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**Ordinance
on Human Research with the Exception of Clinical Trials
(Human Research Ordinance, HRO)**

of 20 September 2013 (Status as of 1 November 2024)

The Swiss Federal Council,
on the basis of the Human Research Act of 30 September 2011¹ (HRA),
ordains:

Chapter 1 General Provisions

Art. 1 Purpose

This Ordinance regulates:

- a. the requirements for the conduct of human research projects with the exception of clinical trials; and
- b. the approval and notification procedures for research projects as specified in letter a.

Art. 1a² Definition

In this Ordinance, *surplus information* means results relating to a specific person, in particular incidental findings, which arise in the course of a research project and which are not required either for the conduct thereof or to answer the scientific question.

Art. 2³ Applicable provisions

The following provisions of the Ordinance of 20 September 2013⁴ on Clinical Trials (ClinO) apply *mutatis mutandis*:

- a. Article 3 concerning scientific integrity;
- b. Article 4 concerning scientific quality;
- c. Article 4a concerning the inclusion of relevant groups of persons.

AS 2013 3381

¹ SR 810.30

² Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

³ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

⁴ SR 810.305

Art. 3 Responsibilities of project leader and sponsor

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

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

Art. 4 Professional qualifications

¹ The project leader responsible for a research project must:

- a. be entitled to practise the profession under his or her own responsibility that specifically qualifies him or her to conduct the research project in question;
- b. have the training and experience required to conduct the research project in question;
- c. be conversant with the legal requirements for research projects or be able to ensure compliance by calling in appropriate expertise;
- d.⁵ 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 The other persons conducting the research project must have the professional knowledge and experience appropriate to the activities in question.

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

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

- a. restrict the handling of the health-related personal data to those persons who require this data to fulfil their duties;
- b. prevent unauthorised or accidental disclosure, alteration, deletion and copying of the health-related personal data;
- c. document all processing operations which are essential to ensure traceability.

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

- a. comply with the principles set out in paragraph 1 *mutatis mutandis*;
- b.⁶ 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 available the resources required for storage.

⁵ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

⁶ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

Art. 5a⁷ Handling of genetic data in connection with insurance

In connection with insurance, Articles 42–44 of the Federal Act of 15 June 2018⁸ on Human Genetic Testing (HGTA) apply to the handling of genetic data from research projects.

Chapter 2

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

Section 1 General Provisions

Art. 6 Research project

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

- a. answer a scientific question; or
- b. make further use for research purposes of the biological material or the health-related personal data.

Art. 6a⁹ Completion of the research project

The completion of a research project under this Chapter is marked by the last collection of health-related personal data or the last sampling of biological material in a research project, in the absence of provisions to the contrary in the protocol.

Art. 7 Categorisation

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

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

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

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

⁷ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

⁸ SR **810.12**

⁹ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

- c. removing or collecting bodily substances without invasive interventions (in particular, saliva, urine and stool samples);
- d. taking swabs;
- e. magnetic resonance imaging scans without a contrast medium, ultrasound examinations or electrograms;
- f.¹⁰ accompanying examinations involving ionising radiation, provided that the effective dose is below 5 mSv per research project and per person concerned, no contrast medium is used, and:
 - 1. the radiopharmaceuticals employed are used in accordance with the authorisation or are exempt from authorisation, or
 - 2. the devices under Article 1 of the Medical Devices Ordinance of 1 July 2020¹¹ bear conformity markings as specified in Article 13 MedDO and are used in accordance with the instructions for use.

Art. 8 Information

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

- a. the effort involved and the obligations arising from participation;
- b. their right to withhold or to revoke their consent without giving reasons;
- c. the consequences of revoking consent to further use of the biological material and personal data collected up to this point;
- d. their right to receive information at any time in response to further questions;
- d^{bis}.¹² 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;
- e. their right to be informed of results concerning their health, and their right to forgo such information or to designate a person who is to take this decision for them;
- f. the measures envisaged to cover any damage arising from the research project, including the procedure in the event of a claim;
- g. the main sources of financing for the research project;
- h. other points relevant to their decision on participation.

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

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

¹⁰ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

¹¹ SR **812.213**

¹² Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

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 information elements must be communicated in an appropriate, structured and clear manner.¹³

Art. 8a¹⁴ 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 HGTA¹⁵) 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 screened for;
- c. medical, psychological and social implications of the test;
- 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. 8b¹⁶ Information in cases of prenatal risk assessment

When a prenatal risk assessment is conducted (Art. 3 let. h HGTA¹⁷), the pregnant woman must additionally be informed about the matters specified in Article 23 HGTA.

Art. 8c¹⁸ 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:

¹³ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

¹⁴ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

¹⁵ SR **810.12**

¹⁶ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

¹⁷ SR **810.12**

¹⁸ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

- a. it has been given 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. 9 Exceptions to written form

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

- a. the research project in question comes under Category A, as defined in this Ordinance, and involves adults with capacity;
- b. provision of written information and consent would be disproportionate, given the project design; and
- c. reference is made to the departure from written form in the application to the responsible research ethics committee (ethics committee).

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

- a. the person concerned, for physical or cognitive reasons, cannot read or cannot write; and
- b. the project leader furnishes proof of the provision of information and consent, specifically by means of written confirmation by witnesses, or by a recording of verbal consent.

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

- a. this could only be implemented with disproportionate effort, given the language skills of the person concerned; and
- b. an independent qualified translator is called in to provide oral information and gives written confirmation thereof.

Art. 9a¹⁹ 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:

¹⁹ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

- 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. 10 Consequences of revocation of consent

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

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

- a. the person concerned expressly renounces this right when revoking consent; or
- b. it is established at the beginning of the research project that anonymisation is not possible and the person concerned, having been adequately informed of this fact, consented to participate.

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

Art. 11 Research projects in emergency situations

For research projects in emergency situations, Articles 15–17 ClinO²⁰ apply *mutatis mutandis*.

Art. 12²¹

Art. 13 Coverage

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

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

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

⁴ In addition, Article 11, Article 13 paragraph 1 and Article 14 ClinO²² apply *mutatis mutandis*.

²⁰ SR 810.305

²¹ Repealed by No I of the O of 7 June 2024, with effect from 1 Nov. 2024 (AS 2024 321).

²² SR 810.305

Section 2 Approval Procedure

Art. 14 Application

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

² The ethics committee may request additional information.

³ The sponsor may submit the application instead of the project leader. In this case, the sponsor assumes the obligations of the project leader as specified in Articles 17–23. The application documents must be co-signed by the project leader.

Art. 15 Review areas

The responsible ethics committee shall review:

- a. the completeness of the application;
- b. the categorisation requested;
- c. the research project with regard to:
 1. scientific quality, in the case of a research project as specified in Article 6 letter a,
 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 and compliance with the prohibition of commercialisation (Art. 9 HRA),
 8. compliance with scientific integrity requirements;

^c_{bis}²³ where applicable, compliance with the requirements for consent in electronic form (Art. 8c para. 3 let. a–c);

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

^d_{bis}²⁴ the consideration given to the right of the persons concerned to receive information (Art. 8 para. 1 HRA);

²³ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

²⁴ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

- e. in the case of Category B research projects: the guaranteeing of the right to compensation in the event of damage (Art. 20 HRA);
- f.²⁵ in the case of accompanying examinations involving ionising radiation: additionally, compliance with radiological protection legislation and the dose estimation, provided the opinion of the Federal Office of Public Health (FOPH) in accordance with Article 19 paragraph 4 is not required;
- g. the professional qualifications of the project leader and the other researchers;
- h. compliance with the requirements concerning the storage of biological material or health-related personal data specified in Article 5;
- i. the suitability of the infrastructure at the research site;
- j. the financing of the research project and the agreements between the sponsor, third parties and the project leader concerning the allocation of tasks, remuneration and publication;
- k. other areas, where this is necessary to assess the protection of participants.

Art. 16 Procedure and deadlines

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

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

³ If the ethics committee requests additional information in accordance with Article 14 paragraph 2, the clock shall be stopped until this information has been received.

Art. 17 Multicentre research projects

¹ The project leader shall submit the application for a multicentre research project to the lead committee in accordance with Article 47 paragraph 2 HRA.

² The lead committee shall acknowledge receipt of the application within 7 days and at the same time notify the project leader whether the application documents submitted are formally in order.

³ At the request of the lead committee, the project leader shall submit the required number of copies of the application documents specified in Annex 2 to the ethics committees responsible at the other research sites (ethics committees concerned). These shall review the local conditions and inform the lead committee of their assessment within 15 days.

⁴ The lead committee shall reach a decision within 45 days of acknowledging receipt of the formally correct application. It shall inform the ethics committees concerned of its decision.

²⁵ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321, 581).

Art. 18 Modifications

¹ Substantial modifications to an approved research project 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 project leader shall submit to the ethics committee any application documents specified in Annex 2 which are affected by the modification. At the same time, the project leader 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.²⁶ modifications to the protocol which concern the goal or the central topic of the research project;
- c. a change of research site or conducting the research project at an additional site; or
- d. a change of project leader or sponsor.

⁴ The ethics committee shall reach a decision on substantial modifications within 30 days. Article 16 applies *mutatis mutandis*.

⁵ For the approval procedure in the case of substantial modifications to approved multicentre research projects, Article 17 applies *mutatis mutandis*.

Art. 19²⁷ Procedure for accompanying examinations involving ionising radiation

¹ In the case of accompanying examinations involving ionising radiation, the project leader shall additionally submit to the responsible ethics committee the documents specified in Annex 2 number 2. Subject to the provisions of paragraphs 2–6, the approval procedure is governed by Articles 14–18.

² The project leader shall additionally submit to the FOPH the application documents specified in Annex 2 number 3 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 MedDO²⁸; or
- c. some other radioactive source is used.

²⁶ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

²⁷ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321, 581).

²⁸ SR 812.213

³ If additional documentation has to be submitted in accordance with paragraph 2, the project leader 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 15 are met; and
- b. after discussion of the opinion specified in paragraph 4, there are no remaining objections to the research project.

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

Section 3 Notifications and Reporting

Art. 20 Notification of safety and protective measures

If immediate safety and protective measures have to be taken during the conduct of a research project, the project leader shall notify the ethics committee of these measures, and of the circumstances necessitating them, within 7 days.

Art. 21 Serious events

¹ If, in the course of a research project, serious events occur in participants, the research project must be interrupted.

² A serious event is defined as any adverse event where it cannot be excluded that the event is attributable to the sampling of biological material or the collection of health-related personal data, and 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; or
- c. is life-threatening or results in death.

³ If necessary in order to guarantee participants' safety and health, further events are to be designated as serious in the protocol or at the request of the responsible ethics committee.²⁹

⁴ The project leader shall report a serious event to the ethics committee within 7 days. In addition, the project leader shall report to the committee on the connection between the event and the collection of health-related personal data or the sampling of biological material. At the same time, he or she shall submit proposals concerning the next steps to be taken.

²⁹ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

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⁶ The ethics committee shall reach a decision on the continuation of the research project within 30 days after receipt of the report.

Art. 22 Notification upon completion or premature termination of a research project

The project leader shall notify the ethics committee of the premature termination or completion of a research project within 90 days.

Art. 23³¹ Assessment, notification and reporting on the use of ionising radiation³²

¹ In the case of research projects involving any use of ionising radiation, the project leader shall assess compliance with the dose constraint specified in Article 45 of the Radiological Protection Ordinance of 26 April 2017^{33,34}

² If the permitted dose constraint is exceeded, the project leader shall notify the competent ethics committee within seven working days of it becoming known.

³ The competent ethics committee may obtain technical advice from the FOPH in order to assess the dose calculation or the dose estimate and to decide what further measures are required.

⁴ Within a year of the completion or premature termination of a research project which included accompanying examinations involving ionising radiation, the project leader shall submit to the FOPH a final report including all information of relevance for radiological protection, and in particular a retrospective dose estimation for the participants.³⁵

⁵ Radiopharmaceuticals used in accordance with the authorisation and medical devices bearing a conformity marking used in accordance with the instructions for use are exempt from the reporting requirements specified in paragraph 4.³⁶

⁶ Within the framework of the opinion delivered in accordance with Article 19, or on request, the FOPH may specify further exemptions from the reporting requirements.

Art. 23a³⁷ Data retention requirements

The project leader must retain all the research project data for a period of at least ten years after the completion or premature termination of the research project.

³⁰ Repealed by No I of the O of 7 June 2024, with effect from 1 Nov. 2024 (AS **2024** 321).

³¹ Amended by Annex 11 No 5 of the Radiation Protection Ordinance of 26 Apr. 2017, in force since 1 Jan. 2018 (AS **2017** 4261).

³² Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

³³ SR **814.501**

³⁴ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

³⁵ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

³⁶ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

³⁷ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

Chapter 3

Further Use of Biological Material and Health-related Personal Data for Research

Section 1 General Provisions

Art. 24 Further use

Further use of biological material and health-related personal data is defined as any handling, for research purposes, of biological material already sampled or data already collected, and in particular:

- a. procuring, bringing together or collecting biological material or health-related personal data;
- b. registration or cataloguing of biological material or health-related personal data;
- c. storage or inclusion in biobanks or databases;
- d. making accessible or available or transferring biological material or health-related personal data.

Art. 25³⁸ Anonymisation

¹ For the anonymisation of biological material and health-related personal data, any association with a specific person must be rendered impossible or eliminated in such a way as to allow this association to be re-established only with disproportionate effort.

² Anonymisation must be effected using a method based on the current state of the art. In particular, items of data which, individually or in combination, allow the association with a specific person to be re-established, such as the first name, surname, address, date of birth or unique identification numbers, must be deleted or modified.

³ The method used for anonymisation must be documented, including a description of the residual risk of reidentification.

Art. 26³⁹ Coding

¹ Biological material and health-related personal data are considered to be correctly coded in accordance with Article 32 paragraph 2 and Article 33 paragraph 2 HRA if, without access to the key or to the source data, it is only possible with disproportionate effort to link the biological material or the health-related data to a specific person.

² Coding must be effected using a method based on the current state of the art. The key must be stored separately from the biological material or personal data and in accordance with the principles of Article 5 paragraph 1, by a person or organisational unit to be designated in the application, not involved in the research project.

³⁸ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

³⁹ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

Art. 27 Conditions for breaking the code

For coded biological material and coded health-related personal data, the code may only be broken if:

- a. breaking the code is necessary to avert an immediate risk to the health of the person concerned;
- b. a legal basis exists for breaking the code; or
- c. breaking the code is necessary to guarantee the rights of the person concerned, and in particular the right to revoke consent.

Section 2 Informed Consent and Information**Art. 28** Informed consent for further use of biological material and genetic personal data in uncoded form for a research project

¹ The persons concerned must receive written and oral information on:

- a. the nature, purpose and duration of, and procedure for, the research project;
- b. their right to withhold or to revoke their consent at any time without giving reasons;
- c. the consequences of revocation of consent for the biological material and personal data used up to this point;
- d. their right to receive information at any time in response to further questions relating to the research project;
- e. their right to be informed of results concerning their health, and their right to forgo such information or to designate a person who is to take this decision for them;
- f. measures to protect the biological material and the personal data;
- g. the main sources of financing for the research project;
- h. other points relevant to their decision.

² The information may be additionally presented in a non-textual form.

³ The form of consent is governed by Article 8c.⁴⁰

⁴ Article 9 applies *mutatis mutandis*.⁴¹

Art. 29 Informed consent for further use of biological material and genetic personal data in coded form for research purposes

¹ The persons concerned must receive written or oral information on:

⁴⁰ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

⁴¹ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

- a. the intended further use of the coded biological material and coded genetic personal data for research purposes;
- b. their right to withhold or to revoke their consent at any time without giving reasons;
- c. measures to protect the biological material and personal data, and in particular management of the key;
- d. the possibility of the biological material and the genetic personal data being passed on to third parties for research purposes.

² The form of consent is governed by Article 8c paragraphs 1, 2 letter a, 3 letters a–c and 4.⁴²

³ Article 9 applies *mutatis mutandis*.⁴³

Art. 30 Information on the intended anonymisation of biological material and genetic personal data for research purposes

The persons concerned must receive written or oral information on:

- a. the intended anonymisation of the biological material and genetic personal data for research purposes;
- b. their right to object;
- c. the consequences of anonymisation with regard to results concerning their health;
- d. the possibility of the biological material and the data being passed on to third parties for research purposes.

Art. 31 Informed consent for further use of non-genetic health-related personal data in uncoded form for research purposes

¹ The persons concerned must receive written or oral information on:

- a. the intended further use of the non-genetic health-related personal data for research purposes;
- b. their right to withhold or to revoke their consent at any time without giving reasons;
- c. their right to be informed of results concerning their health, and their right to forgo such information;
- d. measures to protect the personal data;
- e. the possibility of the personal data being passed on to third parties for research purposes.

⁴² Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

⁴³ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

² The form of consent is governed by Article 8c paragraphs 1, 2 letter a, 3 letters a–c and 4.⁴⁴

³ Article 9 applies *mutatis mutandis*.⁴⁵

Art. 32 Information on the intended further use of non-genetic health-related personal data in coded form for research purposes

The persons concerned must receive written or oral information on:

- a. the intended further use of the non-genetic health-related personal data in coded form for research purposes;
- b. their right to object;
- c. measures to protect the personal data, and in particular management of the key;
- d. the possibility of the personal data being passed on to third parties for research purposes.

Section 3

Approval Procedure and Notification Requirements for Research Projects Involving Biological Material and Health-Related Personal Data

Art. 33 Research project

For the purposes of this Section, a research project is any project in which further use is made of biological material already sampled or health-related personal data already collected in order to answer a scientific question.

Art. 34 Review areas

¹ The responsible ethics committee shall review:⁴⁶

- a. the completeness of the application;
- b. the fulfilment of the conditions specified in Articles 32 and 33 HRA;
- bbis.⁴⁷ the scientific quality;
- c. for research projects involving biological material and health-related personal data in coded form: correct and secure coding;
- d. compliance with the requirements for the storage of biological material or health-related personal data;

⁴⁴ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

⁴⁵ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

⁴⁶ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

⁴⁷ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

- e. the professional qualifications of the project leader and the other persons involved in the research project;
- f. other areas, where this is necessary to assess the protection of the persons concerned.

² In this process, it shall take into account existing approvals from ethics committees with regard to the biological material or the health-related personal data.

Art. 35 Applicable provisions

The following provisions apply *mutatis mutandis*:

- a. for the submission of the application: Article 14;
- b. for the procedure and deadlines: Article 16;
- c. for multicentre research projects: Article 17.

Art. 36 Notification requirements

¹ The project leader shall notify the ethics committee of a change of project leader in advance.

² The project leader shall notify the ethics committee of the completion or premature termination of the research project within 90 days.

Section 4

Approval Procedure and Notification Requirements for further Use of Biological Material and Health-Related Personal Data for Research in the Absence of Informed Consent in accordance with Article 34 HRA

Art. 37 Review areas

The responsible ethics committee shall review:⁴⁸

- a. the completeness of the application;
- b. the reasons, as specified in Article 34 letters a and b HRA;
- c. the interests of the intended research which outweigh the interests of the person concerned in deciding on the further use of his or her biological material and health-related personal data;
- d. the group of persons entitled to pass on the biological material and the personal data;
- e. compliance with the requirements concerning the storage of biological material or health-related personal data and the group of persons with access rights;
- f. the professional qualifications of the persons entitled to receive the biological material and the personal data;

⁴⁸ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

- g. other areas, where this is necessary to assess the protection of the persons concerned.

Art. 38 Applicable provisions

The following provisions apply *mutatis mutandis*:

- a. for the submission of the application: Article 14;
- b. for the procedure and deadlines: Article 16;
- c. for further use or collection according to a standard protocol, but in different cantons: the procedure specified in Article 17.

Art. 39 Approval

The approval shall include at least the following information:

- a. the purpose for which further use may be made of the biological material and the health-related personal data;
- b. the designation of the biological material and health-related personal data covered by the approval;
- c. the group of persons entitled to pass on the biological material and the health-related personal data;
- d. the group of persons entitled to receive the biological material and the personal data.

Art. 40 Notifications

¹ The project leader must notify the ethics committee in advance of any modification to the information given in the approval.

² The project leader must notify the ethics committee of the completion or premature termination of the collection process within 90 days.

Chapter 4 Research Involving Deceased Persons

Art. 41 Review areas

The ethics committee shall review:

- a. the completeness of the application;
- b. the scientific quality;
- c. compliance with the requirements for consent (Art. 36 HRA);
- d. for research projects involving deceased persons undergoing artificial respiration: the need to involve them in the research project (Art. 37 para. 2 HRA) and compliance with the requirement for independence of the persons involved in the determination of their death (Art. 37 para. 3 HRA);

- e. compliance with the requirements for the storage of biological material or health-related personal data;
- f. compliance with the prohibition of commercialisation (Art. 9 HRA);
- g. the professional qualifications of the project leader and the other researchers.

Art. 42 Applicable provisions

The following provisions apply *mutatis mutandis*:

- a. for the submission of the application: Article 14;
- b. for the procedure and deadlines: Article 16;
- c. for multicentre research projects: the procedure specified in Article 17.

Art. 43 Notifications

¹ The project leader must notify the ethics committee in advance of the following modifications to the research project:

- a. change of project leader;
- b. for research projects involving deceased persons undergoing artificial respiration: substantial modifications to the protocol.

² The project leader shall notify the ethics committee of the completion or premature termination of the research project within 90 days.

Chapter 5

Research involving Embryos and Foetuses from Induced Abortions and from Spontaneous Abortions including Stillbirths

Art. 44 Informed consent

¹ For research projects involving embryos and foetuses from induced abortions and from spontaneous abortions including stillbirths, the pregnant woman or the couple concerned must receive written and oral information on:

- a. the use of the embryo or foetus for research purposes;
- b. their right to withhold or to revoke their consent at any time without giving reasons;
- c. measures to protect the biological material and the personal data;
- d. the handling of the embryo or foetus after completion of the research.

² The information may be additionally presented in a non-textual form.

³ The form of consent is governed by Article 8c.⁴⁹

⁴⁹ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).

⁴ Article 9 applies *mutatis mutandis*.⁵⁰

⁵ The consequences of revocation of consent are governed by Article 10.⁵¹

Art. 45 Review areas

The responsible ethics committee shall review:⁵²

- a. the completeness of the application;
- b. the scientific quality;
- c.⁵³ compliance with the requirements for informed consent, and, where applicable compliance with the requirements for consent in electronic form (Art. 8c para. 3 let. a–c);
- d. for research projects involving embryos and foetuses from induced abortions: compliance with the requirements specified in Article 39 paragraphs 1, 2 and 4 HRA;
- e. compliance with the prohibition of commercialisation (Art. 9 HRA);
- f. compliance with the requirements concerning the storage of biological material or health-related personal data;
- g. the professional qualifications of the project leader and the other researchers;
- h. other areas, where this is necessary to assess the protection of the pregnant woman or the couple concerned.

Art. 46 Applicable provisions

The following provisions apply *mutatis mutandis*:

- a. for the submission of the application: Article 14;
- b. for the procedure and deadlines: Article 16;
- c. for multicentre research projects: the procedure specified in Article 17;
- d. for notification requirements: Article 36.

Chapter 6 Final Provisions

Art. 47 Updating of Annexes

The Federal Department of Home Affairs may update the Annexes 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.

⁵⁰ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

⁵¹ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

⁵² Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

⁵³ Amended by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS **2024** 321).

Art. 48 Transitional provisions

¹ Research projects as defined in Chapter 2 which were granted approval before 1 January 2014 are considered to be Category B research projects.

² On request, the authority which approved the research project before 1 January 2014 may assign the research project to Category A. In this case, the liability, coverage and notification requirements are governed by the new law.

³ The ethics committee shall make the decision specified in paragraph 2 according to the simplified procedure specified in Article 6 of the HRA Organisation Ordinance of 20 September 2013⁵⁴.

⁴ The provisions of this Ordinance are applicable:

- a. to the assessment of substantial modifications to research projects as specified in Chapter 2;
- b. to notifications concerning research projects as specified in Chapters 3–5.

⁵ The responsible ethics committee shall make a decision on applications concerning research projects not subject to approval under existing law, submitted in accordance with Article 67 paragraph 2 HRA, within six months after acknowledgement of receipt of the formally correct application documents.

Art. 48a⁵⁵ Transitional provisions to the Amendment of 7 June 2024

¹ Article 23a does not apply to research projects approved before the Amendment of 7 June 2024 comes into force.

² For research projects approved before the before the Amendment of 7 June 2024 comes into force, the liability requirements are governed by the previous law.

Art. 49 Commencement

This Ordinance comes into force on 1 January 2014.

⁵⁴ SR 810.308

⁵⁵ Inserted by No I of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321, 343).

Annex 1
(Art. 13)**Policy values for liability coverage**

For Category B research projects involving persons, 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 research project: 3 million Swiss francs.

*Annex 2*⁵⁶
(Art. 14, 17–19)

Application documents to be submitted to the responsible ethics committee for the procedure

1 Application documents for research projects involving the sampling of biological material or the collection of health-related personal data from persons

- 1.1 Administrative information, including a summary of the protocol and reasons for the requested categorisation;
- 1.2 protocol;
- 1.3 informed consent documents and recruitment documents, in particular the wording of announcements or advertisements;
- 1.4 other documents issued to participants;
- 1.5 information on the type and amount of remuneration for participants;
- 1.6 for Category B research projects: certificate of insurance or other proof of coverage for possible damage;
- 1.7 information on the secure handling of biological material and personal data, and in particular on the storage thereof;
- 1.8 the project leader's CV, including evidence of his or her knowledge and experience, and a list of the other persons involved in the research project, indicating their responsibilities and relevant professional knowledge;
- 1.9 information on the suitability and availability of infrastructure at the research site;
- 1.10 agreements between the project leader and the sponsor or third parties, in particular with regard to the financing of the research project, remuneration of the project leader and publication.

2 Additional application documents for research projects which include accompanying examinations involving ionising radiation

- 2.1 Details of all relevant radiological protection aspects, and in particular a calculation or estimate of the effective dose, organ doses and any tumour doses;
- 2.2 the licences required under Article 28 of the Radiological Protection Act of 22 March 1991⁵⁷.

⁵⁶ Updated by No II of the O of 7 June 2024, in force since 1 Nov. 2024 (AS 2024 321).
⁵⁷ SR 814.50

3 Additional application documents for research projects which include accompanying examinations involving ionising radiation and require an opinion from the FOPH in accordance with Article 19 paragraph 2

- 3.1 Information specified in the FOPH form for research projects involving radiopharmaceuticals or radiolabelled compounds⁵⁸. 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;
- 3.2 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.

4 Application documents for research projects involving further use of biological material or health-related personal data

- 4.1 Administrative information, including a summary of the scientific question;
- 4.2 description of the scientific question;
- 4.3 proof of the origin of the biological material and health-related personal data, and of compliance with the requirements concerning informed consent and information on the right to object specified in Articles 32 and 33 HRA;
- 4.4 for further use of biological material and health-related personal data in coded form: proof of secure and correct coding;
- 4.5 proof of secure handling of biological material and personal data, and in particular the storage thereof;
- 4.6 the project leader's CV, including evidence of his or her knowledge and experience, and a list of the other persons involved in the research project, indicating their responsibilities and relevant professional knowledge;
- 4.7 information on the infrastructure available at the research site;
- 4.8 any approvals granted by ethics committees in Switzerland for the sampling of biological material or the collection of health-related personal data.

⁵⁸ 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.

5 Application documents for further use of biological material or health-related personal data in the absence of informed consent in accordance with Article 34 HRA

- 5.1 Administrative information, including a summary of the project;
- 5.2 planned procedure;
- 5.3 description of the proposed research purposes for which further use is to be made of the biological material or health-related personal data, including an explanation of how the research interests outweigh the interests of the persons concerned;
- 5.4 designation of the biological material or health-related personal data of which further use is to be made;
- 5.5 designation of the group of persons who are to be entitled to pass on the biological material or the health-related personal data;
- 5.6 designation of the persons who are to be entitled to receive the biological material or the health-related personal data;
- 5.7 designation of the persons responsible for protection of the data disclosed;
- 5.8 designation of the group of persons who are to have access rights for the biological material or the health-related personal data;
- 5.9 proof of secure handling of biological material and personal data, and in particular the storage thereof;
- 5.10 information on the duration of storage;
- 5.11 the project leader's CV, including evidence of his or her knowledge and experience, and a list of the other persons involved in the research project, indicating their responsibilities and relevant professional knowledge;
- 5.12 information on the infrastructure available at the research site.

6 Application documents for research projects involving deceased persons

- 6.1 Administrative information, including a summary of the protocol;
- 6.2 protocol;
- 6.3 proof of compliance with the requirements for consent specified in Article 36 HRA;
- 6.4 proof of compliance with the requirement for prior determination of death specified in Article 37 paragraph 1 HRA;
- 6.5 for research projects involving deceased persons undergoing artificial respiration: statement of the reasons why such persons need to be involved in the research project, and proof of the independence of the persons determining death;
- 6.6 documents concerning any remuneration;

- 6.7 proof of secure handling of biological material and personal data, and in particular the storage thereof;
- 6.8 the project leader's CV, including evidence of his or her knowledge and experience, and a list of the other persons involved in the research project, indicating their responsibilities and relevant professional knowledge;
- 6.9 information on the infrastructure available at the research site;
- 6.10 agreements between the project leader and third parties, in particular with regard to the financing of the research project, remuneration of the project leader and publication.

7 Application documents for research projects involving embryos and fetuses from induced abortions and from spontaneous abortions including stillbirths

- 7.1 Administrative information, including a summary of the protocol;
- 7.2 protocol;
- 7.3 informed consent documents and recruitment documents, in particular the wording of announcements or advertisements;
- 7.4 description of measures to ensure compliance with the requirements for consent specified in Article 39 paragraph 1 or Article 40 paragraph 1 HRA;
- 7.5 description of measures to ensure compliance with the requirement for prior determination of death specified in Article 39 paragraph 3 or Article 40 paragraph 2 HRA;
- 7.6 for research projects involving embryos and fetuses from induced abortions: proof of compliance with the requirements specified in Article 39 paragraphs 2 and 4 HRA;
- 7.7 documents concerning any remuneration;
- 7.8 proof of secure handling of biological material and personal data, and in particular the storage thereof;
- 7.9 the project leader's CV, including evidence of his or her knowledge and experience, and a list of the other persons involved in the research project, indicating their responsibilities and relevant professional knowledge;
- 7.10 information on the infrastructure available at the research site;
- 7.11 agreements between the project leader and third parties, in particular with regard to the financing of the research project, remuneration of the project leader and publication.

8 Application documents for the ethics committees concerned in multicentre research projects

- 8.1 Administrative information, including a summary of the research project;
- 8.2 protocol;

- 8.3 for research projects involving persons or research projects involving embryos and fetuses from induced abortions and from spontaneous abortions including stillbirths: informed consent documents and recruitment documents, in particular the wording of announcements or advertisements, used at the research site in question;
- 8.4 for research projects involving deceased persons: proof of compliance with the requirements for consent specified in Article 36 HRA and proof of compliance with the requirement for prior determination of death specified in Article 37 paragraph 1 HRA at the research site in question;
- 8.5 the CV of the person responsible at the research site in question, including evidence of his or her knowledge and experience, and a list of the other persons involved in the research project at the site concerned, indicating their responsibilities and relevant professional knowledge;
- 8.6 proof of the suitability and availability of the infrastructure at the research site in question;
- 8.7 agreements between the sponsor and the person responsible at the research site in question, in particular with regard to his or her remuneration;
- 8.8 for Category B research projects involving persons: certificate of insurance or other proof of coverage for possible damage at the research site in question, including any agreements on this matter between the sponsor and the person responsible at the research site.

