Ordinance on Clinical Trials with the exception of Clinical Trials of Medical Devices[1]

(Clinical Trials Ordinance, ClinO)

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[2] (HRA),
of Article 36 paragraphs 1, 3 and 4 of the Transplantation Act of 8 October 2004[3] (Transplantation Act),
and of Article 54 paragraphs 3, 6 and 7 of the Therapeutic Products Act of 15 December 2000[4] (TPA),

ordains:

Chapter 1 General Provisions

Section 1 Purpose and Definitions

Art. 1 Purpose

1 This Ordinance regulates:

a.[5] the requirements for the conduct of clinical trials as defined in Article 3 letter l HRA:

1.[6] clinical trials with medicinal products, including combinations under Article 2 paragraph 1 letters f and g of the Medical Devices Ordinance of 1 July 2020 (MedDO)[7], or transplant products,

AS **2013** 3407

1 Amended by Annex 2 No 2 of the O of 1 July 2020 on Clinical Trials with Medical Devices, in force since 26 May 2021 (AS **2020** 3033).
2 SR **810.30**
3 SR **810.21**
4 SR **812.21**
5 Amended by Annex 2 No 2 of the O of 1 July 2020 on Clinical Trials with Medical Devices, in force since 26 May 2021 (AS **2020** 3033).
6 Amended by Annex No 2 of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).
7 SR **812.213**

2. clinical trials with in vitro diagnostic medical devices or products under Article 2*a* paragraph 2 TPA[8],
3. clinical trials of transplantation,
4. clinical trials that are not clinical trials under numbers 1 to 3;

b. the authorisation and notification procedures for clinical trials;

c. the duties and responsibilities of research ethics committees (ethics committees), the Swiss Agency for Therapeutic Products (the Agency) and the Federal Office of Public Health (the FOPH) in connection with the authorisation and notification procedures;

d. the registration of clinical trials and public access to the registry.

[2] The following apply:

a. for clinical trials with medical devices under the MedDO: the Ordinance of 1 July 2020[9] on Clinical Trials with Medical Devices;

b. for clinical trials of xenotransplantation: the Xenotransplantation Ordinance of 16 March 2007[10] applies.[11]

Art. 2[12] Definitions

In this Ordinance:

a. *clinical trial* means a research project involving individuals that prospectively assigns them to undergo a health-related intervention in order to study its effects on health or on the structure and function of the human body;

b. *health-related intervention* means a preventive, diagnostic, therapeutic, palliative or rehabilitative measure investigated in a clinical trial;

c. *minimal risks and burdens* means risks and burdens, which, in terms of intensity and quality, and taking into account the vulnerability of the participants and the specific circumstances, will have only a slight and temporary impact on the participants' health; in particular, minimal risks and burdens may be associated with:
   1. surveys and observations,
   2. peripheral venous or capillary blood sampling and skin punch biopsies of limited extent,
   3. removing or collecting bodily substances without invasive interventions, in particular, saliva, urine and stool samples,
   4. taking swabs,

8 Term in accordance with Annex No 2 of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281). This change has been made throughout the text.
9 SR **812.213.3**
10 SR **810.213**
11 Amended by Annex 2 No 2 of the O of 1 July 2020 on Clinical Trials with Medical Devices, in force since 26 May 2021 (AS **2020** 3033).
12 Amended by Annex 2 No 2 of the O of 1 July 2020 on Clinical Trials with Medical Devices, in force since 26 May 2021 (AS **2020** 3033).

5. magnetic resonance imaging scans without a contrast medium, ultrasound examinations or electrograms,
6. examinations using medical devices under Article 3 MedDO[13] bearing conformity markings without a contrast medium, or using authorised medicinal products capable of emitting ionising radiation, provided that the effective dose is below 5 mSv per research project and per person concerned;

d. *sponsor* means a person or institution headquartered or represented in Switzerland that takes responsibility for organising a clinical trial, and in particular for the initiation, management and financing of the trial in Switzerland;

e. *investigator* means a person responsible in Switzerland for the conduct of a clinical trial and for the protection of the participants at the trial site; an investigator who takes responsibility for organising a clinical trial in Switzerland is also a sponsor.

Section 2 Principles

Art. 3 Scientific integrity

[1] The sponsor and the investigator, and the other persons involved in the clinical trial, shall maintain scientific integrity. In particular, it is prohibited:

a. to falsify, fabricate or suppress research results;

b. to fail to disclose conflicts of interest at the planning stage, in the authorisation procedure, or when conducting or publishing research;

c. to impede or prevent research activities without good reason;

d. to prevent or sanction the exposure of scientific misconduct.

[2] The applicable guidelines are the Principles and Procedures for Integrity in Scientific Research issued by the Swiss Academies of Arts and Sciences, as specified in Annex 1 number 1. In justified cases, other recognised scientific integrity guidelines of equivalent standing may be used.

Art. 4 Scientific quality

The sponsor and the investigator of a clinical trial shall ensure scientific quality. In particular:

a. they shall define a research question based on the current state of scientific knowledge;

b. they shall use an appropriate scientific methodology; and

c. they shall ensure the availability of the resources required for the clinical trial and provide the necessary infrastructure.

13 SR **812.213**

Art. 5 Rules of Good Clinical Practice

[1] Clinical trials must be conducted in accordance with the rules of Good Clinical Practice, as specified in Annex 1 number 2.

[2] A clinical trial covered by Chapter 4 may be conducted in accordance with other rules which are recognised in the specialty in question, provided that the protection of participants and data quality and security are guaranteed.

[3] The measures and precautions required in accordance with the rules of Good Clinical Practice must be adapted to the extent of the risks to which participants are exposed. Depending on the extent of these risks, there may be certain deviations from the rules of Good Clinical Practice. Any deviations must be recorded in the protocol. The protection of the participants and data quality and security must be guaranteed in all cases.

Art. 6 Professional qualifications

[1] The clinical trial investigator must:

a. be adequately trained in Good Clinical Practice and have the professional knowledge and experience required for the clinical trial; and

b. be conversant with the legal requirements for clinical trials or be able to ensure compliance by calling in appropriate expertise.

[2] In addition, the investigator in a clinical trial of medicinal products or transplantation must be entitled to practise the medical profession independently.

[3] For clinical trials of in vitro diagnostic medical devices[14] and products under Article 2*a* paragraph 2 TPA and for clinical trials covered by Chapter 4, a person without medical qualifications may also serve as an investigator, provided that this person is entitled to practise independently the profession specifically qualifying him or her to conduct the clinical trial.

[4] The other persons conducting the clinical trial must have the professional knowledge and experience appropriate to the activities in question.

Section 3 Information, Consent and Revocation

Art. 7 Information

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

a. possible alternatives to the intervention under investigation, if the clinical trial is expected to offer a direct benefit;

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

14 Term in accordance with Annex 2 No 2 of the O of 1 July 2020 on Clinical Trials with Medical Devices, in force since 26 May 2021 (AS **2020** 3033). This change has been made throughout the text.

c. their right to withhold or to revoke their consent without giving reasons and without suffering any disadvantages in relation to their medical treatment;

d. the consequences of revocation of consent for their subsequent medical treatment, and for further use of the personal data and biological material collected up to this point;

e. their right to receive information at any time in response to further questions relating to the clinical trial;

f. 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;

g. the measures envisaged to cover any damage arising from the clinical trial, including the procedure in the event of a claim;

h. the sponsor and the main sources of financing for the clinical trial;

i. other points relevant to their decision on participation.

2 If the intention exists to make further use for research of biological material sampled or health-related personal data collected in the clinical trial, the persons concerned must also receive information on the points specified in Articles 28–32 of the Human Research Ordinance of 20 September 2013[15].

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. 8 Exceptions to written form

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

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

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

2 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.

15 SR **810.301**