. These include in particular the name, address, date of birth and unique identification numbers.

Art. 12 Exchange of data with foreign authorities and institutions

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

a. the responsible ethics committee;

b. the cantonal supervisory authority;

c. the Swiss Agency for Therapeutic Products (Agency); and

d. the FOPH.

2 If the confidential data includes personal data, this may only be transmitted to foreign authorities and institutions or to international organisations if the privacy of the data subject is not seriously endangered thereby, in particular due to the absence of legislation that guarantees adequate protection.

3 In the absence of legislation that guarantees adequate protection, personal data may only be transmitted abroad if:

a. disclosure is required in order to protect the life or the physical integrity of the data subject;

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

c. sufficient safeguards, in particular contractual clauses, ensure an adequate level of protection abroad; or

d. the data subject has consented in the particular case.

Chapter 4: Commencement

Art. 13

This Ordinance shall come into force on 1 January 2014.