ETHICAL, LEGAL AND PROFESSIONAL COMPLIANCE LIST FOR HUMAN RESEARCH BIOBANKS APPLICABLE IN SWITZERLAND

STATUS AS OF 1 MARCH 2018

1)
LEGAL STANDARDS

A) INTERNATIONAL

- UNESCO, Universal Declaration on the Human Genome and Human Rights of 11 November 1997 [→]
- UNESCO, International Declaration on Human Genetic Data of 16 October 2003 [→]
- UNESCO, Universal Declaration on Bioethics and Human Rights of 19 October 2005 [→]

B) EUROPEAN

COUNCIL OF EUROPE

- European Convention on Human Rights of 4 November 1950, RS 0.101 [→]
- Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of 4 April 1997, Oviedo, RS 0.810.2 [→]
- Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research of 25 January 2005, Strasbourg [→]
- Recommendation CM/Rec(2016)6 of the Committee of Ministers to Member States on research on biological materials of human origin of 11 May 2016 [→]

EUROPEAN UNION

- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [→]
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), applicable from 25 May 2018 [→]

- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use [→]

- Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products [→]

- Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, the entry into application is currently estimated to occur in 2019 [→]

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [→]

C)
NATIONAL (SWITZERLAND)

- Federal Constitution of the Swiss Confederation (Cst) of 18 April 1999, RS 101 (in particular, art. 118b Cst and fundamental rights) [→]

- Swiss Civil Code (CC) of 10 December 1907, RS 210 (in particular, personality rights, art. 27 et seq. CC) [→]

- Federal Act on the Amendment of the Swiss Civil Code (Part Five: The Code of Obligations) of 30 March 1911, RS 220 [→]

- Swiss Criminal Code of 21 December 1937, RS 311.0 [→]

- Federal Act on Research involving Human Beings (Human Research Act, HRA) of 30 September 2011, RS 810.30 [→]

- Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO) of 20 September 2013, RS 810.301 [→]

- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance; ClinO) of 20 September 2013, RS 810.305 [→]

- Ordinance on Organisational Aspects of the Human Research Act (HRA Organisation Ordinance, OrgO-HRA) of 20 September 2013, RS 810.308 [→]

- Federal Act on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA) of 19 December 2003, RS 810.31 [→]

- Federal Act on Medically Assisted Reproduction (Reproductive Medicine Act, RMA) of 18 December 1998, RS 810.11 [→]

- Federal Act on Data Protection (FADP) of 19 June 1992, RS 235.1 (in a total revision) [→]

- Ordinance to the Federal Act on Data Protection of 14 June 1993, RS 235.11 [→]

- Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 15 December 2000, RS 812.21 [→]

- Ordinance on Good Laboratory Practice (OGLP) of 18 May 2005, RS 813.112.1 [→]

D)
CANTONAL

- Cantonal health laws need to be taken into consideration by human research biobanks to the extent they designate competent authorities and establish procedures on various aspects in the governance of biobanks.

II)
ETHICAL STANDARDS

- World Medical Association (WMA), Declaration of Helsinki – Ethical principles for medical research involving human subjects (amended in October 2013, adopted in June 1964) [→]
- World Medical Association (WMA), Declaration of Taipei on Ethical considerations regarding health databases and biobanks (revised in October 2016, adopted in 2002) [→]
- ICH International Conference on Harmonization – Integrated Addendum to ICH E6 (R1): Guidelines for Good Clinical Practice E6 (R2), November 2016 [→]
- Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Health-related Research Involving Humans, 2016 [→]

III)
PROFESSIONAL STANDARDS

- OECD Best practice guidelines for biological resource centres (BRCs), 2007
- OECD Guidelines on Human Biobanks and Genetic Research Databases, 2009
- OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data, 2013
- International Society for Biological and Environmental Repositories (ISBER), Best Practices: Recommendations for Repositories, Fourth Edition 2018
- International Agency for research on Cancer (IARC), Common minimum technical standards and protocols for biobanks dedicated to cancer research, 2017
- National Cancer Institute (NCI), United States, NCI Best Practices for Biospecimen Resources, March 2016
- French Standard, NF S 96-900, Quality of biological resource centres (BRCs), Management system of a BRC and quality of biological resources from human or micro-organism origin, September 2011