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

Status as of 11 July 2025

HUMAN BIOLOGICAL RESOURCES

I. Legal standards

A. INTERNATIONAL

- UNESCO, Universal Declaration on the Human Genome and Human Rights of 11 November 1997
  https://www.unesco.org/en/legal-affairs/universal-declaration-human-genome-and-human-rights?hub=387
- UNESCO, International Declaration on Human Genetic Data of 16 October 2003
  https://www.unesco.org/en/legal-affairs/international-declaration-human-genetic-data
- UNESCO, Universal Declaration on Bioethics and Human Rights of 20 October 2005
  https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights

B. EUROPEAN

COUNCIL OF EUROPE

- European Convention on Human Rights of 4 November 1950, RS 0.101
  https://www.echr.coe.int/documents/d/echr/convention_ENG
- 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
  https://rm.coe.int/168007cf98
- Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research of 25 January 2005, Strasbourg
  https://rm.coe.int/168008371a
- 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
  https://www.ejprarediseases.org/wp-content/uploads/2021/10/CoE.-CM-Rec-20166-research-on-biological-material.pdf

EUROPEAN UNION

- 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 pf personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
  https://eur-lex.europa.eu/eli/reg/2016/679/oj/eng
- 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
  https://eur-lex.europa.eu/eli/reg/2014/536/oj/eng
- 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
  https://eur-lex.europa.eu/eli/dir/2005/28/oj/eng
- 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 , applicable since 31 January 2022.
  https://eur-lex.europa.eu/eli/reg/2014/536/oj/eng
- 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 (will be repealed by Regulation (EU) 2024/1938 starting 6 August 2027).
  https://eur-lex.europa.eu/eli/dir/2004/23/oj/eng
- Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application.
  https://eur-lex.europa.eu/eli/reg/2024/1938/oj/eng

C. NATIONAL (SWITZERLAND)

- Federal Constitution of the Swiss Confederation (Cst.) of 18 April 1999, RS 101 (in particular art. 118b Cst. and fundamental rights) *(Status as of 3 March 2024)*
  https://www.fedlex.admin.ch/eli/cc/1999/404/en
- Swiss Civil Code (CC) of 10 December 1907, RS 210 (in particular personality rights, art. 27 et seq. CC) *(Status as of 1 January 2025)*
  https://www.fedlex.admin.ch/eli/cc/54/757_781_799/en

- Federal Act on the Amendment of the Swiss Civil Code (Part Five: The Code of Obligations) of 30 March 1911, RS 220 *(Status as of 8 July 2025)*
  https://www.fedlex.admin.ch/eli/cc/54/757_781_799/en
- Swiss Criminal Code of 21 December 1937, RS 311.0 *(Status as of 8 July 2025)*
  https://www.fedlex.admin.ch/eli/cc/54/757_781_799/en
- Federal Act on Research involving Human Beings (Human Research Act, HRA) of 30 September 2011, RS 810.30 *(Status as of 1 of September 2023)*
  https://www.fedlex.admin.ch/eli/cc/54/757_781_799/en
- Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO) of 20 September 2013, RS 810.301 *(Status as of 1 November 2024)*
  https://www.fedlex.admin.ch/eli/cc/54/757_781_799/en
- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO) of 20 September 2013, RS 810.305 *(Status as of 20 May 2025)*
  https://www.fedlex.admin.ch/eli/cc/2013/643/en
- Ordinance on Clinical Trials with Medical Devices (ClinO-MD) of 1 July 2020, RS 810.306 *(Status as of 20 May 2025)*
  https://www.fedlex.admin.ch/eli/cc/2020/553/en
- Ordinance on Organisational Aspects of the Human Research Act (HRA Organisation Ordinance, OrgO-HRA) of 20 September 2013, RS 810.308 *(Status as of 1 November 2024)*
  https://www.fedlex.admin.ch/eli/cc/2013/644/en
- Federal Act on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA) of 19 December 2003, RS 810.31 *(Status as of 1 July 2023)*
  https://www.fedlex.admin.ch/eli/cc/2005/104/en
- Federal Act on Medically Assisted Reproduction (Reproductive Medicine Act, RMA) of 18 December 1998, RS 810.11 *(Status as of 1 July 2023)*
  https://www.fedlex.admin.ch/eli/cc/2000/554/en
- Federal Act on Data Protection (FADP) of 25 September 2020, RS 235.1 *(Status as of 7 July 2025)*
  https://www.fedlex.admin.ch/eli/cc/2022/491/en
- Ordinance to the Federal Act on Data Protection (DPO) of 31 August 2022, RS 235.11 *(Status as of 1 April 2025)*
  https://www.fedlex.admin.ch/eli/cc/2022/568/en
- Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 15 December 2000, RS 812.21 *(Status as of 1 January 2025)*
  https://www.fedlex.admin.ch/eli/cc/2001/422/en
- Ordinance on Good Laboratory Practice (OGLP) of 18 May 2005, RS 813.112.1 *(Status as of 1 December 2012)*
  https://www.fedlex.admin.ch/eli/cc/2005/467/en

D. CANTONAL

- Cantonal health laws need to be taken into consideration by human research biobanks to the extend 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 2024, adopted in June 1964)
  https://www.wma.net/policies-post/wma-declaration-of-helsinki/
- World medical association (WMA), Declaration of Taipei on Ethical considerations regarding health databases and biobanks (revised in October 2016, adopted in 2002)
  https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/
- ICH International Conference on Harmonization – Integrated Addendum to ICH E6 (R1): Guidelines for Good Clinical Practice E6 (R2), November 2016
  https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
- Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Health-related Research Involving Humans, 2016
  https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
- Council for International Organizations of Medical Sciences (CIOMS), International guidelines on good governance practice for research institutions, 2023
  https://cioms.ch/publications/product/international-guidelines-on-good-governance-practice-for-research-institutions
- World Health Organization (WHO), Handbook for Good Clinical Research Practice, 2005
  https://iris.who.int/handle/10665/43392

III. Professional standards

- OECD Best practice guidelines for biological resource centres (BRCs), 2007
  https://www.oecd.org/en/publications/oecd-best-practice-guidelines-for-biological-resource-centres_9789264128767-en.html
- OECD Guidelines on Human Biobanks and Genetic Research Databases, 2009
  https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0375
- OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data, 2013
  https://www.oecd.org/en/publications/oecd-guidelines-on-the-protection-of-privacy-and-trans-border-flows-of-personal-data_9789264196391-en.html
- International Society for Biological and Environmental Repositories (ISBER), Best Practices: Recommendations for repositories, Fifth Edition 2023
  https://www.isber.org/page/BPR
- International Agency for research on Cancer (IARC), Common minimum technical standards and protocols for biobanks dedicated to cancer research, 2017
  https://publications.iarc.who.int/Book-And-Report-Series/Iarc-Technical-Publications/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
  https://dctd.cancer.gov/data-tools-biospecimens/biospecimens-biobanks/resources/best-practices
- All European Academies (ALLEA), European Academies – Science Advisory Council (EASAC) and Federation of European Academies of Medicine (FEAM) joint initiative, International Sharing of Personal Health Data for Research, 2021.
  https://allea.org/portfolio-item/international-sharing-of-personal-health-data-for-research/
- Global Alliance for Genomics and Health , International Code of Conduct for genomic and health-related data sharing, 2014.
  https://pmc.ncbi.nlm.nih.gov/articles/PMC4685157/
- International Organization for Standardization (ISO):
  Restricted, paid-access documents: *https://www.iso.org/store.html*
  - **ISO 20387** Biotechnology – Biobanking – General requirements for biobanking — 2018.
  - **ISO 22758** Biotechnology – Biobanking – Implementation guide for ISO 20387 — 2020.
  - **ISO 21899** Biotechnology – Biobanking – General requirements for the validation and verification of processing methods for biological material in biobanks. — 2020.
  - **ISO 21709** Biotechology – Biobanking – Process and quality requirements for establishment, maintenance and characterization of mammalian cell lines — 2020.
  - **ISO 18162** Biotechology – Biobanking – Requirements for human neural stem cells derived from pluripotent stem cells — 2024.
  - **ISO 22859** Biotechnology – Biobanking – Requirements for human mesenchymal stromal cells derived from umbilical cord tissue — 2022.
  - **ISO 24603** Biotechnology – Biobanking – Requirements for human and mouse pluripotent stem cells — 2022.
  - **ISO 24651** Biotechnology – Biobanking – Requirements for human mesenchymal stromal cells derived from bone marrow — 2022.

NON-HUMAN BIOLOGICAL RESOURCES

I. Legal standards

A. INTERNATIONAL

- United Nations, Convention on Biological Diversity (CBD), ratified by Switzerland on 21st of November 1994.
  https://www.cbd.int/doc/legal/cbd-en.pdf
- Secretariat of the Convention on Biological Diversity:
  - Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2000.
    https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf
  - Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, 2010. ratified in May 2011 by Switzerland. entered into force 5 March 2018.
    https://bch.cbd.int/protocol/parties#tab=1
  - Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity, 2011.
    https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

B. EUROPEAN

EUROPEAN UNION

- Regulation (EU) 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.
  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=oj:JOC_2021_013_R_0001
- Commission implementing Regulation 2015/1866 of 13 October 2015, laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices
  https://eur-lex.europa.eu/eli/reg_impl/2015/1866/oj/eng
- European Commission Guidance document 2021/C 13/01 on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union.
  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=oj:JOC_2021_013_R_0001

C. NATIONAL (SWITZERLAND)

- Animal Welfare Act (AniWA) of 16 December 2005, RS 455 *(Status as of 1 September 2023)*
  https://www.fedlex.admin.ch/eli/cc/2008/414/en
- Ordonnance sur la protection des animaux (OPAn) du 23 avril 2008, RS 455.1 *(Status as of 1 February 2025)*
  https://www.fedlex.admin.ch/eli/cc/2008/416/fr
- Federal Act on the Protection of Nature and Cultural Heritage (NCHA) of 1 July 1966, RS 451. *(Status as of 1 January 2022)*
  https://www.fedlex.admin.ch/eli/cc/1966/1637_1694_1679/en
- Ordinance on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (NagO) of 11 December 2015, RS 451.61. *(Status as of 1 January 2017)*
  https://www.fedlex.admin.ch/eli/cc/2016/39/en
- Ordinance on the Protection of Nature and Cultural Heritage (OPN) of 16 January 1991, RS 451.1 *(Status as of 1 June 2017)*
  https://www.fedlex.admin.ch/eli/cc/1991/249_249_249/en
- Federal Act on Controlling Communicable Human Diseases (Epidemics Act, EpidA) of 28 September 2012, RS 818.101. *(Status as of 1 July 2024)*
  https://www.fedlex.admin.ch/eli/cc/2015/297/en

- Ordonnance sur la lutte contre les maladies transmissibles de l'homme (Ordonnance sur les épidémies, OEp) du 29 avril 2015, RS 818.101.1 *(Status as of 1 July 2024)*
  https://www.fedlex.admin.ch/eli/cc/2015/298/fr?version=20240701&print=true
- Ordinance on Handling Organisms in Contained Systems (Containment Ordinance, ContainO) of 9 May 2012, RS 814.912. *(Status as of 1 September 2024)*
  https://www.fedlex.admin.ch/eli/cc/2012/329/fr
- Ordonnance sur la protection des travailleurs contre les risques liés aux microorganismes (OPTM) du 25 août 1999, RS 832.321 *(first and current version)*
  https://www.fedlex.admin.ch/eli/oc/1999/445/fr
- Tierseuchengesetz / Loi sur les épizooties of 1 July 1966, RS 916.40. *(Status as of 1 September 2023)*
  https://www.fedlex.admin.ch/eli/cc/1966/1565_1621_1604/fr
- Verordnung über den Schutz von Pflanzen vor besonders gefährlichen Schadorganismen / Ordonnance sur la protection des végétaux contre les organismes nuisibles particulièrement dangereux of 31 October 2018, RS 916.20. *(first and current version)*
  https://www.fedlex.admin.ch/eli/oc/2022/756/fr
- Bundesgesetz über den Schutz von Pflanzenzüchtungen / Loi fédérale sur la protection des obtentions végétales of 20 March 1975, RS 232.16 *(Status as of 1 January 2011)*
  https://www.fedlex.admin.ch/eli/cc/1977/862_862_862/fr
- Ordinance on Good Laboratory Practice (OGLP) of 18 May 2005, RS 813.112.1 *(Status as of 1 December 2012)*
  https://www.fedlex.admin.ch/eli/cc/2005/467/en

D. CANTONAL

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

II. Professional standards

- International Society for Biological and Environmental Repositories (ISBER), Best Practices: Recommendations for repositories, Fifth Edition 2023.
  https://www.isber.org/page/BPR
- World Health Organization, Laboratory biosafety manual, 2020.
  https://www.who.int/publications/i/item/9789240011311
- World Organisation for Animal Health (OiE), Terrestrial Animal Health Code, 2021. *(last edition in 2023)*
  https://www.woah.org/en/what-we-do/standards/codes-and-manuals/previous-editions-of-the-terrestrial-code/
- Food and Agriculture Organization of the United Nations (FAO), Animal Production and Health, Cryoconservation of animal genetic resources, 2012.
  https://www.fao.org/4/i3017e/i3017e00.pdf
- Food and Agriculture Organization of the United Nations (FAO), Genebank standards for plant Genetic Resources for Food and Agriculture, 2014.
  https://www.fao.org/4/i3704e/i3704e.pdf
- International Organization for Standardization (ISO):
  Restricted, paid-access documents: *https://www.iso.org/store.html*
  - **ISO 20387** Biotechnology – Biobanking – General requirements for biobanking — 2018
  - **ISO 21709** Biotechnology – Biobanking – Process and quality requirements for establishment, maintenance and characterization of mammalian cell lines — 2020
  - **ISO 21899** Biotechnology – Biobanking – General requirements for the validation and verification of processing methods for biological material in biobanks. — 2020
  - **ISO 22758** Biotechnology – Biobanking – Implementation guide for ISO 20387 — 2020.
  - **ISO 20388** Biotechnology – Biobanking – Requirements for animal biological material
  - **ISO 23105** Biotechnology – Biobanking – Requirements for the biobanking of plant biological material for research and development
  - **ISO 18209-1** Biotechnology – Biobanking of parasites — 2024
  - **ISO 24088-1** Biotechnology – Biobanking of microorganisms — 2022
  - **ISO 24603** Biotechnology – Biobanking – Requirements for human and mouse pluripotent stem cells — 2022