# 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 20 May 2025)

*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:

1.[6] clinical trials of 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 of 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 of 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 of…[8] products under Article 2*a* paragraph 2 TPA[9],
3. clinical trials of transplantation,
4. clinical trials that are not clinical trials under numbers 1 to 3;

b. the approval and notification procedures for clinical trials;

c.[10] the duties and responsibilities of research ethics committees (ethics committees), the Swiss Agency for Therapeutic Products (Swissmedic) and the Federal Office of Public Health (the FOPH) in connection with the approval and notification procedures;

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

2 The conduct of the following clinical trials is not covered by this Ordinance:

a. clinical trials of medical devices under Article 1 MedDO and Article 1 of the Ordinance of 4 May 2022[11] on In Vitro Diagnostic Medical Devices: for such trials, the Ordinance of 1 July 2020[12] on Clinical Trials of Medical Devices (ClinO-MD) applies;

b. clinical trials of xenotransplantation: for such trials, the Xenotransplantation Ordinance of 16 March 2007[13] applies.[14]

**Art. 2**[15] Definitions

In this Ordinance:

a.[16] *clinical trial* means a research project involving individuals that prospectively assigns them to undergo one or more interventions in order to study the effects thereof on health or on the structure and function of the human body;

b.[17] *intervention* means any measure to which the participant is subjected and whose effects on this person are to be investigated;

c. *minimal risks and burdens* mean 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,

8 Term removed by Annex 2 No 2 of the O of 4 May 2022, with effect from 26 May 2022 (AS **2022** 294). This change has been made throughout the text.
9 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.
10 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
11 SR **812.219**
12 SR **810.306**
13 SR **810.213**
14 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
15 Amended by Annex 2 No 2 of the O of 1 July 2020 on Clinical Trials on Medical Devices, in force since 26 May 2021 (AS **2020** 3033).
16 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
17 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

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,
5. magnetic resonance imaging scans without a contrast medium, ultrasound examinations or electrograms,
6.[18] accompanying examinations involving ionising radiation, provided that the effective dose is below 5 mSv per research project and per participant, no contrast medium is used, and:
   – the radiopharmaceuticals employed are used in accordance with the authorisation or are exempt from authorisation, or
   – the devices under Article 1 MedDO[19] bear conformity markings as specified in Article 13 MedDO and are used in accordance with the instructions for use;

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;

f.[20] *surplus information* means results relating to a specific person, in particular incidental findings, which arise in the course of a clinical trial and which are not required either for the conduct thereof or to answer the scientific question;

g.[21] *investigational medicinal product* means a product which is being tested or used as a reference, including as a placebo, in a clinical trial of medicinal products;

h.[22] *placebo* means a product that does not contain an active substance.

## 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;

18 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
19 SR **812.213**
20 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
21 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
22 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

b. to fail to disclose conflicts of interest at the planning stage, in the approval 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 code of conduct for scientific integrity, issued by the Swiss Academies of Arts and Sciences, as specified in Annex 1 number 1, is applicable. In justified cases, other recognised scientific integrity guidelines of equivalent standing may be used.[23]

**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.

**Art. 4*a***[24] Inclusion of relevant groups of persons

1 The sponsor and the investigator must ensure that the criteria for the selection of participants and the trial design permit appropriate representation of the groups of persons that are relevant for answering the scientific question; in particular, they shall take into account the sex ratio and age groups.

2 The exclusion or deliberate underrepresentation of relevant groups of persons must be declared and justified in the application documents.

**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.

23 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
24 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

**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;

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

c.[25] have appropriate knowledge and skills in the areas of data security and data protection or be able to ensure compliance by calling in appropriate expertise.

[2] In addition, the investigator in a clinical trial of medicinal products, products under Article 2*a* paragraph 2 TPA or transplantation must be entitled to practise as a physician under his or her own professional responsibility.[26]

[3] 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 the profession specifically qualifying him or her to conduct the clinical trial under his or her own responsibility.[27]

[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, Communication of Results and Revocation[28]

**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;

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;

25 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
26 Amended by Annex 2 No 2 of the O of 4 May 2022, in force since 26 May 2022 (AS **2022** 294).
27 Amended by Annex 2 No 2 of the O of 4 May 2022, in force since 26 May 2022 (AS **2022** 294).
28 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

e^bis.[29] the possibility of surplus information arising, and the significance of the discovery of surplus information and the significance of exercising one's right to know or not to know;

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;

h^bis.[30] details of the expected publication date of the lay summary of the trial results in accordance with Article 65*a* paragraph 2 and the entry on the portal in accordance with Article 67 under which the summary can be found;

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[31].

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; in particular:

a. the persons concerned must be informed about the purpose of and procedure for the provision of information;

b. the elements of information must be communicated in an appropriate, structured and clear manner.[32]

**Art. 7*a*[33]** Information in cases of genetic testing

1 If, when presymptomatic genetic testing, prenatal genetic testing, or testing for family planning purposes (Art. 3 let. e, g and i of the Federal Act of 15 June 2018[34] on Human Genetic Testing, HGTA) is conducted, results arise which concern the health of the person concerned, he or she must additionally receive information on the following:

a. the purpose, nature and significance of the test;

b. the frequency and nature of the disorder to be screened for;

c. medical, psychological and social implications of the test;

29 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
30 Inserted by No I of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322, 582).
31 SR **810.301**
32 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
33 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
34 SR **810.12**

d. the possible significance of the results for the person concerned and for family members, and their right not to know.

2 When presymptomatic testing is conducted (Art. 3 let. e HGTA), the person concerned must additionally be informed about the conditions under which insurance providers may request the disclosure of data from genetic tests performed (Art. 43 and Art. 44 HGTA).

**Art. 7*b***[35] Information in cases of prenatal risk assessment

When a prenatal risk assessment is conducted (Art. 3 let. h HGTA[36]) the pregnant woman must additionally be informed about the matters specified in Article 23 HGTA.

**Art. 7*c***[37] Form of consent

1 Consent must be signed by hand or given in electronic form.

2 The declaration of consent must:

a. be dated; and

b. be readable during the entire required retention period.

3 Consent given in electronic form is permissible provided that:

a. it has been granted using a method which unequivocally identifies the person concerned;

b. the chosen method prevents an overhasty decision;

c. it is protected against modification in accordance with the state of the art;

d. it is described in the application documents how the requirements specified in letters a–c are met.

4 The person concerned can choose to receive a copy of the information documents and the declaration of consent either on paper or in electronic form.

**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.

35 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
36 SR **810.12**
37 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

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.

**Art. 8*a***[38] Communication of results

1 The right of the persons concerned to receive information as specified in Article 8 paragraph 1 HRA applies to results concerning their health obtained by means of tests meeting current standards of analytical and clinical validity.

2 Results must be communicated to the persons concerned or, where applicable, to their legal representative, designated trusted person or the next of kin (Art. 22–24 HRA) in cases where:

a. the results are subject to a legal notification requirement which stipulates or involves informing the person concerned about the result;

b. the results may entail a public health measure which stipulates or involves informing the person concerned about the result;

c. the results must be noted by the person who is to be informed, in order to protect the life and health of third parties or of the person lacking capacity concerned by the test.

**Art. 9** 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 clinical trial 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.

38 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

## Section 4 Liability and Coverage

### Art. 10 Exemptions from liability

[1] Exempt from liability in relation to clinical trials under Article 19 paragraph 1 HRA shall be any person who proves that the damage is attributable to:

a. the administration of an authorised medicinal product used in accordance with the prescribing information;

b. the administration of an authorised medicinal product, if this is recognised as standard in guidelines prepared in accordance with internationally accepted quality criteria;

c.[39] the use of a product under Article 2*a* paragraph 2 TPA that has been notified under Article 6 paragraph 3 MedDO[40] in its version of 1 January 2002[41] in application of Article 108 paragraph 1 letter b MedDO and used in accordance with the instructions for use;

d.[42] the use of some other intervention which is recognised as standard in guidelines prepared in accordance with internationally accepted quality criteria.

[2] Also exempt from liability under Article 19 paragraph 1 HRA shall be any person who proves that comparable damage could also have occurred if the injured party had undergone standard therapy for their disease.[43]

### Art. 11 Extension of the limitation period

The limitation period for compensation claims in respect of damage:

a. attributable to the use of ionising radiation[44] is governed by Article 40 of the Radiological Protection Act of 22 March 1991[45];

b. attributable to the use of genetically modified organisms is governed by Article 32 of the Gene Technology Act of 21 March 2003[46].

### Art. 12 Exemptions from liability coverage requirements

Exempt from liability coverage requirements are:

a. damage exempt from liability in accordance with Article 10;

39 Amended by Annex 2 No 2 of the O of 4 May 2022, in force since 26 May 2022 (AS **2022** 294).
40 SR **812.213**
41 AS **2001** 3487
42 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
43 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
44 German term amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322). This amendment (not relevant to the English text) has been made throughout the Ordinance.
45 SR **814.50**
46 SR **814.91**

b. Category A clinical trials (Art. 19 para. 1, Art. 20 para. 1, Art. 49 para. 1 and Art. 61 para. 1) involving measures for sampling of biological material or collection of health-related personal data which entail only minimal risks and burdens.

**Art. 13** Requirements for liability coverage

1 The liability coverage requirements can be fulfilled:

a. by taking out insurance; or

b. by providing security of equivalent value.

2 The policy value shall be set in accordance with Annex 2.

3 The liability coverage must cover damage occurring up to 20 years after the completion of the clinical trial.[47]

**Art. 14** Protection of the injured party

1 Cancellation of the insurance policy by the insurance company is not permissible after the occurrence of the insured event.

2 Within the framework of the insurance coverage, the injured party or legal successor has a direct claim against the insurance company. Objections cannot be raised on the basis of the insurance policy or the Insurance Policies Act of 2 April 1908[48].

3 If the insurance company is subject to action under paragraph 2, it shall have a right of recourse against the insured party.

4 Paragraphs 1–3 apply *mutatis mutandis* if security of equivalent value is provided in accordance with Article 13 paragraph 1 letter b.

## Section 5 Clinical Trials in Emergency Situations

**Art. 15** Post hoc consent

1 The sponsor and the investigator must, when planning or conducting a clinical trial in an emergency situation, take any measures necessary to ensure that:

a. the consent of the person concerned can be obtained post hoc as soon as possible;

b. in the case of a clinical trial involving children or adolescents, the consent of the legal representative can be obtained as soon as possible, if this is required in accordance with Articles 22 and 23 HRA;

c. in the case of a clinical trial involving adults permanently lacking capacity, the consent of the person authorised to act as a representative can be obtained

47 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
48 SR **221.229.1**

as soon as possible, if no statement of wishes formulated in a state of capacity is available.

2 The procedure for obtaining post hoc consent must be defined in the protocol.

**Art. 16** Death of the person

1 If a person who was included in a clinical trial in an emergency situation dies before it has been possible to obtain consent or refusal in accordance with Article 15, the biological material and the health-related personal data collected may only be used if this person has consented, in an advance directive or otherwise, to the use of such material and health-related data for research purposes.

2 In the absence of a statement of wishes as specified in paragraph 1, use is permissible if consent is given by the next of kin or a designated trusted person. Consent is governed by Article 8 of the Transplantation Act.

**Art. 17** Handling of biological material and health-related personal data

1 The biological material sampled and the health-related personal data collected during a clinical trial in an emergency situation may only be evaluated when consent has been obtained in accordance with Article 15 or 16.

2 In exceptional cases, the biological material and the health-related personal data may be evaluated before consent has been obtained if:

a. the biological material is only utilisable for a limited period; or

b. this is necessary for the sake of the participants' safety and health.

3 If consent to participate in a clinical trial in an emergency situation is withheld post hoc, the biological material and the health-related personal data must be destroyed.

4 If the validity of the clinical trial or its results is compromised in essential respects by the destruction of the biological material and the health-related personal data, the use thereof in the clinical trial is permissible in spite of refusal of consent. The biological material and the health-related personal data must be anonymised without delay. The right to object of the person concerned is reserved.

5 If it is foreseeable that material or data may be evaluated before consent has been obtained, in accordance with paragraph 2, or used in spite of refusal of consent, in accordance with paragraph 4, this must be stated in the protocol.

## Section 6
## Storage of Health-Related Personal Data and Biological Material

**Art. 18**

1 Any person who stores health-related personal data in connection with a clinical trial 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 in connection with a clinical trial must, in particular:

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

b.[49] ensure that the technical requirements are met for appropriate storage of the biological material; here, nationally and internationally recognised guidelines must be consulted;

c. make resources required for storage available.

## Section 7[50]
## Handling of Genetic Data in connection with Insurance

### Art. 18*a*

In connection with insurance, Articles 42–44 HGTA[51] apply to the handling of genetic data from clinical trials.

# Chapter 2
# Approval and Notification Procedures for Clinical Trials of Medicinal Products, Products under Article 2*a* paragraph 2 TPA and Transplant Products

## Section 1 General Provisions

### Art. 19[52] Categorisation of clinical trials of medicinal products

[1] Clinical trials of medicinal products come under Category A if:

a. the investigational medicinal product is a medicinal product authorised in Switzerland;

b. the investigational medicinal product has not been modified; and

c. the use of the investigational medicinal product:

1. is in accordance with the prescribing information,

2. is in an indication or dosage different from that specified in the prescribing information, but in accordance with the following criteria:

49 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
50 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
51 SR **810.12**
52 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

– the indication is within the same disease group of the International Classification of Diseases (ICD), as specified in Annex 1 number 3,
– the disease in question is self-limiting and the dosage of the medicinal product is lower than that specified in the prescribing information; or

3. is recognised as standard in guidelines prepared in accordance with internationally accepted quality criteria.

2 They come under Category B if the investigational medicinal product:

a. is a medicinal product authorised in Switzerland, which:
   1. is not used as specified in paragraph 1 letter c, or
   2. has undergone a low-risk modification, as specified in Annex 2bis;

b. is a medicinal product authorised in a country that has equivalent medicinal product control in accordance with Article 13 TPA and has either not been modified or has undergone a low-risk modification, as specified in Annex 2bis; or

c. is a placebo specifically manufactured for clinical trials.

3 They come under Category C if the investigational medicinal product contains an active substance and:

a. is a medicinal product authorised in Switzerland or in a country that has equivalent medicinal product control in accordance with Article 13 TPA and has undergone more than a low-risk modification, as specified in Annex 2bis; or

b. is a medicinal product authorised neither in Switzerland nor in a country that has equivalent medicinal product control in accordance with Article 13 TPA.

4 If a clinical trial comes under more than one category, it is assigned to the highest of these categories; the categories are arranged in ascending order from A to C.

**Art. 20**[53] Categorisation of clinical trials of products under Article 2*a* paragraph 2 TPA

1 Clinical trials of products under Article 2a paragraph 2 TPA come under Category A if:

a. the product that is under investigation has been notified under Article 6 paragraph 3 MedDO[54] in its version of 1 January 2002[55] in application of Article 108 paragraph 1 letter b MedDO; and

b. it is used in accordance with the instructions for use.

2 They come under Category C if:

53 Amended by Annex 2 No 2 of the O of 4 May 2022, in force since 26 May 2022 (AS **2022** 294).
54 SR **812.213**
55 AS **2001** 3487

a. the product that is under investigation has not been notified under Article 6 paragraph 3 MedDO in its version of 1 January 2002 in application of Article 108 paragraph 1 letter b MedDO;

b. the product that is under investigation is not used in accordance with the intended purposes specified in the instructions for use; or

c. use of the product that is under investigation is prohibited in Switzerland.

**Art. 21** Clinical trials of transplant products

For clinical trials of transplant products, the provisions of this Ordinance concerning clinical trials of medicinal products apply *mutatis mutandis*.

**Art. 22** Clinical trials of gene therapy and clinical trials of genetically modified or pathogenic organisms

1 For the purposes of this Ordinance, clinical trials of gene therapy are trials in which genetic information is introduced into somatic cells (somatic gene therapy).

2 For the purposes of this Ordinance, clinical trials of genetically modified organisms are trials of medicinal products containing genetically modified organisms as defined in the Release Ordinance of 10 September 2008[56], and in particular replication-competent viruses.

3 For the purposes of this Ordinance, clinical trials of pathogenic organisms are trials of medicinal products containing pathogenic organisms as defined in the Release Ordinance.

4 For clinical trials of gene therapy and for clinical trials of genetically modified or pathogenic organisms, the provisions of this Ordinance concerning clinical trials of medicinal products apply *mutatis mutandis*.

**Art. 23** Coordination and information in approval procedures and deadline for submission of the application to the second authority responsible for approval[57]

1 The investigator and the sponsor may simultaneously submit applications to the responsible ethics committee and to Swissmedic[58].

1bis For Category B and C clinical trials, the application must be submitted to the second authority within two years after approval has been granted by the first authority.[59]

1ter At the request of the approval holder, the first authority may extend the deadline specified in paragraph 1bis. Such a request constitutes a substantial modification to the clinical trial.[60]

56 SR **814.911**
57 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
58 Term amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322). This amendment has been made throughout the Ordinance.
59 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
60 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

1quater If the deadline specified in paragraph 1bis or the deadline extended in accordance with paragraph 1ter is exceeded, or if a request for a deadline extension in accordance with paragraph 1ter is rejected, then the approval granted shall lapse.[61]

2 The responsible ethics committee and Swissmedic shall inform each other about matters relating to the review areas specified in Article 25 and in Article 32, and shall coordinate their assessments.

**Art. 23*a***[62] Deadline for enrolment of the first participant

1 The first participant must be enrolled in the clinical trial within two years after the last approval required has been granted.

2 In the case of clinical trials on rare diseases, the authorities may, in the course of the approval procedure, set a longer deadline at the request of the applicant.

3 The deadline in accordance with paragraph 1 or 2 may be extended at the request of the approval holder. The request must be made to all the authorities involved in the approval procedure and constitutes a substantial modification to the clinical trial. If the modification is not approved, then approvals already granted shall lapse.

4 If the first participant is not enrolled in the clinical trial within the deadline in accordance with paragraphs 1–3, then the clinical trial is considered to be interrupted as specified in Article 38 paragraph 2 third sentence. The clinical trial may only be commenced if a request for a deadline extension in accordance with paragraph 3 has been approved.

## Section 2 Procedure before the Responsible Ethics Committee

**Art. 24** Application

1 The investigator shall submit to the responsible ethics committee the application documents specified in Annex 3 for review.

2 The ethics committee may request additional information.

3 The sponsor may submit the application instead of the investigator. In this case, the sponsor assumes the obligations of the investigator as specified in Articles 29 and 36*a* and also the notification and reporting obligations vis-à-vis the responsible ethics committee.[63]

**Art. 25** Review areas

The responsible ethics committee shall review:

a. the completeness of the application;

b. the categorisation requested;

61 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
62 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
63 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

c. the information intended for registration in accordance with Article 64;

d. the protocol with regard to:

1. the scientific relevance of the topic (Art. 5 HRA), the suitability of the chosen scientific methodology and compliance with Good Clinical Practice,
2. the ratio between the likely risks and burdens and the expected benefits (Art. 12 para. 2 HRA),
3. the measures taken to minimise risks and burdens, and for the protection and follow-up of participants (Art. 15 HRA), including precautionary measures in the handling of personal data,
4. the need to involve persons, and in particular persons who are particularly vulnerable (Art. 11 HRA),
5. the criteria for the selection of participants,
6. the proposed procedure for providing information and obtaining consent, including the appropriateness of the period for reflection,
7. the appropriateness of the remuneration for participants,
8. compliance with scientific integrity requirements;

d^bis.[64] if applicable, compliance with the requirements for consent in electronic form (Art. 7*c* para. 3 let. a–c);

e. the completeness of the documentation for recruitment, information and consent, and its comprehensibility, especially with regard to the possible involvement of particularly vulnerable persons;

e^bis.[65] the consideration given to the right of the persons concerned to receive information (Art. 8 para. 1 HRA);

f. the guaranteeing of the right to compensation in the event of damage (Art. 20 HRA);

g. the adequacy of the knowledge and experience of the investigator and of the other persons conducting the clinical trial, in relation to the discipline concerned and the conduct of a clinical trial;

h. the suitability of the infrastructure at the trial site;

i. the financing of the clinical trial and the agreements between the sponsor, third parties and the investigator concerning the allocation of tasks, remuneration and publication;

j.[66] for Category A clinical trials of medicinal products capable of emitting ionising radiation: additionally, compliance with radiological protection legislation and the dose estimation;

64 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
65 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
66 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

k.[67] for accompanying examinations involving ionising radiation: additionally, compliance with radiological protection legislation and the dose estimation, in cases unless an opinion from the FOPH has to be sought in accordance with Article 36*a* paragraph 4;

l. other areas, where this is necessary to assess the protection of participants.

**Art. 26** Procedure and deadlines

[1] The ethics committee shall acknowledge receipt of the application within 7 days and notify the investigator of any formal deficiencies in the application documents.

[2] It shall reach a decision within 30 days of acknowledgement of receipt of the formally correct application documents.

[3] If the ethics committee requests additional information in accordance with Article 24 paragraph 2, the clock shall be stopped until this information has been received.

[4] It shall inform Swissmedic of its decision in the case of Category B and C clinical trials.

**Art. 27** Multicentre clinical trials

[1] The coordinating investigator shall submit the application for multicentre clinical trials to the lead committee in accordance with Article 47 paragraph 2 HRA. The sponsor may submit the application instead of the coordinating investigator; Article 24 paragraph 3 applies *mutatis mutandis*.

[2] The coordinating investigator is the person responsible in Switzerland for coordination of the investigators responsible at the individual trial sites.

[3] The lead committee shall acknowledge receipt of the application within 7 days and at the same time notify the coordinating investigator whether the application documents are formally in order.

[4] At the request of the lead committee, the coordinating investigator shall submit the required number of copies of the application documents specified in Annex 3 to the ethics committees responsible at the other trial sites (ethics committees concerned). These shall review the local conditions and inform the lead committee of their assessment within 15 days.

[5] The lead committee shall reach a decision within 45 days of acknowledgement of receipt of the formally correct application. It shall inform the ethics committees concerned of its decision and Swissmedic in the case of Category B and C clinical trials.

67 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

**Art. 28**[68]

**Art. 29** Modifications

[1] Substantial modifications to an approved clinical trial must be approved by the ethics committee before being implemented. Exempt from this requirement are measures which have to be taken immediately in order to protect the participants.

[2] The investigator shall submit to the ethics committee any application documents specified in Annex 3 which are affected by the modification. At the same time, the investigator shall provide information on the reasons for the modification.

[3] The following are considered to be substantial modifications:

a. modifications affecting the participants' safety and health, or their rights and obligations;

b. modifications to the protocol, and in particular modifications based on new scientific knowledge which concern the trial design, the method of investigation, the endpoints or the form of statistical analysis;

c. a change of trial site, or conducting the clinical trial at an additional site;

d. a change of sponsor, coordinating investigator or investigator responsible at a trial site; or

e.[69] the extension of a deadline in accordance with Articles 23, 23*a* and 50; in the application to the ethics committee, the investigator shall indicate whether the application documents are still up-to-date, particularly with regard to the scientific relevance of the question; if this is not the case, the investigator shall submit updated application documents.

[4] The ethics committee shall reach a decision on substantial modifications within 30 days. Article 26 applies *mutatis mutandis*.

[5] If a site at which a clinical trial is to be additionally conducted does not lie within the responsibility of the ethics committee which granted approval, the procedure is governed by Article 27 *mutatis mutandis*.

[6] Other modifications must be notified to the ethics committee in the annual safety report specified in Article 43.

## Section 3: Procedure before Swissmedic

**Art. 30**[70] Exemption from mandatory approval

Category A clinical trials are exempted from the requirement for approval by Swissmedic as specified in Article 54 paragraph 1 TPA.

68 Repealed by No I of the O of 7 June 2024, with effect from 1 Nov. 2024 (AS **2024** 322).
69 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
70 Amended by Annex No 2 of the O of 19 May 2021, in force since 26 May 2021 (AS **2021** 281).

**Art. 31** Application

[1] The sponsor shall submit to Swissmedic the application documents specified in Annex 4 for review.

[1bis] Swissmedic may prepare a list of specific documents in accordance with the content of Annex 4 that are required for submission of the application.[71]

[2] Swissmedic may request additional information.

**Art. 32** Review areas

[1] For clinical trials of medicinal products, Swissmedic shall review:

a. the completeness of the application;

b. the safety of the medicinal product, and in particular the preclinical and clinical pharmacology, toxicology, formulation and pharmacokinetics, and the proposed dosage and indication;

c. the risk assessment and risk management based on the medicinal product safety data;

d. the quality of the medicinal product and compliance with Good Manufacturing Practice (GMP);

e. other areas, where this is necessary to assess the safety or quality of the medicinal product.

[2] For Category B clinical trials of medicinal products capable of emitting ionising radiation, it shall additionally review compliance with radiological protection legislation and the dose estimation.

[3] For clinical trials of products under Article 2*a* paragraph 2 TPA, it shall review:

a. the completeness of the application;

b. the requirements specified in Article 54 paragraph 4 letter b TPA.

**Art. 33** Procedure and deadlines

[1] Swissmedic shall acknowledge receipt of the application within 7 days and notify the sponsor of any formal deficiencies in the application documents.

[2] Swissmedic shall reach a decision within 30 days of acknowledgement of receipt of the formally correct application documents.

[3] If a medicinal product or product under Article 2*a* paragraph 2 TPA is to be used in persons for the first time or manufactured in a new process, this deadline may be extended by a maximum of 30 days. Swissmedic shall inform the sponsor of the extended deadline.

[4] If Swissmedic requests additional information in accordance with Article 31 paragraph 2, the clock shall be stopped until this information has been received.

71 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

5 Swissmedic shall inform the responsible ethics committee and other competent cantonal authorities of its decision.

**Art. 34** Modifications

1 Substantial modifications to an approved clinical trial must be approved by Swissmedic before being implemented. Exempt from this requirement are measures which have to be taken immediately in order to protect the participants.

2 The sponsor must submit to Swissmedic any application documents specified in Annex 4 which are affected by the modification. At the same time, the sponsor shall provide information on the reasons for the modification.

3 The following are considered to be substantial modifications:

a. modifications to the medicinal product or product under Article 2*a* paragraph 2 TPA, or to its administration or use;

b. modifications based on new preclinical or clinical data which may affect product safety;

c. modifications concerning the production of the medicinal product or product under Article 2*a* paragraph 2 TPA which may affect product safety; or

d.[72] the extension of a deadline in accordance with Articles 23 and 23*a*; in the application to Swissmedic, the sponsor shall indicate whether the application documents are still up-to-date, particularly with regard to medicinal product safety and quality; if this is not the case, the sponsor shall submit updated application documents.

4 Swissmedic shall reach a decision within 30 days after receipt of the complete application documents affected by the modification. Article 33 applies *mutatis mutandis*.

5 Other modifications which affect the documents submitted to Swissmedic must be notified to Swissmedic as quickly as possible.

## Section 4
## Special Provisions for Clinical Trials of Gene Therapy, for Clinical Trials of Genetically Modified or Pathogenic Organisms, and for Clinical Trials in which Ionising Radiation is used[73]

**Art. 35** Clinical trials of gene therapy and clinical trials of genetically modified or pathogenic organisms

1 For Category B and C clinical trials of gene therapy and for clinical trials of genetically modified or pathogenic organisms as defined in Article 22, the documents specified in Annex 4 number 1 must be submitted to Swissmedic.[74]

72 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
73 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
74 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

2 Before granting approval, Swissmedic shall seek opinions from the Swiss Expert Committee for Biosafety (SECB), the Federal Office for the Environment (FOEN) and the FOPH.

3 In addition to the areas specified in Article 32, Swissmedic shall review whether the quality and biological safety of the product are guaranteed with regard to the participants and to human beings and the environment.

4 It shall grant approval if:

a. the SECB has confirmed the quality and biological safety of the product with regard to the participants and to human beings and the environment; and

b. no objections to the clinical trial have been raised by the FOPH or by the FOEN, based on the assessment of the environmental data.

5 Swissmedic shall make a decision within 60 days of acknowledgement of receipt of the formally correct application documents. It shall inform the competent federal and cantonal authorities of its decision.[75]

6 …[76]

7 Swissmedic, the FOPH and the FOEN shall jointly issue guidelines on assessment of risks to human beings and the environment.

**Art. 36** Clinical trials of medicinal products capable of emitting ionising radiation[77]

1 For Category B and C clinical trials of medicinal products capable of emitting ionising radiation, the documents specified in Annex 4 number 5 must additionally be submitted to Swissmedic.[78]

2 In the case of Category C clinical trials, Swissmedic shall seek an opinion from the FOPH before granting approval. The FOPH shall review compliance with radiological protection legislation and the dose estimation.[79]

3 Swissmedic shall grant approval if:

a. the requirements covered by Article 32 are met; and

b. the FOPH has raised no objections to the clinical trial.

4 Swissmedic shall reach a decision on Category C clinical trials within 60 days of acknowledgement of receipt of the formally correct application documents. Swissmedic shall inform the FOPH of its decision.

5 …[80]

75 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
76 Repealed by No I of the O of 7 June 2024, with effect from 1 Nov. 2024 (AS **2024** 322).
77 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
78 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
79 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
80 Repealed by No I of the O of 7 June 2024, with effect from 1 Nov. 2024 (AS **2024** 322).

**Art. 36*a***[81] Procedure for accompanying examinations involving ionising radiation

[1] In the case of accompanying examinations involving ionising radiation, the investigator shall submit to the responsible ethics committee the additional application documents specified in Annex 3 number 5. Subject to the provisions of paragraphs 2–6, the approval procedure is governed by Articles 24–27 and 29.

[2] The investigator shall additionally submit to the FOPH the application documents specified in Annex 3 number 6 if:

a. a radiopharmaceutical employed is not used in accordance with the authorisation or is not authorised in Switzerland;

b. a medical device employed which is capable of emitting ionising radiation:
   1. is not used in accordance with the instructions for use, or
   2. does not bear a conformity marking in accordance with Article 13 MedDO[82]; or

c. some other radioactive source is used.

[3] If additional documentation has to be submitted in accordance with paragraph 2, the investigator shall inform the ethics committee accordingly.

[4] The FOPH shall, within a reasonable period, deliver an opinion for the ethics committee on compliance with radiological protection legislation and on the dose estimation.

[5] The ethics committee shall grant approval if:

a. the requirements covered by Article 25 are met; and

b. after discussion of the opinion specified in paragraph 4, there are no remaining objections to the clinical trial.

[6] It shall reach a decision within 45 days after acknowledgement of receipt of the formally correct application documents. It shall inform the FOPH of its decision.

## Section 5 Documentation, Notifications and Reporting[83]

**Art. 37** For safety and protective measures[84]

[1] If immediate safety and protective measures have to be taken during the conduct of a clinical trial, the investigator shall notify the ethics committee of these measures, and of the circumstances necessitating them, within 7 days.

[2] In the case of clinical trials of products under Article 2*a* paragraph 2 TPA, this notification shall be made within 2 days.

81 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322, 582).
82 SR **812.213**
83 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
84 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

3 For Category B and C clinical trials, the notifications specified in paragraphs 1 and 2 shall additionally be made to Swissmedic. This obligation rests on the sponsor.[85]

**Art. 38**[86] For the first visit and for completion, premature termination, interruption and resumption of a clinical trial

1 The investigator shall notify the ethics committee, within 30 days, of:

a. the first visit of the first participant in the clinical trial in Switzerland; and

b. the completion of the clinical trial in Switzerland.

1bis The investigator shall notify the ethics committee, within 90 days, of the global completion of a multinational clinical trial.

1ter Completion of a clinical trial is marked by the last participant's final follow-up visit, in the absence of provisions to the contrary in the protocol.

2 The investigator shall notify the ethics committee of the premature termination, interruption or resumption of the clinical trial within 15 days. In the notification, the reasons for the premature termination, interruption or resumption must be stated. An interruption lasting for more than two years is considered to be a premature termination.

3 The investigator shall submit a summary final report to the ethics committee within a year of the completion or premature termination of the clinical trial, unless a longer period is specified in the protocol.

4 If a multicentre clinical trial is terminated prematurely, interrupted or resumed at one of the trial sites, the coordinating investigator shall also notify the ethics committee concerned in accordance with paragraph 2.

5 For Category B and C clinical trials, the notifications and reports specified in paragraphs 1–3 shall additionally be made to Swissmedic. These obligations rest on the sponsor.

**Art. 39** For adverse events (AE) in clinical trials of medicinal products[87]

1 If adverse events occur in the course of a Category C clinical trial, they must be documented by the investigator in a standardised manner.[88]

1bis In the protocol for Category C clinical trials, the sponsor may, in justified exceptional cases, waive the documentation requirements for adverse events identified as not critical to the safety evaluation.[89]

2 If adverse events occur in the course of a Category B clinical trial, they must be documented by the investigator in a standardised manner if:

85 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
86 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
87 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
88 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
89 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

a. the adverse events are identified in the protocol as critical to the safety evaluation; or

b. this was requested by the authorities responsible for approval.[90]

3 For Category A clinical trials, there is no obligation to document adverse events.

4 The definition of adverse events is governed by the rules of Good Clinical Practice as specified in Annex 1 number 2.

**Art. 40** For serious adverse events (SAE) in clinical trials of medicinal products[91]

1 If, in the course of a clinical trial, serious adverse events occur in participants, the investigator must document these in a standardised manner and report them to the sponsor within 24 hours after they become known. Events which are not to be reported according to the protocol are exempted.

2 and3 …[92]

4 The definition of serious adverse events is governed by the rules of Good Clinical Practice as specified in Annex 1 number 2.

**Art. 41** For suspected unexpected serious adverse reactions (SUSAR) in clinical trials of medicinal products[93]

1 If, in the course of a clinical trial, a suspected unexpected serious adverse reaction occurs in a participant, the investigator must document this in a standardised manner and report it to the sponsor within 24 hours after it becomes known.[94]

2 The investigator shall report a suspected unexpected adverse reaction with life-threatening or fatal consequences occurring in Switzerland to the responsible ethics committee within 7 days, and any other suspected unexpected serious adverse reaction within 15 days.[95]

3 If, in the case of a multicentre clinical trial, a suspected unexpected serious adverse reaction occurs at one of the trial sites in Switzerland, the coordinating investigator shall also report it to the ethics committee concerned in accordance with paragraph 2, within the same period.[96]

4 For Category B and C clinical trials, the reports specified in paragraph 2 shall also be made to Swissmedic. This obligation rests on the sponsor. For Category A clinical trials, the sponsor is subject to the notification requirements specified in Article 59 paragraphs 1 and 2 TPA.

90 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
91 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
92 Repealed by No I of the O of 7 June 2024, with effect from 1 Nov. 2024 (AS **2024** 322).
93 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
94 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
95 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
96 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

4bis The requirements specified in paragraphs 1–4 also apply if the investigator or the sponsor becomes aware of a suspected unexpected serious adverse reaction which has occurred after completion of the clinical trial in Switzerland, or if the investigator or the sponsor only becomes aware of a suspected reaction of this kind after completion of the clinical trial.[97]

5 The definition of a suspected unexpected serious adverse reaction is governed by the rules of Good Clinical Practice as specified in Annex 1 number 2.[98]

**Art. 42**[99] For serious adverse events (SAE) and deficiencies in clinical trials of products under Article 2*a* paragraph 2 TPA[100]

1 The investigator shall, within 7 days, report to the responsible ethics committee:

a. serious adverse events which occur in participants in Switzerland in the course of a Category C clinical trial of products under Article 2*a* paragraph 2 TPA and where it cannot be excluded that the events are attributable:
   1. to the product under investigation, or
   2. to an intervention undertaken in the clinical trial;

b. deficiencies in the product under Article 2*a* paragraph 2 TPA under investigation that might have led to serious adverse events if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate.

2 If in the case of a multicentre clinical trial, at one of the trial sites, serious adverse events or deficiencies in the product under Article 2*a* paragraph 2 TPA under investigation occur, the coordinating investigator shall also report them to the ethics committee concerned.[101]

3 For a Category C clinical trial, the reports specified in paragraph 1 shall also be made to Swissmedic. This obligation rests on the sponsor. In addition, the sponsor shall report to Swissmedic any events occurring or deficiencies in the product under Article 2*a* paragraph 2 TPA under investigation observed abroad. In the case of a Category A clinical trial, the sponsor is subject to the reporting requirements specified in Article 15 paragraph 1 MedDO[102] in its version of 1 January 2002[103] in application of Article 103 paragraph 2 MedDO.

4 The definition of serious adverse events and deficiencies in products under Article 2*a* paragraph 2 TPA is governed by the rules of Good Clinical Practice as specified in Annex 1 number 2.

97 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
98 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
99 Amended by Annex 2 No 2 of the O of 4 May 2022, in force since 26 May 2022 (AS **2022** 294).
100 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
101 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
102 SR **812.213**
103 AS **2001** 3487

**Art. 43** Reporting on the safety of participants

[1] Once a year, the investigator shall present to the responsible ethics committee a list of events and deficiencies in the product under Article 2*a* paragraph 2 TPA under investigation and adverse reactions as specified in Articles 40–42. On this basis, the investigator shall submit a report on their severity and causal relationship to the intervention, and on the safety of participants, and shall inform the ethics committee about the general progress of the clinical trial.[104]

[2] In the case of clinical trials also conducted abroad according to the same protocol, the events and deficiencies in the product under Article 2*a* paragraph 2 TPA under investigation and adverse reactions occurring abroad must also be included in the list and the report.[105]

[3] For Category B and C clinical trials, reports as specified in paragraphs 1 and 2 must also be submitted to Swissmedic. This obligation rests on the sponsor.

**Art. 44**[106] For the use of ionising radiation[107]

[1] In clinical trials involving any use of ionising radiation, the investigator shall assess compliance with the dose constraint specified in Article 45 of the Radiological Protection Ordinance of 26 April 2017[108].[109]

[2] If the permitted dose constraint is exceeded at any time, the investigator shall notify the responsible ethics committee within seven working days of it becoming known.

[3] In the case of Category B and C clinical trials of medicinal products capable of emitting ionising radiation, notification in accordance with paragraph 2 must also be made to Swissmedic. This obligation rests on the sponsor.[110]

[4] The responsible ethics committee and Swissmedic may obtain expert advice from the FOPH in order to assess the dose calculation or the dose estimation and to decide what further measures are required.

[5] If any use is made of ionising radiation, the investigator shall document in the summary final report in accordance with Article 38, all information of relevance for radiological protection, and in particular the retrospective dose estimation for the participants.[111]

[6] The reporting requirements specified in paragraph 5 do not apply in the case of radiopharmaceuticals used in accordance with the authorisation and medical devices

104 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
105 Amended by Annex 2 No 2 of the O of 4 May 2022, in force since 26 May 2022 (AS **2022** 294).
106 Amended by Annex 11 No 6 of the Radiological Protection Ordinance of 26 Apr. 2017, in force since 1 Jan. 2018 (AS **2017** 4261).
107 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
108 SR **814.501**
109 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
110 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
111 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

used in accordance with the instructions for use and bearing conformity markings as specified in Article 13 MedDO[112].[113]

[7] Within the framework of the opinion delivered in accordance with Article 36*a*, or on request, the FOPH may specify further exemptions from the reporting requirements specified in paragraph 5.[114]

[8] The investigator shall forward the summary final report to the FOPH if the FOPH has delivered an opinion in accordance with Article 36 or 36*a*.[115]

**Art. 44*a***[116] Assumption of the investigator's notification and reporting obligations by the sponsor

Instead of the investigator, the sponsor may assume the notification and reporting obligations listed in this Section vis-à-vis the ethics committee or ethics committees, if this is provided for in the application documents.

**Art. 45** Data retention requirements

[1] The sponsor must retain all data relating to the clinical trial until the expiry date of the last batch supplied of the medicinal product under investigation or of the last product under Article 2*a* paragraph 2 TPA manufactured, but at least for twenty years after the completion or premature termination of the clinical trial.[117]

[2] The investigator must retain all documents required for the identification and follow-up of participants, and all other original data, for at least twenty years after the completion or premature termination of the clinical trial.[118]

[3] For clinical trials of transplant products and for clinical trials of blood and blood products, the retention requirements are governed by Article 40 paragraph 1 TPA.

## Section 6 Inspections and Official Measures

**Art. 46** Swissmedic inspections

[1] Swissmedic is entitled to inspect all clinical trials of medicinal products, products under Article 2*a* paragraph 2 TPA or transplant products.

[2] If Swissmedic carries out inspections, it shall inform in advance the responsible ethics committee and other competent cantonal and federal authorities. They may participate in the inspection.

112 SR **812.213**
113 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
114 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
115 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
116 Inserted by No I of the O of 7 June 2024, in force since 11 Nov. 2024 (AS **2024** 322).
117 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
118 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

3 Swissmedic's powers are governed by Article 62 of the Medicinal Products Authorisation Ordinance of 14 November 2018[119].

4 Swissmedic may additionally carry out inspections abroad at the sponsor's expense, if this is necessary to assess the clinical trial conducted in Switzerland. The sponsor must be informed in advance.

5 Swissmedic shall inform the responsible ethics committee and other competent cantonal and federal authorities of the results of the inspection.

**Art. 47** Official measures of Swissmedic

Swissmedic may revoke or suspend the approval granted or make the continuation of the clinical trial subject to additional conditions, in particular if:

a. the safety or health of participants is at risk, particularly as a result of inadequate product safety or manufacturing defects;

b. the quality of the data collected is poor;

c. the clinical trial is not conducted in accordance with the application documents approved by Swissmedic or by the ethics committee;

d. the approval and reporting requirements have not been complied with.

**Art. 48** Coordination and information

1 The responsible ethics committee, Swissmedic and the other competent cantonal authorities shall coordinate in advance the official measures to be taken.

2 The right is reserved to take measures which have to be ordered without delay in order to protect the safety or health of the persons concerned. The ethics committees and the other competent federal and cantonal authorities shall immediately inform each other about such measures.

## Chapter 3
## Approval and Notification Procedures for Clinical Trials on the Transplantation of Human Organs, Tissues and Cells

### Section 1 General Provisions

**Art. 49** Categorisation

1 A clinical trial of the transplantation of human organs, tissues and cells comes under Category A if the transplantation to be investigated is recognised as standard in guidelines prepared in accordance with internationally accepted quality criteria.

119 SR **812.212.1**. The reference has been amended on 1 Jan. 2019 pursuant to Art. 12 para. 2 of the Publications Act of 18 June 2004 (SR **170.512**).

2 A clinical trial of the transplantation of human organs, tissues and cells comes under Category C if the transplantation to be investigated is not recognised as standard as specified in paragraph 1.

3 Clinical trials of the transplantation of embryonic and foetal tissues and cells come under Category C.

**Art. 50** Information and coordination in approval procedures and deadline for submission to the second authority responsible for approval[120]

1 The investigator and the sponsor may simultaneously submit applications to the responsible ethics committee and to the FOPH.

1bis For Category C clinical trials, the application must be submitted to the second authority within two years after approval has been granted by the first authority.[121]

1ter At the request of the approval holder, the first authority may extend the deadline specified in paragraph 1bis. Such a request constitutes a substantial modification to the clinical trial.[122]

1quater If the deadline specified in paragraph 1bis or the deadline extended in accordance with paragraph 1ter is exceeded, or if a request for a deadline extension in accordance with paragraph 1ter is rejected, then the approval granted shall lapse.[123]

2 The responsible ethics committee and the FOPH shall inform each other about matters relating to the review areas specified both in Article 25 and in Article 53, and shall coordinate their assessments.

## Section 2 Procedure before the Responsible Ethics Committee

**Art. 51**[124]

For the procedure for the approval of clinical trials of transplantation by the responsible ethics committee, Articles 23*a*–27, 29 and 36*a* apply *mutatis mutandis*.

## Section 3 Procedure before the FOPH

**Art. 52** Exemption from mandatory approval

Category A clinical trials are exempted from the requirement for approval from the FOPH specified in Article 36 paragraph 1 of the Transplantation Act.

120 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
121 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
122 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
123 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
124 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

**Art. 53** Review areas

For clinical trials of transplantation, the FOPH shall review:

a. the completeness of the application;

b. the origin of the organs, tissues or cells used in the clinical trial;

c. compliance with the requirements of the transplantation legislation, particularly with regard to the duties of care in the handling of organs, tissues and cells, and the allocation of organs;

d. the availability of the authorisations required in accordance with the Transplantation Act;

e. other areas, where this is necessary to assess the safety and quality of the organs, tissues or cells used.

**Art. 54** Approval procedure

1 The sponsor shall submit to the FOPH the application documents specified in Annex 4 for review.

2 The FOPH may request additional information.

3 For the procedure and deadlines, Article 33 applies *mutatis mutandis*.

**Art. 55** Modifications

1 Substantial modifications to an approved clinical trial must be approved by the FOPH before being implemented. Exempt from this requirement are measures which have to be taken immediately in order to protect the participants.

2 The sponsor must submit to the FOPH any application documents specified in Annex 4 which are affected by the modification. At the same time, the sponsor shall provide information on the reasons for the modification.

3 The following are considered to be substantial modifications:

a. modifications due to new scientific knowledge, based in particular on new preclinical or clinical data, which affects the assessment of the safety of the organs, tissues or cells used;

b. modifications relating to the origin, the tests to be performed or the storage of the organs, tissues or cells used;

c.[125] in the case of clinical trials of the transplantation of embryonic or foetal tissues and cells: modifications which may affect the safety of the participants; or

d.[126] the extension of a deadline in accordance with Articles 23*a* and 50; in the application to the FOPH, the sponsor shall indicate whether the application documents are still up-to-date, particularly with regard to questions of the

125 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
126 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

origin, safety and quality of the organs, tissues or cells used; if this is not the case, the sponsor shall submit updated application documents.

4 …[127]

5 The FOPH shall reach a decision within 30 days of receipt of the complete set of application documents affected by the modification. Article 33 applies *mutatis mutandis*.

6 Other modifications which affect documents submitted to the FOPH must be notified to the FOPH as quickly as possible.

**Art. 56** Special provisions for clinical trials of the transplantation of embryonic or foetal tissues and cells

1 The FOPH shall grant approval if, in addition to Article 53, the requirements specified in Article 34 of the Transplantation Ordinance of 16 March 2007[128] are met.

2 It shall grant approval within 60 days or, in the case of substantial modifications, within 30 days after receipt of the complete application documents.

3 For clinical trials of the transplantation of embryonic or foetal tissues and cells, Articles 35, 36 and 38 of the Transplantation Ordinance additionally apply.

## Section 4 Notifications and Reporting[129]

**Art. 57** Applicable provisions[130]

1 For documentation, notifications and reporting in the case of clinical trials of transplantation, Articles 37–39, 44 and 44*a* apply *mutatis mutandis*.[131]

2 The obligations which must be fulfilled under these provisions vis-à-vis Swissmedic are to be fulfilled, for clinical trials of transplantation, vis-à-vis the FOPH.

3 For clinical trials of transplantation, the duties of the sponsor and the investigator concerning documentation, traceability and retention of records are governed by Articles 34 and 35 of the Transplantation Act.

**Art. 57*a***[132] Reporting of serious adverse events

1 If, in the course of a clinical trial, serious adverse events occur in participants, the investigator must document these in a standardised manner and report them to the sponsor within 24 hours after they become known. Events which are not to be reported according to the protocol are exempted.

127 Repealed by No I of the O of 7 June 2024, with effect from 1 Nov. 2024 (AS **2024** 322).
128 SR **810.211**
129 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
130 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
131 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
132 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

2 The investigator shall report a serious adverse event with life-threatening or fatal consequences occurring in Switzerland to the responsible ethics committee within 7 days, and any other serious adverse event within 15 days.

3 If, in the case of a multicentre clinical trial, a serious adverse event occurs at one of the trial sites in Switzerland, the coordinating investigator shall also report it to the ethics committee concerned in accordance with paragraph 2, within the same period.

4 For Category C clinical trials, the reports specified in paragraph 2 shall also be made to the FOPH. This obligation rests on the sponsor.

5 The requirements specified in paragraphs 1–4 are also applicable if the investigator or the sponsor become aware of a serious adverse event which has occurred after completion of the clinical trial in Switzerland, or if the investigator or the sponsor only become aware of such an event after completion of the clinical trial.

6 The definition of serious adverse events is governed by the rules of Good Clinical Practice as specified in Annex 1 number 2.

**Art. 57*b***[133] Reporting on the safety of participants

1 Once a year, the investigator shall present to the responsible ethics committee a list of events as specified in Article 57*a*. On this basis, the investigator shall submit a report on their severity and causal relationship to the intervention, and on the safety of participants, and shall inform the ethics committee about the general progress of the clinical trial.

2 In the case of clinical trials also conducted abroad according to the same protocol, the events occurring abroad must also be included in the list and the report.

3 For Category C clinical trials, reports as specified in paragraphs 1 and 2 must also be submitted to the FOPH. This obligation rests on the sponsor.

## Section 5 Inspections and Official Measures

**Art. 58** FOPH inspections

1 The FOPH may carry out inspections at any time and inspect all documents and data relating to a clinical trial of transplantation. It may request the cantonal authorities or third parties to carry out inspections.

2 Other powers and duties of cooperation are governed by Article 63 paragraphs 2 and 3 and Article 64 of the Transplantation Act.

**Art. 59** Official measures

1 The FOPH may revoke or suspend the approval granted or make the continuation of the clinical trial subject to additional conditions, particularly if:

133 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

a. it has reason to assume that the requirements are no longer met, the documents specified in Article 54 have been modified without due notification having been made, or the trial is not being conducted in accordance with these documents;

b. such measures are necessitated by new information concerning safety or the scientific basis.

2 For the coordination of measures and the exchange of information between the FOPH, the responsible ethics committee and other competent cantonal authorities, Article 48 applies *mutatis mutandis*.

## Chapter 4 Other Clinical Trials

## Section 1 General Provisions

### Art. 60 Scope

This Chapter applies to clinical trials which are neither trials of medicinal products, products under Article 2*a* paragraph 2 TPA or transplant products nor trials of transplantation.

### Art. 61 Categorisation

1 A clinical trial comes under Category A if the intervention investigated:[134]

a. entails only minimal risks and burdens; or

b. is recognised as standard in guidelines prepared in accordance with internationally accepted quality criteria.

2 A clinical trial comes under Category B if the intervention investigated:[135]

a. entails more than minimal risks and burdens; and

b. is not recognised as standard as specified in paragraph 1 letter b.

## Section 2 Approval and Notification Procedures for the Responsible Ethics Committee

### Art. 62 Applicable provisions

The provisions which apply *mutatis mutandis* are:

a.[136] for the approval procedure for clinical trials, Articles 24–27, 29 and 36*a*;

134 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
135 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
136 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

abis.[137] for the setting of a time limit for the approval, Article 23*a*;

b. for the notification of safety and protective measures, Article 37 paragraph 1;

c.[138] for the notification of the first visit of the first participant and for notification and reporting upon completion, premature termination, interruption or resumption of a clinical trial, Article 38 paragraphs 1–4;

d. for reporting on the safety of participants, Article 43 paragraphs 1 and 2;

dbis.[139] for notification and reporting in the case of accompanying examinations involving ionising radiation, Article 44;

e. for data retention requirements, Article 45 paragraph 2.

**Art. 63** Documentation and reporting of serious adverse events

1 If, in the course of a clinical trial, serious adverse events occur in participants in Switzerland, and it cannot be excluded that the events are attributable to the intervention under investigation, the investigator must document them in a standardised manner. In addition, the investigator shall report these events:

a. to the sponsor within 24 hours after they become known; and

b. to the responsible ethics committee within 15 days.

2 A serious adverse event is defined as any event which:

a. requires inpatient treatment not envisaged in the protocol or extends a current hospital stay;

b. results in permanent or significant incapacity or disability;

c. is life-threatening or results in death; or

d. causes a congenital anomaly or birth defect.

3 If necessary, in order to guarantee participants' safety and health, further adverse events which must be documented or reported are to be designated in the protocol or at the request of the responsible ethics committee.

4 If, in the case of a multicentre clinical trial, serious adverse events occur at one of the trial sites, the coordinating investigator shall also report the events as specified in paragraphs 1 and 3 to the ethics committee concerned, within the same period.[140]

137 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
138 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
139 Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
140 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

## Chapter 5 Registration and Publication[141]

### Art. 64 Registration and data to be entered[142]

[1] The sponsor must register and publish an authorised clinical trial by entering the data specified in Annex 5 number 1:[143]

a. in a primary registry[144] recognised by the World Health Organization (WHO); or

b. in the registry of the U.S. National Library of Medicine[145].

[2] The sponsor shall additionally enter the data specified in Annex 5 numbers 2.1–2.9, using the Swiss national languages in which recruitment is planned, in the cantonal information system specified in Article 56*a* HRA.[146]

[2bis] For Phase I clinical trials in which the medicinal product under investigation is administered exclusively to adults, the data specified in Annex 5 number 3.1 may initially be excluded from entry in accordance with paragraphs 1, 2 and 4; it must however be entered and automatically published at the latest within the period specified in Annex 5 number 3.2.[147]

[3] The data must be entered in the version approved by the responsible ethics committee. It must be regularly updated.[148]

[4] Registration and entry in accordance with paragraphs 1 and 2 must take place before the conduct of the clinical trial, and within six months after approval has been granted for it.[149]

[5] The data specified in Annex 5 numbers 2.1-2.14 shall be automatically published on the portal specified in Article 67 no later than six months after approval has been granted for the clinical trial.[150]

### Art. 65[151]

### Art. 65*a*[152] Publication of trial results

[1] The sponsor must ensure that, within a year after completion or premature termination of the clinical trial, a summary of the trial results is entered and published in a

141 Amended by No I of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322).
142 Amended by No I of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322).
143 Amended by No I of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322).
144 The registries can be consulted at: www.who.int/ > Programmes and projects > Clinical Trials – International Registry Platform.
145 The registry can be consulted at: www.clinicaltrials.gov.
146 Amended by No I of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322).
147 Inserted by No I of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322).
148 Amended by No I of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322).
149 Inserted by No I of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322).
150 Inserted by No I of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322).
151 Repealed by No I of the O of 7 June 2024, with effect from 1 March 2025 (AS **2024** 322).
152 Inserted by No I of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322).

registry as specified in Article 64 paragraph 1 letter a or b. An interruption lasting for more than two years is considered to be a premature termination.

2 For the purpose of publication on the portal specified in Article 67, the sponsor must additionally ensure that a lay summary of the trial results in accordance with Annex 5 number 2.15 is entered in the cantonal information system; the deadline specified in paragraph 1 applies. The entry must be made at least in the Swiss national languages used for recruiting the participants.[153]

3 For Phase I clinical trials in which the medicinal product under investigation is administered exclusively to adults, publication of the trial results in accordance with paragraphs 1 and 2 must take place no later than within the period specified in Annex 5 number 3.2.

4 If publication in accordance with paragraphs 1 and 2 is not possible within the specified period for scientific reasons, the sponsor must explain this in the application documents and indicate when publication will take place.

**Art. 66** Responsibility

The sponsor is responsible for the accuracy and completeness of the data entered.

**Art. 67**[154] Portal

1 The FOPH shall operate a portal ensuring public access to information on clinical trials conducted in Switzerland via online access to one or more registries.

2 The portal shall enable in particular the linking of data to be entered under Articles 64 and 65*a*, as well as Articles 41 and 42 ClinO-MD[155], and the publication of this and other data from the cantonal information system as specified in Annex 5.

## Chapter 6 Final Provisions

**Art. 68** Updating of Annexes

The Federal Department of Home Affairs may update Annexes 1–5 in accordance with international or technical developments. It shall undertake updates which may give rise to technical barriers to trade in consultation with the Federal Department of Economic Affairs, Education and Research.

**Art. 69** Repeal of other legislation

The following Ordinances shall be repealed:

1. Ordinance of 14 June 1993[156] on the Waiver of Professional Confidentiality in Medical Research;

153 Correction of 20 May 2025 (AS **2025** 325).
154 Amended by No I of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322).
155 SR **810.306**
156 [AS **1993** 1983]

2. Ordinance of 17 October 2001[157] on Clinical Trials of medicinal products, in vitro diagnostic medical devices or combinations under Article 2 letters f–h MedDO;
3. HIV Studies Ordinance of 30 June 1993[158].

**Art. 70** Amendment of other legislation

The amendment of other legislation is regulated in Annex 6.

**Art. 71** Transitional provisions for clinical trials approved under existing law

[1] Clinical trials of therapeutic products and transplant products and trials of transplantation which were approved before 1 January 2014 are considered to be Category C clinical trials.

[2] Other approved clinical trials are considered to be Category B clinical trials.

[3] On request, the authority which approved the clinical trial before 1 January 2014 may assign the clinical trial to a different category. In this case, the liability, coverage, notification, reporting and documentation requirements are governed by the new law.

[4] The responsible ethics committee shall make the decision specified in paragraph 3 according to the simplified procedure specified in Article 6 of the HRA Organisation Ordinance of 20 September 2013[159].

[5] The assessment of substantial modifications is governed by the new law.

**Art. 72**[160] Transitional provisions to the Amendment of 7 June 2024

[1] The time limits specified in Article 23*a* paragraph 1, Article 38 paragraph 2 third sentence, and Article 65*a* paragraph 1 second sentence begin, for ongoing clinical trials approved before the Amendment of 7 June 2024 comes into force, when this Amendment comes into force; for clinical trials that have only one of two required approvals prior to this Amendment coming into force, the time limit specified in Article 23 paragraph 1[bis] and Article 50 paragraph 1[bis] begins when this Amendment comes into force.

[2] For ongoing clinical trials approved before the Amendment of 7 June 2024 comes into force, all the notification, reporting and documentation requirements specified in Chapter 2 Section 5, Chapter 3 Section 4 and Chapter 4 Section 2 can be fulfilled under existing law up to a year after this Amendment comes into force.

[3] For clinical trials approved before the Amendment of 7 June 2024 comes into force, the liability, liability coverage and retention requirements are governed by existing law. If approval for the clinical trial was granted for a limited period, these requirements are governed by the amended law when the approval is renewed.

157 [AS **2001** 3511; **2004** 4037 No I 6; **2007** 5651 No II 3; **2010** 1215 Annex 7, 4043; **2012** 2777 Annex 5 No 4]
158 [AS **1993** 2294]
159 SR **810.308**
160 Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

4 If, after the Amendment of 7 June 2024 comes into force, an approved clinical trial of medicinal products, under the amended law, comes under a different category in accordance with Article 19, then, for up to a year after the Amendment of 7 June 2024 comes into force, the sponsor may apply for an adjustment of the category in the form of a substantial modification. This application must be submitted first to Swissmedic and then, after being approved, to the responsible ethics committee.

**Art. 73**[161]

**Art. 74** Commencement

This Ordinance comes into force on 1 January 2014.

161 Repealed by No I of the O of 7 June 2024, with effect from 1 Nov. 2024 (AS **2024** 322).

*Annex 1*[162]
(Art. 3, 5, 19, 39–42)

# Rules and classifications

## 1 Guidelines on scientific integrity

The applicable guidelines are the code of conduct for scientific integrity, issued by the Swiss Academies of Arts and Sciences, in the version dated May 2021[163].

## 2 Rules of Good Clinical Practice

The applicable rules of Good Clinical Practice are:

1. for clinical trials of medicinal products and transplant products: the Guideline for Good Clinical Practice issued by the International Conference on Harmonisation, in the version dated 9 November 2016[164] (ICH Guideline);
2. for clinical trials of products under Article 2*a* paragraph 2 TPA: Annexes VIII and X to Directive 93/42/EEC[165] and Annexes 6 and 7 to Directive 90/385/EEC[166] and the requirements specified in EN ISO 14155:2011[167]. The definition of serious adverse events in accordance with Article 42 is based on the Guidelines on Medical Devices (MEDDEV 2.7/3) of May 2015[168];
3. for clinical trials as specified in Chapters 3 and 4: the ICH Guideline *mutatis mutandis*.

162 Revised by No I of the FDHA Ordinance of 24 March 2017 (AS **2017** 2439), Annex No 1 of the O of 25 Oct. 2017 (AS **2017** 5935) and No II para. 1 of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
163 www.akademien-schweiz.ch > Publikationen > Weitere Publikationen
164 This Guideline can be consulted free of charge at the Federal Office of Public Health, CH-3003 Bern; it can also be accessed online at: www.bag.admin.ch > Medizin & Forschung > Forschung am Menschen or at: www.clinicaltrials.gov > Work products > ICH Guidelines > Efficacy Guidelines.
165 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1; last amended by Directive 2007/47/EC, OJ L 247, 21.9.2007, p. 21.
166 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189, 20.7.1990, p. 17; last amended by Directive 2007/47/EC, OJ L 247, 21.9.2007, p. 21.
167 This standard can be consulted free of charge at the Federal Office of Public Health, CH-3003 Bern and at the Swiss Agency for Therapeutic Products, CH-3003 Bern. It can also be purchased from the Swiss Association for Standardisation, Sulzerallee 70, 8404 Winterthur; www.snv.ch.
168 These guidelines can be consulted free of charge at the Federal Office of Public Health, CH-3003 Bern, or accessed online at: www.ec.europa.eu/growth/ > Sectors > Medical devices > Guidance.

## 3 International Classification of Diseases

The applicable classification is the 2010 version of the International Classification of Diseases issued by the World Health Organization (WHO) (ICD-10)[169]; the relevant disease groups are those identified by three-character codes.

169 The classification can be obtained against payment or consulted free of charge at the Federal Office of Public Health, CH-3003 Bern; it can also be accessed online at: www.bag.admin.ch > Medizin & Forschung > Forschung am Menschen, or at www.who.int/ > Data > Classifications.

*Annex 2*[170]
(Art. 13)

## Policy values for liability coverage

1. For Category A clinical trials where any measures for the collection of health-related personal data or the sampling of biological material entail more than only minimal risks and burdens, the policy value shall be at least:
   a. per person: 250 000 Swiss francs;
   b for damage to property: 20 000 Swiss francs;
   c. for the entire clinical trial: 3 million Swiss francs.
2. For all clinical trials not coming under Number 1, the policy value shall be at least:
   a. per person: 1 million Swiss francs;
   b. for damage to property: 50 000 Swiss francs;
   c. for the entire clinical trial: 10 million Swiss francs.

[170] Amended by No II para. 1 of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

*Annex 2bis*[171]
(Art. 19)

## Low-risk modifications to an investigational medicinal product

The following are considered to be low-risk modifications:

1. modification to the secondary packaging, provided that its protective function is not impaired;
2. modification to the primary packaging, provided that the product in question is not a sterile medicinal product or an immunological product, and it has been demonstrated that shelf life will not be impaired if the product is stored as specified in the product information;
3. modification by over-encapsulation of an otherwise unchanged solid medicinal product, which does not affect absorption and where it has been demonstrated that shelf life will not be impaired if the product is stored as specified in the product information.

171 Inserted by No II para. 3 of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).

*Annex 3*[172]
(Art. 24, 27, 29 and 36*a*)

# Application documents to be submitted to the responsible ethics committee for the procedure for clinical trials

## 1 Application documents for Category A clinical trials of medicinal products, products under Article 2*a* paragraph 2 TPA and transplant products

1.1 Administrative information, including a summary of the protocol and reasons for the requested categorisation;

1.2 protocol;

1.3 case report form (CRF);

1.4 informed consent documents and recruitment documents, in particular the wording of announcements or advertisements;

1.5 other documents issued to participants;

1.6 information on the type and amount of remuneration for participants;

1.7 for clinical trials of medicinal products: the prescribing information;

1.8 for clinical trials of products under Article 2*a* paragraph 2 TPA that have been notified under Article 6 paragraph 3 MedDO[173] in its version of 1 January 2002[174] in application of Article 108 paragraph 1 letter b MedDO: the information provided in the report on conformity, the intended use and instructions for use;

1.9 for clinical trials not using proprietary products: proof of compliance with Good Manufacturing Practice and correct labelling of the medicinal products, products under Article 2*a* paragraph 2 TPA;

1.10 the investigator's CV, including evidence of his or her knowledge and experience, and a list of the other persons conducting the clinical trial, indicating their responsibilities and relevant professional knowledge;

1.11 information on the suitability and availability of infrastructure at the trial site;

1.12 information on the secure handling of personal data;

1.13 agreements between the sponsor, or third parties acting on the sponsor's behalf, and the investigator, in particular with regard to the financing of the clinical trial, remuneration of the investigator and publication;

172 Amended by the correction of 27 Dec. 2013 (AS **2013** 5579), Annex 2 No 2 of the O of 4 May 2022 (AS **2022** 294) and No II para. 1 of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
173 SR **812.213**
174 AS **2001** 3487

1.14 certificate of insurance or other proof of coverage for possible damage, including agreements on this matter between the sponsor, or a third party acting on the sponsor's behalf, and the investigator;

1.15 any decisions or opinions of ethics committees abroad concerning the clinical trial, including any conditions imposed and the reasons given.

## 2 Application documents for Category B and C clinical trials of medicinal products, products under Article 2*a* paragraph 2 TPA or transplant products

2.1 Administrative information, including a summary of the protocol and reasons for the requested categorisation;

2.2 protocol;

2.3 case report form (CRF);

2.4 informed consent documents and recruitment documents, in particular the wording of announcements or advertisements;

2.5 other documents issued to participants;

2.6 information on the type and amount of remuneration for participants;

2.7 for Category B clinical trials of medicinal products: the prescribing information and the Investigator's Brochure (IB), giving details of how the use of the product differs from the dosage/indication specified in the prescribing information;

2.8 for Category C clinical trials of medicinal products: the Investigator's Brochure (IB);

2.9 for Category C clinical trials of medical devices with no assessment of conformity: the documents specified in Annex 4 number 3.4 letter a;

2.10 for Category C clinical trials of products under Article 2*a* paragraph 2 TPA that have been notified under Article 6 paragraph 3 MedDO in its version of 1 January 2002 in application of Article 108 paragraph 1 letter b MedDO and which are not used in accordance with the intended purpose or the instructions for use: the documents specified in Annex 4 number 3.5 letters a–d;

2.11 the investigator's CV, including evidence of his or her knowledge and experience, and a list of the other persons conducting the clinical trial, indicating their responsibilities and relevant professional knowledge;

2.12 information on the suitability and availability of infrastructure at the trial site;

2.13 information on the secure handling of personal data;

2.14 agreements between the sponsor, or third parties acting on the sponsor's behalf, and the investigator, in particular with regard to the financing of the clinical trial, remuneration of the investigator and publication;

2.15 certificate of insurance or other proof of coverage for possible damage, including agreements on this matter between the sponsor, or a third party acting on the sponsor's behalf, and the investigator;

2.16 for clinical trials of gene therapy: the information specified in Annex 4 number 1;

2.17 any decisions or opinions of ethics committees abroad concerning the clinical trial, including any conditions imposed and the reasons given.

## 3 Application documents for clinical trials of transplantation and for clinical trials not involving medicinal products or products under Article 2*a* paragraph 2 TPA

3.1 Administrative information, including a summary of the protocol and reasons for the requested categorisation;

3.2 protocol;

3.3 case report form (CRF);

3.4 informed consent documents and recruitment documents, in particular the wording of announcements or advertisements;

3.5 other documents issued to participants;

3.6 information on the type and amount of remuneration for participants;

3.7 for clinical trials of transplantation of human organs, tissues and cells: information on donor information and consent;

3.8 for Category A clinical trials of transplantation of human organs, tissues and cells: in addition to the information specified in number 3.7, information on:

a. the origin and quality of the organs, tissues or cells used, and in particular on the tests performed in this connection,

b. compliance with duties of care, particularly with regard to the assessment of fitness to donate and mandatory testing, and the subsequent handling of organs, tissue and cells,

c. authorisation, if handling of the organs, tissues or cells used is subject to authorisation under the Transplantation Act;

3.9 the investigator's CV, including evidence of his or her knowledge and experience, and a list of the other persons conducting the clinical trial, indicating their responsibilities and relevant professional knowledge;

3.10 information on the suitability and availability of infrastructure at the trial site;

3.11 information on the secure handling of personal data;

3.12 agreements between the sponsor, or third parties acting on the sponsor's behalf, and the investigator, in particular with regard to the financing of the clinical trial, remuneration of the investigator and publication;

3.13 certificate of insurance or other proof of coverage for possible damage, including agreements on this matter between the sponsor, or a third party acting on the sponsor's behalf, and the investigator;

3.14 for clinical trials of transplantation of genetically modified human organs, tissues and cells: the information specified in Annex 4 number 6.7;

3.15 any decisions or opinions of ethics committees abroad concerning the clinical trial, including any conditions imposed and the reasons given.

## 4 Application documents for the ethics committees concerned in multicentre clinical trials

4.1 Administrative information, including a summary of the protocol and reasons for the requested categorisation;

4.2 protocol;

4.3 informed consent documents and recruitment documents, in particular the wording of announcements or advertisements, used at the site in question;

4.4 the CV of the investigator responsible at the site in question, including evidence of his or her knowledge and experience, and a list of the other persons conducting the clinical trial at the site in question, indicating their responsibilities and relevant professional knowledge;

4.5 information on the suitability and availability of infrastructure at the trial site in question;

4.6 agreements between the sponsor, or third parties acting on the sponsor's behalf, and the coordinating investigator and other investigators at the other sites, in particular with regard to the remuneration of the investigator at the site in question;

4.7 certificate of insurance or other proof of coverage for possible damage occurring at the trial site in question, including agreements on this matter between the sponsor, or a third party acting on the sponsor's behalf, and the investigator.

## 5 Additional application documents for Category A clinical trials of medicinal products capable of emitting ionising radiation, and for accompanying examinations involving ionising radiation

5.1 Details of all relevant radiological protection aspects, and in particular a calculation or estimate of the effective dose, organ doses and any tumour doses;

5.2 the licences required under Article 28 of the Radiological Protection Act of 22 March 1991[175].

175 SR **814.50**

## 6 Additional application documents for clinical trials which include accompanying examinations involving ionising radiation and require an opinion from the FOPH in accordance with Article 36*a* paragraph 4

6.1 Information specified in the FOPH form for clinical trials involving radiopharmaceuticals or radiolabelled compounds[176]. This comprises:

a. information on the properties, and in particular on pharmacokinetics, quality, stability, radiochemical purity and radionuclide purity;

b. information on the effective dose and on organ doses;

c. for authorised radiopharmaceuticals: the prescribing information;

d. for non-authorised radiopharmaceuticals or radiolabelled compounds: information on production and on the professional qualifications of the persons responsible;

e. the persons responsible for the use of the radiopharmaceutical in humans and their professional qualifications.

6.2 Information on the properties of the medical device, and in particular the type and intensity of ionising radiation, and on the nature of the deviation from the instructions for use.

176 This form can be obtained [in French/German] from the Federal Office of Public Health, Radiological Protection Division, CH-3003 Bern; it can also be accessed online at: www.bag.admin.ch > Gesetze & Bewilligungen > Gesuche & Bewilligungen > Strahlenschutz: Bewilligungen, Voraussetzungen und Aufsicht.

*Annex 4*[177]
(Art. 31, 34–36, 54, 55)

# Application documents to be submitted to Swissmedic or to the FOPH for the procedure for clinical trials of medicinal products, products under Article 2*a* paragraph 2 TPA or transplant products, for clinical trials of gene therapy and of genetically modified or pathogenic organisms, and for clinical trials of transplantation

## 1 Application documents for Category B or C clinical trials of medicinal products, transplant products, gene therapy and genetically modified or pathogenic organisms

1.1 Administrative information;

1.2 protocol;

1.3 documents on the method of administration, on the safety and the risk-benefit assessment of the products under investigation, based on clinical and non-clinical data;

1.4 documents on the quality and on the production of the products under investigation, including proof of compliance with Good Manufacturing Practices (GMP);

1.5 proof of compliance with correct labelling;

1.6 information on any ongoing or completed approval procedures involving drug regulatory authorities in other countries;

1.7 information on any ongoing or completed approval procedures involving an ethics committee in Switzerland

## 2 …

## 3 Application documents for Category C clinical trials of products under Article 2*a* paragraph 2 TPA

3.1 Administrative information;

3.2 protocol;

3.3 case report form (CRF);

3.4 for clinical trials of a product under Article 2*a* paragraph 2 TPA that has not been notified under Article 6 paragraph 3 MedDO[178] in its version of 1 Janu-

177 Amended by Annex 2 No 2 of the O of 4 May 2022 (AS **2022** 294) and No II para. 1 of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 322).
178 SR **812.213**

ary 2002[179] in application of Article 108 paragraph 1 letter b MedDO: the relevant documentation, comprising:

a. Investigator's Brochure (IB), with a compilation of current clinical and non-clinical information on the product under investigation and its components,

b. list of the applicable standards for products under Article 2*a* paragraph 2 TPA and description of all deviations,

c. documentation of and reasons for any deviations from the standard ISO 14155,

d. manufacturer's statement or release in accordance with Annex VIII to Directive 93/42/EEC[180] or Annex 6 to Directive 90/385/EEC[181],

e. confirmation that documentation is being kept available as specified in Annex VIII to Directive 93/42/EEC or Annex 6 to Directive 90/385/EEC,

f. if the sponsor of the clinical trial and the manufacturer of the product are not identical: agreement on risk management between the sponsor and manufacturer;

3.5 for clinical trials of a product under Article 2*a* paragraph 2 TPA that has been notified under Article 6 paragraph 3 MedDO in its version of 1 January 2002 in application of Article 108 paragraph 1 letter b MedDO which is not used in accordance with the intended purpose or the instructions for use: the relevant documentation, comprising:

a. information on the conformity of the product under Article 2*a* paragraph 2 TPA,

b. product information on the product under Article 2*a* paragraph 2 TPA,

c. risk analysis for the new use and safety measures derived therefrom,

d. other elements of the IB concerning the new use,

e. list of the applicable standards for products under Article 2*a* paragraph 2 TPA, description of deviations from these standards associated with the new use,

f. documentation of and reasons for any deviations from the standard ISO 14155;

3.6 informed consent documents;

3.7 any decisions of foreign medical device regulatory authorities concerning the clinical trial, including any conditions imposed and the reasons given;

179 AS **2001** 3487

180 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1; last amended by Directive 2007/47/EC, OJ L 247, 21.9.2007, p. 21.

181 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189, 20.7.1990, p. 17; last amended by Directive 2007/47/EC, OJ L 247, 21.9.2007, p. 21.

3.8 information on any applications currently being reviewed by an ethics committee in Switzerland, and on any decisions of ethics committees in Switzerland.

**4 …**

## 5 Additional application documents for clinical trials of medicinal products capable of emitting ionising radiation

5.1 Details of all relevant radiological protection aspects, and in particular a calculation or estimate of the effective dose, organ doses and any tumour doses;

5.2 the licences required under Article 28 of the Radiological Protection Act of 22 March 1991[182];

5.3 for medicinal products capable of emitting ionising radiation: information specified in the FOPH form for clinical trials involving radio-pharmaceuticals or radiolabelled compounds[183]. This comprises:

a. information on the properties, and in particular on pharmacokinetics, quality, stability, radiochemical purity and radionuclide purity,

b. information on the effective dose and on organ doses,

c. for authorised radiopharmaceuticals: the prescribing information,

d. for non-authorised radiopharmaceuticals or radiolabelled compounds: information on production and on the professional qualifications of the persons responsible,

e. the persons responsible for the use of the radiopharmaceutical in humans and their professional qualifications.

## 6 Application documents for Category C clinical trials of transplantation of human organs, tissues and cells

6.1 Administrative information;

6.2 protocol;

6.3 proof of the origin of the organs, tissues or cells used;

6.4 documents on the quality of the organs, tissues or cells used, and in particular on the tests performed;

182 SR **814.50**

183 This form can be obtained [in French/German] from the Federal Office of Public Health, Radiological Protection Division, CH-3003 Bern; it can also be accessed online at: www.bag.admin.ch > Gesetze & Bewilligungen > Gesuche & Bewilligungen > Strahlenschutz: Bewilligungen, Voraussetzungen und Aufsicht.

6.5 proof of compliance with duties of care, particularly with regard to the assessment of fitness to donate and mandatory testing, and the procedure in the event of reactive test results;

6.6 proof of compliance with correct labelling;

6.7 authorisation, if handling of the organs, tissues or cells used is subject to authorisation;

6.8 any decisions of foreign regulatory authorities concerning the clinical trial, including any conditions imposed and the reasons given;

6.9 information on any applications currently being reviewed by an ethics committee in Switzerland, and on any decisions of ethics committees in Switzerland.

*Annex 5*[184]
(Art. 64 and 65*a*)

# Data to be entered and published on the portal

## 1 Data to be entered in a register

The data specified in Version 1.3.1[185] of the WHO Trial Registration Data Set must be entered in a register as specified in Article 64 paragraph 1.

## 2. Data to be entered in the cantonal information system

2.1 The name of the register specified in Article 64 paragraph 1 in which the data was entered and the registration number assigned by the registry;

2.2 the title of the clinical trial and a lay summary of the protocol;

2.3 the disease or condition under investigation;

2.4 an indication of whether a rare disease is being investigated in the clinical trial;

2.5 the intervention under investigation;

2.6 inclusion and exclusion criteria;

2.7 trial sites in Switzerland;

2.8 contact details of a person responsible for the clinical trial;

2.9 status of recruitment in Switzerland;

2.10 the sponsor and additionally, in the case of a sponsor abroad, the sponsor's representative in Switzerland;

2.11 the date of approval of the trial by the ethics committee and the name of the ethics committee granting approval;

2.12 the ethics committee's study identification number;

2.13 an indication of whether special study populations are participating and, if so, which ones;

2.14 the date of the beginning and end of the clinical trial in Switzerland;

2.15 the lay summary of the trial results, and in particular:

a. the title and identification numbers of the clinical trial (i.e. protocol code number, ethics committee's study identification number and registration number in the register specified in Art. 64 para. 1),

b. the name and contact details of the sponsor,

184 Amended by No II para. 2 of the O of 7 June 2024, in force since 1 March 2025 (AS **2024** 322).

185 www.who.int > Data > Data collections > International Clinical Trials Registry Platform (ICTRP) > ICTRP Registry Network > WHO data set

c. general information about the clinical trial (in particular, where and when the trial was conducted, the main objectives of the trial and an explanation of the reasons for the conduct of the trial),
d. a description of the study population; in particular, the number of persons who participated in the clinical trial in Switzerland and other countries, their distribution by age groups and sex, and inclusion and exclusion criteria,
e. the name of the intervention studied, including comparison interventions or placebos,
f. a description of intervention-related adverse effects and their frequency,
g. the overall results of the clinical trial,
h. comments on the outcome of the clinical trial,
i. an indication whether follow up clinical trials are foreseen,
j. an indication where additional information can be found.

## 3. Exceptions to registration and publication for Phase I clinical trials in which the medicinal product under investigation is administered exclusively to adults

### 3.1. Data with delayed registration requirements

3.1.1 Lay summary of the protocol;

3.1.2 precise indication of the disease investigated; the ICD disease group must however be indicated;

3.1.3 medicinal product investigated;

3.1.4 inclusion and exclusion criteria;

3.1.5 primary and secondary endpoints.

### 3.2. Deadline for delayed entry, registration and publication

30 months after completion or early termination of the clinical trial.

*Annex 6*
(Art. 70)

## Amendment of other legislation

The following ordinances are amended as follows:

…[186]

[186] The amendments may be consulted under AS **2013** 3407..