# 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 118*b* paragraph 1 of the Federal Constitution[1],
and having considered the Dispatch of the Federal Council dated 21 October 2009[2],
*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 2003[3];

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. 9**[5] 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.