Ordinance on Human Research with the Exception of Clinical Trials

(Human Research Ordinance, HRO)

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

The Swiss Federal Council,

on the basis of the Human Research Act of 30 September 2011[1] (HRA),

ordains:

Chapter 1 General Provisions

Art. 1 Purpose

This Ordinance regulates:

a. the requirements for the conduct of human research projects with the exception of clinical trials; and

b. the authorisation and notification procedures for research projects as specified in letter a.

Art. 2 Applicable provisions

The provisions concerning scientific integrity and scientific quality set out in Articles 3 and 4 of the Ordinance of 20 September 2013[2] on Clinical Trials (ClinO) apply *mutatis mutandis*.

Art. 3 Responsibilities of project leader and sponsor

1 The project leader is responsible for the conduct of the research project in Switzerland and for protection of the participants at the research site.

2 The project leader is also responsible for organising the research project, and in particular for the initiation, management and financing of the project in Switzerland, provided that no other person or institution headquartered or represented in Switzerland takes responsibility for this (sponsor).

AS **2013** 3381

1 SR **810.30**

2 SR **810.305**

Art. 4 Professional qualifications

[1] The project leader responsible for a research project must:

a. be entitled to practise independently the profession specifically qualifying him or her to conduct the research project in question;

b. have the training and experience required to conduct the research project in question;

c. be conversant with the legal requirements for research projects or be able to ensure compliance by calling in appropriate expertise.

[2] The other persons conducting the research project must have the professional knowledge and experience appropriate to the activities in question.

Art. 5 Storage of health-related personal data and biological material

[1] Any person who stores health-related personal data for research must take appropriate operational and organisational measures to protect it, and in particular:

a. restrict the handling of the health-related personal data to those persons who require this data to fulfil their duties;

b. prevent unauthorised or accidental disclosure, alteration, deletion and copying of the health-related personal data;

c. document all processing operations which are essential to ensure traceability.

[2] Any person who stores biological material for research must, in particular:

a. comply with the principles set out in paragraph 1 *mutatis mutandis*;

b. ensure that the technical requirements are met for appropriate storage of the biological material;

c. make available the resources required for storage.

Chapter 2
Research Involving Measures for Sampling of Biological Material or Collection of Health-Related Personal Data from Persons

Section 1 General Provisions

Art. 6 Research project

For the purposes of this Chapter, a research project is any project in which biological material is sampled or health-related personal data is collected from a person in order to:

a. answer a scientific question; or

b. make further use for research purposes of the biological material or the health-related personal data.

Art. 7 Categorisation

[1] A research project comes under Category A if the planned measures for sampling biological material or collecting personal data entail only minimal risks and burdens.

[2] A research project comes under Category B if the planned measures entail more than only minimal risks and burdens.

[3] Sampling biological material or collecting health-related personal data entails minimal risks and burdens if the measures, in terms of intensity and quality, and taking into account the vulnerability of the participants and the specific circumstances, have only a slight and temporary impact on the participants' health. In particular, minimal risks and burdens may be associated with:

a. surveys and observations;

b. peripheral venous or capillary blood sampling and skin punch biopsies of limited extent;

c. removing or collecting bodily substances without invasive interventions (in particular, saliva, urine and stool samples);

d. taking swabs;

e. magnetic resonance imaging scans without a contrast medium, ultrasound examinations or electrograms;

f.[3] examinations using medical devices in accordance with Article 3 of the Medical Devices Ordinance of 1 July 2020[4] that bear a conformity marking and are used without a contrast medium, and examinations using authorised medicinal products capable of emitting ionising radiation, provided that the effective dose is below 5 mSv per research project and per participant.

Art. 8 Information

[1] In addition to the points specified in Article 16 paragraph 2 HRA, the persons concerned must receive information on:

a. the effort involved and the obligations arising from participation;

b. their right to withhold or to revoke their consent without giving reasons;

c. the consequences of revoking consent to further use of the biological material and personal data collected up to this point;

d. their right to receive information at any time in response to further questions;

e. their right to be informed of results concerning their health, and their right to forgo such information or to designate a person who is to take this decision for them;

3 Amended by Annex 2 No 1 of the O of 1 July 2020 on Clinical Trials with Medical Devices, in force since 26 May 2021 (AS **2020** 3033).
4 SR **812.213**

f. the measures envisaged to cover any damage arising from the research project, including the procedure in the event of a claim;

g. the main sources of financing for the research project;

h. other points relevant to their decision on participation.

2 If the intention exists to make further use for research of the biological material sampled or the health-related personal data collected, the persons concerned must also receive information on the points specified in Articles 28–32.

3 The information may be provided in stages. It may be additionally presented in a non-textual form.

4 Appropriate measures must be taken to ensure that the persons concerned have understood the essential elements of the information provided.

Art. 9 Exceptions to written form

1 Information and consent may be provided and documented in a non-written form if:

a. the research project in question comes under Category A, as defined in this Ordinance, and involves adults with capacity;

b. provision of written information and consent would be disproportionate, given the project design; and

c. reference is made to the departure from written form in the application to the responsible research ethics committee (ethics committee).

2 In individual cases, information may be provided and consent granted in a non-written form if:

a. the person concerned, for physical or cognitive reasons, cannot read or cannot write; and

b. the project leader furnishes proof of the provision of information and consent, specifically by means of written confirmation by witnesses, or by a recording of verbal consent.

3 In individual cases, the requirement to provide information in written form may be waived if:

a. this could only be implemented with disproportionate effort, given the language skills of the person concerned; and

b. an independent qualified translator is called in to provide oral information and gives written confirmation thereof.

Art. 10 Consequences of revocation of consent

1 If consent is revoked, the biological material and health-related personal data of the person concerned must be anonymised after data evaluation has been completed.

2 Anonymisation of the biological material and personal data may be dispensed with if:

a. the person concerned expressly renounces this right when revoking consent; or

b. it is established at the beginning of the research project that anonymisation is not possible and the person concerned, having been adequately informed of this fact, consented to participate.

3 Persons revoking consent must be offered any follow-up care required to protect their health.

Art. 11 Research projects in emergency situations

For research projects in emergency situations, Articles 15–17 ClinO[5] apply *mutatis mutandis*.

Art. 12 Exemptions from liability

Any person who proves that:

a. the damage is only slight and temporary; and

b. the extent of the damage is no greater than would be expected in the current state of scientific knowledge

shall be exempt from liability under Article 19 paragraph 1 HRA.

Art. 13 Coverage

1 Category A research projects are exempt from the liability coverage requirements specified in Article 20 HRA.

2 For Category B research projects, the policy value shall be set in accordance with Annex 1.

3 The liability coverage must cover damage occurring up to 10 years after the completion of the research project.

4 In addition, Article 11, Article 13 paragraph 1 and Article 14 ClinO[6] apply *mutatis mutandis*.

Section 2 Authorisation Procedure

Art. 14 Application

1 The project leader shall submit the application documents specified in Annex 2 to the responsible ethics committee for review.

2 The ethics committee may request additional information.

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6 SR **810.305**