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Federal Act on Research involving Human Beings (Human Research Act, HRA)

of 30 September 2011 (Status as of 26 May 2021)

*The Federal Assembly of the Swiss Confederation,
on the basis of Article 118b paragraph 1 of the Federal Constitution¹,
and having considered the Dispatch of the Federal Council dated 21 October 2009²,
decrees:*

Chapter 1 General Provisions

Section 1 Purpose, Scope and Definitions

Art. 1 Purpose

¹ The purpose of this Act is to protect the dignity, privacy and health of human beings involved in research.

² It is also designed to:

- a. create favourable conditions for research involving human beings;
- b. help to ensure the quality of research involving human beings;
- c. ensure the transparency of research involving human beings.

Art. 2 Scope

¹ This Act applies to research concerning human diseases and concerning the structure and function of the human body, which involves:

- a. persons;
- b. deceased persons;
- c. embryos and foetuses;
- d. biological material;
- e. health-related personal data.

AS 2013 3215

¹ SR 101

² BBl 2009 8045

² It does not apply to research which involves:

- a. IVF embryos in accordance with the Stem Cell Research Act of 19 December 2003³;
- b. anonymised biological material;
- c. anonymously collected or anonymised health-related data.

Art. 3 Definitions

In this Act:

- a. *Research* means method-driven search for generalisable knowledge;
- b. *Research concerning diseases* means research on the causes, prevention, diagnosis, treatment and epidemiology of impairments of physical and mental health in human beings;
- c. *Research concerning the structure and function of the human body* means basic research, in particular on human anatomy, physiology and genetics, and non-disease-related research concerning interventions and impacts on the human body;
- d. *Research project with an expected direct benefit* means a research project whose results can be expected to improve the health of the participants;
- e. *Biological material* means bodily substances derived from living persons;
- f. *Health-related personal data* means information concerning the health or disease of a specific or identifiable person, including genetic data;
- g. *Genetic data* means information on a person's genes, obtained by genetic testing;
- h. *Coded biological material and coded health-related personal data* means biological material and data linked to a specific person via a code;
- i. *Anonymised biological material and anonymised health-related data* means biological material and health-related data which cannot (without disproportionate effort) be traced to a specific person;
- j. *Child* means a legal minor under 14 years of age;
- k. *Adolescent* means a legal minor aged 14 years or more;
- l.⁴ ...

³ SR 810.31

⁴ Repealed by Annex of the FA of 22 March 2019, with effect from 26 May 2021 (AS 2020 2961; BBl 2019 1).

Section 2 Principles

Art. 4 Primacy of individual interests

The interests, health and welfare of the individual human being shall prevail over the interests of science and society.

Art. 5 Scientifically relevant topic

Research involving human beings may only be carried out if it addresses a topic of scientific relevance concerning:

- a. the understanding of human diseases;
- b. the structure and function of the human body; or
- c. public health.

Art. 6 Non-discrimination

¹ Nobody is to be subjected to discrimination in connection with research.

² With regard to the selection of participants in particular, no group of persons shall be disproportionately included in or excluded from research without good reason.

Art. 7 Consent

¹ Research involving human beings may only be carried out if, in accordance with the provisions of this Act, the persons concerned have given their informed consent or, after being duly informed, have not exercised their right to dissent.

² The persons concerned may withhold or revoke their consent at any time, without stating their reasons.

Art. 8 Right to receive information

¹ The persons concerned are entitled to be informed of results relating to their health. The information is to be communicated in an appropriate manner. The persons concerned may choose to forgo such information.

² They are entitled to be informed about all the personal data held in relation to them.

Art. 9⁵ Prohibition of commercialisation

¹ It is prohibited to offer, grant, demand or accept payment or any other non-cash advantage in exchange for the human body or parts thereof as such.

⁵ Amended by Annex No 2 of the FD of 19 June 2020 on the Approval of the Council of Europe Convention against Trafficking in Human Organs and on its Implementation, in force since 1 Feb. 2021 (AS 2020 6567; BBl 2019 5971).

² It is also prohibited to use the human body or parts thereof if they have been subject to a prohibited act as specified in paragraph 1.

Art. 10 Scientific requirements

¹ Research involving human beings may only be carried out if:

- a. the recognised regulations concerning scientific integrity are complied with, in particular with regard to the handling of conflicts of interest;
- b. scientific quality requirements are met;
- c. the recognised international Good Practice guidelines for research involving human beings are complied with; and
- d. the persons responsible have appropriate professional qualifications.

² The Federal Council shall specify which national and international regulations must be complied with.

Chapter 2 General Requirements for Research involving Persons
Section 1 Protection of Participants

Art. 11 Subsidiarity

¹ A research project involving persons may only be carried out if equivalent findings cannot be obtained by other means.

² A research project involving particularly vulnerable persons may only be carried out if equivalent findings cannot be obtained by other means.

Art. 12 Risks and burdens

¹ In every research project, the risks and burdens for the participants must be minimised as far as possible.

² The likely risks and burdens for the participants must not be disproportionate to the expected benefits of the research project.

Art. 13 Placebo

In research projects with an expected direct benefit, the use of a placebo or non-treatment is only permissible if no additional risk of serious or irreversible harm is to be expected for the persons concerned and:

- a. no standard treatment is available; or
- b. the use of a placebo is required for compelling, scientifically sound methodological reasons, in order to establish the efficacy or safety of a treatment method.

Art. 14 Non-remunerative participation

¹ No person may receive payment or any other non-cash advantage for participation in a research project with an expected direct benefit. Participation in a research project with no expected direct benefit may be appropriately remunerated.

² No person may demand or accept payment or any other non-cash advantage from another in return for the latter's participation in a research project.

Art. 15 Safety and protective measures

¹ Anyone who conducts a research project must, before it begins, take all the measures required to protect the participants.

² If, during the research project, circumstances arise which could jeopardise the safety or health of the participants or lead to a disproportionate relationship between the risks and burdens and the benefits, all the measures required to ensure protection are to be taken without delay.

Section 2 Information and Consent**Art. 16** Informed consent

¹ Persons may only be involved in a research project if they have given their informed consent. Consent must be given in writing; the Federal Council may specify exemptions.

² The persons concerned must receive comprehensible oral and written information on:

- a. the nature, purpose and duration of, and procedure for, the research project;
- b. the foreseeable risks and burdens;
- c. the expected benefits of the research project, in particular for themselves or for other people;
- d. the measures taken to protect the personal data collected;
- e. their rights.

³ Before a decision on consent is made by the persons concerned, they must be allowed an appropriate period for reflection.

⁴ The Federal Council may specify further elements of the information to be provided.

Art. 17 Consent to further use for research

If the intention exists to make further use for research of biological material sampled or health-related personal data collected, the consent of the persons concerned must be obtained at the time of such sampling or collection, or they must be informed of their right to dissent.

Art. 18 Incomplete information

¹ In exceptional cases, the persons concerned may be given incomplete information regarding individual aspects of a research project before it begins:

- a. insofar as this is essential for methodological reasons; and
- b. if the research project entails no more than minimal risks and burdens.

² The participants must subsequently be duly informed as soon as possible.

³ Once they have been informed in accordance with paragraph 2, they may give or withhold their consent to the use of their biological material or their data. Only when such consent has been given is the biological material or data to be used for the research project.

Section 3 Liability and Coverage**Art. 19** Liability

¹ Any person who carries out a research project involving persons shall be liable for damage suffered by them in connection with the project. The Federal Council may specify exemptions from liability.

² Compensation claims prescribe in accordance with Article 60 of the Swiss Code of Obligations.⁶ The Federal Council may specify a longer prescriptive period for particular research areas.⁷

³ The provisions of the Code of Obligations on tort are otherwise applicable; in the exercise of official duties, the Government Liability Act of 14 March 1958⁸, or cantonal government liability law, is applicable.

Art. 20 Coverage

¹ Liability must be appropriately covered through insurance or in some other manner. The Federal Government and its public-law institutions and corporations are exempt from the liability coverage requirements.

² The Federal Council may:

- a. specify requirements for insurance and other forms of coverage;
- b. exempt research areas or classes of damage from the liability coverage requirements.

³ For the protection of the injured party, it may:

- a. grant this party a direct claim against the party providing liability coverage;

⁶ SR 220

⁷ Amended by Annex No 17 of the FA of 15 June 2018 (Revision of the Law on Prescription), in force since 1 Jan. 2020 (AS 2018 5343; BBl 2014 235).

⁸ SR 170.32

- b. restrict the cancellation rights and objections of the party providing liability coverage, while granting appropriate rights of recourse.

Chapter 3

Additional Requirements for Research Involving Particularly Vulnerable Persons

Section 1

Research involving Children, Adolescents and Adults lacking Capacity

Art. 21 Involvement of persons lacking capacity in the consent procedure

¹ Children, adolescents and adults lacking capacity must be involved as far as possible in the consent procedure.

² Increasing weight must be accorded to the views of children and adolescents lacking capacity the older and more mature they are.

Art. 22 Research projects involving children

¹ A research project with an expected direct benefit may only be carried out in children who are capable of judgement if:

- a. the child has given informed consent; and
- b. the legal representative has given informed consent in writing.

² A research project with no expected direct benefit may only be carried out in children who are capable of judgement if, in addition to paragraph 1:

- a. it entails no more than minimal risks and burdens; and
- b. it can be expected to yield substantial findings which could in the long term be beneficial for persons with the same disease or disorder, or in the same situation.

³ A research project with an expected direct benefit may only be carried out in children who lack capacity if:

- a. the legal representative has given informed consent in writing; and
- b. the child does not visibly express opposition to the research intervention either verbally or by his or her behaviour.

⁴ A research project with no expected direct benefit may only be carried out in children who lack capacity if the requirements specified in paragraphs 2 and 3 are met.

Art. 23 Research projects involving adolescents

¹ A research project with or without an expected direct benefit may only be carried out in adolescents who are capable of judgement if:

- a. the adolescent has given informed consent in writing; and

- b. the legal representative has given informed consent in writing if the research project entails more than minimal risks and burdens.

² A research project with an expected direct benefit may only be carried out in adolescents who lack capacity if:

- a. the legal representative has given informed consent in writing; and
- b. the adolescent does not visibly express opposition to the research intervention either verbally or by his or her behaviour.

³ A research project with no expected direct benefit may only be carried out in adolescents who lack capacity if, in addition to the requirements specified in paragraph 2:

- a. it entails no more than minimal risks and burdens; and
- b. it can be expected to yield substantial findings which could in the long term be beneficial for persons with the same disease or disorder, or in the same situation.

Art. 24 Research projects involving adults lacking capacity

¹ A research project with an expected direct benefit may only be carried out in adults who lack capacity if:

- a. this is permitted by the consent of the person concerned, granted while in a state of capacity and duly documented;
- b. informed consent has been given in writing by the legal representative, a designated trusted person or the next of kin, if no documented consent is available; and
- c. the person concerned does not visibly express opposition to the research intervention either verbally or by his or her behaviour.

² A research project with no expected direct benefit may only to be carried out in adults who lack capacity if, in addition to the requirements specified in paragraph 1:

- a. it entails no more than minimal risks and burdens; and
- b. it can be expected to yield substantial findings which could in the long term be beneficial for persons with the same disease or disorder, or in the same situation.

Section 2

Research involving Pregnant Women and Embryos and Foetuses *in vivo*

Art. 25 Prohibited research projects

Research projects designed to modify properties of an embryo or foetus for non-disease-related reasons are prohibited.

Art. 26 Research projects involving pregnant women and embryos and foetuses *in vivo*

¹ A research project with an expected direct benefit for a pregnant woman or for an embryo or foetus may only be carried out if the foreseeable risks and burdens, both for the pregnant woman and for the embryo or foetus, are not disproportionate to the expected benefits.

² A research project with no expected direct benefit for the pregnant woman or for the embryo or foetus may only be carried out if:

- a. it entails no more than minimal risks and burdens for the embryo or foetus; and
- b. it can be expected to yield substantial findings which could in the long term be beneficial for pregnant women or for embryos or foetuses.

Art. 27 Research projects concerning methods of induced abortion

¹ A pregnant woman may only be asked whether she wishes to participate in a research project concerning methods of induced abortion after she has decided to undergo an abortion.

² Article 26 does not apply.

Section 3 Research involving Prisoners

Art. 28 Research projects involving prisoners

¹ For research projects with an expected direct benefit which involve prisoners, the general requirements for research involving persons apply; however, Article 11 paragraph 2 does not apply.

² A research project with no expected direct benefit which involves prisoners may only be carried out if it entails no more than minimal risks and burdens.

Art. 29 Prohibition of a relaxation of conditions

Participation in a research project must not be associated with relaxing the conditions of imprisonment.

Section 4 Research in Emergency Situations

Art. 30 Research projects in emergency situations

¹ A research project with an expected direct benefit may be carried out in emergency situations if:

- a. the necessary measures have been taken so that the wishes of the person concerned can be determined as soon as possible;

- b. the person concerned does not visibly express opposition to the research intervention through either verbally or by his or her behaviour; and
- c. a physician who is not participating in the research project is called in to safeguard the interests of the person concerned before he or she is involved in the project; in exceptional cases, where there are good reasons for doing so, the physician may be called in at a later stage.

² A research project with no expected direct benefit may be carried out in emergency situations if, in addition to the requirements specified in paragraph 1:

- a. it entails no more than minimal risks and burdens; and
- b. it can be expected to yield substantial findings which could in the long term be beneficial for persons with the same disease or disorder, or in the same situation.

Art. 31 Post hoc or proxy consent

¹ The person concerned must be duly informed about the research project as soon as this becomes possible. He or she may subsequently give or withhold consent.

² If the person concerned refuses to give post hoc consent, the biological material and data may no longer be used for the research project.

³ The Federal Council shall specify the procedure for the procurement of post hoc or proxy consent, in particular with regard to the involvement of children, adolescents and adults lacking capacity.

Chapter 4
Further Use of Biological Material and Health-Related Personal Data for Research

Art. 32 Further use of biological material and genetic data

¹ Further use may be made of biological material and genetic data in uncoded form for a research project if informed consent has been given by the person concerned, or by the legal representative or next of kin. For consent, Articles 16 and 22–24 apply *mutatis mutandis*.

² Further use may be made of biological material and genetic data in coded form for research purposes if informed consent has been given by the person concerned, or by the legal representative or next of kin. For consent, Articles 16 and 22–24 apply *mutatis mutandis*.

³ Biological material and genetic data may be anonymised for research purposes if the person concerned or the legal representative or next of kin have been informed in advance and have not dissented to anonymisation. For dissent, Articles 22–24 apply *mutatis mutandis*.

Art. 33 Further use of non-genetic health-related personal data

¹ Further use may be made of non-genetic health-related personal data in uncoded form for research purposes if informed consent has been given by the person concerned, or by the legal representative or next of kin. For consent, Articles 16 and 22–24 apply *mutatis mutandis*.

² Further use may be made of non-genetic health-related personal data in coded form for research purposes if the person concerned or the legal representative or next of kin have been informed in advance and have not dissented. For dissent, Articles 22–24 apply *mutatis mutandis*.

Art. 34 Absence of informed consent

If the requirements for informed consent specified in Articles 32 and 33 are not met, further use may be made of biological material or health-related personal data for research purposes in exceptional cases if:

- a. it is impossible or disproportionately difficult to obtain consent or to provide information on the right to dissent, or this would impose an undue burden on the person concerned;
- b. no documented refusal is available; and
- c. the interests of research outweigh the interests of the person concerned in deciding on the further use of his or her biological material and data.

Art. 35 Anonymisation and coding

The Federal Council shall specify the requirements for correct and secure anonymisation and coding and also the conditions for breaking the code.

Chapter 5 Research involving Deceased Persons**Art. 36** Consent

¹ Research may be carried out in deceased persons if, before their death, the persons concerned consented to the use of their body for research purposes.

² If no documented consent or refusal of the deceased person is available, the body or parts thereof may be used for research purposes if consent is given by the next of kin or by a trusted person designated during the lifetime of the deceased person.

³ The consent of the next of kin or the trusted person is governed by Article 8 of the Transplantation Act of 8 October 2004⁹.

⁴ In the case of deceased persons whose death occurred more than 70 years previously, research may be carried out without consent being given as specified in paragraph 2. If such research is opposed by the next of kin, it may not be carried out.

⁹ SR 810.21

Art. 37 Additional requirements

¹ A research project may be carried out in deceased persons when their death has been determined.

² A research project may be carried out in deceased persons undergoing artificial respiration if, in addition to the requirement specified in paragraph 1, equivalent findings cannot be obtained with deceased persons not undergoing artificial respiration. The Federal Council may specify further conditions.

³ Anyone who carries out a research project in accordance with paragraph 2 must not have been involved in the determination of death or be authorised to issue instructions to the persons involved in this procedure.

Art. 38 Research in connection with an autopsy or transplantation

Small quantities of bodily substances removed in the course of an autopsy or transplantation may be anonymised for research purposes without consent, in the absence of a documented refusal of the deceased person.

Chapter 6**Research involving Embryos and Foetuses from Induced Abortions and from Spontaneous Abortions including Stillbirths****Art. 39** Requirements for research in embryos and foetuses from induced abortions

¹ A pregnant woman may only be asked whether she wishes to make her embryo or foetus available for research purposes after she has decided to undergo an abortion. For consent, Articles 16 and 22–24 apply *mutatis mutandis*.

² The time and method of induced abortion must be chosen without regard to the research project.

³ Embryos and foetuses from induced abortions may be used for a research project when death has been determined.

⁴ Anyone who carries out a research project in accordance with paragraph 3 must not be involved in the abortion or be authorised to issue instructions to the persons involved in this procedure.

Art. 40 Requirements for research in embryos and foetuses from spontaneous abortions including stillbirths

¹ Embryos and foetuses from spontaneous abortions including stillbirths may only be used for research purposes with the consent of the couple concerned. For consent, Article 16 applies *mutatis mutandis*.

² Embryos and foetuses from spontaneous abortions may be used for a research project when death has been determined.

Chapter 7 Transfer, Export and Storage

Art. 41 Transfer for purposes other than research

Biological material or health-related personal data which has been sampled or collected or of which further use has been made for research purposes may only be passed on for purposes other than research if:

- a. a legal basis exists for such a transfer; or
- b. in the particular case, informed consent to the transfer has been given by the person concerned.

Art. 42 Export

¹ Biological material or genetic data may be exported for research purposes if informed consent has been given by the person concerned. For consent, Articles 16 and 22–24 and 32 apply *mutatis mutandis*.

² Non-genetic health-related personal data may be disclosed abroad for research purposes if the requirements specified in Article 6 of the Federal Act of 19 June 1992¹⁰ on Data Protection are met.

Art. 43 Storage

¹ Anyone who stores biological material or health-related personal data for research purposes must take appropriate technical and organisational measures to prevent unauthorised use thereof, and fulfil the operational and professional requirements.

² The Federal Council shall specify the requirements for storage.

Art. 44 Deceased persons, embryos and foetuses including stillbirths

Articles 41–43 apply *mutatis mutandis* to deceased persons, to embryos and foetuses including stillbirths and parts thereof, and to data collected in this connection.

Chapter 8 Authorisation, Notifications and Procedure

Art. 45 Mandatory authorisation

¹ Authorisation from the responsible ethics committee is required for:

- a. conducting a research project; or
- b. making further use of biological material or health-related personal data for research purposes in cases where consent has not been obtained or information on the right to dissent has not been provided (Art. 34).

¹⁰ SR 235.1

² Authorisation is granted if the ethical, legal and scientific requirements of this Act are met. The decision must be available within two months of submission of the application. The Federal Council may:

- a. specify shorter, risk-adapted maximum limits for processing periods;
- b. adjust the processing periods, if this is required by recognised international regulations.¹¹

³ The Federal Council may make changes to research projects subject to authorisation. In doing so, it shall have regard to recognised international regulations.

Art. 46 Notification and information requirements

¹ The Federal Council may specify notification or information requirements, in particular with regard to:

- a. the completion or discontinuation of a research project;
- b. adverse events observed in connection with a research project;
- c. the occurrence of circumstances during the conduct of a research project which could affect the safety or health of the participants.

² In doing so, it shall have regard to recognised international regulations.

Art. 47 Responsible ethics committee

¹ The responsible ethics committee is that of the canton in whose territory the research is conducted.

² If a research project is carried out according to a standard protocol, but in different cantons (multicentre research project), authorisation is required from the ethics committee which is responsible at the site of activity of the project coordinator (the lead committee).

³ In order to assess whether the professional and operational requirements are fulfilled in other cantons, the lead committee shall seek the opinion of the ethics committees concerned. It shall be bound by their opinion.

⁴ Paragraphs 2 and 3 apply *mutatis mutandis* to authorisation for the use in accordance with Article 34 of biological material and health-related personal data of which further use is made or which are collected according to a standard protocol, but in different cantons.

Art. 48 Official measures

¹ If the safety or health of the persons concerned is at risk, the ethics committee may revoke or suspend its authorisation or make the continuation of the research project subject to additional conditions.

¹¹ Amended by Annex of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

² The ethics committee may request information or documentation from the holder of the authorisation. This must be provided or made available free of charge.

³ The competent federal and cantonal authorities retain the right to take measures.

⁴ The authorities and ethics committees shall keep each other informed and coordinate their measures.

Art. 49 Procedure

¹ The documents for the authorisation and notification procedures, and for reporting and supervision, shall be submitted to the cantonal information system referred to in Article 56a.¹²

^{1bis} The Federal Council shall specify requirements for the procedure so as to ensure consistent enforcement and the implementation of national and international regulations. It may stipulate that the submission of applications, correspondence and the publication of decisions must be effected electronically.¹³

² In particular for research projects involving biological material and genetic data in accordance with Article 32, or non-genetic health-related personal data in accordance with Article 33, it may specify less stringent procedural requirements.

³ Cantonal procedural law otherwise applies.

Art. 50 Right of appeal

¹ The procedure for appeals against ethics committee decisions is governed by cantonal procedural law and the general provisions concerning the administration of federal justice.

² The appealing party may not file an appeal based on substantive inappropriateness.

Chapter 9 Research Ethics Committees

Art. 51 Duties

¹ Within the framework of their responsibilities under Chapter 8, ethics committees shall assess whether research projects and the conduct thereof comply with the ethical, legal and scientific requirements of this Act. In particular, they shall assess whether the protection of the persons concerned is guaranteed.

² They may advise researchers in particular on ethical questions and, if so requested by the researchers, comment on research projects not subject to this Act, and specifically projects carried out abroad.

¹² Amended by Annex of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

¹³ Inserted by Annex of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

Art. 52 Independence

¹ Ethics committees shall exercise their duties in a professionally independent manner, without being subject to instructions from the supervisory authority in this regard.

² The members of ethics committees shall disclose their interests. Each ethics committee shall maintain a publicly accessible register of interests.

³ Members who are interested parties shall not participate in the assessment and decision procedures.

Art. 53 Composition

¹ Ethics committees must be composed in such a way that they have the professional skills and experience required to discharge their duties. The members must include:

- a. experts in various disciplines, in particular medicine, ethics and law; and
- b. at least one person representing patients.¹⁴

² Ethics committees may call in external specialists to serve as experts.

³ The Federal Council shall enact additional regulations concerning the composition of ethics committees and the requirements to be fulfilled by their members. In doing so, it shall have regard to recognised international regulations.

Art. 54 Organisation and financing

¹ Each canton shall designate the ethics committee responsible for its territory and appoint the members thereof. It shall oversee the activities of the ethics committee.

² Each canton has at most one ethics committee. Several cantons may appoint a joint ethics committee or agree that one canton's ethics committee is also to be responsible for other cantons.

³ The Federal Council may issue guidelines concerning the minimum number of research projects to be assessed by an ethics committee per year. It shall first consult the cantons.

⁴ Each ethics committee shall have a scientific secretariat. Details of the organisation and working methods are to be publicly accessible in by-laws.

⁵ The canton shall assure the financing of the ethics committee. It may make provision for the charging of fees.

Art. 55 Coordination and information

¹ The Federal Office of Public Health (FOPH) is responsible for coordination between ethics committees and with other supervisory authorities. It may delegate this responsibility to third parties.

¹⁴ Amended by Annex of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

² Ethics committees shall report annually to the FOPH on their activities, in particular on the type and number of research projects assessed and on the processing periods.

³ The FOPH shall publish a list of ethics committees and inform the public regularly about their activities.

⁴ In consultation with the ethics committees and other supervisory authorities concerned, it may issue recommendations for appropriate harmonisation of procedures and of assessment practice.

Chapter 10 Transparency and Data Protection

Art. 56 Registration

¹ Authorised clinical trials must be recorded in a public registry. The Federal Council shall define the clinical trials in more detail and may specify exemptions from mandatory registration; in doing so, it shall be guided by recognised international regulations.¹⁵

² It shall designate the registry, provide information on access thereto and specify the content of registration, as well as notification requirements and the notification procedure. In doing so, it shall have regard to recognised international regulations and if possible take existing registries into consideration.

³ It may:

- a. entrust public- or private-law organisations with the establishment and management of the registry;
- b.¹⁶ specify that the results of registered research projects must be published on a recognised platform.

Art. 56a¹⁷ Cantonal information system

¹ The cantons shall operate a shared information system for the conduct of authorisation and notification procedures, the transmission of reports and the supervision of research projects.

² The system shall contain data, including personal data on administrative or criminal proceedings and sanctions or on health, which is necessary for the conduct of authorisation and notification procedures and for reporting and supervision in accordance with this Act.

¹⁵ Second sentence amended by Annex of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

¹⁶ Amended by Annex of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

¹⁷ Inserted by Annex of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

³ The cantons shall ensure that the information system is compatible with the Medical Devices Information System of the Swiss Agency for Therapeutic Products and with the European database on medical devices (Eudamed).

⁴ The Federal Council may specify that:

- a. the data referred to in paragraph 2 concerning clinical trials with medical devices is to be automatically aligned with the Medical Devices Information System of the Swiss Agency for Therapeutic Products or with Eudamed;
- b. any data referred to in paragraph 2 which is not sensitive is to be published with due protection of professional confidentiality and trade secrets.

Art. 57 Duty of confidentiality

Persons responsible for the enforcement of this Act have a duty to maintain confidentiality.

Art. 58 Processing of personal data

In discharging their duties, ethics committees and the other enforcement bodies are entitled to process personal data. Sensitive personal data may be processed, insofar as this is necessary.

Art. 59 Disclosure of data

¹ Where no conflicting private interest of overriding importance exists, data may be disclosed to:

- a. the federal and cantonal agencies responsible for enforcement of this Act, and to public- or private-law organisations and persons if they require the data to fulfil the duties assigned to them under this Act;
- b. criminal investigation authorities if the data is required to prosecute or prevent a felony or an offence under this Act.

² Where no conflicting private interest of overriding importance exists, data may, in individual cases, following a written request, be disclosed to:

- a. civil courts if the data is required to judge a court case;
- b. criminal courts and criminal investigation authorities if the data is required to investigate a felony or misdemeanour.

³ Data which is of general interest and relates to the application of this Act may be published. The data subjects must not be identifiable.

⁴ In other cases, data may be disclosed to third parties as follows:

- a. data not relating to specific persons, provided that there is an overriding interest in this data being made available;
- b. personal data, provided that the data subject has given written consent in each case.

⁵ Only the data which is required for the purpose in question may be disclosed.

⁶ The Federal Council shall regulate the details of the disclosure of data and the notification of the persons concerned.

Art. 60 Transmission of data to foreign authorities and international organisations

¹ Confidential data may only be transmitted to foreign authorities and institutions or to international organisations if:

- a. this is required by agreements under international law or resolutions passed by international organisations;
- b. this is necessary to avert an imminent danger to life or health; or
- c. this would enable serious offences under this Act to be exposed.

² The Federal Council shall regulate responsibilities and the procedures for exchanging data with foreign authorities and institutions and with international organisations.

Art. 61 Evaluation

¹ The FOPH is responsible for assessing the effectiveness of this Act.

² The Federal Department of Home Affairs shall report to the Federal Council on the results of the evaluation and submit proposals for further action.

Chapter 11 Criminal Provisions

Art. 62 Misdemeanours

¹ Unless a more serious offence has been committed under the Criminal Code¹⁸, any person who wilfully:

- a. conducts a research project without the authorisation of an ethics committee or deviating from an authorised protocol (Art. 45) and thereby endangers the health of the participants;
- b. conducts a research project as defined in Chapter 2, 3, 5 or 6 without obtaining the consent required under this Act (Arts. 16, 17, 18 para. 3, Art. 22 paras. 1, 3 let. a and 4, Arts. 23, 24, 26, 28, 30, 36 paras. 1 and 2, 39 para. 1, 40);
- c.¹⁹ offers, grants, demands or accepts payment or any other non-cash advantage in exchange for the human body or parts thereof as such;
- c^{bis}.²⁰ uses the human body or parts thereof if they have been subject to a prohibited act as specified in letter c;

¹⁸ SR 311.0

¹⁹ Amended by Annex No 2 of the FD of 19 June 2020 on the Approval of the Council of Europe Convention against Trafficking in Human Organs and on its Implementation, in force since 1 Feb. 2021 (AS 2020 6567; BBl 2019 5971).

- d. conducts a research project designed to modify properties of the embryo or foetus for non-disease-related reasons (Art. 25);
- e. uses embryos or foetuses from induced or spontaneous abortions for a research project before death has been determined (Art. 39 para. 3, Art. 40 para. 2)

shall be liable to a custodial sentence not exceeding three years or to a monetary penalty.

² If the act is committed for commercial gain, the penalty shall be a custodial sentence not exceeding three years; this shall be combined with a monetary penalty.

³ If the act is committed through negligence, the penalty shall be a monetary penalty not exceeding 180 daily penalty units.

Art. 63 Contraventions

¹ Any person who wilfully or negligently:

- a. commits an offence as specified in Article 62 paragraph 1 letter a without the participants' health being endangered;
- b. makes a payment or provides any other non-cash advantage to a person for participation in a research project with an expected direct benefit, or demands or accepts payment or any other non-cash advantage from a person for participation in a research project (Art. 14);
- c. makes further use of biological material or health-related personal data without the informed consent required under this Act (Arts. 32, 33), in cases where the conditions specified in Article 34 are not met and appropriate authorisation has not been obtained from the responsible ethics committee;
- d. transfers biological material or health-related personal data for non-research-related purposes in the absence of a legal basis or without the requisite consent (Art. 41)

shall be liable to a fine.

² A contravention and the penalty for a contravention become time-barred after five years.

Art. 64 Jurisdiction and administrative criminal law

¹ The cantons have jurisdiction for the prosecution and judgment of offences.

² Articles 6, 7 (offences committed within a business) and 15 (forgery of documents, obtaining a false certificate by fraud) of the Federal Act of 22 March 1974²¹ on Administrative Criminal Law apply.

²⁰ Inserted by Annex No 2 of the FD of 19 June 2020 on the Approval of the Council of Europe Convention against Trafficking in Human Organs and on its Implementation, in force since 1 Feb. 2021 (AS 2020 6567; BBl 2019 5971).

²¹ SR 313.0

³ The competent authorities shall inform the FOPH of all judgments passed in accordance with Article 62 paragraph 1 letters b–c^{bis} or Article 63 paragraph 1 letter c on account of an offence involving the human body or parts thereof.²²

Chapter 12 Final Provisions

Art. 65 Implementing provisions

¹ The Federal Council shall enact the implementing provisions.

² In doing so, it shall consider the different extents to which individual research areas and methods involve risks to dignity and privacy, in particular when specifying:

- a. the scientific requirements (Art. 10);
- b. any exemptions from liability (Art. 19) and liability coverage requirements (Art. 20);
- c. the requirements for insurance and other forms of coverage (Art. 20);
- d. the procedural requirements (Art. 49).

Art. 66 Amendment of current legislation

Current legislation shall be amended as specified in the Annex.

Art. 67 Transitional provisions

¹ Authorisations granted by cantonal ethics committees for the conduct of research projects remain valid for the term of the authorisation.

² If no authorisation, as defined in paragraph 1, has been granted for a research project which is already under way when this Act comes into effect, an application for authorisation in accordance with Article 45 paragraph 1 letter a shall be submitted to the responsible ethics committee within six months after the commencement of this Act.

³ Authorisations for the waiver of professional confidentiality in medical research remain valid for the term of the authorisation. If the authorisation has been granted for an unlimited term, an application for authorisation in accordance with Article 45 paragraph 1 shall be submitted to the responsible ethics committee within a year of the commencement of this Act.

⁴ The Federal Council shall regulate the registration under Article 56 of research projects which are in progress when this Act comes into force.

²² Inserted by Annex No 2 of the FD of 19 June 2020 on the Approval of the Council of Europe Convention against Trafficking in Human Organs and on its Implementation, in force since 1 Feb. 2021 (AS 2020 6567; BBl 2019 5971).

Art. 68 Referendum and commencement

¹ This Act is subject to an optional referendum.

² The Federal Council shall determine the commencement date.

Commencement Date: 1 January 2014²³

²³ FCD of 20 Sept. 2013.

Annex
(Art. 66)

Amendment of current legislation

The federal acts below are amended as follows:

...²⁴

²⁴ The amendments may be consulted under AS **2013** 3215.

