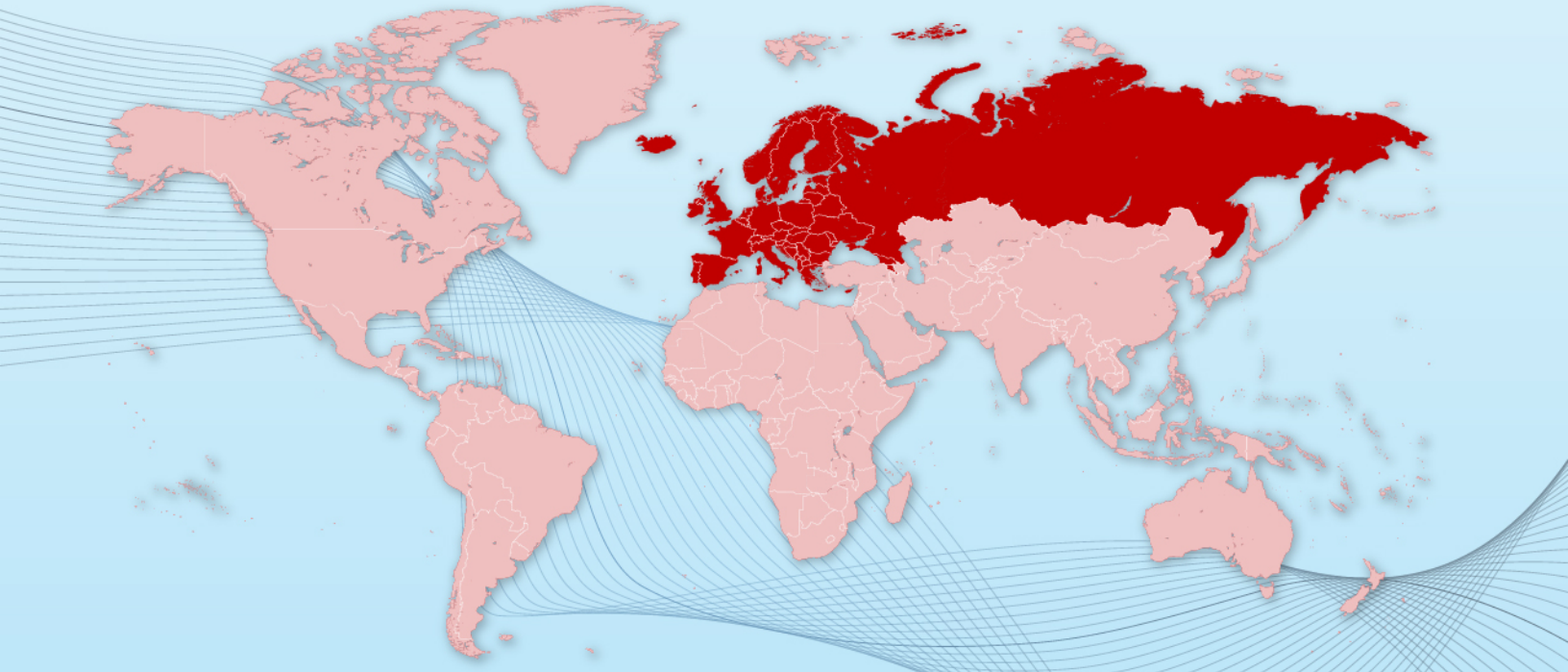
International Compilation of Human Research Standards
2021 Edition

Compiled By:
Office for Human Research Protections (OHRP)
Office of the Assistant Secretary for Health (OASH)
U.S. Department of Health and Human Services (HHS)

Europe



OASH | Office for Human Research Protections

EUROPE

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PURPOSE

The International Compilation of Human Research Standards enumerates over 1,000 laws, regulations, and guidelines (collectively referred to as "standards") that govern human subject protections in 131 countries, as well as standards from various international and regional organizations. First published in 2005, the Compilation is intended for use by researchers, IRBs/Research Ethics Committees, sponsors, and others who are involved in human subjects research protections around the world.

Collaborators from around the world, some who are acknowledged at the end of the Compilation, provided updates (or confirmations of prior listings), which are reflected in the hundreds of changes entered into this Edition. However, not all countries provided corroboration, so some of the information contain in this document may be outdated or incomplete (please see disclaimer below).

ORGANIZATION

This document only includes Europe. To access the complete International Compilation, please visit: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html. You may jump to a specific country by clicking its name in the Table of Contents.

This document is organized by world region in alphabetical order: Africa, Asia/Pacific, Europe, Latin America and the Caribbean, Middle East/North Africa, and North America. Under each region, you will find the countries organized also in alphabetical order. For each country, the information is then categorized as it relates to:

1. General, *i.e.*, applicable to most or all types of human subjects research
2. Drugs, Biologics, and Devices
3. Clinical Trial Registries
4. Research Injury
5. Social-Behavioral Research
6. Privacy/Data Protection
7. Human Biological Materials
8. Genetic
9. Embryos, Stem Cells, and Cloning

These nine categories often overlap, so it may be necessary to review other categories for a more complete understanding of a country's standards. The information under these nine categories is divided into Key Organizations and Relevant Standards. Key Organizations may include governmental and non-governmental organizations. Relevant Standards may include, laws, legislations, regulations, guidance, official opinions or positions, *etc*. Since the meaning of these terms often vary significantly by county, they all have been grouped together under Relevant Standards, regardless to whether they include mandatory requirements or voluntary guidelines.

Where possible, a link has been provided to specific Key Organizations and Relevant Standards. In many cases, the documents and webpages are available in English. When the URL links to a non-English website or document, an online language translator usually can render an English version. Many operating systems may also be able to translate a document or webpage. For example, in Chrome, you may be able to right click a document or page and select "translate to [your native language]."

TOPICS NOT COVERED

In order to focus its scope to human research protections, the International Compilation of Human Research Standards attempts to not include:

1. Standards from the state, provincial, or local levels
2. Enabling legislation, i.e., laws that authorize an agency to promulgate human subjects standards, but do not direct the content of those regulations
3. Laws, regulations, or guidelines that are disease-specific or focus on research integrity, clinical bioethics, product liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, or informed consent in clinical practice
4. Ethics codes of academic, medical, or other professional organizations – see the Ethics Codes Collection: http://ethics.iit.edu/ecodes/about
5. Working papers, drafts, commentaries, or discussion papers

NEW STANDARDS, UPDATES, AND BROKEN LINKS

To request inclusion of a new standard in the Compilation, or to provide updated information or report broken links, please contact OHRP-Edu@hhs.gov.

If you would like to provide information for a country not currently included in the Compilation, we would love to hear from you. Please contact us at OHRP-Edu@hhs.gov.

DISCLAIMER

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new standards are issued on a continuing basis, this Compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to human subject protections. The information contain in this Compilation may incomplete or outdated. While in-country persons have been requested to review listings to assure their accuracy and completeness, researchers and other individuals should check with local authorities and/or research ethics committees before commencing research activities.

TABLE OF CONTENTS

EUROPE – Regionwide

General

European Commission, European Group on Ethics in Science and New Technologies (EGE): https://ec.europa.eu/research/ege/index.cf m

European Commission, Directorate-General for Research and Innovation: https://ec.europa.eu/info/research-and-innovation_en

- European Commission, Research and Innovation, Law and Regulations: https://ec.europa.eu/info/research-and-innovation/law-and-regulations_en
- Ethical Aspects of Clinical Research inDeveloping Countries (2003): http://ec.europa.eu/bepa/european-group- ethics/docs/avis17_en.pdf
- Horizon 2020: How to Complete your Ethics Self –Assessment (2015): http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-msca-if-2015/1645175-h2020_-_guidance_ethics_self_assess_en.pdf

Council of Europe, Bioethics Unit: http://www.coe.int/bioethics

- Convention on Human Rightsand Biomedicine (Convention ofOviedo), Articles 15-18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG
- Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, CETS No.195 (2005): https://www.coe.int/en/web/conventions/
- Guide for research ethics committee members: https://www.coe.int/en/web/bioethics/guide-for-research-ethics-committees-members

Drugs, Biologics, and Devices

Drugs

European Commission, DG SANTE: Directorate-General for Health and Food Safety: http://ec.europa.eu/health/index_en.htm

- Directive 2001/20/EC 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: https://ec.europa.eu/health/human-use/clinical-trials/directive_en
- Directive 2005/28/EC Laying Down Principles and Detailed Guidelines for Good Clinical Practice as Regards Investigational Medicinal Products for Human Use, as Well as the Requirements for Authorization of the Manufacturing or Importation of Such Products: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32005L0028&qid=1634151900874&from=EN
- Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf
- Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the Detailed Arrangements for the Good Clinical Practice Inspection Procedures Pursuant to Regulation (EU) No. 536/2014 of the European Parliament and Council: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0556&from=EN

- EudraLex Volume 10: Clinical Trials: http://ec.europa.eu/health/documents/eudralex/vol-10/

European Medicines Agency: http://www.ema.europa.eu/

- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997): https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/3cc1aen_en.pdf
- Reflection Paper on Ethical and GCP Aspects of Clinical Trials of Medicinal Products for Human Use Conducted Outside of the EU/EEA and Submitted in Marketing Authorization Applications to the EU Regulatory Authorities (2012): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/04/WC500125437.pdf
- Guideline for Good Clinical Practice E6(R2) (2016): http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf

Devices

European Commission, DG GROWTH: Internal Market, Industry, Entrepreneurship, SMEs: https://ec.europa.eu/growth/sectors/medical-devices_en

- Directive 93/42/EEC Concerning Medical Devices: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF
- Directive 98/79/EC on in vitro Diagnostic Medical Devices (IVD): https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en
- Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 Amending Council Directive 90/385/EEC on Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007L0047&from=EN
- Various: http://ec.europa.eu/consumers/sectors/medical-devices/documents/guidelines/index_en.htm

Clinical Trial Registries

EU Clinical Trials Register: https://www.clinicaltrialsregister.eu/

- FAQs: https://www.clinicaltrialsregister.eu/doc/EU_CTR_FAQ.pdf

Research Injury

European Commission, DG SANTE: Directorate-General for Health and Food Safety: https://knowledge4policy.ec.europa.eu/organisation/dg-sante-dg-health-food-safety_en

- Clinical Trials Directive 2001/20/EC: https://ec.europa.eu/health/human-use/clinical-trials/directive_en
- Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: https://ec.europa.eu/health/human-use/clinical-trials/regulation_en

Council of Europe, Bioethics Unit: http://www.coe.int/bioethics

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG
- Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, Article 13, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG
- Council of Europe Committee on Bioethics Guide for research ethics committee members: https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000001680307e6c

Privacy/Data Protection

European Data Protection Board (EDPB): https://edpb.europa.eu/

- 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): http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN
- Guidelines on consent under Regulation 2016/679, WP259 rev.01: http://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051
- Transfers of Personal Data to Third Countries: Applying Articles 25 and 26 of the EU Data Protection Directive (1998): http://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/1998/wp12_en.pdf
- Working Document on Adequacy Referential (2018): https://ec.europa.eu/newsroom/article29/items/614108
- Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (2019): https://edpb.europa.eu/our-work-tools/our-documents/opinion-art-70/opinion-32019-concerning-questions-and-answers_en

European Medicines Agency (EMA): http://www.ema.europa.eu/

- European Medicines Agency policy on publication of clinical data for medicinal products for human use https://www.ema.europa.eu/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf
- Questions and Answers on the European Medicines Agency Policy on Publication of Clinical Data for Medicinal Products for Human Use (2015): http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/10/WC500174378.pdf
- External Guidance on the Implementation of the European Medicines Agency Policy on the Publication of Clinical Data for Medicinal Products for Human Use (2016): https://www.ema.europa.eu/documents/regulatory-procedural-guideline/external-guidance-implementation-european-medicines-agency-policy-publication-clinical-data_en-1.pdf

Council of Europe, Data Protection and Cybercrime Division:
http://www.coe.int/t/dghl/standardsetting/dataprotection/default_EN.asp

- Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981): http://conventions.coe.int/Treaty/Co mmun/QueVoulezVous.asp?NT=10 8&CL=ENG
- Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (2018): https://rm.coe.int/16808ac918
- Recommendation No. R (97) 5 on the Protection of Medical Data (1997): https://wcd.coe.int/ViewDoc.jsp?id=571075&S ite=CM&BackColorInternet=C3C3C3&BackC olorIntranet=EDB021&BackColorLogged=F5 D383
- Recommendation CM/Rec(2019)2 of the Committee of Ministers to member States on the protection of health-related data (2019): https://edoc.coe.int/en/international-law/7969-protection-of-health-related-date-recommendation-cmrec20192.html
- Article 29 Working Party Documentation: http://ec.europa.eu/justice/data- protection/article-29/index_en.htm

Human Biological Materials

European Commission, European Group on Ethics in Science and New Technologies: http://ec.europa.eu//research/ege/index.cfm

- Directive 2004/23/EC on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage, and Distribution of Human Tissues and Cells: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0023:EN:HTML
- Guidelines on Good Clinical Practice Specific to Advanced Therapy Medicinal Products: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/atmp_guidelines_en.pdf

Council of Europe, Bioethics Unit: http://www.coe.int/bioethics

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG
- Recommendation Rec (2016) 6 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff

Genetic Research

European Medicines Agency: http://www.ema.europa.eu/

- Regulation (EC) No. 1394/2007 on Advanced Therapy Medicinal Products and Amending Directive 2001/83/EC and Regulation (EC) No. 726/2004: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF

Council of Europe, Bioethics Unit: http://www.coe.int/bioethics

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG

- Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research, CETS No. 195 (2005): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG
- Recommendation No. R (92) on Genetic Testing and Screening for Health Care Purposes (1992): http://wcd.coe.int/ViewDoc.jsp?id=612007&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75
- Recommendation Rec (2006)4 of the Committee of Ministers to Members States on Research on Biological Materials of Human Origin (2016): https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff
- Recommendation Rec(2016)8 of the Committee of Ministers to Member States on the Processing of Personal Health-Related Data for Insurance Purposes, Including Data Resulting from Genetic Tests (2016): https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016806b2c5f

Embryos, Stem Cells, and Cloning

European Commission, European Group on Ethics in Science and New Technologies: http://ec.europa.eu//research/ege/index.cfm

- Statements by the Commission Re: Article 6 (2006): http://www.uv.es/operuv/docs_7pm/FP7ECStatementsComm_Ethical.pdf
- Statement of the Commission Related to Research Activities Involving Human Embryonic Stem Cells (2013): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF
- Commission Staff Working Paper Report on Human Embryonic Stem Cell Research (2003): https://ec.europa.eu/research/press/2003/pdf/sec2003-441report_en.pdf
- Opinion No. 22 - The Ethics Review of hESC FP7 Research Projects (2007): http://bookshop.europa.eu/ga/recommendations-on-the-ethical-review-of-hesc-fp7-research-projects-pbKAAJ07022/downloads/KA-AJ-07-022-EN-C/KAAJ07022ENC_002.pdf;pgid=y8dIS7GUWMdSR0EAlMEUUsWb0000dz-kvfzb;sid=Iexx3tq0IOFxyokBvtfvebiRJj93DZfXP54=?FileName=KAAJ07022ENC_002.pdf&SKU=KAAJ07022ENC_PDF&CatalogueNumber=KA-AJ-07-022-EN-C

Council of Europe, Bioethics Unit: http://www.coe.int/bioethics

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG
- Additional Protocol on Prohibition of Human Cloning, ETS No. 168 (1998): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=168&CM=7&DF=9/15/2008&CL=ENG
- Statement on Genome Editing Technologies by the Committee on Bioethics (2015): https://rm.coe.int/168049034a

EUROPE – Armenia

NOTE: For an overview of human subject protections in Armenia, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 1: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf

Drugs, Biologics, and Devices

Key Organizations

- Drug and Medical Technology Agency: http://www.pharm.am/
- Ethics Committee of the Ministry of Health
- Ethical Committee of the National Center for AIDS Prevention

Relevant Standards

- Law of the Republic of Armenia of May 4, 1996: About Medical Aid, The Maintenance of the Population, Article 21: http://www.arlis.am/DocumentView.aspx?DocID=71619
- Resolution of the Government of Armenia of January 24, 2002: Procedure for Clinical Trials of New Medications in Armenia: http://www.arlis.am/DocumentView.aspx?docID=9154
- RA Law on Prevention of Disease Caused by HIV (2012): http://www.arlis.am/DocumentView.aspx?DocID=78616
- Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2013)

EUROPE – Austria

General

Key Organization

- Ministry of Health: http://www.bmg.gv.at
- Forum of Austrian Ethics Committees: http://www.ethikkommissionen.at
- Bioethics Commission: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission.html

Relevant Standards

- University Act (2011): http://www.ris.bka.gv.at/Dokumente/Erv/ERV_2002_1_120/ERV_2002_1_120.pdf
- Hospitals Act (2014): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010285&ShowPrintPreview=True
- Regulation on Leading Ethics Committees (2004): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20003352&ShowPrintPreview=True
- Bioethics Commission, various publications: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Ministry of Health: http://www.bmg.gv.at
- Austrian Agency for Health and Food Safety: https://www.ages.at/en/ages/basics/
- Austrian Federal Office for Safety in Health Care: https://www.basg.gv.at/en/

Relevant Standards

- Austrian Drug Law (2013): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True
- Various: https://www.basg.gv.at/en/healthcare-professionals/clinical-trials

Devices

Key Organizations

- Ministry of Health: http://www.bmg.gv.at
- Austrian Agency for Health and Food Safety: https://www.ages.at/en/ages/basics/
- Austrian Federal Office for Safety in Health Care: https://www.basg.gv.at/en/

Relevant Standards

- Medical Devices Act (2014): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003
- Medical Devices, Various: http://www.basg.at/medizinprodukte/formulare/klinische-pruefung/

Research Injury

Key Organizations

- Austrian Agency for Health and Food Safety: https://www.ages.at/en/ages/basics/
- Austrian Federal Office for Safety in Health Care: https://www.basg.gv.at/en/

Relevant Standards

- Austrian Drug Law, Article 32 (2013): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441&ShowPrintPreview=True
- 2. Austrian Medical Devices Law, Article 47 (2017): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003&ShowPrintPreview=True

Privacy/Data Protection

NOTE: The Austrian states also have privacy/data protection laws.

Key Organizations

- Austrian Data Protection Authority: https://www.dsb.gv.at/DesktopDefault.aspx?alias=dsken

Relevant Standards

- Data Protection Act No. 165/1999: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10001597
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj

Human Biological Materials

Key Organizations

- Ministry of Health: http://www.bmg.gv.at
- Bioethics Commission: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission.html

Relevant Standards

- Law on Safety of Blood (2009): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011145&ShowPrintPreview=True
- Law on Quality and Safety of Human Tissue and Cells (2013): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005698&ShowPrintPreview=True
- Regulation on Tissue Banks (2014): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005848&ShowPrintPreview=True
- Bioethics Commission, various publications: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html

Genetic Research

Key Organizations

- Ministry of Health: http://www.bmg.gv.at
- Bioethics Commission: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission.html

Relevant Standards

- Gene Technology Act (2012): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826&ShowPrintPreview=True
- Bioethics Commission, various publications: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Health: http://www.bmg.gv.at
- Bioethics Commission: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission.html

Relevant Standards

- Reproductive Medicine Act (2010): http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10003046&ShowPrintPreview=True
- Bioethics Commission, various publications: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html

EUROPE – Belarus

NOTE: For an overview of human subject protections in Belarus, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 3: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf

General

Key Organization

- Ministry of Health (MOH): http://minzdrav.gov.by/en/
- National Bioethics Committee
- Center for examinations and tests in health service: https://www.rceth.by/en

Relevant Standards

- Constitution of the Republic of Belarus, Article 25 (2004): https://president.gov.by/en/gosudarstvo/constitution
- Law on Health Care System, Articles 40, 46 (2010): http://pravo.by/webnpa/text.asp?RN=v19302435
- Ordinance No. 274 on Establishing the National Bioethics Committee (2006)
- Decree No. No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/pravo/norm2009/num05/d05639.html
- Code of Medical Ethics (1999): http://www.levonevski.net/pravo/norm2009/num37/d37726.html
- Guidelines for Ethics Committees on Standard Operational Proceedings (No. 55-0004, 2000): http://www.levonevski.net/pravo/norm2009/num35/d35896/index.html
- Methodological Guidelines of Health Ministry (2000)

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Ministry of Health (MOH): http://minzdrav.gov.by/en/
- State Pharmacological Committee
- Center for examinations and tests in health service: https://www.rceth.by/en

Relevant Standards

- Law on Drugs, Articles 15,16 (2009)
- Law on Health Care System, Article 40 (2010): http://pravo.by/webnpa/text.asp?RN=v19302435

- Ordinance No. 254 on Clinical Drug Trials and Good Clinical Practice (1999): http://www.levonevski.net/pravo/norm2009/num36/d36922/index.html
- Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999): http://www.levonevski.net/pravo/norm2009/num37/d37336.html
- Decree No. 55 on Ethics Committees (2008): http://www.levonevski.net/pravo/norm2009/num05/d05639.html
- Decree No. 50 on Certain Aspects of Clinical Drug Trials (2009)
- Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004): http://www.levonevski.net/pravo/norm2009/num24/d24926.html

Devices

Key Organizations

- Ministry of Health (MOH): http://minzdrav.gov.by/en/
- Center for examinations and tests in health service: https://www.rceth.by/en

Relevant Standards

- Law on Health Care System, Article 40 (2010): http://pravo.by/webnpa/text.asp?RN=v19302435
- Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999): http://www.levonevski.net/pravo/norm2009/num37/d37336.html
- Decree No. 216 on Certain Aspects of Clinical Trials of Medical Devices (2008) (Russian)
- Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004): http://www.levonevski.net/pravo/norm2009/num24/d24926.html

Clinical Trial Registries

Key Organizations

- Center for examinations and tests in health service: https://www.rceth.by/en

Research Injury

Key Organizations

- Center for examinations and tests in health service: https://www.rceth.by/en
- Local Ethical Committees
- Insurance companies

Social-Behavioral Research

Key Organizations

- The Republican Scientific and Practical Center of Medical Technologies, Informatization, Management and Economics of Public Health (RSPC MT): https://belcmt.by/en

Privacy/Data Protection

Key Organizations

- Ministry of Health: http://minzdrav.gov.by/en/
- National Bioethics Committee
- Center for examinations and tests in health service: https://www.rceth.by/en

Relevant Standards

- Constitution of the Republic of Belarus, Article 28 (2004): https://president.gov.by/en/gosudarstvo/constitution
- Law on Health Care System, Article 46 (2010): http://pravo.by/webnpa/text.asp?RN=v19302435

Human Biological Materials

Key Organizations

- Ministry of Health (MOH): http://minzdrav.gov.by/en/
- National Bioethics Committee
- State Service of Forensic Medicine (SSFM)
- Center for examinations and tests in health service: https://www.rceth.by/en

Relevant Standards

- Law on Health Care System, Articles 40 and 46 (2010): http://pravo.by/webnpa/text.asp?RN=v19302435
- Ordinance No. 111 on Further Development of National Pathology Service (1993)
- Ordinance No. 38-c on Rules for Conducting Morphological Examinations (1999)

EUROPE – Belgium

NOTE: For an overview of human subject standards in Belgium, see The Ethics Committees: https://www.famhp.be/en/human_use/medicines/medicines/research_development/ethic_committee

General

Key Organization

- Federal Agency for Medicines and Health Products (FAMHP): https://www.famhp.be/en/human_use/medicines/medicines
- Belgian Advisory Committee on Bioethics (BACB): https://www.health.belgium.be/en/belgian-advisory-committee-bioethics

Relevant Standards

- Law Relating to Experimentation on Humans (2004): http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2004050732&table_name=loi
- Royal Decree Dated 4 April 2014 Determining the Measures for Carrying Out the Law Dated 7 May 2004 Relating to Experiments on Humans Regarding the Ethics Committee:

http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2014040446&table_name=loi

- Royal Decree Dated 30 June 2004 Determining the Measures for Carrying Out the Law Dated 7 May 2004 Relating to Experiments on Humans, Modified by the Royal Decree Dated 18 May 2006: http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2004063030&table_name=loi
- FAMHP, Various Circulars: https://www.famhp.be/en/human_use/medicines/medicines/research_development/ethic_committee
- BACB, various: https://www.health.belgium.be/en/list-opinions

Drugs, Biologics, and Devices

Key Organizations

- Federal Agency for Medicines and Health Products (FAMHP), Drugs: https://www.famhp.be/en/human_use/medicines/medicines/research_development/clinical_trials
- Federal Agency for Medicines and Health Products (FAMHP), Devices:
- https://www.famhp.be/en/human_use/health_products/medical_devices_accessories
- Belgian Advisory Committee on Bioethics (BACB): https://www.health.belgium.be/en/belgian-advisory-committee-bioethics
- Clinical Trial College: https://consultativebodies.health.belgium.be/en/advisory-and-consultative-bodies/ct-college-clinical-trial-college

Relevant Standards

- Law Relating to Experimentation on Humans (2004): http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2004050732&table_name=loi
- Royal Decrees to Experimentation on Humans: https://www.famhp.be/en/human_use/medicines/medicines/research_development/ethic_committee
- Royal Decrees on Clinical Trials: https://consultativebodies.health.belgium.be/en/advisory-and-consultative-bodies/ct-college-clinical-trial-college
- BACB, Opinion No. 58: Financing Expensive Medication: https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/opinion_58_web.pdf

Research Injury

Key Organizations

- Federal Agency for Medicines and Health Products (FAMHP): https://www.famhp.be/en/human_use/medicines/medicines

Relevant Standards

- Law Relating to Experimentation on Humans, Chapter XVII (Responsibility and Insurance) Article 29 (2004): https://www.famhp.be/en/human_use/medicines/medicines/research_development/ethic_committee

Privacy/Data Protection

Key Organizations

- Belgian Data Protection Authority: https://www.dataprotectionauthority.be/

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Act on the Protection of Natural Persons with Regard to the Processing of Personal Data (30 July 2018)
- Belgian Data Protection Authority, various publications: https://www.privacycommission.be/citoyen/publications/toutes-les-publications

Human Biological Materials

Key Organizations

- Federal Agency for Medicines and Health Products (FAMHP): https://www.famhp.be/en/human_use/medicines/medicines
- Belgian Advisory Committee on Bioethics (BACB): http://www.health.belgium.be/en
- Superior Health Council (CSS): http://www.health.belgium.be/eportal/Aboutus/relatedinstitutions/SuperiorHealthCouncil/index.htm

Relevant Standards

- Law Relating to the Use of Human Biological Materials (19 December 2008): https://www.afmps.be/fr/humain/produits_de_sante/materiel_corporel_humain/banques_de_materiel_corporel_humain/legislation/apres_le_01_12_2009
- Royal Decrees to the Use of Human Biological Materials: https://www.afmps.be/fr/humain/produits_de_sante/materiel_corporel_humain/banques_de_materiel_corporel_humain/legislation/apres_le_01_12_2009
- BACB, various: http://www.health.belgium.be/en/belgian-advisory-committee-bioethics
- CSS, various: https://www.health.belgium.be/en/superior-health-council?f%5B0%5D=field_shc_doc%3A1145

Embryos, Stem Cells, and Cloning

Key Organizations

- Federal Commission for Medical and Scientific Research on Embryos in Vitro: http://health.belgium.be/eportal/Healthcare/Consultativebodies/Commissions/Embryoinvitro/19076630?ie2Term=research&ie2section=83
- Federal Agency for Medicines and Health Products (FAMHP): https://www.famhp.be/en/human_use/medicines/medicines
- Belgian Advisory Committee on Bioethics: https://www.health.belgium.be/en/belgian-advisory-committee-bioethics

Relevant Standards

- Act on Research on Embryos in Vitro (2003): https://organesdeconcertation.sante.belgique.be/fr/organe-d'avis-et-de-concertation/commission-federale-embryons

- Law on Medically Assisted Reproduction and the Destination of Supernumerary Embryos and Gametes (2007): https://www.afmps.be/fr/humain/produits_de_sante/materiel_corporel_humain/banques_de_materiel_corporel_humain/legislation/apres_le_01_12_2009
- Royal Decree Fixing the Criteria for the Program Applicable to the Care Programs 'Reproductive Medicine' (15 February 1999): https://organesdeconcertation.sante.belgique.be/fr/organe-d'avis-et-de-concertation/commission-federale-embryons
- BACB, various: http://www.health.belgium.be/en/belgian-advisory-committee-bioethics

EUROPE – Bosnia and Herzegovina

General

Federation of Bosnia and Herzegovina

Key Organization

- Agency for drugs and medical devices of Bosnia and Herzegovina: http://www.almbih.gov.ba/
- Ministry of Health of Federation of Bosnia and Herzegovina: http://www.fmoh.gov.ba/

Relevant Standards

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (2007): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164
- Additional Protocol Concerning Biomedical Research, CETS No. 195 (2007)
- Law on Health Protection, MoH Republic of Srpska (2015): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20zdravstvenoj%20zastiti%20sa%20izmjenama%20106-99%20%2044-15.pdf
- Law on Health Protection, MoH Federation of Bosnia and Herzegovina, No. 46/10: http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-zdravstvenoj-zastiti
- Other documents: http://www.almbih.gov.ba/dokumenti/

Republic of Srpska

Key Organization

- Ministry of Health and Social Welfare of Republic of Srpska: https://www.vladars.net/eng/vlada/ministries/MHSW/Pages/default.aspx

Drugs, Biologics, and Devices

Federation of Bosnia and Herzegovina

Key Organizations

- Ministry of Health of Federation of Bosnia and Herzegovina: http://www.fmoh.gov.ba/
- Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/

Relevant Standards

- Law on Drugs No. 58/08: http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf

- Law on Changes and Amendments of the Law on Drugs No. 29/05: http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-zastiti-stanovnistva-od-zaraznih-bolesti
- Law on Drugs Federation of Bosnia and Herzegovina, No. 109/2012: http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-lijekovima-fbih
- Regulation about Clinical testing of IMP and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf
- Regulation about Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_ms_bos.pdf
- Standards of GCP in Conducting CTs (2012): http://www.almbih.gov.ba/_doc/regulative/Smjernice_dobre_klinicke_prakse-bo.pdf
- Instructions on Manner of Reporting on Safety in the Framework of Clinical Trials (2016): http://www.almbih.gov.ba/_doc/upustva-vodici/uputstvo_o_nacinu_izvjestavanja_o_sigurnosti.pdf
- Other regulations: http://www.almbih.gov.ba/dokumenti/regulative/
- Legislation at the state level: http://www.almbih.gov.ba/en/documents/regulations/

Republic of Srpska

Key Organizations

- Ministry of Health and Social Welfare of Republic of Srpska: https://www.vladars.net/eng/vlada/ministries/MHSW/Pages/default.aspx

Relevant Standards

- Law on Drugs No. 58/08: http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf
- Law on Changes and Amendments of Law on Drugs No. 34/08
- Regulation about Clinical testing of IMP and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf
- Regulation about Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_ms_bos.pdf
- Standards of GCP in Conducting CTs (2012): http://www.almbih.gov.ba/_doc/regulative/Smjernice_dobre_klinicke_prakse-bo.pdf
- Instructions on Manner of Reporting on Safety in the Framework of Clinical Trials (2016): http://www.almbih.gov.ba/_doc/upustva-vodici/uputstvo_o_nacinu_izvjestavanja_o_sigurnosti.pdf

Clinical Trial Registries

Key Organizations

- Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/

Relevant Standards

- Clinical trials: http://www.almbih.gov.ba/klinicka-ispitivanja/

Research Injury

Federation of Bosnia and Herzegovina

Key Organizations

- Medicines and Medical Devices Agency of Bosnia and Herzegovina: http://www.almbih.gov.ba/
- Ministry of Health of Federation of Bosnia and Herzegovina: http://www.fmoh.gov.ba/

Relevant Standards

- Medicinal Products and Medicinal Devices Act, Articles 52 and 116 (2008): http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf
- Law on Health Insurance of the Federation of Bosnia and Herzegovina, Official Gazette No. 46/10
- Regulation about Clinical Testing of IMP and Medical Devices, 4/10: http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf
- Legislation at the state level: http://www.almbih.gov.ba/en/documents/regulations/

Republic of Srpska

Key Organizations

- Ministry of Health and Social Welfare of Republic of Srpska: https://www.vladars.net/eng/vlada/ministries/MHSW/Pages/default.aspx

Relevant Standards

- Medicinal Products and Medicinal Devices Act, Article 52 and 116
- Law on Health Insurance of the Republic of Srpska, Official Gazette Republic of Srpska No. 106/09: http://www.farmaceutska-komora.org/images/stories/5Zakon_o_zdravstvenoj_zastiti.pdf
- Regulation about Clinical Testing of IMP and Medical Devices, 4/10: http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf

Social-Behavioral Research

Federation of Bosnia and Herzegovina

Key Organizations

- Institute for Public Health FBiH: https://www.zzjzfbih.ba/sluzba-za-socijalnu-medicinu-i-organizaciju-zdravstvene-djelatnosti/

Republic of Srpska

Key Organizations

- Institute for Public Health of the Republika Srpska: https://www.phi.rs.ba/index.php?view=clanak&id=24

Privacy/Data Protection

Key Organizations

- Institute for Public Health of the Republika Srpska: https://www.phi.rs.ba/index.php?view=clanak&id=24

Relevant Standards

- Law on the Protection of Personal Data in Bosnia and Herzegovina (2005): https://www.legislationline.org/download/id/5523/file/BiH_law_protection_secret_data_2005_amendments_2011_en.pdf
- Law on Amendments to the Law on the Protection of Personal Data in Bosnia and Herzegovina, Official Gazette of Bosnia and Herzegovina No. 76/11 (2011): https://www.legislationline.org/download/id/5523/file/BiH_law_protection_secret_data_2005_amendments_2011_en.pdf
- Regulation on the Manner of Keeping the Records of Personal Data Filing Systems and the Pertinent Records Form (2009)

Human Biological Materials

Federation of Bosnia and Herzegovina

Key Organizations

- Ministry of Health of Federation of Bosnia and Herzegovina: http://www.fmoh.gov.ba/

Relevant Standards

- https://www.fmoh.gov.ba/index.php/zakoni-i-strategije/lista-zakonskih-i-podzakonskih-akata

Republic of Srpska

Key Organizations

- Ministry of Health and Social Welfare of Republic of Srpska: https://www.vladars.net/eng/vlada/ministries/MHSW/Pages/default.aspx

Relevant Standards

- Health Protection Laws and Regulations: https://www.fmoh.gov.ba/index.php/zakoni-i-strategije/lista-zakonskih-i-podzakonskih-akata

Genetic Research

Federation of Bosnia and Herzegovina

Key Organizations

- Ministry of Health of Federation of Bosnia and Herzegovina: http://www.fmoh.gov.ba/

Relevant Standards

- https://www.fmoh.gov.ba/index.php/zakoni-i-strategije/lista-zakonskih-i-podzakonskih-akata

Republic of Srpska

Key Organizations

- Ministry of Health and Social Welfare of Republic of Srpska: https://www.vladars.net/eng/vlada/ministries/MHSW/Pages/default.aspx

Relevant Standards

- Health Protection Laws and Regulations: https://www.fmoh.gov.ba/index.php/zakoni-i-strategije/lista-zakonskih-i-podzakonskih-akata

Embryos, Stem Cells, and Cloning

Federation of Bosnia and Herzegovina

Key Organizations

- Ministry of Health of Federation of Bosnia and Herzegovina: http://www.fmoh.gov.ba/

Relevant Standards

- Law on Transplantation of Organs and Tissues, Official Gazette of Bosnia and Herzegovina No. 75/09: http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-transplantaciji-organa-i-tkiva-u-svrhu-lijecenja; https://www.fmoh.gov.ba/index.php/zakoni-i-strategije/zakoni/zakon-o-transplantaciji-organa-i-tkiva-u-svrhu-lijecenja
- Law on Blood and Blood Products, Official Gazette of Bosnia and Herzegovina No. 09/10: http://www.fbihvlada.gov.ba/bosanski/zakoni/2010/zakoni/8bos.htm

Republic of Srpska

Key Organizations

- Ministry of Health and Social Welfare of Republic of Srpska: https://www.vladars.net/eng/vlada/ministries/MHSW/Pages/default.aspx

Relevant Standards

- Law on Transplantation of Organs (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20transplantaciji%20ljudskih%20organa.pdf
- Law on Transplantation of Human Tissues and Cells (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20transplantaciji%20ljudskih%20tkiva%20i%20celija.pdf
- Rulebook about Testing Procedure for Donor of Transplant Organs in Terms of Diseases Which can be Transmitted by Transplantation (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/%d0%9f%d1%80%d0%b0%d0%b2%d0%b8%d0%bb%d0%bd%d0%b8%d0%ba_%d0%be_%d0%ba%d1%80%d0%b8%d1%82%d0%b5%d1%80%d0%b8%d1%98%d1%83%d0%bc%d0%b8%d0%bc%d0%b0_%d0%b7%d0%b0_%d1%82%d0%b5%d1%81%d1%82%d0%b8%d1%80%d0%b0%d1%9a%d0%b5_%d0%b4%d0%b0%d0%b2%d0%b0%d0%bb%d0%b0%d1%86%d0%b0_%d1%99%d1%83%d0%b4%d1%81%d0%ba%d0%b8%d1%85_%d0%be%d1%80%d0%b3%d0%b0%d0%bd%d0%b0_64_10.pdf
- Health Protection Laws and Regulations: https://www.fmoh.gov.ba/index.php/zakoni-i-strategije/lista-zakonskih-i-podzakonskih-akata

EUROPE – Bulgaria

General

Key Organization

- Ministry of Healthcare: http://www.mh.government.en/

Relevant Standards

- Constitution of the Republic of Bulgaria, Amendment SG. 18/25, Article 29 (2015): http://www.parliament.bg/bg/const

- Oviedo Convention on Human Rights and Biomedicine (2003): https://www.coe.int/en/web/bioethics/oviedo-convention
- Law Ratifying the Additional Protocol on Biomedical Research (2006): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf
- Medicinal Products in Human Medicine Act (2017): http://www.bda.bg/images/stories/documents/regulations/zakoni/ZLPHM_28122017.pdf
- Healthcare Act, Articles 197-206 (2018): http://www.mh.government.bg/media/filer_public/2018/02/27/zakon-za-zdraveto.pdf
- List of Laws: https://www.mh.government.bg/bg/normativni-aktove/zakoni/

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Ministry of Healthcare (MOH): http://www.mh.government.bg/
- Bulgarian Drug Agency (BDA): http://www.bda.bg/en/

Relevant Standards

- Medicinal Products in Human Medicine Act, Chapter 4 (2018): https://www.lex.bg/laws/ldoc/2135549536
- Regulation No. 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice (2012): http://www.bda.bg/images/stories/documents/regulations/naredbi/20180320_Naredda_31.pdf
- Medical Devices Act: https://www.bda.bg/images/stories/documents/legal_acts/20210208_ZMI_english.pdf
- Ordinance No. 10 (2008): https://www.bda.bg/images/stories/documents/legal_acts/Ordinance_Clinical_investigations_MD_EN.pdf

Devices

Key Organizations

- Bulgarian Drug Agency (BDA): http://www.bda.bg/en/

Relevant Standards

- Medical Devices Act (2016): http://www.bda.bg/images/stories/documents/legal_acts/ZMI_en_20160308.pdf
- Ordinance No. 10 (2008): http://www.bda.bg/images/stories/documents/legal_acts/Ordinance_Clinical_investigations_MD_EN.pdf
- Various: http://www.bda.bg/en/114-information-for-companies-section/medical-devices-category
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

- 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: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536&qid=1633444926711

Clinical Trial Registries

Key Organizations

- Bulgarian Drug Agency (BDA): http://www.bda.bg/en/

Relevant Standards

- Medical Products in Human Medicine Act: https://www.bda.bg/images/stories/documents/legal_acts/MEDICINAL%20PRODUCTS%20IN%20HUMAN%20MEDICINE%20ACT.pdf
- Ordinance No. 31 for Determining the Principles of Good Clinical Practice: https://www.bda.bg/images/stories/documents/regulations/naredbi/20210415/%D0%9D%D0%90%D0%A0%D0%95%D0%94%D0%91%D0%90%20%E2%84%96%2031%20%D0%9E%D0%A2%2012%20%D0%90%D0%92%D0%93%D0%A3%D0%A1%D0%A2%202007%20%D0%93.pdf

Research Injury

Key Organizations

- Bulgarian Drug Agency (BDA): http://www.bda.bg/en/

Relevant Standards

- Medicinal Products in Human Medicine Act, Chapter 4, Articles 91 and 92 (2016): http://www.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf
- Regulation 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice, Section 5.8 (2012) (Bulgarian): http://www.bda.bg/images/stories/documents/regulations/naredbi/20180320_Naredda_31.pdf
- Others: https://www.mh.government.bg/media/filer_public/2021/03/08/zakon_za_lekarstvenite_produkti_v_humannata_medicina.pdf
  https://www.bda.bg/images/stories/documents/regulations/naredbi/20210415/%D0%9D%D0%90%D0%A0%D0%95%D0%94%D0%91%D0%90%20%E2%84%96%2031%20%D0%9E%D0%A2%2012%20%D0%90%D0%92%D0%93%D0%A3%D0%A1%D0%A2%202007%20%D0%93.pdf

Privacy/Data Protection

Key Organizations

- Bulgarian Commission for Personal Data Protection: https://www.cpdp.bg/en/index.php?p=rubric&aid=2
- Ombudsman: www.ombudsman.bg

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Law for Protection of Personal Data (2018): https://www.cpdp.bg/en/index.php?p=element&aid=373

- General (2018): https://www.cpdp.bg/index.php?p=element&aid=1163
- Research (2018): https://www.cpdp.bg/en/index.php?p=element&aid=1162
- Consent (2018): https://www.cpdp.bg/en/index.php?p=element&aid=1162
- Personal Data Protection Act https://www.cpdp.bg/userfiles/file/ZZLD/ZZLD_26_11_2019_En.pdf
- Regulation (EU) 2016/679 https://eur-lex.europa.eu/eli/reg/2016/679/oj

Human Biological Materials

Key Organizations

- Executive Agency Medical Supervision: https://iamn.bg/en/home/

Relevant Standards

- Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf
- Act on Transplantation of Organs, Tissues and Cells https://iamn.bg/en/legislation/
- Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf
- Regulation No. 13 of 4 April 2007 for the Terms and Conditions of Informing Bulgarian Citizens on the Activities regarding the Transplantation of Organs, Tissues and Cells: http://www2.bgtransplant.bg/sites/default/files/docs/naredbi/Naredba_no13_ot_04_april_2007_g.rtf

Genetic Research

Key Organizations

- Ministry of Healthcare: http://www.mh.government.bg/

Relevant Standards

- Law on Health: https://www.mh.government.bg/media/filer_public/2021/03/08/zakon_za_zdraveto.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Healthcare: http://www.mh.government.bg/

Relevant Standards

- Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf

- Act on Transplantation of Organs, Tissues and Cells: https://iamn.bg/en/legislation/
- Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006): https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifitsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf

EUROPE – Croatia

General

Key Organization

- Central Ethics Committee: http://www.halmed.hr/en/O-HALMED-u/Sredisnje-eticko-povjerenstvo-SEP/
- Ministry of Health: https://zdravlje.gov.hr/
- Agency for Medicinal Products and Medical Devices: http://www.halmed.hr/

Relevant Standards

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 15-18, ETS No. 164 (1997): http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG
- Patient Protection Act, Article 20 (2008): http://www.zakon.hr/z/255/Zakon-o-za%C5%A1titi-prava-pacijenata

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Ministry of Health: https://zdravlje.gov.hr/
- Agency for Medicinal Products and Medical Devices: http://www.halmed.hr/

Relevant Standards

- Medicinal Product Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html
- Rule Book on Amendments to Medicinal Product Act (2014): http://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html
- Ordinance on Clinical Trials and Good Clinical Practice (2015): http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html
- Ordinance on Amendments to the Ordinance on Clinical Trials and Good Clinical Practice (2015): https://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html

Devices

Key Organizations

- Ministry of Health: https://zdravlje.gov.hr/
- Agency for Medicinal Products and Medical Devices: http://www.halmed.hr/

Relevant Standards

- Medical Devices Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1521.html
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745
- 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 (effective 31 January 2022): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536&qid=1633444926711

Clinical Trial Registries

Key Organizations

- Ministry of Health: https://zdravlje.gov.hr/
- Agency for Medicinal Products and Medical Devices: http://www.halmed.hr/

Relevant Standards

- Various: https://zdravlje.gov.hr/?id=1349&pregled=1&datum=Wed%20Mar%2013%202019%2014:46:45%20GMT+0100%20(Central%20European%20Standard%20Time)
- HALMED Front Page for Industry Representatives: https://www.halmed.hr/Predstavnici-industrije/

Research Injury

Key Organizations

- Agency for Medicinal Products and Medical Devices of Croatia: http://www.halmed.hr/
- Ministry of Health: https://zdravlje.gov.hr/
- Croatian Health Insurance Fund: http://www.hzzo.hr/en/

Relevant Standards

- Law on Mandatory Health Insurance (2013): http://www.hzzo.hr/wp-content/uploads/2013/10/ZOZO_PROCISCENI_TEKSTv2.pdf?6d8ad4
- Medicinal Product Act (2013): http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html
- Rule Book on Amendments to Medicinal Product Act (2014): http://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html
- Ordnance on Clinical Trials and Good Clinical Practice, Articles 11 and 16, Act 5.8., 6.8., and 8.2.5 (2015): http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html
- Various: https://zdravlje.gov.hr/arhiva-80/zakonodavstvo/zakoni-i-pravilnici/pravilnici/pravilnici-zakon-o-lijekovima/1061

Privacy/Data Protection

Key Organizations

- Croatian Personal Data Protection Agency: http://www.azop.hr/

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Implementation Act of the General Data Protection Act (NN 42/18) (2018): https://narodne-novine.nn.hr/clanci/sluzbeni/2018_05_42_805.html
- General (2018): http://azop.hr/info-servis/detaljnije/smjernice

Human Biological Materials

Key Organizations

- Ministry of Health: https://zdravlje.gov.hr/

Relevant Standards

- Law about Blood and Blood Products (2006): http://narodne-novine.nn.hr/clanci/sluzbeni/2006_07_79_1916.html
- Rule Book on Amendments to Law about Blood and Blood Products (2011): http://narodne-novine.nn.hr/clanci/sluzbeni/2011_11_124_2476.html
- Law on the Implementation of Human Tissues and Cells (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3070.html
- Law on Transplantation of Human Organs for the Purpose of Treatment (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3071.html
- Ordinance on the Conditions of Space, Professional Workers, Medical-Technical Equipment and Quality Assurance for Collection, Retrieval, Testing, Processing, Preservation, Storage, and Allocation of Human Tissues and Cells (2013): http://www.propisi.hr/print.php?id=9354
- Various: https://zdravlje.gov.hr/arhiva-80/zakonodavstvo/zakoni-i-pravilnici/701

Genetic Research

Key Organizations

- Ministry of Health: https://zdravlje.gov.hr/

Relevant Standards

- Various: https://zdravlje.gov.hr/arhiva-80/zakonodavstvo/zakoni-i-pravilnici/701

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Health: https://zdravlje.gov.hr/

Relevant Standards

- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2003): http://zakon.poslovna.hr/public/Konvencija-o-zastiti-ljudskih-prava-i-dostojanstva-ljudskog-bica-u-pogledu-primjene-biologije-i-medicine-u-vezi-presadivanja-organa-i-tkiva-ljudskog-porijekla/243337/zakoni.aspx
- Medical Fertilization Act, Article 32: (2012): http://www.hzzo-net.hr/dload/zakoni/20_01.pdf

- Law on the Implementation of Human Tissues and Cells (2012): http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3070.html
- Ordinance on the Conditions of Space, Professional Workers, Medical-Technical Equipment and Quality Assurance for Collection, Retrieval, Testing, Processing, Preservation, Storage and Allocation of Human Tissues and Cells (2013): http://www.propisi.hr/print.php?id=9354
- Various Ordinances - Law on the taking and transplantation of parts of the human body for the purpose of treatment: https://zdravlje.gov.hr/arhiva-80/zakonodavstvo/zakoni-i-pravilnici/pravilnici/pravilnici-zakon-o-uzimanju-i-presadjivanju-dijelova-ljudskog-tijela-u-svrhu-lijecenja/1057

EUROPE – Cyprus

General

Relevant Standards

- Law No. 31 (III)/2001: Oviedo Convention on Human Rights and Biomedicine: https://www.coe.int/en/web/bioethics/oviedo-convention
- The Safeguarding and Protection of Patients' Rights Law (2004): http://www.bioethics.gov.cy/Moh/cnbc/cnbc.nsf/All/745717D26F068582C2257CCA003B350F/$file/Patients%20Rights%20Law-English%20translation.pdf

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health, Pharmaceutical Services: https://www.moh.gov.cy/moh/moh.nsf/page15_en/page15_en?OpenDocument
- Ministry of Health, National Bioethics Committee: http://www.bioethics.gov.cy/moh/cnbc/cnbc.nsf/index_en/index_en?OpenDocument

Relevant Standards

- Law for Good Clinical Practice (2004)

Research Injury

Key Organizations

- Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/moh/moh.nsf/index_en/index_en?OpenDocument

Relevant Standards

- Legislation Concerning Medicinal Products of Human Use (Good Clinical Practice) No. 452/2004 Article 11 (8)

Privacy/Data Protection

Key Organizations

- Commissioner's Office for the Protection of Personal Data: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/home_el/home_el?opendocument#:~:text=The%20Commissioner%20for%20personal%20data,processing%20of%20their%20personal%20data

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Protection of Natural Persons Against the Processing of Personal Data and the Free Circulation of such Data Act of 2018 (Law 125 (I)): http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/all/DE97F6F59835A03AC22582DD003D895E/$file/%CE%9D%CF%8C%CE%BC%CE%BF%CF%82%20125(%CE%99)_2018.pdf?openelement

Embryos, Stem Cells, and Cloning

Relevant Standards

- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002)

EUROPE – Czech Republic

General

Key Organization

- Ministry of Health, Central Ethics Committee: http://www.mzcr.cz

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (2001): https://www.coe.int/en/web/bioethics/oviedo-convention
- Act No. 130/2002 Collection on Research and Development Support, as Amended (2018)
- Act No. 372/2011 on Healthcare Services, As Amended (2019)
- Act. No. 373/2011 on Specific Healthcare Services, As Amended (2018)

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Ministry of Health (MOH): http://www.mzcr.cz
- State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lred=1

Relevant Standards

- Act No. 378/2007 Collection on Pharmaceuticals, As Amended (2019)

- Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf
- Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products: https://www.sukl.eu/uploads/Legislativa/226_2008_clinical_trials.pdf
- Various: http://www.sukl.cz/medicinal-products-clinical-trials-guidelines-1

Devices

Key Organizations

- State Institute for Drug Control (SUKL): http://www.sukl.cz/index.php?lchan=1&lred=1

Relevant Standards

- Regulation (EU) 2017/745 on medical devices: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745
- Act No. 89/2021 Coll., on Medical Devices:
- Act No. 90/2021 Coll, on Medical Devices (the "Act on In Vitro Diagnostic Medical Devices")
- Various: http://www.sukl.cz/medical-devices?highlightWords=501%2F2000

Clinical Trial Registries

Key Organizations

- EU Clinical Trials Register

Relevant Standards

- EU Clinical Trials Register: https://www.clinicaltrialsregister.eu/

Research Injury

Relevant Standards

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164
- Law No. 89/2012 Coll. Civil Code: https://is.muni.cz/el/1422/podzim2015/SOC038/um/NObcZ_anglicky_strojovy_preklad.pdf

Privacy/Data Protection

Key Organizations

- Office for Personal Data Protection: https://www.uoou.cz/en/

Relevant Standards

- Act No. 110/2019 Coll., On Personal Data Processing: https://www.uoou.cz/en/assets/File.ashx?id_org=200156&id_dokumenty=1837
- General Data Protection Regulation (2018): https://gdpr-info.eu/; https://www.uoou.cz/gdpr-strucne/ds-4843/p1=4843
- International Data Transfer (2018): https://www.uoou.cz/en/vismo/zobraz_dok.asp?id_org=200156&id_ktg=1165&p1=1165

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Education, Youth, and Sport: http://www.msmt.cz/index.php?lchan=1&lred=1
- Research and Development Council, Bioethical Commission: http://www.vyzkum.cz/FrontClanek.aspx?idsekce=15908

Relevant Standards

- Act of 26 April 2006 on Research on Human Embryonic Stem Cells No. 227/2006 Sb. (Coll.), as amended (2017)

EUROPE – Denmark

General

Key Organization

- National Committee on Health Research Ethics (NVK): http://www.nvk.dk/english

Relevant Standards

- Act No. 1338 on Research Ethics Review of Health Research and Health Data Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/1338
- Executive Order No. 825 on Obligation to Notify Health Research and Health Data Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/825
- Guidelines about Notification (Checklist) (2019): http://www.nvk.dk/forsker/forskervejledning

Drugs, Biologics, and Devices

Key Organizations

- Committees on Medicine Research Ethics (VMK): https://www.dvmk.dk/
- Danish Medicines Agency: https://laegemiddelstyrelsen.dk/en/

Relevant Standards

- Regulation No. 745 on Medical Devices (2017): https://eur-lex.europa.eu/legal-content/DA/TXT/?uri=CELEX%3A32017R0745&qid=1634208852127
- Regulation No. 536 on Clinical Trials on Medicinal Products for Human Use (2014): https://eur-lex.europa.eu/legal-content/DA/TXT/?uri=CELEX%3A32014R0536&qid=1632471483160
- Act No. 1252 on Clinical Trials on Medicinal Products (2018): https://www.retsinformation.dk/eli/lta/2018/1252
- Act. No. 1853 on Research Ethics Review of Clinical Trials on Medical Devices etc. (2020): https://www.retsinformation.dk/eli/lta/2020/1853
- Executive Order No. 295 on Clinical Trials of Medicinal Products on Humans (2004): https://www.retsinformation.dk/eli/lta/2004/295
- Executive Order No. 965 on Reporting Significant Health Findings from Health Research and Health Data Research Projects, Clinical Trials on Medical Devices etc. and Certain Register Studies (2021): https://www.retsinformation.dk/eli/lta/2021/965

- Guidelines for Applications for Authorisation of Clinical Trials of Medical Products in Humans (2021): https://laegemiddelstyrelsen.dk/en/licensing/clinical-trials/trials-in-humans/guideline-for-applications-for-authorisation-of-clinical-trials-of-medicinal-products-in-humans/

Clinical Trial Registries

Key Organizations

- National Committee on Health Research Ethics (NVK): https://en.nvk.dk/

Relevant Standards

- Act No. 1338 on Research Ethics Review of Health Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/1338
- Executive Order No. 825 on Obligation to Notify Health Research and Health Data Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/825
- Executive Order No. 965 on Reporting Significant Health Findings from Health Research and Health Data Research Projects, Clinical Trials on Medical Devices etc. and Certain Register Studies (2021): https://www.retsinformation.dk/eli/lta/2021/965

Research Injury

Key Organizations

- Patient Compensation Association: http://pebl.dk/en.aspx

Relevant Standards

- Act No. 995 on the Right to Complain and Receive Compensation within the Health Service (2018): https://www.retsinformation.dk/eli/lta/2018/995

Privacy/Data Protection

Key Organizations

- Danish Data Protection Agency (DPA): https://www.datatilsynet.dk/english/

Relevant Standards

- Act No. 429 on Processing of Personal Data (2007): https://www.datatilsynet.dk/media/6894/danish-data-protection-act.pdf
- General Data Protection Regulation (2016): https://eurlex.europa.eu/eli/reg/2016/679/oj
- Data Protection Act (2018): https://www.retsinformation.dk/eli/lta/2018/502
- Health Act No. 903, Chapter 9 (2019): https://www.retsinformation.dk/Forms/R0710.aspx?id=210110#id56770dec-1ec6-44de-9fb0-8fabec8f4a62

Human Biological Materials

Key Organizations

- National Committee on Health Research Ethics (NVK): http://www.nvk.dk/english

Relevant Standards

- Act No. 1338 on Research Ethics Review of Health Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/1338
- Health Act No. 903 (2019): https://www.retsinformation.dk/eli/lta/2019/903
- Guidelines on the Use of Biological Material in Health Research Projects (2017): http://www.nvk.dk/emner/biobanker/vejledning-om-bio-mat

Genetic Research

Key Organizations

- National Committee on Health Research Ethics (NVK): http://www.nvk.dk/english

Relevant Standards

- Act No. 1338 on Research Ethics Review of Health Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/1338
- Executive Order No. 825 on Obligation to Notify Health Research and Health Data Research Projects (2020): https://www.retsinformation.dk/eli/lta/2020/825
- Executive Order No. 965 on Reporting Significant Health Findings from Health Research and Health Data Research Projects, Clinical Trials on Medical Devices etc. and Certain Register Studies (2021): https://www.retsinformation.dk/eli/lta/2021/965
- Guidelines on Health Research Projects Involving Genome Research (2018): https://www.nvk.dk/~/media/NVK/Dokumenter/Guidelines-on-Genomics-Research.pdf?la=da

Embryos, Stem Cells, and Cloning

Key Organizations

- Danish Council of Ethics: http://www.etiskraad.dk/english

Relevant Standards

- Act No. 440 on Danish Council of Ethics (2004): https://www.retsinformation.dk/forms/r0710.aspx?id=9909
- Executive Order No. 902 on Medically Assisted Procreation (2019): https://www.retsinformation.dk/Forms/R0710.aspx?id=210080

EUROPE – Estonia

General

Key Organization

- Estonian Council on Bioethics: http://www.eetikakeskus.ut.ee/en

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (2002): https://www.coe.int/en/web/bioethics/oviedo-convention
- Constitution of the Republic of Estonia, Paragraph 18 (2016): https://www.riigiteataja.ee/en/eli/521052015001/consolide

- Code of Ethics of Estonian Scientists: https://www.akadeemia.ee/wp-content/uploads/2020/06/code_ethics2002-3.pdf

Drugs, Biologics, and Devices

Key Organizations

- State Agency of Medicines: https://ravimiamet.ee/en/state-agency-medicines-0#:~:text=State%20Agency%20of%20Medicines%20is,for%20human%20and%20veterinary%20use
- Minister of Social Affairs (MSA): https://www.sm.ee/en
- Estonian Health Board: http://www.terviseamet.ee/en/medical-devices.html

Relevant Standards

- Medicinal Products Act, Chapter 5 (2015): https://www.riigiteataja.ee/en/eli/ee/525112013005/consolide/current
- MSA, Rules of Procedure of Medical Ethics Committee for Clinical Trials, a List of Data to be Submitted for Obtaining Approval, Procedure for Adoption of Resolutions and Format of Application for Obtaining Approval (2005): https://www.riigiteataja.ee/en/eli/502052017001/consolide
- MSA, Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 (2005): https://www.riigiteataja.ee/en/eli/502052017002/consolide
- Medical Devices Act (2004): https://www.riigiteataja.ee/en/eli/ee/509012015001/consolide/current
- Regulation No. 86: 2010 of the Minister of Social Affairs on the Conditions and Procedures for the Clinical Investigation of Medical Devices

Research Injury

Key Organizations

- Minister of Social Affairs (MSA): https://www.sm.ee/en
- Estonian Health Insurance Fund: https://www.haigekassa.ee/en

Relevant Standards

- Medicinal Products Act, Section 90: https://www.riigiteataja.ee/en/eli/ee/525112013005/consolide/current
- Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 of the Minister of Social Affairs of (2005): https://www.riigiteataja.ee/en/eli/502052017002/consolide

Privacy/Data Protection

Key Organizations

- Estonian Data Protection Inspectorate: https://www.aki.ee/en

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Personal Data Protection Act (2016): https://www.riigiteataja.ee/en/eli/ee/512112013011/consolide/current

- International Data Transfer (2018): http://www.aki.ee/en/guidelines/transfer-personal-data-foreign-country

Genetic Research

Relevant Standards

- Human Genes Research Act (RT I 2000, 104, 685) (2014): https://www.riigiteataja.ee/en/eli/ee/518062014005/consolide

Embryos, Stem Cells, and Cloning

Relevant Standards

- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002) (Estonian): https://www.riigiteataja.ee/akt/78569
- Artificial Insemination and Embryo Protection Act, RT I 1997, 51, 824 (2011): https://www.riigiteataja.ee/en/eli/ee/530102013057/consolide/current

EUROPE – Finland

General

Key Organization

- Ministry of Social Affairs and Health: http://www.stm.fi/en/frontpage
- National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en
- Finnish Advisory Board on Research Integrity (TENK): http://www.tenk.fi/en
- Finnish Institute for Health and Welfare (THL) https://thl.fi/en/web/thlfi-en
- Findata: https://findata.fi/en/
- Finnish Medicines Agency Fimea: https://www.fimea.fi/web/en

Relevant Standards

- Decree of the National Research Ethics Council of Finland No. 1347/1991
- Decree on Medical Research Nos. 986/1999, 313/2004, and 65/2016
- Decrees on the National Committee on Medical Research Ethics No. 820/2010 and 788/2018
- Operating Procedures of the National Committee on Medical Research Ethics (2019)
- Decree on Fees, No. 1287/2018
- Report on Children in Medical Research (2003): https://tukija.fi/documents/1481661/1546647/2003_children.pdf/54924377-820e-4a26-be33-47fcaa64f5f0/2003_children.pdf?t=1438856851000
- Various Guidelines: http://tukija.fi/en/publications1
- Act on Data Protection (1050/2018): https://www.finlex.fi/fi/laki/kaannokset/2018/en20181050.pdf
- Criminal Code of Finland (39/1889, numerous amendments; the link includes amendments up until 766/2015): https://www.finlex.fi/fi/laki/kaannokset/1889/en18890039_20150766.pdf

- Act on the Secondary Use of Health and Social Data (552/2019): https://www.finlex.fi/fi/laki/alkup/2019/20190552#Lidp445824016 (https://stm.fi/documents/1271139/1365571/The+Act+on+the+Secondary+Use+of+Health+and+Social+Data/a2bca08c-d067-3e54-45d1-18096de0ed76/The+Act+on+the+Secondary+Use+of+Health+and+Social+Data.pdf; unofficial translation)
- Medical Research Act No. 488/1999 (Amended 295/2004, 794/2010, 143/2015 and one related to a Government Proposal to the Parliament HE 18/2020vp in relation to the application of EU Clinical Trials Regulation 536/2014) upcoming): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488
- Government Decree on the National Institute for Health and Welfare (668/2008), latest amendment 1122/2015, https://www.finlex.fi/en/laki/kaannokset/2008/en20080675
- Responsible Conduct of Research and Procedures for Handling Allegations of Misconduct in Finland (2012): https://tenk.fi/sites/tenk.fi/files/HTK_ohje_2012.pdf
- The Ethical Principles of Research with Human Participants and Ethical Review in the Human Sciences in Finland (2019): https://tenk.fi/sites/default/files/2021-01/Ethical_review_in_human_sciences_2020.pdf
- Agreeing on Authorship. Recommendation for Research Publications: https://tenk.fi/sites/tenk.fi/files/TENK_suositus_tekijyys.pdf

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Finnish Medicines Agency (FIMEA): https://www.fimea.fi/web/en/frontpage
- Ministry of Social Affairs and Health (MSAH): http://stm.fi/en/frontpage
- National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en
- Regional Medical Ethics Committees: https://tukija.fi/alueelliset-eettiset-toimikunnat

Relevant Standards

- Medicines Act (395/1987): http://www.finlex.fi/fi/laki/smur/1987/19870395
- Medical Research Act No. 488/1999 (Amended 295/2004, 794/2010, and 143/2015): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488
- Decree of the National Research Ethics Council of Finland No. 1347/1991: https://www.finlex.fi/fi/laki/alkup/1991/19911347
- Decree on Medical Research, Nos. 986/1999, 313/2004 and 65/2016: https://finlex.fi/fi/laki/alkup/1999/19990986, https://finlex.fi/fi/laki/alkup/2016/20160065
- Decrees on the National Committee on Medical Research Ethics No. 820/2010 and 788/2018: https://finlex.fi/fi/laki/alkup/2010/20100820, https://www.finlex.fi/fi/laki/alkup/2018/20180788
- Operating Procedures of the National Committee on Medical Research Ethics (2021): https://tukija.fi/documents/1481661/0/TUKIJAn+toimintaohje_07062021_EN.pdf/5a2a86df-6a18-d68b-56d8-8dbba3ce5ba2/TUKIJAn+toimintaohje_07062021_EN.pdf?t=1623235604734

- Decree on Fees, No. 1171/2020: https://tukija.fi/documents/1481661/0/Maksuasetus+20201171+(3).pdf/e7e9dc90-f06f-47b3-98ee-e3beb7253d87/Maksuasetus+20201171+(3).pdf?t=1610024226291
- Decree on Clinical Trials on Medicinal Products No. 841/2010
- Other Decrees related to Medicines Act: http://www.finlex.fi/fi/laki/smur/1987/19870395#nojalla
- Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2012
- Templates for Clinical Trial Information Leaflet and Consent Form (2018): https://tukija.fi/lomakkeet-ja-asiakirjamallit
- Templates for Clinical Trial Information Leaflet and Consent Form (2018): http://tukija.fi/en/publications1
- Administrative Regulation on Clinical Investigations (2010): http://www.finlex.fi/data/normit/39644-maarays_3_2010_kliininen_laitetutkimus.pdf
- Finnish Medicines Agency Administrative Regulation on Clinical Trials on Medicinal Products (8/2019): https://www.fimea.fi/documents/542809/9377176/Regulation+8-2019+Clinical+Trials+-+EN.pdf/8f64f47e-a072-f385-833b-7989111ae81a?t=1575897566370
- Various Guidelines: http://tukija.fi/en/publications1
- Report on Children in Medical Research (2003): https://tukija.fi/documents/1481661/1546647/2003_children.pdf/54924377-820e-4a26-be33-47fcaa64f5f0/2003_children.pdf?t=1438856851000

Devices

Key Organizations

- National Supervisory Authority for Welfare and Health (VALVIRA): https://www.valvira.fi/web/en

Relevant Standards

- Medical Devices Act No. 629/2010 (Finnish): http://www.finlex.fi/fi/laki/kokoelma/2010/20100085.pdf
- Act on Specific Medical Devices Regulated by EU Directive (629/2010, amended 720/2021): https://www.finlex.fi/fi/laki/ajantasa/2010/20100629
- Administrative Regulation. Pharmaceutical Safety and Development Center: Operator and Device Registration Notifications to Authorities Related to Medical Devices: https://finlex.fi/fi/viranomaiset/normi/558001/47297
- Various: http://www.valvira.fi/en/licensing/medical_devices/legislation
- EU Regulations, Medical Device Regulation 2017/745: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN
- EU Regulations, In Vitro Diagnostic Medical Devices Regulation 2017/746: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746&from=EN

Clinical Trial Registries

Key Organizations

- Finnish Medicines Agency Fimea: https://www.fimea.fi/web/en/supervision/clinical_drug_trials

Research Injury

Key Organizations

- Finnish Patient Insurance Centre: https://www.pvk.fi/fi/
- Pharmaceutical Injuries Insurance: http://www.laakevahinko.fi/in-english/

Relevant Standards

- Patient Injuries Act (948/2019): https://www.finlex.fi/fi/laki/ajantasa/2019/20190948
- Pharmaceutical Injuries Insurance: General Terms and Conditions (2017): https://www.laakevahinko.fi/en/potilaille/vakuutusehdot/

Social-Behavioral Research

Key Organizations

- Finnish Advisory Board on Research Integrity (TENK): http://www.tenk.fi/en/

Relevant Standards

- The Ethical Principles of Research with Human Participants and Ethical Review in the Human Sciences in Finland (2019): https://www.tenk.fi/en/ethical-review-in-finland

Privacy/Data Protection

Key Organizations

- Office of the Data Protection Ombudsman: https://tietosuoja.fi/en/home

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Data Protection Act (1050/2018): https://www.finlex.fi/en/laki/kaannokset/2018/20181050

Human Biological Materials

Key Organizations

- Finnish Medicines Agency Fimea: https://www.fimea.fi/web/en
- National Supervisory Authority for Welfare and Health (Valvira): http://www.valvira.fi/web/en

Relevant Standards

- Act on the Medical Use of Human Organs, Tissues, and Cells No. 101/2001 (Finnish and Swedish): http://www.finlex.fi/fi/laki/ajantasa/2001/20010101
- Law on Biobanks, No. 688/2012 (Finnish and Swedish): http://www.finlex.fi/fi/laki/ajantasa/2012/20120688
- Decree on Consent for Biobank No. 643/2013: http://www.finlex.fi/fi/laki/alkup/2013/20130643
- Decree on information on Biobank No. 649/2013: http://www.finlex.fi/fi/laki/alkup/2013/20130649
- Government Decree on Medical Use of Human Organs, Tissues, and Cells No. 594/2007
- Ministry Decree on Medical Use of Human Organs, Tissues, and Cells No. 1302/2007

Genetic Research

Key Organizations

- National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en
- Board for Gene Technology: http://www.geenitekniikanlautakunta.fi/en

Relevant Standards

- Gene Technology Act (377/1995) (Amended multiple times, the last one 481/2021): https://www.finlex.fi/fi/laki/ajantasa/1995/19950377

Embryos, Stem Cells, and Cloning

Key Organizations

- National Supervisory Authority for Welfare and Health: http://www.valvira.fi/web/en
- National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en
- Finnish Advisory Board on Research Integrity (TENK): http://www.tenk.fi/en/
- National Advisory Board on Social Welfare and Health Care Ethics (ETENE): http://www.etene.fi/en

Relevant Standards

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning (2002): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=168
- Medical Research Act No. 488/1999 (amended 295/2004, 749/2010, and 143/2015): http://www.finlex.fi/en/laki/kaannokset/1999/en19990488
- Act on Assisted Fertility Treatments No. 1237/2006: http://www.finlex.fi/fi/laki/ajantasa/2006/20061237
- Criminal Code of Finland (39/1889), Chapter 22, Section 4: Cloning of a Human is Forbidden: https://www.finlex.fi/en/laki/kaannokset/1889/en18890039.pdf
- Report on Stem Cells, Cloning, and Research (2005): http://tukija.fi/documents/1481661/1546647/2005cells.pdf/c14b7dd0-11b4-428d-bdae-539566ade614

EUROPE – France

General

Key Organization

- Ministry of Social affairs and Health: http://www.sante.gouv.fr/
- National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr/en
- National Commission for Information and Freedoms (CNIL): https://www.cnil.fr/en/home

Relevant Standards

- Law No. 2012-300 of 5 March 2012 on Research Involving Human Persons: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025441587

- Law No. 2011-814 of 7 July 2011 on Bioethics
- Public Health Code Articles R1121-1 and subsequent sections: http://legifrance.gouv.fr/
- CCNE, various: http://www.ccne-ethique.fr/en/type_publication/avis

Drugs, Biologics, and Devices

Key Organizations

- National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr
- National Health Products Safety Agency (ANSM): http://ansm.sante.fr/

Relevant Standards

- Medications for Human Use, Articles 5111-1 and Subsequent Sections for Drugs and Medical Devices: https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665
- Decision on Good Clinical Practices: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000819256
- CCNE, various: http://www.ccne-ethique.fr/en/type_publication/avis

Social-Behavioral Research

Key Organizations

- National Consultative Ethics Committee

Relevant Standards

- Opinion on the Ethics of Research in the Sciences of Human Behavior No. 38 (1993): http://www.ccne-ethique.fr/en/publications/opinion-ethics-research-sciences-human-behaviour#.WNkybNfytEY

Privacy/Data Protection

Key Organizations

- National Commission of Information and Liberty (CNIL): https://www.cnil.fr/en/home
- National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr

Relevant Standards

- Act No. 78-17 of 6 January 1978 on Information Technology, Data Files, and Civil Liberties (2018): https://www.cnil.fr/fr/la-loi-informatique-et-libertes
- Law No. 2016-1321 of 7 October 2016 for a Numeric Republic: https://www.legifrance.gouv.fr/affichLoiPubliee.do?idDocument=JORFDOLE000031589829&type=general&legislature=14
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Data Protection Act (2018): https://www.legifrance.gouv.fr/affichLoiPreparation.do;jsessionid=AD5660270AD9F70B94275AC823321680.tplgfr22s_3?idDocument=JORFDOLE000036195293&type=contenu&id=2&typeLoi=proj&legislature=15

- CNIL, Decree NO. 2019-536 of 29 May 2019 Enacted for the Application of Act No. 78-17 of 6 January 1978 on Data Processing, Data Files, and Civil Liberties: https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000038528420&categorieLien=id
- CNIL, Health Research: CNIL Adopts New Simplification Measures (2018): https://www.cnil.fr/fr/recherches-dans-le-domaine-de-la-sante-la-cnil-adopte-de-nouvelles-mesures-de-simplification
- CNIL, Health Research with Consent (2018): https://www.cnil.fr/fr/declaration/mr-001-recherches-dans-le-domaine-de-la-sante-avec-recueil-du-consentement
- CNIL, Health Research without Consent (2018): https://www.cnil.fr/fr/declaration/mr-003-recherches-dans-le-domaine-de-la-sante-sans-recueil-du-consentement
- CNIL, Practical Guide on the Protection of Personal Data: What Framework Applies to Research? (2018): https://www.cnil.fr/sites/default/files/atoms/files/guide-cnom-cnil.pdf
- CCNE, various opinions: http://www.ccne-ethique.fr/en/type_publication/avis

Human Biological Materials

Key Organizations

- Protection of Persons Committee (CPP)
- Ministry of Higher Education, Research, and Innovation: http://www.enseignementsup-recherche.gouv.fr/
- National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr

Relevant Standards

- Donation and Use of the Components and Products of the Human Body, Articles L1211-1 to L1274-3 (2004): http://www.legifrance.gouv.fr/
- Public Health Code Articles L1243-3 and following sections (2012): http://www.legifrance.gouv.fr/initRechCodeArticle.do
- Decree No. 2017-1549 of 8 November 2017 on the Conservation and Preparation for Scientific Purposes of Elements of the Human Body and Amending the Public Health Code
- CCNE, various: http://www.ccne-ethique.fr/en/type_publication/avis

Genetic Research

Key Organizations

- National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr
- Biomedicine Agency: https://www.agence-biomedecine.fr/About-us

Relevant Standards

- Civil Code Articles 16-10 to 16-13: http://www.legifrance.gouv.fr/affichCode.do;jsessionid=D2DE023194483D3384DE19DE8959BDDA.tpdjo17v_3?idSectionTA=LEGISCTA000006136513&cidTexte=LEGITEXT000006070721&dateTexte=20131006

- Article R1131-1 and Subsequent Sections of the Public Health Code: https://www.legifrance.gouv.fr/affichCode.do?idArticle=LEGIARTI000018615563&idSectionTA=LEGISCTA000006196158&cidTexte=LEGITEXT000006072665&dateTexte=20191011
- CCNE, various: http://www.ccne-ethique.fr/en/type_publication/avis

Embryos, Stem Cells, and Cloning

Key Organizations

- National Consultative Bioethics Committee for Health and Life Sciences (CCNE): http://www.ccne-ethique.fr
- Biomedicine Agency: http://www.enseignementsup-recherche.gouv.fr/

Relevant Standards

- Law No. 2013-715 of 6th August 2013: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000027811435&dateTexte=&categorieLien=id
- Decree No. 2015-155 of 11 February, 2015: Public Health Code on Research on Embryos Article R2151-1 and Following Sections: http://legifrance.gouv.fr/affichCode.do?idArticle=LEGIARTI000030233469&idSectionTA=LEGISCTA000006190409&cidTexte=LEGITEXT000006072665&dateTexte=20151015
- CCNE, various: http://www.ccne-ethique.fr/en/type_publication/avis

EUROPE – Georgia

NOTE: For an overview of human subject protections in Georgia, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 4: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf

General

Key Organization

- Bioethics and Health Law Studies Society

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine ETS No.164 (2001): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164
- Additional Protocol to the Convention's on Human Rights and Biomedicine, concerning Biomedical Research, ETS No. 195 (2010)
- Law on Health Care, Chapter XIX (2017): https://matsne.gov.ge/en/document/view/29980?publication=37
- Law on Medicines and Pharmaceutical Activities No. 659 and 1586 (2015): https://matsne.gov.ge/en/document/view/29836?impose=translateEn&publication=22

Drugs, Biologics, and Devices

Key Organizations

- State Regulatory Agency for Medical and Pharmaceutical Activities (LEPL) of the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia

Relevant Standards

- Regulation about the Rules and Conditions of Issuing of the Approval of Clinical Trials Approved #176 (2005): https://matsne.gov.ge/en/document/view/29836?publication=22
- Order of Health Minister about Implementation of "ICH: E6 Good Clinical Practice: Consolidated Guidance" (1996) including WMA: Declaration of Helsinki (2013): http://rama.moh.gov.ge/res/docs/9539N233.pdf

Clinical Trial Registries

Key Organizations

- State Regulatory Agency for Medical and Pharmaceutical Activities (LEPL) of the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia: http://rama.moh.gov.ge/

Relevant Standards

- No public registry

Research Injury

Key Organizations

- State Regulatory Agency for Medical and Pharmaceutical Activities (LEPL) of the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia: http://rama.moh.gov.ge/

Relevant Standards

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164
- Regulation about the Rules and Conditions of Issuing of the Approval of Clinical Trials Approved #176 (2005): https://matsne.gov.ge/en/document/view/29836?publication=22

Social-Behavioral Research

Key Organizations

- Social and Psychological Agency

Relevant Standards

- Various: https://epsy.ge/en, https://personaldata.ge/en

Privacy/Data Protection

Key Organizations

- Office of the Personal Data Protection Inspector: https://personaldata.ge/en

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Law on Data Protection (2018): https://matsne.gov.ge/en/document/view/1561437?publication=15
- Various: https://personaldata.ge/en

Human Biological Materials

Key Organizations

- Bioethics and Health Law Studies Society

Relevant Standards

- Various: https://matsne.gov.ge/en/document/view/29980?publication=37

Embryos, Stem Cells, and Cloning

Key Organizations

- Convention on Human Rights and Biomedicine (Convention of Oviedo)

Relevant Standards

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Additional Protocol on Prohibition of Human Cloning ETS No. 168 (2001): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=168
- Law on Health Care, Article 142 (2017): https://matsne.gov.ge/en/document/view/29980?publication=37
- Law of Georgia on Health Care: https://matsne.gov.ge/en/document/view/29980?publication=37

EUROPE – Germany

General

Key Organization

- German Medical Association (BÄK): https://www.bundesaerztekammer.de/weitere-sprachen/english/german-medical-association/
- Central Ethics Committee of the German Medical Association (ZEKO): https://www.zentrale-ethikkommission.de/
- Permanent Working Party of Research Ethics Committees in Germany: http://www.ak-med-ethik-komm.de/
- German Ethics Council: https://www.ethikrat.org/en/
- Federal Ministry of Health (BMG): https://www.bundesgesundheitsministerium.de/en/index.html
- German Research Foundation (DFG), Permanent Senate Commission on Key Questions in Clinical Research (SCCR): https://www.dfg.de/en/dfg_profile/statutory_bodies/senate/clinical_research/index.html

Relevant Standards

- BÄK, (Model) Professional Code for Physicians in Germany, Article 15 (2018): https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/MBO/MBO-AE_EN_2018.pdf

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Federal Institute for Drugs and Medical Devices (BfArM): https://www.bfarm.de/EN/Home/_node.html
- Paul-Ehrlich-Institut (PEI): https://www.pei.de/EN/home/home-node.html
- Federal Ministry of Health (BMG): https://www.bundesgesundheitsministerium.de/en/index.html

Relevant Standards

- 2021 German version: Medicinal Products Act, Division 6 (2021): http://www.gesetze-im-internet.de/amg_1976/
- 2020 English version: Medicinal Products Act, Division 6 (2020): https://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p1005
- Promulgation on the Principles of the Conduct of Clinical Trials of Drugs According to the Rules (1987)
- Second Promulgation on the Clinical Trial of Drugs in Human (1997)
- Regulation on the Application of Good Clinical Practice in the Conduct of Clinical Trials of Medicinal Products for Human Use (2012): http://www.gesetze-im-internet.de/gcp-v/

Devices

Key Organizations

- Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html
- Paul-Ehrlich-Institut (PEI): http://www.pei.de/EN/home/node.html4
- Federal Ministry of Health (BMG): https://www.bundesgesundheitsministerium.de/en/ministry/the-federal-ministry-of-health.html

Relevant Standards

- Medical Device Law Implementation Act, Division 4 (2021): https://www.gesetze-im-internet.de/mpdg/

Clinical Trial Registries

Key Organizations

- German Clinical Trials Register (DRKS): https://www.drks.de/drks_web/setLocale_EN.do

Relevant Standards

- FAQs: https://www.drks.de/drks_web/navigate.do?navigationId=faq&messageEN=FAQ

Research Injury

Relevant Standards

- Medicinal Products Act, Section 40(3) (2020): https://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p1005
- Medical Device Law Implementation Act, Section 26 (2021): https://www.gesetze-im-internet.de/mpdg/__26.html

Privacy/Data Protection

Key Organizations

- Federal Commissioner for Data Protection and Freedom of Information: https://www.bfdi.bund.de/EN/
- Datenschutzkonferenz (DSK): https://www.datenschutzkonferenz-online.de/

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Federal Data Protection Act (BDSG) (2019): https://www.gesetze-im-internet.de/englisch_bdsg/index.html
- Data Protection Laws in German States: http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html
- DSK, Short Paper No. 4: Data Transmission to Third Countries: https://www.datenschutzkonferenz-online.de/media/kp/dsk_kpnr_4.pdf

Human Biological Materials

Key Organizations

- German Ethics Council: https://www.ethikrat.org/en/
- Central Ethics Committee of the German Medical Association (ZEKO): http://www.zentrale-ethikkommission.de/
- German Society of Surgery (DGCH): http://www.dgch.de/index.php?id=118

Relevant Standards

- German Ethics Council, Act of Quality and Security of Human Tissue and Cells (2019): https://www.buzer.de/s1.htm?g=Gewebegesetz&f=1
- German Ethics Council, Transfusion Law (2020): http://www.gesetze-im-internet.de/tfg/
- German Ethics Council, Transplantation Law (2021): http://www.gesetze-im-internet.de/tpg/
- German Ethics Council, Opinion on Human Biobanks for Research (2010): https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/DER_StnBiob_Engl_Online_mitKennwort.pdf
- ZEKO, Opinion on the (Re)Use of Human Body Material for Medical Research Purposes (2003): http://www.zentrale-ethikkommission.de/fileadmin/user_upload/downloads/pdf-Ordner/Zeko/Koerpermat-1.pdf

- ZEKO, First Addendum: The (Re)Use of Human Body Material of Deceased Persons for Medical Research Purposes (2003): http://www.zentrale-ethikkommission.de/fileadmin/user_upload/downloads/pdf-Ordner/Zeko/Erste_Ergaenzung_Koerpermaterialien.pdf
- DGCH, Guidelines on Good Professional Practice (GPP) for the Procurement of Human Tissue and Cells for Drug Production: http://www.dgch.de/fileadmin/media/pdf/servicemeldungen/069_Gewebegesetz_GFP-Leitfaden_der_DGCH_fuer_die_Gewinnung_menschlicher_Gewebe.pdf

Genetic Research

Key Organizations

- German Society of Human Genetics (GfH): https://gfhev.de/en/home.html
- German Research Foundation (DFG), Permanent Senate Commission on Genetic Research: http://www.dfg.de/en/dfg_profile/statutory_bodies/senate/genetic_research/index.html

Relevant Standards

- Embryo Protection Act (2011): http://www.gesetze-im-internet.de/eschg/
- Genetic Engineering Act (2021): http://www.gesetze-im-internet.de/gentg/
- German Research Foundation, Statements and Publications: http://www.dfg.de/en/dfg_profile/statutory_bodies/senate/genetic_research/publications/index.html

Embryos, Stem Cells, and Cloning

Key Organizations

- Federal Ministry of Education and Research (BMBF): https://www.bmbf.de/bmbf/en/home/home_node.html
- German Ethics Council: https://www.ethikrat.org/en/
- Central Ethics Committee of the German Medical Association (ZEKO): http://www.zentrale-ethikkommission.de/
- German Research Foundation (DFG): http://www.dfg.de/en/
- Central Ethics Committee for Stem Cell Research (ZES): http://www.rki.de/EN/Content/Institute/Committees/StemCell/StemCell_content.html

Relevant Standards

- BMBF, Embryo Protection Act (2011): http://www.gesetze-im-internet.de/eschg/
- BMBF, Stem Cell Act (2017): http://www.gesetze-im-internet.de/stzg/
- BMBF, Regulation on the Central Ethics Committee for Stem Cell Research and the Competent Authority Pursuant to the Stem Cell Act (2017): http://www.gesetze-im-internet.de/zesv/
- German Ethics Council, The Import of Human Embryonic Stem Cells (2001): https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/Archiv/Stellungnahme_Stammzellimport.pdf
- German Ethics Council, Cloning for Reproductive Purposes and Cloning for the Purposes of Biomedical Research (2004): https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/Archiv/Stellungnahme_Klonen.pdf

- German Ethics Council, Should the Stem Cell Law be Amended? (2007): https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/Archiv/Stn_Stammzellgesetz.pdf
- German Ethics Council, Human-Animal Mixtures in Research (2011): https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/opinion-human-animal-mixtures-in-research.pdf
- German Ethics Council, Stem Cell Research - New Challenges for the Ban on Cloning and Treatment of Artificially Created Germ Cells? (2014): https://www.ethikrat.org/fileadmin/Publikationen/Ad-hoc-Empfehlungen/englisch/recommendation-stem-cell-research.pdf
- German Ethics Council, Germline Intervention in the Human Embryo (2017): https://www.ethikrat.org/fileadmin/Publikationen/Ad-hoc-Empfehlungen/englisch/recommendation-germline-intervention-in-the-human-embryo.pdf
- German Ethics Council, Intervening in the Human Germline (2019): https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/opinion-intervening-in-the-human-germline-summary.pdf
- ZEKO, Opinion on Stem Cell Research (2002): http://www.zentrale-ethikkommission.de/fileadmin/user_upload/downloads/pdf-Ordner/Zeko/Stammzell.pdf
- DFG, Opinion on Stem Cell Research (2006): https://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2006/stammzellforschung_deutschland_lang_0610.pdf

EUROPE – Greece

General

Key Organization

- National Bioethics Commission (NBC): http://www.bioethics.gr/

Relevant Standards

- Research Ethics for Biological Sciences (2008): http://www.bioethics.gr/index.php/en/gnomes/86-research-ethics-in-biological-sciences
- A Guide for Research Ethics Committees for Biological Research (2008): http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/guide.pdf
- Conflict of Interest in Biomedical Research (2014): http://www.bioethics.gr/images/pdf/EKDOSEIS/OPINIONS_AND_REPORTS_2008-2013_EN.pdf
- Incidental Findings in Research and Clinical Practice (2015): http://www.bioethics.gr/index.php/en/gnomes/983-incidental-findings-in-research-and-clinical-practice

Drugs, Biologics, and Devices

Key Organizations

- National Organization for Medicines (NOM): http://www.eof.gr/web/guest/home
- National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3

Relevant Standards

- Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998)
- Act 3418/2005 Code on Medical Ethics
- Ministerial Decision ΔΥΓ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC
- Ministerial Decision ΔΥΓ 3 α/79602/2007: Harmonization of the Greek Legislation with EU Legislation, according to the Directive 2005/28/EC
- NBC, Recommendation on Clinical Trials: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/recom_clinical_trials_en.pdf
- NBC, Control of Non-Invasive Clinical Trials for Drugs (2013): http://www.bioethics.gr/index.php/en/gnomes/532-control-of-non-invasive-clinical-trials-for-drugs

Research Injury

Key Organizations

- National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3

Relevant Standards

- Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998)
- Act 3418/2005 Code on Medical Ethics
- Ministerial Decision ΔΥΓ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC
- Ministerial Decision ΔΥΓ 3 α/79602/2007 Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2005/28/EC

Privacy/Data Protection

Key Organizations

- Hellenic Data Protection Authority: http://www.dpa.gr/

Relevant Standards

- Greek Constitution 1975/1986/2001 Article 9.1
- Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998)
- Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by Laws 2819/2000 and 2915/2000)
- Act 3418/2005 Code on Medical Ethics
- General Data Protection Regulation (2016): https://www.lawspot.gr/nomikes-plirofories/nomothesia/genikos-kanonismos-gia-tin-prostasia-dedomenon?lspt_context=gdpr

Genetic Research

Key Organizations

- National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3

Relevant Standards

- Greek Constitution 1975/1986/2001, Article 5.5
- Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998)
- Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by Laws 2819/2000 and 2915/2000)
- Act 3418/2005 Code on Medical Ethics
- Recommendation on Banks of Biological Material of Human Origin (Biobanks) in Biomedical Research: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/biobanks_recom_eng.pdf
- Recommendation on the Collection and Use of Genetic Data: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/recom_genetic_data_eng.pdf
- Opinion on Prenatal and Pre-Implantation Diagnosis and Embryo Treatment: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/1_pd_pgd_opin_eng2.pdf
- Opinion on Direct-To-Consumer Genetic Testing (2012): http://www.bioethics.gr/index.php/en/gnomes/91-direct-to-consumer-dtc-genetic-testing
- Opinion on Incidental Findings in Research and Clinical Practice (2015): http://www.bioethics.gr/images/pdf/GNOMES/OPINION_Incidental_Findings_FINAL_.pdf
- Opinion on Advances in Human Genome Editing (2016): http://www.bioethics.gr/images/pdf/GNOMES/OPINION__gene%20editing_Final_EN.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

- National Bioethics Commission (NBC): http://www.bioethics.gr/index.php?category_id=3
- National Authority for Medically Assisted Reproduction

Relevant Standards

- Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998)
- Civil Code (Act 3089/2002, Medically Assisted Reproduction)
- Act 3305/2005 Application of Medically Assisted Reproduction
- NBC, various: http://www.bioethics.gr/index.php/gnomes

EUROPE – Hungary

General

Key Organization

- Ministry of Human Capacities (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma
- Medical Research Council, Research Ethics Committees (KFEB, TUKEB, HRB): https://ett.aeek.hu/en/secretariat/

Relevant Standards

- Fundamental Law of Hungary, Updated with the Fifth Amendment (2016), Articles II-III: http://njt.hu/cgi_bin/njt_doc.cgi?docid=140968.322953
- Act CLIV of 1997 on Health Care, Chapters VIII and IX: http://njt.hu/cgi_bin/njt_doc.cgi?docid=30903.339193
- Act VI. of 2002 on the Promulgation of the Oviedo Convention on Human Rights and Biomedicine: http://njt.hu/cgi_bin/njt_doc.cgi?docid=64201.264663
- Act LXXXI of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research
- Act C of 2012 on the Criminal Code, Chapter XVI Medical Procedures and Criminal Offenses Against the Order of Research, Sections 168-175
- Decree 23/2002 (V. 9.) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam
- Decree 35/2005 (VIII.26.) of the Minister of Health on the Clinical Trials of Investigational Medicinal Products for Human Use and on the Application of Good Clinical Practice: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM
- Decree No. 235/2009 (X.20.) from the Hungarian Government on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products, and for the Clinical Studies of the Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900235.KOR&celpara=#xcelparam
- 1997 CLIV. Law, Healthcare, Chapters VIII and IX: http://njt.hu/cgi_bin/njt_doc.cgi?docid=30903.339193

Drugs, Biologics, and Devices

Drugs

Key Organizations

- National Institute of Pharmacy and Nutrition: http://www.ogyei.gov.hu
- Medical Research Council, Ethics Clinical Pharmacology Ethics Committee (KFEB): https://ett.aeek.hu/kfeb/

Relevant Standards

Clinical Trials:

- Act XCV of 2005 on Medicinal Products for Human Use, Section 3: https://net.jogtar.hu/jogszabaly?docid=A0500095.TV&searchUrl=/gyorskereso%3Fextraparams%3D%7B%2522Year%2522%3A%25222005%2522%2C%2522SerialNumber%2522%3A%252295%2522%2C%2522ID%2522%3A%2522FullTextSearch%2522%7D
- Decree 35/2005 (VIII. 26) of the Minister of Health on the Clinical Trial and Application of Correct Clinical Practices of Investigational Medicinal Products Intended for Use in Humans: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM&celpara=#xcelparam
- 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 (it will come in application on 31 January 2022): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0537

Non-Interventional Trials:

- Act CLIV of 1997 on Health Care, Chapter VIII, Section 164/A: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV
- Decree 23/2002. (V. 9) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam
- Act CLIV of 1997 on Health Care, Chapter VIII, Section 159: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV

Devices

Key Organizations

- Authority for Medical Devices, National Healthcare Service System: http://www.enkk.hu/index.php/hun/
- Medical Research Council, Ethics Committee for Clinical Pharmacology: https://ett.aeek.hu/kfeb/

Relevant Standards

- Act CLIV of 1997 on Health Care, Chapter VIII, Section 159: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV

Clinical Trials:

- Decree 4/2009. (III. 17.) of the Minister of Health on Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900004.EUM&celpara=#xcelparam

Non-Interventional Trials:

- Decree 23/2002. (V. 9.) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0200023.EUM&celpara=#xcelparam
- Government Decree 235/2009. (X.20.) on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products and for the Clinical Studies of the Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900235.KOR&celpara=#xcelparam
- Government Decree 27/2015 (II.25.) About the National Health Care Service System: http://njt.hu/cgi_bin/njt_doc.cgi?docid=174246.343548

Research Injury

Key Organizations

- National Institute of Pharmacy and Nutrition: http://www.ogyei.gov.hu

Relevant Standards

- Register of clinical trials: https://ogyei.gov.hu/klinikai_vizsgalatok_nyilvantartasa

Privacy/Data Protection

Key Organizations

- National Institute of Pharmacy and Nutrition: http://www.ogyei.gov.hu

Relevant Standards

- Act XCV of 2005 on Medicinal Products for Human Use, Section 3, Paragraph 5: https://net.jogtar.hu/jogszabaly?docid=A0500095.TV&searchUrl=/gyorskereso%3Fextraparams%3D%7B%2522Year%2522%3A%25222005%2522%2C%2522SerialNumber%2522%3A%252295%2522%2C%2522ID%2522%3A%2522FullTextSearch%2522%7D

Human Biological Materials

Key Organizations

- Hungarian National Authority for Data Protection and Freedom of Information: http://www.naih.hu/general-information.html

Relevant Standards

- Act XLVII of 1997 on the Handling of Medical and Other Related Data: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700047.TV&celpara=#xcelparam
- Act CXII of 2011 on Right of Informational Self-Determination and Freedom of Information: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A1100112.TV&celpara=#xcelparam
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Preparing to Apply the Privacy Policy in 12 Steps: Guidance for Data Controllers and Data Processors (2018): http://www.naih.hu/felkeszueles-az-adatvedelmi-rendelet-alkalmazasara.html

Genetic Research

Key Organizations

- The National Center for Public Health: https://www.nnk.gov.hu/

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Human Capacities (EMMI): http://www.kormany.hu/hu/emberi-eroforrasok-miniszteriuma

Relevant Standards

- Act LXXX of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Transplantation of Organs and Tissues of Human Origin: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0600080.TV&celpara=#xcelparam
- Decree 18/1998 (XII 27) EüM on Implementing Act CLIV of 1997 on Health Care as Regards Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam

EUROPE – Iceland

General

Key Organization

- Ministry of Health: https://www.government.is/ministries/ministry-of-health/
- National Bioethics Committee (NBC): http://www.vsn.is/en

Relevant Standards

- Act on Scientific Research in the Health Sector No. 44/2014: https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Health-Sector-Research-Act-No-44-2014.pdf
- Oviedo Convention on Human Rights and Biomedicine (2004): https://www.coe.int/en/web/bioethics/oviedo-convention
- Regulation on the Structure of Research Projects in the Health Sector, Including Research Protocol, Internal Monitoring, and the Responsibilities of the Principal Investigator No. 520/2018: https://www.reglugerd.is/reglugerdir/eftir-raduneytum/velferdarraduneyti/nr/21073
- NBC, Vulnerable Groups Including Children: http://www.vsn.is/en/content/vulnerable-groups-including-children
- NBC, Informed Consent: http://www.vsn.is/en/content/informed-consent
- NBC, Withdrawal of Consent: http://www.vsn.is/en/content/withdrawal-consent
- NBC, Duty to Report Unexpected Events: http://www.vsn.is/en/content/duty-report-unexpected-events
- NBC, Advertising to Recruit Participants: http://www.vsn.is/en/content/advertising-recruit-participants

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Icelandic Medicines Agency (MCA): http://www.ima.is/
- National Bioethics Committee (NBC): www.visindasidanefnd.is

Relevant Standards

- Medicinal Products Act No. 93/1994 (2013): http://eng.velferdarraduneyti.is/acts-of-Parliament/nr/20128
- MCA, Regulation on Clinical Trials of Medicinal Products in Humans No. 443/2004 (2010): https://www.government.is/media/velferdarraduneyti-media/media/Reglugerdir-enska/Regulation-on-clinical-trials-of-medicinal-products-in-humans-no-443-2004-as-amended.pdf
- NBC, various: http://www.vsn.is/en/content/clinical-trials

Devices

Key Organizations

- Ministry of Health: https://www.government.is/ministries/ministry-of-health/

Relevant Standards

- Act on Medical Devices No. 16/2001 (2011): https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Medicinal-Products-Act-NoMedicinal-Products-Act-No-93-1994-as-amended.pdf
- Regulation on Medical Devices No. 934/2010 (2010): http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/16012012_Act-on-Medical-Devices-No-16-2001-as-amended.pdf

- Regulation on Active Implantable Medical Devices No. 320/2011: http://www.stjornartidindi.is/Advert.aspx?ID=c50d676c-4651-46c2-83b5-ad946f3deeaa
- Regulation on In Vitro Diagnostic Medical Devices No. 936/2011: http://stjornartidindi.is/Advert.aspx?ID=f20b3e4e-ab25-44d3-8e32-e5f42a7b02f0

Research Injury

Key Organizations

- Icelandic Health Insurance Agency (MCA): http://www.sjukra.is/english

Relevant Standards

- Act on Patient Insurance No. 111/2000 (2011): https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Act-on-Patient-Insurance-as-amended.pdf
- Act on Health Insurance No. 112/2008 (2012): https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Act-on-Health-Insurance-No-112-2008-16.pdf
- Regulation on Clinical Trials of Medicinal Products in Humans No. 443/2004 (2010): https://www.government.is/media/velferdarraduneyti-media/media/Reglugerdir-enska/Regulation-on-clinical-trials-of-medicinal-products-in-humans-no-443-2004-as-amended.pdf

Privacy/Data Protection

Key Organizations

- Data Protection Authority: http://www.personuvernd.is/information-in-english/

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Act No. 90/2018 on Data Protection and the Processing of Personal Data: https://www.althingi.is/altext/148/s/1296.html

Human Biological Materials

Key Organizations

- Ministry of Health: https://www.government.is/ministries/ministry-of-health/
- National Bioethics Committee (NBC): www.visindasidanefnd.is/en

Relevant Standards

- Biobanks Act No. 110/2000 (2015): https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Biobanks-Act-as-amended-2015.pdf
- Regulations on the Keeping and Utilization of Biological Samples in Biobanks No. 1146/2010: https://www.reglugerd.is/reglugerdir/eftir-raduneytum/heilbrigdisraduneyti/nr/16910
- NBC, Access to and Utilisation of Health Data and Bio-Samples: http://www.vsn.is/en/content/access-and-utilisation-health-data-and-bio-samples
- NBC, Biobanks: http://www.vsn.is/en/content/biobanks

Embryos, Stem Cells, and Cloning

Relevant Standards

- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2004)
- Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No. 55/1996 (2010): https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Act_No_55_1996_on_Artificial_Fertilisation_etc_as_amended.pdf
- Regulation on Artificial Fertilization No. 144/2009: https://www.reglugerd.is/reglugerdir/eftir-raduneytum/heilbrigdis/nr/10797

EUROPE – Ireland

General

Key Organization

- Department of Health: http://health.gov.ie/

Relevant Standards

- Operational Procedures for Research Ethics Committees: Guidance 2004: http://health.gov.ie/wp-content/uploads/2014/07/Operational_Procedures1.pdf
- Health Service Executive National Consent Policy, Part 3: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Policy/

Drugs, Biologics, and Devices

Key Organizations

- Department of Health: http://health.gov.ie/
- Health Products and Regulatory Authority: https://www.hpra.ie/

Relevant Standards

- See this summary on Clinical Trials Involving Medical Products: http://health.gov.ie/blog/policy/clinical-trials-involving-medicinal-products/
- European Communities (Clinical Trials on Medicinal Products for Human Use) Amendment 2004 (S.I. No. 190 of 2004): http://www.irishstatutebook.ie/eli/2004/si/878/made/en/print
- Various: https://www.hpra.ie/homepage/site-tools/search?query=clinical%20trials

Research Injury

Key Organizations

- Health Products and Regulatory Authority: https://www.hpra.ie/

Relevant Standards

- European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004, Section 13(6)(k) and Schedule 1, Part 2, Paragraph 4 (S.I. No. 190 of 2004): http://www.irishstatutebook.ie/eli/2004/si/190/made/en/html

Privacy/Data Protection

Key Organizations

- Data Protection Commissioner (DPC): http://www.dataprotection.ie/docs/Home/4.htm
- Health Research Board (HRB): http://www.hrb.ie/

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Data Protection Act 2018: https://www.oireachtas.ie/en/bills/bill/2018/10/
- Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018: http://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/health-research-regulations-2018/
- DPC, For Organisations: http://gdprandyou.ie/organisations/
- DPC, International Transfers: https://www.dataprotection.ie/en/organisations/international-transfers/one-stop-shop-oss
- HRB, Health Research Regulations 2018 FAQ: http://www.hrb.ie/funding/gdpr-guidance-for-researchers/general-gdpr-faq/

Human Biological Materials

Key Organizations

- Health Products and Regulatory Authority: https://www.hpra.ie/

Relevant Standards

- Human Biological Material: Recommendations for Collection, Use, and Storage in Research (2005): http://health.gov.ie/wp-content/uploads/2014/07/Human_Biological_Material1.pdf

Genetic Research

Key Organizations

- Health Products and Regulatory Authority: https://www.hpra.ie/

Relevant Standards

- Irish Medicines Board, Guidelines for Pharmacogenetic Research (2006): https://www.lenus.ie/bitstream/handle/10147/96983/Pharmacogenetic06.pdf?sequence=1&isAllowed=y

EUROPE – Italy

General

Key Organization

- National Bioethics Committee (CNB): http://www.governo.it/bioetica/eng/index.html
- National Observatory on Clinical Trials (OsSC): https://www.aifa.gov.it/en/osservatorio-nazionale-sperimentazione-clinica

Relevant Standards

- OSS, Ministerial Decree of 12 May 2006: Terms of Reference for the Establishment and the Functioning of Ethics Committees
- CNB, Various: http://www.governo.it/bioetica/eng/opinions.html

Drugs, Biologics, and Devices

Drugs

Key Organizations

- National Observatory on Clinical Trials (OsSC): https://www.aifa.gov.it/en/osservatorio-nazionale-sperimentazione-clinica
- Italian Medicines Agency: http://www.agenziafarmaco.it/
- Ministry of Health (MOH): http://www.ministerosalute.it

Relevant Standards

- Decree of the President of the Republic: Regulations to Simplify the Procedures and to Verify and Check New Systems and Experimental Therapeutic Protocols (September 21, 2001) (Italian)
- Legislative Decree No. 211: Transposition of Directive 2001/20/EC Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Clinical Use (2003)
- Legislative Decree No. 200: Transposition of Directive 2005/28 EC Laying down Principles and Detailed Guidelines as Regards Investigational Medical Products for Human Use, as Well as the Requirements for Authorizing of Manufacturing or Importing of such Products (2007)
- Ministerial Decree of 21 December 2007: Directions for Submitting the Request for Authorisation of a Clinical Trial on a Medicinal Product for Human Use to the Competent Authority, for Communicating Substantial Amendments, for Declaring the End of the Trial and for the Request of an Opinion to the Ethics Committee
- Ministerial Decree of 31 March 2008: Definition of the Minimum Requirements that Contract Research Organisations (CROs) Shall Satisfy in Order to Work within Clinical Trials on Medicinal Products

Devices

Key Organizations

- Ministry of Health, Directorate General for Medicines and Medical Devices: http://www.ministerosalute.it

Relevant Standards

- Ministerial Decree 2 of August 2005: Procedures for the Presentation of Documentation to Notify about Clinical Investigations with Medical Devices
- Administrative Procedures Concerning the Conduction of Clinical Investigations with CE-Marked Medical Devices (2007)

Research Injury

Key Organizations

- Ministry of Labour and Social Policy: www.lavoro.gov.it

Relevant Standards

- Ministerial Decree 14 of July 2009: Minimum Requirements for Insurance Policies Which Safeguard Participants to Clinical Trials of Medicinal Products

Privacy/Data Protection

Key Organizations

- Italian Data Protection Independent Authority: http://www.garanteprivacy.it/garante/navig/jsp/index.jsp?solotesto=N

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Italian Personal Data Protection Code, Legislative Decree No. 196 of June 30, 2003: http://www.garanteprivacy.it/garante/navig/jsp/index.jsp?folderpath=Normativa%2FItaliana%2FIl+Codice+in+materia+di+protezione+dei+dati+personali
- Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000)
- Regulation for the Implementation of Articles No. 20 and 21 of the Legislative Decree No. 196 of June 30, 2003
- Ministerial Decree No. 277 (2007)
- General Principles of Processing Personal Data (2018): https://www.garanteprivacy.it/home/doveri#2

Genetic Research

Key Organizations

- Instituto Superiore di Sanita (ISS): https://www.iss.it/
- Italian Society of Human Genetics (SIGU): http://www.sigu.net/

Relevant Standards

- ISS, Guidelines for Phase I Clinical Trials with Investigational Medicinal Products Employed in Gene Somatic Therapy (2004): http://www.iss.it/binary/publ/publi/0478.1106653420.pdf
- SIGU, various: http://www.sigu.net/show/documenti/5/1/linee%20guida

Embryos, Stem Cells, and Cloning

Relevant Standards

- Regulation of Medically Assisted Reproduction, Law No. 40, Article 13 (2004)

EUROPE – Latvia

General

Key Organization

- Central Medical Ethics Committee

Relevant Standards

- Statutes of Central Medical Ethics Committees (1998): http://likumi.lv/doc.php?id=46597

Drugs, Biologics, and Devices

Drugs

Key Organizations

- State Agency of Medicines: http://www.zva.gov.lv/?setlang=en&large
- Central Medical Ethics Committee

Relevant Standards

- Law on Pharmacy, Section 26 (2013): https://likumi.lv/ta/en/en/id/43127-pharmaceutical-law
- Cabinet Regulation No. 289: Regulations Regarding the Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal Products, Labelling of Investigational Medicinal Products and the Procedures for Assessment of Conformity of Clinical Trial of Medicinal Products with the Requirements of Good Clinical Practice: https://likumi.lv/ta/en/en/id/207398-regulations-regarding-the-procedures-for-conduct-of-clinical-trials-and-non-interventional-trials-of-medicinal-products-labelling-of-investigational-medicinal-products-and-the-procedures-for-assessment-of-conformity-of-clinical-trial-of-medicinal-products-with-the-requirements-of-good-clinical-practice

Devices

Key Organizations

- State Agency of Medicines: http://www.zva.gov.lv/?setlang=en&large

Relevant Standards

- Medical Treatment Law, Section 34 (2014): https://likumi.lv/ta/en/en/id/44108-medical-treatment-law
- Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for Human Use (2010): https://likumi.lv/ta/en/en/id/218764-procedures-for-the-clinical-trial-of-medical-devices-intended-for-human-use

Research Injury

Key Organizations

- State Agency of Medicines: http://www.zva.gov.lv/?setlang=en&large

Relevant Standards

- Drugs: Cabinet Regulation No. 289: Regulations Regarding the Procedures for Conduct of Clinical Trials and Non-interventional Trials of Medicinal Products, Labelling of Investigational Medicinal Products and the Procedures for Assessment of Conformity of Clinical Trial of Medicinal Products with the Requirements of Good Clinical Practice, Sections 22, 31.6, 54.10, 55.9, and 61.14 (2010): https://likumi.lv/ta/en/en/id/207398-regulations-regarding-the-procedures-for-conduct-of-clinical-trials-and-non-interventional-trials-of-medicinal-products-labelling-of-investigational-medicinal-products-and-the-procedures-for-assessment-of-conformity-of-clinical-trial-of-medicinal-products-with-the-requirements-of-good-clinical-practice
- Devices: Cabinet Regulation No. 891: Procedures for the Clinical Trial of Medical Devices Intended for Human Use, Sections 42.7 and 62.5 (2010): https://likumi.lv/ta/en/en/id/218764-procedures-for-the-clinical-trial-of-medical-devices-intended-for-human-use

Privacy/Data Protection

Key Organizations

- Data State Inspectorate: http://www.dvi.gov.lv/en/

Relevant Standards

- Personal Data Processing Law (2014): https://likumi.lv/ta/en/en/id/300099-personal-data-processing-law
- Law on the Rights of Patients, Section 10 (2013): https://likumi.lv/ta/en/en/id/203008-law-on-the-rights-of-patients
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Cabinet Regulation No. 446: Procedures for Using Patient Data in a Specific Research Study (2015): https://likumi.lv/ta/en/en/id/275747-procedures-for-using-the-patient-data-in-a-specific-research

Human Biological Materials

Key Organizations

- Central Medical Ethics Committee

Relevant Standards

- Law on the Protection of the Body of Deceased Human Beings and the Use of Human Tissues and Organs in Medicine (2008): https://likumi.lv/ta/en/en/id/62843-on-the-protection-of-the-body-of-deceased-human-beings-and-the-use-of-human-tissues-and-organs-in-medicine
- Cabinet Regulation No. 1176 (2013) Procedures for Use of Human Tissues and Cells: http://likumi.lv/ta/id/261810-cilveka-audu-un-sunu-izmantosanas-kartiba

Genetic Research

Key Organizations

- Ministry of Health: http://www.vm.gov.lv/en/
- Data State Inspectorate: http://www.dvi.gov.lv/en/
- Central Medical Ethics Committee

Relevant Standards

- Human Genome Research Law (2005): https://likumi.lv/ta/en/en/id/64093-human-genome-research-law
- Law on the Development and Use of the National DNA Database (2006): https://likumi.lv/ta/en/en/id/90819-law-on-development-and-use-of-the-national-dna-database
- Regulation of the Cabinet of Ministers: "Procedures for Genetic Research" (2004): http://likumi.lv/doc.php?id=92330

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Health: http://www.vm.gov.lv/en/
- Central Medical Ethics Committee

Relevant Standards

- Sexual and Reproductive Health Law, Sections 15-20 (2004): https://likumi.lv/ta/en/en/id/58982-sexual-and-reproductive-health-law
- Cabinet Regulation No. 1176 (2013) Procedures for Use of Human Tissues and Cells: http://likumi.lv/ta/id/261810-cilveka-audu-un-sunu-izmantosanas-kartiba

EUROPE – Lithuania

General

Key Organization

- Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG
- Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?1608991497

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (2002): http://conventions.coe.int/treaty/en/treaties/html/164.htm
- Law on Ethics of Biomedical Research (2019): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/asr
- Changes of Law on Ethics of Biomedical Research No. 536/2014 (2017): https://www.e-tar.lt/portal/lt/legalAct/43db5e50d05f11e7910a89ac20768b0f
- V-405, Decree on the Procedure for Keeping a Record of Biomedical Research, Collecting, Storage, and Providing Information on Biomedical Research (2010): https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.372121
- Government of the Republic of Lithuania: Decree No. 1458 on State Fees (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.E3A145C8DD49/adJtSaHbRM
- V-15, Decree on the Procedure for Calculating and Paying Compensation for the Expenses Incurred Due to Participation in Biomedical Research and the Time Spent (2018): https://www.e-tar.lt/portal/lt/legalAct/2a0242a0b5fe11e5a6588fb85a3cc84b/ILdhwknYPP

- V-28, Decree on the Detailed Requirements for the Content of a Person's Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent (2018): https://www.e-tar.lt/portal/lt/legalAct/0f2f1b70b9db11e5a6588fb85a3cc84b/asr
- V-1483, Decree on the List of Interventional Methods of Biomedical Research Causing a Slightly Detrimental and Temporary Impact on the Subject's Health (2018): https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/828d53e095ef11e4b92e9028929aad91/asr
- V-235/A1-83, Decree on the Procedure for a Minor's Participation in Biomedical Research (2018): https://www.e-tar.lt/portal/lt/legalAct/104c2540d3e711e583a295d9366c7ab3
- V-28, Decree on the Procedure to Conduct Biomedical Research on Medical Documents, No. V-28 (2011): https://www.e-tar.lt/portal/lt/legalAct/TAR.480CDD584ADB
- V-7, Decree on the Sample Form of the Biomedical Research Protocol, Summary of the Protocol and the CV of Investigator (2017): https://www.e-tar.lt/portal/lt/legalAct/352d55b0c44111e583a295d9366c7ab3/asr
- V-24, Decree on the Procedure for Submission of the Documents to the Lithuanian Bioethics Committee to Issue Favorable Opinion to Conduct a Clinical Trial on Medicinal Products or Approval to Conduct Biomedical Research by the Sponsor of the Clinical Trial on Medicinal Product or Other Type of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/3790a050be7e11e5a6588fb85a3cc84b
- V-4, Decree on the Request to Issue Approval to Conduct Biomedical Research, the Application Form and the Biomedical Research Ethical Assessment Form (2016): https://www.e-tar.lt/portal/lt/legalAct/27a3460090f011e4bb408baba2bdddf3/UqgJXDRUqi
- Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical Research of the LBEC (2018): http://bioetika.sam.lt/get_file.php?file=bmNlV3pKeWhhWjJlcW1xZ2xxQnNrWlprbXM2VWtKblJ5Wlp1ekptZG1hV2V5c3JXbUdGa3IzR2NrNkNab1pxVng2aVprR2ZIWk0yWG81ekxrMnlYY21tV3lwSEtvbWFjbkp4bWNwcCUyQmNZT2FlMjdUWThacno4ZW1iTlBHbWNlbmJzbVZ4SjJWYWFHZW9HYW1tNmhvajVobmFwR1ZrbW1jbFdSd2xwdGxsR1pzbHB5WnlXQmdxRzZhWVozRmNKMXJuZyUzRCUzRA==&view=1

Drugs, Biologics, and Devices

Drugs

Key Organizations

- State Medicines Control Agency (SMCA): https://www.vvkt.lt/index.php?1148175238
- Lithuanian Bioethics Committee (LBEC): http://bioetika.sam.lt/index.php?1608991497

Relevant Standards

- Law on Ethics of Biomedical Research (2019): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL
- Law on Pharmacy of the Republic of Lithuania, Consolidated Version from 01/01/2021 to 31/12/2021: https://www.e-tar.lt/portal/lt/legalAct/TAR.FF33B3BF23DD/asr
- Decree No. 320 on the Rules of Good Clinical Practice (2006): https://www.e-tar.lt/portal/lt/legalAct/TAR.EF5F8A32B830/WkRbILGNxF

- Corrections of GCP Terminology in Lithuanian (2006): https://www.e-tar.lt/portal/lt/legalAct/TAR.1C6613E02B96
- Decree No. V-6 on the Sample Form of the Request to Issue Favorable Opinion to Conduct Clinical Trial on Medicinal Product Form and the Ethical Assessment Form (2016): https://www.e-tar.lt/portal/lt/legalAct/b65b5ca0c44011e583a295d9366c7ab3/qcrDrSCSCJ
- Decree No. 435 on the Procedure for Issuing a Favorable Opinion to Conduct Clinical Trials on Medicinal Product, Approval for Clinical Trials on Medicinal Product, and Conducting and Controlling Clinical Trials (2017): https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.277308/QPLLKpOUKw
- Guidelines to Advertise Clinical Trials, Adopted by the Group of Experts on Biomedical Research of the LBEC (2018): http://bioetika.sam.lt/get_file.php?file=bXNlVnpKV2hacDJkcXBPZ3lLQnhrY1prbXM1c2tHalJ5SmFlekpLZHc2Vnl5c3JXeDJGa3IybWNscUNYb1oyVmxxaHJrR1RIYmMzTG8yN0xtbTJaYTJ1Vm1wSElvcFdjblp4bGNweDVucFdXb1d6VGJNWnB6OHFqbk1mR29jYWlidFBIekp5bllLdWNvWlNjbktHYWtwZWVhYzVqMW1tMG5IaWN1cHVLeDRLYnQ1VzNuWHVTaG1xS1puaVRaV2xobm1adWwyeVBsOVNjbTU3TWwyJTJCWmRKbyUzRA==&view=1

Devices

Key Organizations

- Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG
- State Health Care Accreditation Agency Under the Ministry of Health (SHCA): http://www.vaspvt.gov.lt/en

Relevant Standards

- Decree No. V-2 on the Procedure to Issue Approvals to Conduct Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.47B235393D3A/zpczrvbOOR
- Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/dReKXfNQaQ
- Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/43db5e50d05f11e7910a89ac20768b0f
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745
- 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 (Effective 31 January 2022): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0537

Clinical Trial Registries

Key Organizations

- Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG

Relevant Standards

- Law on Ethics of Biomedical Research (2019): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL

- Decree No. 745 on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor (2016): https://www.e-tar.lt/portal/lt/legalAct/c86cf490b3be11e598c4c7724bda031b/IaIhDiebov

Research Injury

Key Organizations

- Research Council of Lithuania, Committee of Humanities and Social Sciences: https://www.lmt.lt/en/about-the-research-council/contacts/2279/committee-of-humanities-and-social-sciences/d22

Social-Behavioral Research

Key Organizations

- State Data Protection Inspectorate: https://www.ada.lt/go.php/eng

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Law of the Republic of Lithuania on the Legal Protection of Personal Data: https://www.e-tar.lt/portal/lt/legalAct/TAR.5368B592234C/sqyPjSiFfg

Privacy/Data Protection

Key Organizations

- Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG

Relevant Standards

- All standards and links provided under "General" apply.

Human Biological Materials

Key Organizations

- Lithuanian Bioethics Committee: http://bioetika.sam.lt/index.php?1610097551

Relevant Standards

- Legislation Governing the Conduct of Clinical Trials for Medical Products: http://bioetika.sam.lt/index.php?1958596978

Genetic Research

Key Organizations

- Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG

Relevant Standards

- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2002): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=168

- Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/wKarWpLPIL
- Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/43db5e50d05f11e7910a89ac20768b0f
- Decree No. V-660 on the Procedure to Issue Authorization for the Transit of Tissues of Human Embryonic Tissue, Embryonic Stem Cells and their Lines, Fetal Tissue, and Fetal Stem Cells throughout the Territory of the Republic of Lithuania (2007): https://www.e-tar.lt/portal/lt/legalAct/TAR.8A75E79827FD
- Decree No. V-659 on the Procedure for Importing of the Stem Cells Taken from the Umbilical Cord or Placenta after the Birth of a Child and the Samples Taken for Genetic Research into the Territory of the Republic of Lithuania and Exporting Therefrom (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.E2473B1958CA/gEtbNSRzzc

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Health (MOH): http://www.sam.lt/go.php/lit/IMG

Relevant Standards

- Approval of Samples of Stem Cells Extracted from the Umbilical Cord or Placenta After the Birth of a Child for the Purpose of Biomedical Research: https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.302907

EUROPE – Luxembourg

General

Key Organization

- National Ethics Consultative Commission: http://www.cne.lu
- Health Ministry: https://msan.gouvernement.lu/en.html
- Health Directorate: https://guichet.public.lu/en/organismes/organismes_citoyens/ministere-sante/direction-sante.html
- National Research Ethics Committee (CNER): https://www.cner.lu/en-gb/Home

Relevant Standards

- National Ethics Commission, Opinion, various: http://www.cne.public.lu/fr/publications/avis.html
- Regulation of the Government in Council of November 28, 2014 establishing an independent National Consultative Ethics Commission […]: http://www.cne.public.lu/fr/commission/statut.html
- CNER, Various Statutes and Legislations, General (International) Framework: https://www.cner.lu/en-gb/Statutes-Legislation
- CNER, Various Statutes and Legislations, Luxemburg Framework: https://www.cner.lu/en-gb/Statutes-Legislation

Drugs, Biologics, and Devices

Key Organizations

- Health Ministry: https://msan.gouvernement.lu/en.html
- Health Directorate: https://guichet.public.lu/en/organismes/organismes_citoyens/ministere-sante/direction-sante.html
- National Research Ethics Committee (CNER): https://www.cner.lu/en-gb/Home
- Division of Pharmacy and Medicines of the Ministry of Health: http://www.sante.public.lu/fr/politique-sante/ministere-sante/direction-sante/div-pharmacie-medicaments/index.html

Relevant Standards

- Law of 8 March 2018 relating to hospitals and hospital planning: http://legilux.public.lu/eli/etat/leg/loi/2018/03/08/a222/jo
- Grand-Ducal Decree of May 30, 2005 on the Conduct of Clinical Trials on Medicinal Products for Human Use: http://www.legilux.public.lu/leg/a/archives/2005/0084/2005A15161.html
- CNER, Publications and Guidance, various: https://www.cner.lu/en-gb/Publications
- Clinical trials, Regulation (EU) No 536/2014: https://ec.europa.eu/health/human-use/clinical-trials/regulation_en
- Medical Devices, Regulation (EU) 2017/745: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
- Health Directorate, Commercialization pof Medical Devices in Luxemburg: https://sante.public.lu/fr/politique-sante/ministere-sante/direction-sante/div-pharmacie-medicaments/medical-devices-EN.pdf

Clinical Trial Registries

Key Organizations

- Health Ministry: https://msan.gouvernement.lu/en.html
- Health Directorate: https://guichet.public.lu/en/organismes/organismes_citoyens/ministere-sante/direction-sante.html
- National Research Ethics Committee (CNER): https://www.cner.lu/en-gb/Home

Privacy/Data Protection

Key Organizations

- National Data Protection Commission: http://www.cnpd.public.lu/fr/index.html

Relevant Standards

- 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): https://eur-lex.europa.eu/eli/reg/2016/679/oj

- Act of 1 August 2018 on the Organisation of the National Data Protection Commission, Articles 63-65: https://cnpd.public.lu/dam-assets/fr/legislation/droit-lux/Act-of-1-August-2018-on-the-organisation-of-the-National-Data-Protection-Commission-and-the-general-data-protection-framework.pdf

Human Biological Materials

Key Organizations

- Health Ministry: https://msan.gouvernement.lu/en.html

Relevant Standards

- Law of 1 August 2007 Relating to Human Tissues and Cells Intended for Human Applications: https://legilux.public.lu/eli/etat/leg/loi/2007/08/01/n12/jo

Genetic Research

Key Organizations

- National Research Ethics Committee (CNER): https://www.cner.lu/en-gb/Home

Relevant Standards

- Guidelines Regarding Incidental Findings and Informed Consent Management in the Framework of Whole Genome Sequencing Research Projects: https://www.cner.lu/fr-fr/Publications

EUROPE – Malta

General

Key Organization

- Bioethics Committee: http://health.gov.mt/en/regcounc/Bioethics-Committee/Pages/CommitteeMembers.aspx

Relevant Standards

- Various: http://health.gov.mt/en/regcounc/Bioethics-Committee/Pages/Opinions.aspx

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Medicines Authority: http://medicinesauthority.gov.mt/

Relevant Standards

- Medicines Act, 2003: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8924&l=1
- Subsidiary Legislation, 458.43, Clinical Trials Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11281&l=1
- Subsidiary Legislation, 458.47, Good Clinical Practice and Requirements for Manufacturing or Import Authorisation of Investigational Medicinal Products (Human Use) Regulations, 2004: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11285&l=1

- Guidance Notes on Good Clinical Practice (2018): https://globi-reg.com/wp-content/uploads/2020/01/Guidance-Notes-on-Good-Clinical-Practice.pdf

Devices

Key Organizations

- Medicines Authority: http://medicinesauthority.gov.mt/
- Malta Competition and Consumer Affairs Authority, Technical Regulations Division: https://mccaa.org.mt/Section/index?sectionId=1063

Relevant Standards

- Product Safety Act, 2001: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8893&l=1
- Subsidiary Legislation, 427.16, *In Vitro* Diagnostic Medical Devices Regulations, 2003: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10756&l=1
- Subsidiary Legislation, 427.44, Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10781&l=1
- Subsidiary Legislation, 427.10, Active Implantable Medical Devices Regulations, 2010: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=10753&l=1

Privacy/Data Protection

Key Organizations

- Office of the Information and Data Protection Commissioner: https://idpc.org.mt/

Relevant Standards

- Data Protection Act, 2002: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8906&l=1
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj

EUROPE – Moldova

NOTE: For an overview of human subject protections in Moldova, see "Ethical Review of Biomedical Research in the CIS Countries," Chapter 3, Section 7: http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf

General

Key Organization

- Ministry of Health, National Committee for Ethical Expertise of Clinical Trials: http://ms.gov.md/?q=comitetul-national-etica

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (2002): https://www.coe.int/en/web/bioethics/oviedo-convention
- Law No. 1409 Dated 17.12.1997 on Medicines, Articles 11 and 12: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=31 1586

- Law No. 263 Dated 27.10.2005 on Patients' Rights and Responsibilities. Articles 9, 10, 11, 12, 13, and 14: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=313060

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health, National Committee for Ethical Expertise of Clinical Trials: http://ms.gov.md/?q=comitetul-national-etica
- Medicines and Medical Devices Agency: http://www.amed.md/

Relevant Standards

- Law No. 1409 Dated 17.12.1997 on Medicines, Articles 11 and 12: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311586
- Law No. 263 Dated 27.10.2005 on Patients' Rights and Responsibilities. Articles 9, 10, 11, 12, 13, and 14: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=313060
- Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Expertise of Clinical Trial: http://lex.justice.md/md/362783/
- Order No.648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in the Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf

Research Injury

Key Organizations

- Ministry of Health (MOH): http://www.ms.gov.md/

Relevant Standards

- Law No. 411-XIII Dated 28.03.1995 on Health: http://lex.justice.md/viewdoc.php?action=view&view=doc&id=312823&lang=1
- Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Expertise of Clinical Trials: http://lex.justice.md/md/362783/
- Order No. 648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in the Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf

Privacy/Data Protection

Key Organizations

- National Center for Personal Data Protection of the Republic of Moldova: https://datepersonale.md/en/

Relevant Standards

- Convention No. 108 for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981): https://www.coe.int/en/web/data-protection/moldova
- Decision of Parliament No. 483-XIV Dated 02.07.1999 on Ratification of Convention No. 108: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=309121

- Law No. 982 Dated 11.05.2000 on Access to Information: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311759
- Law No.133 Dated 08.07.2011 on the Protection of Personal Data: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=340495
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- LP143 Din 19.07.18, MO309-320/17.08.18 Article 482
- Decision of Government No. 1123 Dated 14.12.2010 on the Approval of the Requirements for the Assurance of Personal Data Security at their Processing within the Information Systems of Personal Data: http://old.datepersonale.md/file/hotariri/cerinte_securitate%20eng_101228.pdf
- Law on personal data protection (2011); The Law on enunciation of certain declarations to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data by the Republic of Moldova: https://datepersonale.md/en/legislation/national-legislation/law/

Human Biological Materials

Key Organizations

- Ministry of Health (MOH): http://www.ms.gov.md/
- Transplant Agency: http://lex.justice.md/md/334622

Relevant Standards

- Law No. 42 Dated 06.03.2008 on Transplantation of Organs, Tissues and Human Cells: http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=327709
- LP79 Din 24.05.18, MO195-209/15.06.18 Article 338
- Order No.648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Health (MOH): http://www.ms.gov.md/

Relevant Standards

- REGULATION No. 902 of 09.02.2000 on the manner of issuing licenses for conducting research in the field of genetics and microbiology in the Republic of Moldova: http://www.vertic.org/media/National%20Legislation/Moldova/MD_Regulation_902_Genetics_Microbiology.pdf

EUROPE – Montenegro

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health of Montenegro: https://www.gov.me/en/mzd
- Institute for Medicines and Medical Devices: https://www.cinmed.me/Portal/faces/glavna.jspx?_adf.ctrl-state=ye0txrsh1_4

Relevant Standards

- Various, Legislations: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967271693989170&paramPut=Legislation++%3E++Laws&paramRender=2&paramS=94&_adf.ctrl-state=ye0txrsh1_122
- Various, Rulebooks: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967358763502102&paramPut=Legislation++%3E++Rulebooks&paramRender=2&paramS=95&_adf.ctrl-state=ye0txrsh1_161
- Various, Decrees and Orders: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967402452526204&paramPut=Legislation++%3E++Decrees+and+Orders&paramRender=2&paramS=98&_adf.ctrl-state=ye0txrsh1_195
- Various, Good Practice Guidelines: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967427083926799&paramPut=Legislation++%3E++Good+Practice+guidelines&paramRender=2&paramS=99&_adf.ctrl-state=ye0txrsh1_229
- Forms, Medicines: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967477611251621&paramPut=Legislation++%3E++Forms+%E2%80%93+Medicines&paramRender=2&paramS=62&_adf.ctrl-state=ye0txrsh1_297
- Forms, Devices: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967525698520403&paramPut=Legislation++%3E++Forms+-+Medical+devices&paramRender=2&paramS=100&_adf.ctrl-state=ye0txrsh1_331
- Various, Instructions: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967545352596410&paramPut=Legislation++%3E++Instructions&paramRender=2&paramS=96&_adf.ctrl-state=ye0txrsh1_365

Research Injury

Key Organizations

- Ministry of Health of Montenegro: https://www.gov.me/en/mzd
- Institute for Medicines and Medical Devices: https://www.cinmed.me/Portal/faces/glavna.jspx?_adf.ctrl-state=ye0txrsh1_4

Relevant Standards

- Law on Medicines, see various, Legislations: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967271693989170&paramPut=Legislation++%3E++Laws&paramRender=2&paramS=94&_adf.ctrl-state=ye0txrsh1_122
- Law on Medical Devices, see various, Legislations: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967271693989170&paramPut=Legislation++%3E++Laws&paramRender=2&paramS=94&_adf.ctrl-state=ye0txrsh1_122

Privacy/Data Protection

Key Organizations

- National Security Agency: http://www.anb.gov.me/en/Home?alphabet=lat

Relevant Standards

- Law on the Protection of Personal Data (Official Gazette of Montenegro No. 79/08, 70/09, 44/12): http://www.azlp.me/docs/zajednicka/zakoni/zakon-o-zastiti-podataka-o-licnosti.pdf

Human Biological Materials

Key Organizations

- Ministry of Health of Montenegro: https://www.gov.me/en/mzd

Relevant Standards

- Law on the Collection and Use of Biological Samples (Official Gazette of Montenegro No. 14/2010): http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=57491&rType=2&file=ZAKON%20O%20UZIMANJU%20I%20KORI%C5%A0%C4%86ENJU%20BIOLO%C5%A0KIH%20UZORAKA.pdf

Genetic Research

Key Organizations

- Ministry of Health of Montenegro: https://www.gov.me/en/mzd

Relevant Standards

- Law on the Protection of Genetic Data (Official Gazette of Montenegro No. 25/2010): http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=57566&rType=2&file=ZAKON%20O%20ZA%C5%A0TITI%20GENETI%C4%8CKIH%20PODATAKA%20.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Health of Montenegro: https://www.gov.me/en/mzd

Relevant Standards

- Rulebook on the Collection, Storage, and Use of Stem Cells (2012): http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=222783&rType=2&file=Pravilnik%20o%20postupku%20prikupljanja,%20%C4%8Duvanja%20i%20upotrebe%20mati%C4%8Dnih%20%C4%87elija%2056-2012.pdf

EUROPE – Netherlands

General

Key Organization

- Central Committee for Research Involving Human Subjects (CCMO): https://english.ccmo.nl/

Relevant Standards

- Population Screening Act (1996): https://wetten.overheid.nl/BWBR0005699/2021-07-01
- Medical Research Involving Human Subjects Act (1998): https://wetten.overheid.nl/BWBR0009408/2021-07-01
- Various, Laws: https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/laws
- Various, Decrees and Ministerial Regulations: https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/decrees-and-ministerial-regulations
- Various, CCMO Directives: https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/ccmo-directives
- Various, Codes of Conduct: https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research/codes-of-conduct

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health, Welfare, and Sport (VWS): http://www.government.nl/ministries/vws#ref-minvws
- Central Committee for Research Involving Human Subjects (CCMO): https://english.ccmo.nl/
- Medicines Evaluation Board (MEB): http://english.cbg-meb.nl/

Relevant Standards

- VWS, Medicines Act (2007): http://wetten.overheid.nl/BWBR0021505
- VWS, Medicines Act Decree (2007): https://wetten.overheid.nl/BWBR0021672/2018-08-01
- VWS, Medicines Act Regulation (2007): http://wetten.overheid.nl/BWBR0022160
- CCMO, Clinical Research with Medicinal Products in the Netherlands: Instructional Manual (2005)
- CCMO Memorandum, Definition of Medical Research: https://english.ccmo.nl/investigators/publications/publications/2005/11/25/ccmo-memorandum-definition-of-medical-research

Clinical Trial Registries

Key Organizations

- Netherlands Trial Register: http://www.trialregister.nl/trialreg/index.asp
- CCMO Register: https://www.toetsingonline.nl/to/ccmo_search.nsf/Searchform?OpenForm

Research Injury

Key Organizations

- Ministry of Health, Welfare and Sport: http://www.government.nl/ministries/vws#ref-minvws

Relevant Standards

- Medical Research Involving Human Subjects Act, Article 7 (1998): https://wetten.overheid.nl/BWBR0009408/2021-07-01

- CCMO, Decree of 2014 containing rules for compulsory insurance in medical research involving human subjects and explanatory memorandum: https://english.ccmo.nl/publications/publications/2020/08/12/decree-2014-containing-rules-for-compulsory-insurance-in-medical-research-involving-human-subjects-and-explanatory-memorandum

Social-Behavioral Research

Key Organizations

- National Ethics Council for Social and Behavioural Sciences: http://www.nethics.nl/

Relevant Standards

- Ethical Code (2018): http://www.nethics.nl/Gedragscode-Ethical-Code/
- CCMO, Memorandum Behavioural Research: https://english.ccmo.nl/investigators/publications/publications/2002/01/01/ccmo-memorandum-behavioural-research

Privacy/Data Protection

Key Organizations

- Dutch Data Protection Authority: https://cbpweb.nl/en
- Central Committee for Research Involving Human Subjects (CCMO): https://english.ccmo.nl/

Relevant Standards

- Law for the Protection of Personal Information (2000): http://wetten.overheid.nl/BWBR0011468
- General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj

Human Biological Materials

Key Organizations

- Central Committee for Research Involving Human Subjects (CCMO): https://english.ccmo.nl/

Relevant Standards

- Civil Code, Article 467 (1994)
- Human Tissue and Medical Research: Code of Conduct for responsible use (2011): https://www.bbmri.nl/sites/bbmri/files/styles/Federa_code_of_conduct_english.pdf

Genetic Research

Key Organizations

- Dutch Health Care Inspectorate (IGZ): http://www.igz.nl/english/
- Central Committee for Research Involving Human Subjects (CCMO): https://english.ccmo.nl/

Relevant Standards

- Medical Research Involving Human Subjects Act (1998): https://wetten.overheid.nl/BWBR0009408/2021-07-01
- Guidelines for Researchers and Sponsors with Regard to the Assessment by Official Bodies of Clinical Research Involving Gene Therapeutics in the Netherlands (2012)

Embryos, Stem Cells, and Cloning

Key Organizations

- Central Committee for Research Involving Human Subjects (CCMO): https://english.ccmo.nl/

Relevant Standards

- Foetal Tissue Act (2001) (Dutch): http://wetten.overheid.nl/BWBR0012983/
- Embryos Act (2002): https://wetten.overheid.nl/BWBR0013797/2021-07-01

EUROPE – North Macedonia, Republic of

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Ministry of Health of Republic of Macedonia: www.zdravstvo.gov.mk
- Drug and Devices Register: https://lekovi.zdravstvo.gov.mk/
- Drug Agency: http://malmed.gov.mk/

Relevant Standards

- Law on Medicinal Products and Medical Devices (Official Gazette No.106/2007) and Laws Amending and Supplementing the Law: https://lekovi.zdravstvo.gov.mk/documents/2
- Health Care Law (Official Gazette No. 43/2012) and Laws Amending and Supplementing the Law, Article 275: http://www.fzo.org.mk/default.asp?ItemID=37115BDC6DEF524D877A8C36F95A85F6
- Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2009): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/817325622?t:ac=1/1
- Rulebook on Amending and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2010): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/879452170?t:ac=1/1
- Rulebook on Amending and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2012): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/880033320?t:ac=1/1
- Rulebook on Amending and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents and Annex No.3 (Guideline for the Clinical Trial Applicant) (Document No. 23.3) (2012): https://lekovi.zdravstvo.gov.mk/documents/1/1
- Rulebook on Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents (2016) (Document No. 23.4): https://lekovi.zdravstvo.gov.mk/documents/1/1
- Regulation on the Manner of Reporting, Contents of the Reporting Form for Adverse Reactions to Medicinal Products and the Manner of Organisation of Pharmacovigilance System (2012): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/880287913?t:ac=1/1

- Guideline for the Clinical Trial Applicant (Annex 3) (Sub-folder 23.2) (2012): https://lekovi.zdravstvo.gov.mk/documents/1/1
- Guideline for Good Clinical Practice, Official Gazette No.62/2009, Document No. 19: https://lekovi.zdravstvo.gov.mk/documents/1/1
- Rulebook for the Required Documentation and the Method of Application for Clinical Trials on Medical Devices and the Amendments, and Reporting of Drug Adverse Reactions and Events (Official Gazette No. 62/2010): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/844338380?t:ac=1/2

Devices

Key Organizations

- Ministry of Health of Republic of Macedonia: https://vlada.mk/node/17970?ln=en-gb
- Drug and Devices Register: https://lekovi.zdravstvo.gov.mk/
- Drug Agency: http://malmed.gov.mk/

Relevant Standards

- Law on Medicinal Products and Medical Devices (Official Gazette No.106/2007) and Laws Amending and Supplementing the Law: https://lekovi.zdravstvo.gov.mk/documents/2
- Rulebook for the Required Documentation and the Method of Application for Clinical Trials on Medical Devices and the Amendments, and Reporting of Drug Adverse Reactions and Events (Official Gazette No. 62/2010): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/844338380?t:ac=1/2
- Rulebook on the Manner of Reporting Adverse Effects During the Use of Medical Devices, Types of Reactions they Cause, the Actions of Health Workers and Suppliers, As Well as the Manner of Organizing the System of Monitoring Adverse Effects and Reactions to Medical Devices (Official Gazette No.100/2016) (Document No.8): https://lekovi.zdravstvo.gov.mk/documents/1/2

Research Injury

Key Organizations

- Ministry of Health of Republic of Macedonia: https://vlada.mk/node/17970?ln=en-gb
- Drug Agency: http://malmed.gov.mk/

Relevant Standards

- Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and Documentation Contents (2009): https://lekovi.zdravstvo.gov.mk/documents.documentcomponent:downloadfile/817325622?t:ac=1/1

Social-Behavioral Research

Key Organizations

- Center for public health, Department for Social Medicine: https://www.cph.mk/en/sio/ozsm

Privacy/Data Protection

Key Organizations

- Directorate for Personal Data Protection: www.dzlp.mk

Relevant Standards

- Law on Ratification on Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2005)
- Law on Ratification on Additional Protocol to the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2008)
- Law on Personal Data Protection, Consolidated (2016): https://www.dzlp.mk/sites/default/files/Law_on_Personal_Data_Protection_Cleared_version_0.pdf ; and amendments (2021): https://www.dzlp.mk/sites/default/files/u4/lpdp_2020.pdf
- Regulations on Protection of Personal Data: https://dzlp.mk/sites/default/files/77121008d1284263a9e519ae9b24f80c.pdf
- Directorate for Personal Data Protection, Rule book for the Manner of Performing Inspection Supervision: https://www.dzlp.mk/sites/default/files/u4/RULEBOOK%20FOR%20THE%20MANNER%20OF%20PERFORMING%20INSPECTION%20SUPERVISION.pdf
- Rulebook on transfer of personal data: https://dzlp.mk/sites/default/files/052e8e10cf2e4bd48e7827e7bc85fb62.pdf

Human Biological Materials

Key Organizations

- Ministry of Health of Republic of Macedonia: https://vlada.mk/node/17970?ln=en-gb
- Health Insurance Fund of Republic of Macedonia: http://www.fzo.org.mk

Relevant Standards

- Law on Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, With Additional Protocol on the Prohibition of Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (2009): http://www.pravo.org.mk/documentDetail.php?id=5543
- Law on Health Protection: (Official Gazette No. 43/2012) and Laws Amending and Supplementing the Law (2012-2016): http://zdravstvo.gov.mk/zakon-za-zdravstvenata-zashtita/
- Law on Taking and Transplanting of Human Body Organs (Official Gazette No. 47/2011) and Laws Amending and Supplementing the Law (2011-2016): http://zdravstvo.gov.mk/zakon-za-zemanje-i-presaduvanje-na-delovi-na-chovechkoto-telo-zaradi-lekuvanje/
- Sub-Law Acts: http://www.fzo.org.mk/default.asp?ItemID=6541AC10FFC3C5498F0887C57131D996
- Regulations for Transplantation of Tissues and Organs (13 regulations): http://www.fzo.org.mk/default.asp?ItemID=6541AC10FFC3C5498F0887C57131D996

- Regulation on Criteria Relating to Space, Personnel and Equipment for Collection, Transplantation and Exchange of Organs and Tissues, the Necessary Space, Equipment and Staff Required to be Provided by the Health Institution for the Collection, Transfer, Exchange and Storage of Organs and Tissues from Human Body for Treatment Purposes (2012): http://zdravstvo.gov.mk/wp-content/uploads/2012/12/za_pobliskite_kriteriumi_vo_odnos_na_prostorot_kadarot_i_opremata_za_zemawe_presaduvawe_i_razmenuvawe_na_organite_i_tkivata_za_potrebniot_pr.pdf

Genetic Research

Key Organizations

- Ministry of Health of Republic of Macedonia: https://vlada.mk/node/17970?ln=en-gb

Relevant Standards

- Law on Patient Rights Protections, Article 21: Action on Human Genome (2012): http://zdravstvo.gov.mk/wp-content/uploads/2012/12/zakon-za-zastita-na-pravata-na-pacientite-precisten.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Health of Republic of Macedonia: https://vlada.mk/node/17970?ln=en-gb

Relevant Standards

- Law on Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, With Additional Protocol on the Prohibition of Cloning Human Beings and Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (2009): http://www.pravo.org.mk/documentDetail.php?id=5543

EUROPE – Norway

General

Key Organization

- National Committee for Medical and Health Research Ethics (NEM): https://www.etikkom.no/en/our-work/about-us/the-national-committee-for-medical-and-health-research-ethics-nem/
- Regional Committees for Medical and Health Research Ethics (REK): https://helseforskning.etikkom.no/forside?_ikbLanguageCode=us
- National Committee for Research Ethics in Science and Technology (NENT): https://www.etikkom.no/en/our-work/about-us/the-national-committee-for-research-ethics-in-science-and-technology-nent/
- National Committee for Research Ethics on Human Remains: https://www.etikkom.no/en/our-work/about-us/the-national-committee-for-research-ethics-on-human-remains/

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (2006): https://www.coe.int/en/web/bioethics/oviedo-convention

- Law regarding Ethics and Integrity in Research (2006): http://www.ub.uio.no/ujur/ulovdata/lov-20060630-056-eng.pdf
- Act on Health Care Research (2008): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&
- Organization of Health Research: https://lovdata.no/dokument/SF/forskrift/2009-07-01-955
- Population-Based Health Survey: https://lovdata.no/dokument/SF/forskrift/2018-04-27-645
- Right of Children Between 12-16 Years to Consent to Participate in Health Research: https://lovdata.no/dokument/SF/forskrift/2017-06-28-1000
- Guidelines for Research on Persons with Impaired Informed Consent Capacity (2005)
- Payment for Research Participants in Medical and Health Research (2009)
- Guidelines for Research Ethical and Scientific Evaluation of Qualitative Research Projects in Medical and Health Research (2009): https://www.etikkom.no/forskningsetiske-retningslinjer/Medisin-og-helse/Kvalitativ-forskning/
- Guidelines for Ethical Evaluation and Post-marketing Studies (2003)
- Guidelines for Genetic Research of Humans (2016) (Norwegian): https://www.etikkom.no/forskningsetiske-retningslinjer/Medisin-og-helse/retningslinjer-for-bruk-av-genetiske-undersokelser-av-mennesker-i-medisinsk-og-helsefaglig-forskning/
- NENT, Research Ethics Guidelines for Science and Technology (2016): https://www.etikkom.no/en/ethical-guidelines-for-research/guidelines-for-research-ethics-in-science-and-technology/
- Guidelines for Research Ethics on Human Remains: https://www.etikkom.no/en/ethical-guidelines-for-research/guidelines-for-research--ethics-on-human-remains/

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Norwegian Medicines Agency: https://legemiddelverket.no/english

Relevant Standards

- Medicines Act: https://lovdata.no/dokument/NL/lov/1992-12-04-132?q=lov%20om%20legemidler
- Act on Health Care Research: https://lovdata.no/dokument/NL/lov/2008-06-20-44?q=helseforskningsloven
- Regulation Relating to Clinical Trials on Medicinal Products for Human Use (2009): http://lovdata.no/dokument/SF/forskrift/2009-10-30-1321?q=forskrift+om+kliniske+utpr%C3%B8vning
- Guidelines for the Regulations Concerning Clinical Trials of Human Drugs (1999): http://www.legemiddelverket.no/Godkjenning_og_regelverk/Klinisk-utproving/Regelverk%20og%20veiledninger/Documents/Veiledning%20-%20revidert%20versjon%202.2%2006.11.2012.pdf

Devices

Key Organizations

- Norwegian Medicines Agency: https://legemiddelverket.no/english

Relevant Standards

- Act of 12 January 1995 No. 6 Relating to Medical Devices (1995): http://lovdata.no/dokument/NL/lov/1995-01-12-6?q=lov+om+medisinsk+utstyr
- Act on Health Care Research: https://lovdata.no/dokument/NL/lov/2008-06-20-44?q=helseforskningsloven
- Regulation of December 15th 2005 No. 1690 Relating to Medical Devices (2005): http://lovdata.no/dokument/SF/forskrift/2005-12-15-1690?q=forskrift+medisinsk+utstyr
- Various: https://legemiddelverket.no/english/medical-devices/regulatory-information-regarding-medical-devices

Research Injury

Key Organizations

- Norwegian System of Patient Injury Compensation: https://www.npe.no/en/information-compensation-claimants/drug-injury/clinical-trials/

Relevant Standards

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2007): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164
- Act on Patient Injury Compensation (2001): https://lovdata.no/dokument/NL/lov/2001-06-15-53
- Act on Product Liability, Chapter 3: https://lovdata.no/dokument/NL/lov/1988-12-23-104?q=produktansvarsloven

Social-Behavioral Research

Key Organizations

- National Committee for Research Ethics in the Social Sciences and the Humanities (NESH): https://www.etikkom.no/en/our-work/about-us/the-national-committee-for-research-ethics-in-the-social-sciences-and-the-humanities-nesh/
- National Committee for Research Ethics on Human Remains (NCEHR): https://www.etikkom.no/en/our-work/about-us/the-national-committee-for-research-ethics-on-human-remains/

Relevant Standards

- Research Ethics Act (2017): https://lovdata.no/dokument/NL/lov/2017-04-28-23?q=forskningsetikk
- Act of Cultural Heritage (1978): https://lovdata.no/dokument/NL/lov/1978-06-09-50
- NESH, Guidelines for Research Ethics in the Social Sciences, Law, and the Humanities (2016): https://www.etikkom.no/en/ethical-guidelines-for-research/guidelines-for-research-ethics-in-the-social-sciences--humanities-law-and-theology/
- NESH, Guide to Internet Research Ethics (2018): https://www.etikkom.no/en/ethical-guidelines-for-research/ethical-guidelines-for-internet-research/

- NCEHR, Guidelines for Research Ethics on Human Remains: https://www.etikkom.no/en/ethical-guidelines-for-research/guidelines-for-research--ethics-on-human-remains/

Privacy/Data Protection

Key Organizations

- Norwegian Data Protection Authority: https://www.datatilsynet.no/en/

Relevant Standards

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Personal Data Act (2018): https://lovdata.no/dokument/NL/lov/2018-06-15-38?q=personopplysningsloven

Human Biological Materials

Key Organizations

- National Committee for Medical and Health Research Ethics (NEM): https://www.etikkom.no/en/our-work/about-us/the-national-committee-for-medical-and-health-research-ethics-nem/
- Regional Committees for Medical and Health Research Ethics (REK): https://helseforskning.etikkom.no/forside?_ikbLanguageCode=us

Relevant Standards

- Act Relating to the Application of Biotechnology in Human Medicine, etc. (Biotechnology Act) (December 5, 2003, No. 100): https://lovdata.no/dokument/NL/lov/2003-12-05-100?q=humanmedisinsk%20bruk
- Act on Health Care Research (2008): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&

Genetic Research

Key Organizations

- Norwegian Directorate of Health: https://www.helsedirektoratet.no/tema/genteknologi
- Norwegian Biotechnology Advisory Board: http://www.bion.no/english/
- National Committee for Medical and Health Research Ethics (NEM): https://www.etikkom.no/en/our-work/about-us/the-national-committee-for-medical-and-health-research-ethics-nem/
- Regional Committees for Medical and Health Research Ethics (REK): https://helseforskning.etikkom.no/forside?_ikbLanguageCode=us
- National Committee for Research Ethics in Science and Technology (NENT): https://www.etikkom.no/en/our-work/about-us/the-national-committee-for-research-ethics-in-science-and-technology-nent/

Relevant Standards

- Act Relating to the Application of Biotechnology in Human Medicine, Etc. (December 5, 2003, No. 100): https://lovdata.no/dokument/NL/lov/2008-06-20-44?q=helseforskningsloven

- Gene Technology Act: https://lovdata.no/dokument/NL/lov/1993-04-02-38?q=genteknologi
- Act on Health Care Research: https://lovdata.no/dokument/NL/lov/2008-06-20-44?q=helseforskningsloven
- Guidelines for Genetic Research in Humans (Norwegian): https://www.etikkom.no/forskningsetiske-retningslinjer/Medisin-og-helse/retningslinjer-for-bruk-av-genetiske-undersokelser-av-mennesker-i-medisinsk-og-helsefaglig-forskning/
- Guidelines for Research Ethics in Science and Technology (2016): https://www.etikkom.no/en/ethical-guidelines-for-research/guidelines-for-research-ethics-in-science-and-technology/

Embryos, Stem Cells, and Cloning

Key Organizations

- Norwegian Directorate of Health: https://www.helsedirektoratet.no/tema/genteknologi
- National Committee for Medical and Health Research Ethics (NEM): https://www.etikkom.no/en/our-work/about-us/the-national-committee-for-medical-and-health-research-ethics-nem/
- Regional Committees for Medical and Health Research Ethics (REK): https://helseforskning.etikkom.no/forside?_ikbLanguageCode=us

Relevant Standards

- Act Relating to the Application of Biotechnology in Human Medicine, etc. (Biotechnology Act) (December 5, 2003, No. 100): https://lovdata.no/dokument/NL/lov/2003-12-05-100?q=humanmedisinsk%20bruk
- Act on Health Care Research: https://lovdata.no/dokument/NL/lov/2008-06-20-44?q=helseforskningsloven

EUROPE – Poland

General

Key Organization

- Ministry of Health, Bioethics Appeals Commission (MOH) Bioethics Appeals Commission (MOH): https://www.gov.pl/zdrowie/odwolawcza-komisja-bioetyczna
- Center of Bioethics, Polish Chamber of Physicians and Dentists (NIL): https://nil.org.pl/dzialalnosc/osrodki/osrodek-bioetyki

Relevant Standards

- Constitution of the Republic of Poland, Article 39 (1997): http://www.sejm.gov.pl/prawo/konst/polski/kon1.htm
- Medical Profession Act, Articles 21-29 (1996): http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20190000537
- Order of the Minister of Health and Social Welfare on How to Establish, Finance, and the Mode of Action of Bioethics Committees (1999): http://isap.sejm.gov.pl/DetailsServlet?id=WDU19990470480
- Code of Medical Ethics, Chapter II (2003): http://www.nil.org.pl/dokumenty/kodeks-etyki-lekarskiej

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/en

Relevant Standards

- Pharmaceutical Law (2017): http://prawo.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20190000499
- Decree of the Minister of Health on Clinical Trials on Minors (2004): http://prawo.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20041041108
- Act on Medical Devices: http://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20190000175/U/D20190175Lj.pdf
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745
- 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 (Effective 31 January 2022): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536

Devices

Key Organizations

- Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/en/medical-devices

Relevant Standards

- Act on Medical Devices: http://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20190000175/U/D20190175Lj.pdf
- Regulation of the Minister of Health on Detailed Conditions to be Met for Clinical Evaluation of Medical Devices or Active Implantable Medical Devices (2011): http://prawo.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20110630331
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745
- Various: http://www.urpl.gov.pl/pl/wyroby-medyczne/akty-prawne/przepisy-rp

Clinical Trial Registries

Key Organizations

- Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/en/office

Relevant Standards

- The Central Register of Clinical Trials: https://bkwp.pl/

Research Injury

Key Organizations

- Minister of Development Funds and Regional Policy: https://www.gov.pl/web/funds-regional-policy
- Minister of Finance: https://www.gov.pl/web/finance

Relevant Standards

- Pharmaceutical Law, Chapter 36b: http://prawo.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20190000499
- Order of the Minister of Finance Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2004): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20041011034
- Order of the Minister of Finance Amending the Regulation Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2005): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20051010845
- Order of the Minister of Finance Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors in Clinical Trials of Medicinal Products (2010): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20101941290

Social-Behavioral Research

Key Organizations

- Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/en/office

Relevant Standards

- Pharmacy Law: http://prawo.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20190000499

Privacy/Data Protection

Key Organizations

- Personal Data Protection Office: https://uodo.gov.pl/en

Relevant Standards

- EU General Data Protection Regulation (GDPR): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Act on the Protection of Personal Data: https://uodo.gov.pl/en/594

Human Biological Materials

Key Organizations

- Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/en/biocidal-products

Relevant Standards

- Act of 6 September 2021 on the Public Blood Service: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210001749
- Act Regarding Sampling, Storage, and Transplanting of Cells, Tissues, and Organs: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20170001000

Genetic Research

Key Organizations

- Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/en/office

Relevant Standards

- Regulations of the Minister of Health of August 19, 2015, amending the regulation on quality standards for medical diagnostic and microbiological laboratories and microbiological laboratories: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001372
- Act of 27 July 2001 on laboratory diagnosis: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20011001083

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Health, Office for Registration of Therapeutic, Medical, and Biocidal Products: http://www.urpl.gov.pl/en/office

Relevant Standards

- Act of 1 July 2005 on collection, storage and transplantation of cells, tissues and organs: http://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20051691411/U/D20051411Lj.pdf
- Act of December 5, 1996 on Medical and Dental Professions: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU19970280152
- Regulation of the Minister of Health of 15 October 2015 on detailed requirements to be met by the documentation on germ cells and embryos: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001686
- Act of July 1, 2005 on collection, storage and transplantation of cells, tissues and organs: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20051691411
- Regulation of Minister of Health of 21 October 2015 On the export from and import into the territory of the Republic of Poland of germ cells and embryos: https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001748

EUROPE – Portugal

General

Key Organization

- National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (2001): https://www.coe.int/en/web/bioethics/oviedo-convention
- Various: http://www.cnecv.gov.pt/cnecv/en/opinions/

Drugs, Biologics, and Devices

Drugs

Key Organizations

- National Institute of Pharmacy and Medicines: http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH
- Ethics Commission for Clinical Research (CEIC): http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/CEIC

Relevant Standards

- Approval of the Applicable Legal Standards for the Conduct of Clinical Trials of Medicines for Human Use, Law No. 46/2004
- Approval of the Composition, Operations, and Financing of the Ethics Commission for Clinical Research, Decree No. 57/2005: http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/portaria_57-2005.pdf
- Decree-Law No. 102/2007 of April 2

Devices

Key Organizations

- National Institute of Pharmacy and Medicines: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS

Relevant Standards

- Various: http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMACEUTICA_COMPILADA/TITULO_V/TITULO_V_CAPITULO_II
- Various: http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS/NOTAS_INFORMATIVAS

Research Injury

Relevant Standards

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164

Privacy/Data Protection

Key Organizations

- National Data Protection Commission: https://www.cnpd.pt/

Relevant Standards

- Constitution, Article 35 (1997)
- Act on the Protection of Personal Data, No. 67/98 (1998): http://www.cnpd.pt/english/bin/legislation/Law6798EN.HTM

- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- FAQs: Consent (2018): https://www.cnpd.pt/bin/faqs/faqs.htm#consentimento

Genetic Research

Key Organizations

- Ministry of Health: http://www.portugal.gov.pt/en/the-ministries/ministry-of-health.aspx

Relevant Standards

- Law 12/2005

Embryos, Stem Cells, and Cloning

Key Organizations

- National Council of Ethics for the Life Sciences: http://www.cnecv.gov.pt/cnecv/en/

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine, Additional Protocol on Prohibition of Human Cloning (2001): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=168
- Portuguese Law on Assisted Reproductive Technologies, Articles 7 and 9 (2006)
- Opinion 15/CNECV/95 on Embryo Research (1995)
- Opinion 47/CNECV/2005 on Stem Cell Research (2005): http://www.cnecv.gov.pt/NR/rdonlyres/F13B34FD-F9F7-4C9D-96DC-419999D9B693/0/47CNECV2005.pdf
- Opinion 48/CNECV/2006 on Human Cloning (2006): http://www.cnecv.gov.pt/NR/rdonlyres/770EA390-9326-4FF9-B28D-D70A7E9AD961/0/p048_en.pdf

EUROPE – Romania

General

Key Organization

- Ministry of Health (MOH): http://www.ms.ro/

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (2001): https://www.coe.int/en/web/bioethics/oviedo-convention
- Ordinance No. 57/16.08.2002 (2002): http://www.research.gov.ro/uploads/sistemul-de-cercetare/legislatie-organizare-si-functionare/legislatia-sistemului-de-cercetare/ordonanta-57-2002.pdf

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health (MOH): http://www.ms.ro/

- National Agency for Medicines and Medical Devices: https://www.anm.ro/en/
- National Bioethics Committee for Medicines and Medical Devices: http://www.bioetica-medicala.ro/

Relevant Standards

- Order 904/25July 2006 on Approval of Rules Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use -- Transposition of 2001/20/EC Directive, and various legislation for CTs
- Various legislation for clinical trials: https://www.anm.ro/medicamente-de-uz-uman/studii-clinice/legislatie-specifica-pentru-studii-clinice/"
- 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 (it will come in application on 31 January 2022): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0537

Clinical Trial Registries

Key Organizations

- National Agency for Medicines and Medical Devices: https://www.anm.ro/en/

Relevant Standards

- Public information from clinical trials: https://www.anm.ro/medicamente-de-uz-uman/studii-clinice/informatii-publice-din-studiile-clinice/

Research Injury

Key Organizations

- National Agency for Medicines and Medical Devices: https://www.anm.ro/en/
- National Bioethics Committee for Medicines and Medical Devices: http://www.bioetica-medicala.ro/

Relevant Standards

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2001): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164
- Various legislation for clinical trials: https://www.anm.ro/medicamente-de-uz-uman/studii-clinice/legislatie-specifica-pentru-studii-clinice/

Social-Behavioral Research

Key Organizations

- The Romanian Academic Society of Behavioral Sciences: https://stiinte-comportamentale.ro/en/

Privacy/Data Protection

Key Organizations

- National Supervisory Authority for Personal Data Processing: http://www.dataprotection.ro/index.jsp?page=documents&lang=en

Relevant Standards

- Law No. 667/2001 On the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data: http://www.dataprotection.ro/servlet/ViewDocument?id=174
- EU General Data Protection Regulation (2016): https://gdpr-info.eu/

Human Biological Materials

Key Organizations

- Ministry of Health (MOH): http://www.ms.ro/

Relevant Standards

- Law No. 95/2006 Regarding the Reform in Health Field. Title VI. Performing of Sampling and Transplant of Organs, Tissues and Human Origin Cells with Therapeutic Purpose: http://legislatie.just.ro/Public/DetaliiDocument/71139
- ORDER no. 1,527 of December 16, 2014, On the Methodological Norms for the Application of Title VI "Carrying out the Collection and Transplantation of Organs, Tissues and Cells of Human Origin for Therapeutic Purposes": http://legislatie.just.ro/Public/DetaliiDocument/164199
- ORDER no. 855 of July 26, 2017, For the Approval of Therapeutic Protocols for the Removal of Organs, Tissues and Cells of Human Origin from Living and/or Deceased Donors: http://legislatie.just.ro/Public/DetaliiDocument/192507
- Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on Standards of Quality and Safety of Human Organs Intended for Transplantation: https://eur-lex.europa.eu/legal-content/RO/TXT/?uri=LEGISSUM:sp0008

Genetic Research

Key Organizations

- Regional Centers of Medical Genetics (CRGM): https://geneticamedicala.ro/en/home-2/

Relevant Standards

- ORDER no. 1,358 of November 13, 2014 on the establishment of the medical genetics network: http://legislatie.just.ro/Public/DetaliiDocument/163135

Embryos, Stem Cells, and Cloning

Relevant Standards

- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings: https://rm.coe.int/168007f2ca
- Law No. 301 from 2004 Penal Code – Chapter IV – Crimes and Felonies Regarding Genetic Manipulation

EUROPE – Russia

NOTE: For an overview of human subject protections in Russia, see http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf

General

Key Organization

- Ministry of Healthcare of the Russian Federation (MOH): http://www.rosminzdrav.ru
- Federal Service on Surveillance in Healthcare (Roszdravnadzor): http://www.roszdravnadzor.ru/
- Russian Committee for Bioethics: http://www.bioethics.ru/eng/

Relevant Standards

- Constitution of the Russian Federation, Article 21 (1993): http://www.constitution.ru/en/10003000-03.htm
- Federal Law #FZ 323 "On Foundations of Protection of Citizen's Health in the Russian Federation" (2011): http://acto-russia.org/en/index.php?option=com_content&task=view&id=105
- Federal Law #FZ55 "On Introduction of Changes in FZ "On Foundations of Protection of Citizens' Health in the Russian Federation" with Regard to Questions of Organization of Medical Aid Administered in the Course of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation" (2015): http://www.consultant.ru/document/cons_doc_LAW_176159
- Ministry of Health Order 433n (July 10, 2015) "On Adoption of the Regulations on Organization of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation (Including Order of Patients' Assignment for Administering Such Medical Help), Standard Form of Protocol for Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment, and Rehabilitation": http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=183847
- Ministry of Health Order 435h "On Ethics Committee of the Ministry of Health of the Russian Federation" (July 10, 2015): http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=183677

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Healthcare of the Russian Federation (MOH): http://www.rosminzdrav.ru
- Association of Clinical Trials Organizations: http://acto-russia.org/en/
- Federal Agency for Technical Regulation and Metrology (GOST): https://www.rst.gov.ru/portal/eng

Relevant Standards

- Federal Law No. 61FZ "On Circulation of Medicines" (2011): http://acto-russia.org/files/zakon_ob_obr_ls_en.docx
- Ministry of Health Order No. 753n (August 26, 2010)
- MOH, "On Assertion of Order of Organization and Carrying out of Ethical Review…" (Russian): http://base.garant.ru/12178437/
- Ministry of Health Order No. 774n (August 31, 2010) "On Council of Ethics" (Russian): http://www.rg.ru/2013/02/22/etika-dok.html

- Ministry of Health Order of April 1, 2016 No. 200н "On Approval of the Rules of Good Clinical Practice": http://acto-russia.org/files/prikaz_200n.docx
- GOST, Good Clinical Practice. GOST-R 52379-2005 (September 27, 2005): http://acto-russia.org/index.php?option=com_content&task=view&id=17

Research Injury

Relevant Standards

- Federal Law No. 61FZ "On Circulation of Medicines" (2011), Art. 38-44: http://acto-russia.org/files/zakon_ob_obr_ls_en.docx

Privacy/Data Protection

Relevant Standards

- Federal Law of the Russian Federation on Information, Information Technologies, and Protection of Information (2006): http://www.consultant.ru/document/cons_doc_LAW_165971/
- Federal Law of the Russian Federation No. 152-FZ on Personal Data (2006): http://base.garant.ru/12148567/

Genetic Research

Key Organizations

- Interdepartmental Commission on Genetic-Engineering Activity

Relevant Standards

- Federal Law of July 5, 1996, N OF 8'-FZ "About the State Control in the Area of Genetic-Engineering Activity": http://base.garant.ru/10135402/
- Order of the Ministry of Education and Science of the Russian Federation #154: "Statute of the Inter-Departmental Commission on Genetic-Engineering Activity" (2005): http://www.zakonprost.ru/content/base/part/438157

Embryos, Stem Cells, and Cloning

Relevant Standards

- Federal Law #30-FZ "On Introduction of Change in Art. 1 of the Federal Law "On Temporary Ban on Human Cloning" (2010): http://base.garant.ru/184467/

EUROPE – San Marino

General

Key Organization

- San Marino Bioethics Committee (Italian): http://www.sanita.sm/on-line/home/bioetica/comitato-sammarinese-di-bioetica.html

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (1998): https://www.coe.int/en/web/bioethics/oviedo-convention

Research Injury

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine, Article 24, ETS No. 164 (1998): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164

EUROPE – Serbia

General

Key Organization

- Ministry of Health (MOH): http://www.zdravlje.gov.rs/
- Medicines and Medical Devises Agency of Serbia: https://www.alims.gov.rs/eng/

Relevant Standards

- Medicines and Medical Devises Agency of Serbia, Regulations: https://www.alims.gov.rs/eng/regulations/

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health (MOH): http://www.zdravlje.gov.rs/
- Medicines and Medical Devises Agency of Serbia: https://www.alims.gov.rs/eng/

Relevant Standards

- Law on Medicines and Medical Devices: https://www.alims.gov.rs/eng/files/2013/04/Law-on-Medicines-and-Medical-Devices-2010.pdf
- Rulebook on the Contents of the Application, and/or Documentation on the Approval of Clinical Trials for Medicines and Medical Devices, as well as the Method of Implementation for Clinical Trials of Medicines and Medical Devices, Official Gazette of RS, 64/2011, 91/2013, 60/2016, and 9/2018: https://www.alims.gov.rs/eng/files/2012/10/7-Rules-on-clinical-trials.pdf
- Various rules for medicinal products: https://www.alims.gov.rs/eng/regulations/rules-for-medicinal-products/
- Various rules for medical devices: https://www.alims.gov.rs/eng/regulations/rules-for-medical-devices/

Clinical Trial Registries

Key Organizations

- Medicines and Medical Devises Agency of Serbia: https://www.alims.gov.rs/eng/

Relevant Standards

- Search approved clinical trials: https://www.alims.gov.rs/eng/medicinal-products/search-for-the-approved-clinical-trials/

Research Injury

Key Organizations

- Ministry of Health (MOH): http://www.zdravlje.gov.rs/
- Medicines and Medical Devises Agency of Serbia: https://www.alims.gov.rs/eng/

Relevant Standards

- Law on Medicines and Medical Devices, Article 72: https://www.alims.gov.rs/eng/files/2013/04/Law-on-Medicines-and-Medical-Devices-2010.pdf
- Rulebook on the Contents of the Application, and/or Documentation on the Approval of Clinical Trials for Medicines and Medical Devices, as well as the Method of Implementation for Clinical Trials of Medicines and Medical Devices, Official Gazette of RS, 64/2011, 91/2013, 60/2016, and 9/2018: https://www.alims.gov.rs/eng/files/2012/10/7-Rules-on-clinical-trials.pdf
- Law on Patients' Rights, Article 25 Official Gazette of RS, 45/2013 and 25/2019: https://www.paragraf.rs/propisi/zakon_o_pravima_pacijenata.html

Social-Behavioral Research

Key Organizations

- Ministry of Health (MOH): http://www.zdravlje.gov.rs/
- Institute of Mental Health: https://imh.org.rs/english.php

Privacy/Data Protection

Key Organizations

- Commissioner for Information of Public Importance and Personal Data Protection: https://www.poverenik.rs/en/

Relevant Standards

- Law on the Protection of Personal Data, Official Gazette 87/2018: https://www.paragraf.rs/propisi/zakon-o-zastiti-podataka-o-licnosti.html

Genetic Research

Key Organizations

- Ministry of Health (MOH): http://www.zdravlje.gov.rs/

Relevant Standards

- Law on the Prevention and Diagnosis of Genetically Conditioned Diseases, Genetically Caused Anomalies and Rare Diseases, Official Gazette 8/2015: https://www.paragraf.rs/propisi/zakon_o_prevenciji_i_dijagnostici_genetickih_bolesti_geneticki_uslovljenih_anomalija_i_retkih_bolesti.html

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Health (MOH): http://www.zdravlje.gov.rs/

- National Health Insurance Fund: http://www.rfzo.rs/

Relevant Standards

- Law on Organ Transplantation, Official Gazette No. 57/2018: https://www.paragraf.rs/propisi_download/zakon-o-presadjivanju-ljudskih-organa.pdf
- Law on Human Cells and Tissues, Official Gazette No. 57/2018: https://www.paragraf.rs/propisi/zakon-o-ljudskim-celijama-i-tkivima.html

EUROPE – Slovakia

General

Key Organization

- Ministry of Health (Slovak): http://www.health.gov.sk/
- Institute of Medical Ethics and Bioethics: http://www.bioethics.sk/

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (1998): https://www.coe.int/en/web/bioethics/oviedo-convention
- Additional Protocol on Biomedical Research (2005)
- Act No. 576/2004 Coll on Health Care, As Amended by Acts No. 350/2005, 282/2006, 662/2007, 345/2009 Coll.

Drugs, Biologics, and Devices

Key Organizations

- State Institute for Drug Control: http://www.sukl.sk/en

Relevant Standards

- Act No. 140/1998 Coll. on Drugs and Medical Devices, as amended by Acts No. 9/2004 and 542/2006, 489/2008, and 402/2009 Coll.
- Ministerial Regulation No. 239/2004 Coll. on Requirements for Clinical Trials and Good Clinical Practice, as Amended by Ministerial Regulation No. 148/2009 Coll.

Research Injury

Relevant Standards

- Law 277/1994 on Health Care, Section 44

Privacy/Data Protection

Key Organizations

- Office for Personal Data Protection: https://dataprotection.gov.sk/uoou/en

Relevant Standards

- Act No. 428/2002 Coll. on Protection of Personal Data, as amended by Act No. 90/2005 Coll.
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj

- Act no. 18/2018 On Personal Data Protection and Amending and Supplementing Certain Acts (2018): https://dataprotection.gov.sk/uoou/sites/default/files/2019_10_03_act_18_2018_on_personal_data_protection_and_amending_and_supplementing_certain_acts.pdf#overlay-context=sk/content/182018#overlay-context=sk/content/182018%22

Human Biological Materials

Relevant Standards

- Act No. 576/2004 Coll. on Health Care, Sections 35-39, and 26.10.a.
- Act No. 489/2008 Coll. on Drugs and Medical Devices, Section 18 (29b).
- Governmental Regulation No. 20/2007 Coll. on Tissue and Cell Collection
- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998)

Embryos, Stem Cells, and Cloning

Relevant Standards

- Act No. 576/2004 Coll. on Health Care, Sections 35-39, and 26.10.a
- Act No. 489/2008 Coll. on Drugs and Medical Devices, Section 18 (29b)
- Governmental Regulation No. 20/2007 Coll. on Tissue and Cell Collection
- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998)

EUROPE – Slovenia

General

Key Organization

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/zbirke/delovna-telesa/komisija-rs-za-medicinsko-etiko/
- Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/

Relevant Standards

- Health Services Act: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO214
- Decree Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research (2005): http://pisrs.si/Pis.web/pregledPredpisa?id=URED3728
- Patient Rights Act, Official Gazette No. 15/2008 55/2017: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO4281 and https://www.uradni-list.si/glasilo-uradni-list-rs/vsebina/2017-01-2526?sop=2017-01-2526

- Mental Health Act, Official Gazette Nos. 77/2008 and 46/2015: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO2157
- Code of Medical Ethics (2016): https://www.zdravniskazbornica.si/docs/default-source/zbornicni-akti/kodeks-2016.pdf?sfvrsn=2

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/zbirke/delovna-telesa/komisija-rs-za-medicinsko-etiko/
- Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/

Relevant Standards

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/zbirke/delovna-telesa/komisija-rs-za-medicinsko-etiko/
- Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/

Devices

Key Organizations

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/zbirke/delovna-telesa/komisija-rs-za-medicinsko-etiko/
- Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/

Relevant Standards

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/zbirke/delovna-telesa/komisija-rs-za-medicinsko-etiko/
- Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/

Clinical Trial Registries

Key Organizations

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/zbirke/delovna-telesa/komisija-rs-za-medicinsko-etiko/
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/

Research Injury

Key Organizations

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/zbirke/delovna-telesa/komisija-rs-za-medicinsko-etiko/
- Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/

Relevant Standards

- Medicinal Products Act, Official Gazette No. 17/2014: http://www.uradni-list.si/1/objava.jsp?sop=2014-01-0539
- Medical devices Act Official Gazette No. 98/2009: http://www.pisrs.si/Pis.web/pregledPredpisa?id=ZAKO5503
- Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1999): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=164
- Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research (2005)
- Decree ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research: http://pisrs.si/Pis.web/pregledPredpisa?id=URED3728
- Rules on Clinical Testing of Medicinal Products, Official Gazette, No. 54/2006 and 17/2014: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV6611
- Rules on Medical Devices, Official Gazette Nos. 37/2010 and 66/2012: http://www.pisrs.si/Pis.web/pregledPredpisa?id=PRAV9508

Social-Behavioral Research

Key Organizations

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/zbirke/delovna-telesa/komisija-rs-za-medicinsko-etiko/
- Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/
- National Institute of Public Health: https://www.nijz.si/en

Privacy/Data Protection

Key Organizations

- Information Commissioner of the Republic of Slovenia: http://www.ip-rs.si/

Relevant Standards

- Personal Data Protection Act No. 94/2007: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO3906
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj

Human Biological Materials

Key Organizations

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/zbirke/delovna-telesa/komisija-rs-za-medicinsko-etiko/
- Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/
- Institute for transplantation of Organs and Tissues of the Republic of Slovenia: https://www.slovenija-transplant.si/en/index.php
- Institute Service of Slovenia for Transfusion Medicine: http://www.ztm.si/en/

Relevant Standards

- Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin (2006)
- Act on Quality and Safety of Human Tissues and Cells, for the Purposes for Medical Treatment, Official Gazette No. 61/2007: http://www.uradni-list.si/1/objava.jsp?sop=2007-01-3297
- Rules on Donation and Procurement of Human Tissues and Cells, Official Gazette Nos. 70/2008, 67/2014, and 79/2014
- Act Regulating the Collection and Transplantation of Human Body Parts for the Purposes of Medical Treatment, Official Gazette No. 56/2015: http://www.uradni-list.si/1/objava.jsp?sop=2015-01-2357
- Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999): https://www.coe.int/en/web/bioethics/oviedo-convention
- On Interventions into the Human Corpse Which are Not Part of the Routine Autopsy and on Handling with Biologic Material of Human Origin (2004)

Genetic Research

Key Organizations

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/zbirke/delovna-telesa/komisija-rs-za-medicinsko-etiko/

Relevant Standards

- Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes (2009)

Embryos, Stem Cells, and Cloning

Key Organizations

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/zbirke/delovna-telesa/komisija-rs-za-medicinsko-etiko/
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/

Relevant Standards

- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998): https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=168
- Infertility Treatment and Procedures of Biomedically-Assisted Procreation Act, Official Gazette No. 70/2000, Section 9 (Slovenian): http://www.uradni-list.si/1/objava.jsp?sop=2000-01-3307
- Act on Quality and Safety of Human Tissues and Cells, for the Purposes for Medical Treatment, Official Gazette No. 61/2007 (Slovenian): http://www.uradni-list.si/1/objava.jsp?sop=2007-01-3297
- Rules on Donation and Procurement of Human Tissues and Cells, Official Gazette Nos. 70/2008, 67/2014, and 79/2014

EUROPE – Spain

NOTE: Many of the 17 Spanish autonomous regions have their own laws and regulations on human subject protections.

General

Key Organization

- Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US
- Coordinating Center for Ethical Committees on Clinical Research (Spanish): http://www.msc.es/profesionales/farmacia/ceic/home.htm
- Ministry of Science and Innovation https://ciencia.sede.gob.es/

Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (1999): http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/ETS164Spanish.pdf
- Law 14/2007 on Biomedical Research: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Spanish Agency of Medicines and Medical Devices: https://www.aemps.gob.es/

Relevant Standards

- Order SCO/362/2008 that Modifies Order SCO/256/2007: http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rcl_2008_410.pdf
- Order SAS/3470/2009 on Drugs Post Authorization Research: http://www.aemps.gob.es/legislacion/espana/medicamentosUsoHumano/docs/farmacovigilancia/rcl_2009_2577.pdf
- Royal Decree 1015/2009: Drug Availability for Special Purposes: http://www.boe.es/boe/dias/2009/07/20/pdfs/BOE-A-2009-12002.pdf

- Royal Decree 577/2013 Regulating Pharmacovigilance in Human Use Medicines: http://www.boe.es/diario_boe/txt.php?id=BOE-A-2013-8191
- Royal Decree 1090/2015 Regulating Clinical Trials with Medicinal Products, Ethics Committees for Investigation with Medicinal Products and the Spanish Clinical Studies Registry: http://noticias.juridicas.com/base_datos/Admin/565124-rd-1090-2015-de-4-dic-regula-los-ensayos-clinicos-con-medicamentos-los-comites.html

Devices

Key Organizations

- Spanish Agency of Medicines and Medical Devices: https://www.aemps.gob.es/

Relevant Standards

- Royal Decree 1591/2009, Regulating Sanitary Devices: http://www.ont.es/infesp/Legislacin/RD_1591_2009.pdf
- Various: https://www.aemps.gob.es/productos-sanitarios/prodsanitarios/

Research Injury

Key Organizations

- Spanish Agency of Medicines and Medical Devices: https://www.aemps.gob.es/

Relevant Standards

- Law 14/2007 on Biomedical Research, Article 18: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf
- Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014R0536&from=EN
- Royal Decree 1090/2015 Regulating Clinical Trials with Medicinal Products, Ethics Committees for Investigation with Medicinal Products and the Spanish Clinical Studies Registry: https://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/Royal-Decree-1090-2015_4-December.pdf

Privacy/Data Protection

Key Organizations

- Spanish Data Protection Authority: https://www.agpd.es/portalweb/index-ides-idphp.php
- Spanish Agency of Medicines and Medical Devices (AEMPS): https://www.aemps.gob.es/

Relevant Standards

- Law 14/2007 on Biomedical Research, Title I, Article 5: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf
- EU General Data Protection Regulation (2018): https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN
- Organic Law 3/2018 of December 5 on the Protection of Personal Data and Guaranteeing Digital Rights:

https://www.boe.es/biblioteca_juridica/codigos/codigo.php?id=055_Proteccion_de_Datos_de_Caracter_Personal&modo=1

- Royal Decree 1720/2007: https://www.boe.es/buscar/pdf/2008/BOE-A-2008-979-consolidado.pdf
- AEMPS, Revised Instructions for Updating the Section "Protection of Personal Data in the Subject Information Sheet (HIP /CI) Regarding the Regulation (EU) No. 2016/679 General Data Protection (2018): https://www.aemps.gob.es/investigacionClinica/medicamentos/docs/anexo8c-Ins-AEMPS-EC.pdf

Human Biological Materials

Key Organizations

- Ministry of Health, Consumer Affairs, and Social Welfare: https://www.mscbs.gob.es/en/home.htm

Relevant Standards

- Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf
- Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples: http://www.boe.es/boe/dias/2006/02/07/pdfs/A04626-04636.pdf
- Royal Decree 1723/2012 Regarding Activities of Collection, Clinical Use and Territorial Coordination of Human Organs for Transplants and Establishing Their Quality and Safety Requirements: http://noticias.juridicas.com/base_datos/Admin/rd1716-2011.html
- Royal Decree 1716/2011 on Biobanks: http://www.comitedebioetica.es/normativa/docs/RD%201716_2011_de%20autorizacion%20y%20funcionamiento%20de%20los%20biobancos.pdf
- Royal Decree 9/2014 on Quality and Security Rules Regarding Donating, Gathering, Evaluation, Processing, Storage, Preservation, and Distribution of Human Cells and Tissues and Rules Regarding Coordination and Functioning of their Use in Human Beings: http://www.boe.es/buscar/doc.php?id=BOE-A-2014-7065

Genetic Research

Key Organizations

- Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US

Relevant Standards

- Law 14/2007 of July 3 on Biomedical Research, Title I, Articles 6-9; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

- Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US

- Commission for the Donation and Use of Human Cells and Tissues: https://www.isciii.es/QueHacemos/Servicios/ComitesEtica/ComisionGarantias/Paginas/FuncionesComposicion.aspx
- National Biobank Network: https://redbiobancos.es/
- National Bank of Cell Lines: https://www.isciii.es/QueHacemos/Servicios/BIOBANCOS/BNLC/Paginas/default.aspx

Relevant Standards

- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2000)
- Law 14/2006 on Methods of Assisted Human Reproduction, Chapters IV and V
- Law 14/2007 of July 3 on Biomedical Research, Title III: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf
- Royal Decree 1527/2010 By Which the Guarantees Commission for the Donation and Use of Human Cells and Tissues and Registration Research Projects is Regulated: http://www.boe.es/diario_boe/txt.php?id=BOE-A-2010-18654
- National Biobank Network, various, Documents of Interest: https://redbiobancos.es/valor-anadido-de-la-rnbb/documentos-de-interes/

EUROPE – Sweden

For an overview of human subject protections in Sweden, see CODEX: Rules and Guidelines for Research: https://www.codex.uu.se/?languageId=1

General

Key Organization

- Swedish Ethical Review Authority: https://etikprovningsmyndigheten.se/
- Ethics Review Appeal Board: https://www.onep.se/en/start/
- Swedish Research Council: http://www.vr.se/english

Relevant Standards

- Act No. 460 on the Ethical Review of Research Involving Humans (2003): https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2003460-om-etikprovning-av-forskning-som_sfs-2003-460
- Ordinance No. 615 Concerning the Ethical Vetting of Research Involving Humans (2003): https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-2003615-om-etikprovning-av_sfs-2003-615
- Statute with Instructions for the Swedish Ethical Review Authority (2018:1879): https://svenskforfattningssamling.se/sites/default/files/sfs/2018-11/SFS2018-1879.pdf
- Statute with Instructions for the Ethics Review Appeals Board (2007:1068): http://rkrattsbaser.gov.se/sfst?bet=2007:1068
- Good Research Practice (2017): https://www.vr.se/english/analysis-and-assignments/we-analyse-and-evaluate/all-publications/publications/2017-08-31-good-research-practice.html

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Medical Products Agency: https://lakemedelsverket.se/english/

Relevant Standards

- Pharmaceuticals Act No. No. 2015:315: https://open.karnovgroup.se/halso-och-sjukvard/lakemedelslagen
- MPA Regulations on Clinical Trials in Humans -- LVFS 2011:19: http://www.lakemedelsverket.se/upload/lvfs/LVFS_2011_19.pdf

Devices

Key Organizations

- Medical Products Agency: http://www.lakemedelsverket.se/english/product/Medical-devices/Clinical-Investigations/

Relevant Standards

- Swedish Medical Devices Act (SFS 1993:584): http://www.notisum.se/rnp/sls/lag/19930584.htm
- Medical Devices Ordinance (SFS1993:876): http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-1993876-om-medicintekniska_sfs-1993-876
- Swedish Implementation of Directive 93/42/EEC -- LVFS 2003:11: https://lakemedelsverket.se/upload/lvfs/LVFS_2003-11.pdf
- HSLF-FS 2021:52 The National Board of Health and Welfare's regulations on the use of medical devices in health care: https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/foreskrifter-och-allmanna-rad/2021-6-7503.pdf

Social-Behavioral Research

Key Organizations

- Swedish Research Council: http://www.vr.se/english

Relevant Standards

- Good Research Practice: Observational Studies Conducted Through Participating, Observing, and Recording (2017): https://www.vr.se/english/analysis-and-assignments/we-analyse-and-evaluate/all-publications/publications/2017-08-31-good-research-practice.html

Privacy/Data Protection

Key Organizations

- Swedish Authority for Privacy Protection: https://www.imy.se/en/

Relevant Standards

- Patient Data Act: SFS 2008:355: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/patientdatalag-2008355_sfs-2008-355

- SFS 2009:400 - Public Access to Information and Secrecy Act: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/offentlighets--och-sekretesslag-2009400_sfs-2009-400
- Act on Certain Health Research Registers, SFS 2013:794: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2013794-om-vissa-register-for-forskning-om_sfs-2013-794
- General Data Protection Regulation (2016): https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Act (2018:218) Complement to the GDPR: https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2018218-med-kompletterande-bestammelser_sfs-2018-218
- SFS 2009:641 - Public Access to Information and Secrecy Ordinance: http://www.notisum.se/rnp/sls/lag/20090641.htm
- General Data Protection Regulation (2018): https://www.datainspektionen.se/lagar--regler/dataskyddsforordningen/
- Transmission to Third Countries (2018): https://www.datainspektionen.se/lagar--regler/dataskyddsforordningen/tredjelandsoverforing/

Human Biological Materials

Key Organizations

- Health and Social Care Inspectorate (IVO): https://www.ivo.se/om-ivo/other-languages/english/
- Biobank Sweden: http://biobanksverige.se/

Relevant Standards

- Biobanks in Medical Care Act No. 297 (2002): https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/lag-2002297-om-biobanker-i-halso--och_sfs-2002-297
- Regulation No. 746 (2002): http://www.notisum.se/rnp/sls/lag/20020746.htm
- HSLF-FS 2018: 52 The National Board of Health and Welfare's regulations on amendments to the regulations and general guidelines (SOSFS 2009: 32) on the use of tissues and cells in health care and clinical research, etc. (updated 2021): https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/dokument-webb/vagledning/ett-standardiserat-insatsforlopp-vid-demenssjukdom-en-modell-for-mangprofessionell-samverkan.pdf

Genetic Research

Key Organizations

- Medical Products Agency: https://lakemedelsverket.se/english/
- The Swedish Gene Technology Advisory Board (SGTAB): https://www.genteknik.se/

Relevant Standards

- Act on Genetic Integrity (2006:351): http://www.notisum.se/rnp/sls/lag/20060351.htm
- Drug Administration Regulations and Guidelines (LVFS 2004:10) on the Intentional Release of Clinical Trials of Medicinal Products Containing or Consisting of Genetically Modified Organisms: http://www.lakemedelsverket.se/upload/lvfs/LVFS_2004-10.pdf

- SGTAB, Advice for Ethical Assessments: https://www.genteknik.se/wp-content/uploads/2017/09/072_2010-Etisk-v%C3%A4gledning.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

- National Board of Health and Welfare (SOS): http://www.socialstyrelsen.se/english

Relevant Standards

- Act on Genetic Integrity (2006:351): http://www.notisum.se/rnp/sls/lag/20060351.htm
- Legal Regulation of Stem Cell Research 2002:119: http://www.regeringen.se/sb/d/108/a/2717
- Regulations and Guidelines for the Use of Tissues and Cells in Healthcare and Clinical Research - SOSFS 2009:32: https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/foreskrifter-och-allmanna-rad/2010-1-17.pdf
- HSLF-FS 2018: 52 The National Board of Health and Welfare's regulations on amendments to the regulations and general guidelines (SOSFS 2009: 32) on the use of tissues and cells in health care and clinical research, etc. (updated 2021): https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/dokument-webb/vagledning/ett-standardiserat-insatsforlopp-vid-demenssjukdom-en-modell-for-mangprofessionell-samverkan.pdf

EUROPE – Switzerland

General

Key Organization

- Federal Office of Public Health (FOPH): https://www.bag.admin.ch/bag/en/home.html
- Federal Office of Public Health, Portal for Human Research (FOPH): http://kofam.ch/en/home/
- National Advisory Commission on Biomedical Ethics (NEK-CNE): https://www.nek-cne.admin.ch/en/links/overview
- Swiss Association of Research Ethics Committees: https://swissethics.ch/en/

Relevant Standards

- Council of Europe Convention on Human Rights and Biomedicine of 4 April 1997, ETS No. 164, Articles 15-18: http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG
- Federal Constitution of the Swiss Confederation of 18 April, 1999, RS 101, Article 118b: http://www.admin.ch/opc/en/classified-compilation/19995395/index.html
- Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance of 20 September 2013 on Clinical Trials in Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO), RS 810.305: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html

- Ordinance of 20 September 2013 on Organizational Aspects of the Human Research Act (HRA Organisational Ordinance, OrgO-HRA), RS 810.308: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html
- Swiss Clinical Trial Organisation, Guidelines for Good Operational Practice (GGOP) (2017): https://www.scto.ch/en/publications/guidelines.html
- Ethical considerations in HIV prevention trials: https://www.unaids.org/sites/default/files/media_asset/ethical-considerations-hiv-prevention-trials_en.pdf

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en
- Federal Office of Public Health (FOPH): https://www.bag.admin.ch/bag/en/home.html

Relevant Standards

- Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), RS 812.21, Articles 53-54: http://www.admin.ch/opc/en/classified-compilation/20002716/index.html
- Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Article 7 (2014): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO), RS 810.305: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html
- Ordinance of 20 September 2013 on Organisational Aspects of the Human Research Act (HRA Organisational Ordinance, OrgO-HRA), RS 810.308, Articles 6-7: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html

Devices

Key Organizations

- Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en

Relevant Standards

- Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), RS 812.21, Articles 1-2, 45-67: https://www.admin.ch/opc/en/classified-compilation/20002716/index.html
- Federal Act of 30 September 2011on Research involving Human Beings, (Human Research Act, HRA), RS. 810.30: https://www.admin.ch/opc/en/classified-compilation/20061313/index.html

- Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Article 7: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html
- Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO), RS 810.305 articles 20, 32, 37, 42-45 and Annexes 1, 3 and 4: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html
- Ordinance of 20 September 2013 on Organisation Aspects of the Human Research Act (HRA Organisation Ordinance, OrgO-HRA), RS 810.308, Articles 6-7: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html
- Swissmedic Guide to the Regulation of Medical Devices: https://www.swissmedic.ch/swissmedic/en/home/medical-devices/regulation-of-medical-devices.html

Clinical Trial Registries

Key Organizations

- Swiss National Clinical Trials Portal: https://www.kofam.ch/en/snctp-portal/

Relevant Standards

- Federal Act on Research Involving Human Beings, Articles 56, 64, 65, and 67 (2014): https://www.admin.ch/opc/en/classified-compilation/20061313/index.html

Research Injury

Key Organizations

- Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/index.html?lang=en
- Federal Office of Public Health (FOPH): https://www.bag.admin.ch/bag/en/home.html

Relevant Standards

- Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 19-20: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Articles 8, 12, 13, and 15, and Annexes 1-2: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html
- Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance ClinO), RS 810.305, Articles 7, 10-13, 25, and 71, and Annexes 2-3: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html

Privacy/Data Protection

NOTE: Most Swiss cantons have enacted laws regarding data collection in the public sector that are similar to the Federal Act on Data Protection.

Key Organizations

- Federal Data Protection and Information Commissioner (FDPIC): https://www.edoeb.admin.ch/edoeb/en/home/the-fdpic/links/data-protection---switzerland.html

Relevant Standards

- Federal Act of 19 June 1992 on Data Protection (FADP), RS 235.1: http://www.admin.ch/opc/en/classified-compilation/19920153/index.html
- Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 2, 3, 8, 16-18, 31-35, 41-45, 47, 49, 58-60, and 63: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 5 - 8, 10, 15, 21, 24-34, 37-39, 41, and 44-45, and Annex 2: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305 Articles 5, 7, 9, 12, 16-18, and 25, and Annexes 2-3: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html

Human Biological Materials

Key Organizations

- Federal Office of Public Health (FOPH): https://www.bag.admin.ch/bag/en/home.html
- Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/en/News/News.html

Relevant Standards

- Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 2, 3, 17, 18, 31, 32 - 35, 41-43, 45, 47, 49, and 63: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance of 14 February 2007 on Human Genetic Testing, RS 810.122.1: http://www.admin.ch/opc/fr/classified-compilation/20051790/index.html
- Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301 Articles 5 - 8, 10, 15, 21, 24-30, 33-34, 37 - 39, 41, 44-45 and Annex 2): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 7, 9, 12, 16 - 18 and Annex 2: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html

Genetic Research

Key Organizations

- Federal Office of Public Health (FOPH): https://www.bag.admin.ch/bag/en/home.html

Relevant Standards

- Federal Constitution of the Swiss Confederation of 18 April 1999, RS 101, Article 119: http://www.admin.ch/opc/en/classified-compilation/19995395/index.html
- Federal Act of 8 October 2004 on Human Genetic Testing (HGTA), RS 810.12: http://www.admin.ch/opc/en/classified-compilation/20011087/index.html

- Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 3, 32 - 35, 42, and 49: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance of 14 February 2007 on Human Genetic Testing, RS 810.122.1 (French): http://www.admin.ch/opc/fr/classified-compilation/20051790/index.html
- Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 28 - 32: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305 Articles 22 and 35, and Annexes 3 and 4: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html

Embryos, Stem Cells, and Cloning

Key Organizations

- Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE): https://www.nek-cne.admin.ch/en/homepage-nek-cne

Relevant Standards

- Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30 Articles 2, 25 - 27, 39, 40, 44, and 62: http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Federal Act of 19 December 2003 on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), RS 810.31: http://www.admin.ch/opc/en/classified-compilation/20022165/index.html
- Ordinance of 2 February 2005 on Research involving Embryonic Stem Cells (Stem Cell Research Ordinance, SCRO), RS 810.311: http://www.admin.ch/opc/en/classified-compilation/20042542/index.html
- Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 44 – 46, and Annex 2: http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 49, 53, 55, and 56, and Annexes 3 and 4: http://www.admin.ch/opc/en/classified-compilation/20121176/index.html
- Research Involving Human Embryos and Fetuses. Opinion No. 11/2006: https://www.nek-cne.admin.ch/inhalte/Themen/Stellungnahmen/en/embryonen_en.pdf
- Pre-Implantation Genetic Diagnosis II, Opinion No. 14/2007: https://www.nek-cne.admin.ch/inhalte/Themen/Stellungnahmen/PID_II_d.pdf

EUROPE – Ukraine

General

Key Organization

- Ukrainian Ministry of Health: http://www.moz.gov.ua/en/

Relevant Standards

- To search all documents in the Ukraine Legislation database visit: https://zakon.rada.gov.ua/laws/main/ay2021
- Constitution of Ukraine Art. 28 (1996)
- Health Care Law, Article 45 (1992)
- Criminal Code of Ukraine 2001, Article 141 and 142

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health of Ukraine State Expert Center: http://www.dec.gov.ua
- National Academy of Sciences Bioethics Committee

Relevant Standards

- Ministry of Health Act on Procedure of Clinical Trials and Basic Statute of Ethics Commission 23.09/2009 No. 690: https://zakon.rada.gov.ua/laws/show/z1010-09#n16
- Preclinical studies, various laws: https://www.dec.gov.ua/materials/doklinichni-doslidzhennya/
- Clinical Trials, various laws: https://www.dec.gov.ua/materials/klinichni-vyprobuvannya/
- Medical Products, various legislation: https://www.dec.gov.ua/materials/pereklady-normatyvno-pravovyh-aktiv-anglijskoyu-movoyu/
- Various guidelines and instructions: https://www.dec.gov.ua/materials/nastanovi/
- Bioethics Committee, Information Letters on Ethics Questions of Clinical Trials and Implementation of Medicines (2006)
- Bioethics Committee, Ethics Expertise of Clinical Trials Medicines (2007)
- Bioethics Committee, Methodological Aspects of Central EC Activity of Ukrainian Ministry of Health (2007)
- Bioethics Committee, Ethical Aspects of Placebo Controlled Clinical Trials in Patients with MS (2008)
- Bioethics Committee, Optimization of Local Ethics Committee Activities (2009)

Research Injury

Key Organizations

- Ukrainian Ministry of Health: http://www.moz.gov.ua/en/

Relevant Standards

- On Medicines, Article 8 No. 123/96BP (2014): https://zakon.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80#n110

Privacy/Data Protection

Key Organizations

- State Service of Ukraine on Personal Data Protection
- Ukrainian Parliament Commissioner for Human Rights: www.ombudsman.gov.ua

Relevant Standards

- Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2010)
- On Protection of Personal Data Act, 01.06.2010 with changes from 19.10.2017

Human Biological Materials

Key Organizations

- Ukrainian Ministry of Health: http://www.moz.gov.ua/en/

Relevant Standards

- To search all documents in the Ukraine Legislation database visit: https://zakon.rada.gov.ua/laws/main/ay2021
- Cabinet Ministry of Ukraine Act No. 286 on 02.03.2016 License Conditions on Providing Activities of Banks of Cord Blood and Other Human Tissues and Cells
- Ministry of Health Act 20.04.12 No. 276 On Approving the List of Human Tissues and Cells, Allowing the Use of Banks of Cord Blood and Other Human Tissues and Cells
- Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) with Changes from 23.09.2009 No. 690

Embryos, Stem Cells, and Cloning

Key Organizations

- National Academy of Sciences Bioethics Committee
- Ukrainian Ministry of Health: http://www.moz.gov.ua/en/

Relevant Standards

- To search all documents in the Ukraine Legislation database visit: https://zakon.rada.gov.ua/laws/main/ay2021
- Act on the Banning of Human Reproductive Cloning (2004)
- Act on the Transplantation on Human Using Anatomic Materials (2019)
- Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007)
- Ukrainian Ministry of Health Order No. 787 on Approval of the Use of Reproductive Technologies in Ukraine 09.09.2013

EUROPE – United Kingdom

NOTE: For an overview of clinical research regulations in the United Kingdom, see the ClinRegs report: *http://clinregs.niaid.nih.gov/single_country.php?c_id=226*

NOTE: Unless otherwise noted, all laws, regulations, and guidelines listed for England also apply to the entire United Kingdom

General

England

Key Organization

- Health Research Authority (HRA): http://www.hra.nhs.uk/
- Department of Health and Social Care (DHSC): https://www.gov.uk/government/organisations/department-of-health-and-social-care
- Medical Research Council (MRC): https://www.mrc.ac.uk/

Relevant Standards

- HRA, Research Governance Framework for Health and Social Care UK Policy Framework for Health and Social Care Research (2018): https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- HRA, Governance Arrangements for Research Ethics Committees (2018): https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/
- HRA, Guidance: https://www.hra.nhs.uk/planning-and-improving-research/
- HRA, Integrated Research Application System: https://www.myresearchproject.org.uk/
- DHSC, Mental Capacity Act (2005) (England and Wales only): http://www.legislation.gov.uk/ukpga/2005/9/contents
- DHSC, Health and Social Care Act (2012): http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted
- DHSC, Care Act (2014): http://www.legislation.gov.uk/ukpga/2014/23/contents/enacted/data.htm
- DHSC, Ionising Radiation (Medical Exposure) Regulations (2017): http://www.legislation.gov.uk/uksi/2017/1322/contents/made
- MRC, Research Involving Human Participants in Developing Societies (2004): https://mrc.ukri.org/publications/browse/research-involving-human-participants-in-developing-societies/
- MRC, Medical Research Involving Children (2004): https://mrc.ukri.org/documents/pdf/medical-research-involving-children/
- MRC, Medical Research Involving Adults Who Cannot Consent (2007): https://mrc.ukri.org/documents/pdf/medical-research-involving-adults-who-cannot-consent/
- MRC, Good Research Practice: Principles and Guidelines (2012): https://mrc.ukri.org/publications/browse/good-research-practice-principles-and-guidelines/

Scotland

Key Organizations

- NHSScotland, Chief Scientist Office (CSO): http://www.cso.scot.nhs.uk/
- NHS Research Scotland: http://www.nhsresearchscotland.org.uk/

Relevant Standards

- Adults with Incapacity (Scotland) Act 2000, Section 51: https://www.legislation.gov.uk/asp/2000/4/body

- Adults with Incapacity (Ethics Committee) (Scotland) Amendment Regulations (2002): https://www.legislation.gov.uk/ssi/2002/302/contents/made
- CSO, Research Governance Framework for Health and Community Care (2006): http://www.cso.scot.nhs.uk/wp-content/uploads/2013/02/RGF-Second-Edition-February-06.pdf

Wales

Key Organizations

- Health and Care Research Wales: http://www.healthandcareresearchwales.org/

Relevant Standards

- Research Governance Framework for Health and Social Care in Wales Second Edition (2009): http://www.wales.nhs.uk/sites3/Documents/952/Research%20Governance%20Framework%202009%20%28English%291.pdf

Northern Ireland

Key Organizations

- Department of Health, Social Services and Public Safety: http://www.dhsspsni.gov.uk/
- Office for Research Ethics Committees Northern Ireland: http://www.hscbusiness.hscni.net/orecni.htm

Relevant Standards

- Ionising Radiation (Medical Exposure) (Northern Ireland) Regulations (2018): http://www.legislation.gov.uk/nisr/2018/17/contents/made

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
- Administration of Radioactive Substances Advisory Committee (ARSAC) (UK): https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee
- Department of Environment, Food & Rural affairs (DEFRA): https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs
- Health and Safety Executive (HSE): http://www.hse.gov.uk/
- Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk
- National Institute for Health Research: http://www.nihr.ac.uk/
- Health Research Authority (HRA): http://www.hra.nhs.uk/

Relevant Standards

- Medicines Act (1968): http://www.legislation.gov.uk/ukpga/1968/67/contents
- Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031 (2004): http://www.legislation.gov.uk/uksi/2004/1031/contents/made

- Amendment Regulations (SI 2006/1928): http://www.legislation.gov.uk/uksi/2006/1928/contents/made
- Amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 and Adults with Incapacity (Scotland) Act 2000 to Facilitate Clinical Research in Emergency Settings (SI 2006/2984): http://www.legislation.gov.uk/uksi/2006/2984/pdfs/uksi_20062984_en.pdf
- SI 2008 No.941 The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment Regulations 2008: http://www.legislation.gov.uk/uksi/2008/941/contents/made
- Genetically Modified Organisms (Deliberate Release) Regulations 2002: http://www.legislation.gov.uk/uksi/2002/2443/contents/made
- Genetically Modified Organisms (Contained Use) Regulations 2014 (England, Scotland and Wales): http://www.legislation.gov.uk/uksi/2014/1663/part/1/made
- Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015: http://www.legislation.gov.uk/nisr/2015/339/contents/made
- ABPI, Guidelines for Phase I Clinical Trials (2018): https://www.abpi.org.uk/publications/guidelines-for-phase-i-clinical-trials-2018-edition/
- National Institute for Health Research, Clinical Trials Toolkit: http://www.ct-toolkit.ac.uk/
- HRA, Clinical Trials of Investigational Medicinal Products (CTIMPs) – Resource page: http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/clinical-trials-of-investigational-medicinal-products/

Devices

Key Organizations

- Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/collections/regulatory-guidance-for-medical-devices
- Health Research Authority (HRA): http://www.hra.nhs.uk/

Relevant Standards

- Medical Devices Regulations (2002): http://www.opsi.gov.uk/si/si2002/20020618.htm
- Medical Devices (Amendment) Regulations 2008 No. 2936: http://www.legislation.gov.uk/uksi/2008/2936/contents/made
- Clinical Trials for Medical Devices: https://www.gov.uk/government/collections/regulatory-guidance-for-medical-devices
- Notify MHRA About a Clinical Investigation for a Medical Device: https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device
- HRA, Medical Devices Guidance: http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/medical-devices-research-2/

Clinical Trial Registries

Key Organizations

- ISRCTN: http://www.isrctn.com/
- Health Research Authority (HRA): http://www.hra.nhs.uk/

Relevant Standards

- ISRCTN, FAQs: http://www.isrctn.com/page/faqs
- HRA, Transparency: Researchers' Responsibilities: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-and-research-project-identifiers/

Research Injury

Key Organizations

- Medicines and Healthcare Products Regulatory Agency (MHRA): https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
- Department of Health (DH): https://www.gov.uk/government/organisations/department-of-health
- Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk
- Association of the British Healthcare Industry (ABHI): http://www.abhi.org.uk/

Relevant Standards

- MHRA, Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031, Regulation 15(5)(i)(j)(k) and Schedule 3 Part 1, Paragraphs 1(g) and 3(c) (2004): http://www.legislation.gov.uk/uksi/2004/1031/contents/made
- DH, NHS Indemnity Arrangements for Clinical Negligence Claims in the NHS: https://resolution.nhs.uk/wp-content/uploads/2018/10/NHS-Indemnity.pdf
- ABPI, Insurance and Compensation in the Event of Injury in Phase I Clinical Trials (2012): https://www.abpi.org.uk/media/1647/phase-i-clinical-trials-insurance-guidance.pdf
- ABPI, Clinical Trial Compensation Guidelines (2014): https://www.abpi.org.uk/media/1607/compensation_guidelines_2014.pdf
- ABHI, Clinical Investigations Compensation Guidelines (2014): http://www.abhi.org.uk/multimedia/groups/clinical-investigations/ci_compensationguidelines.doc

Social-Behavioral Research

Key Organizations

- Economic and Social Research Council: https://esrc.ukri.org/
- UK Research Integrity Office: https://ukrio.org/

Relevant Standards

- ESRC, Framework for Research Ethics (2015): http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/
- Good Practice in Research: Internet-Mediated Research (2016): http://ukrio.org/wp-content/uploads/UKRIO-Guidance-Note-Internet-Mediated-Research-v1.0.pdf

Privacy/Data Protection

United Kingdom

Key Organization

- Information Commissioner's Office: https://ico.org.uk/

- Health Research Authority (HRA): https://www.hra.nhs.uk
- Medical Research Council (MRC): http://www.mrc.ac.uk/

Relevant Standards

- Data Protection Act (2018): http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted
- ICO, Guide to the General Data Protection Regulation (2018): https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/
- ICO, International Transfers (2018): https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/international-transfers/
- HRA, GDPR Guidance: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/
- HRA, Consent in Research (2018): https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/consent-research/
- MRC, Using Information About People in Health Research (2017): https://mrc.ukri.org/documents/pdf/using-information-about-people-in-health-research-2017/

England and Wales

Key Organizations

- Health Research Authority (HRA) (England): http://www.hra.nhs.uk/
- Confidentiality Advisory Group (CAG): http://www.hra.nhs.uk/about-the-hra/our-committees/section-251

Relevant Standards

- Health Service (Control of Patient Information) Regulations 2002 (HS (CPI) Regs): http://www.legislation.gov.uk/uksi/2002/1438/made?view=plain
- HRA, Research Data and Tissue Resources: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-data-and-tissue-resources/
- Section 251 and the Confidentiality Advisory Group (CAG): http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/

Human Biological Materials

United Kingdom

Key Organization

- Human Tissue Authority (HTA): http://www.hta.gov.uk/
- Medical Research Council (MRC): https://www.mrc.ac.uk/

Relevant Standards

- Human Tissue Act (2004) (Applies to England, Wales, and Northern Ireland. Section 45 also applies in Scotland.): http://www.legislation.gov.uk/ukpga/2004/30/contents
- Statutory Instrument 2006 No. 1260: The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations (2006) (Applies to England, Wales, and Northern Ireland.): http://www.legislation.gov.uk/uksi/2006/1260/contents/made

- Statutory Instrument 2006 No. 1659: The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations (2006) (Different provisions apply to England, Wales, Northern Ireland, and/or Scotland): http://www.legislation.gov.uk/uksi/2006/1659/contents/made
- HTA, Guidance for Professionals: https://www.hta.gov.uk/guidance-professionals
- MRC, Human Tissue and Biological Samples for Use in Research (2014): https://mrc.ukri.org/publications/browse/human-tissue-and-biological-samples-for-use-in-research/

Scotland

Key Organizations

- Healthcare Improvement Scotland: https://www.healthcareimprovementscotland.org/

Relevant Standards

- Human Tissue (Scotland) Act 2006: http://www.legislation.gov.uk/asp/2006/4/contents

Genetic Research

Key Organizations

- Public Health Genetics Foundation: http://www.phgfoundation.org/
- Gene Therapy Advisory Committee: http://www.hra.nhs.uk/resources/applying-to-recs/gene-therapy-advisory-committee-gtac/
- Genomics England: https://www.genomicsengland.co.uk/

Embryos, Stem Cells, and Cloning

Key Organizations

- Human Fertilisation and Embryology Authority: http://www.hfea.gov.uk/
- Human Tissue Authority (HTA): https://www.hta.gov.uk/

Relevant Standards

- Human Fertilisation and Embryology Act (1990): http://www.legislation.gov.uk/ukpga/1990/37/contents
- HFE Act (2008): http://www.legislation.gov.uk/ukpga/2008/22/contents
- Human Fertilisation and Embryology Regulation and Chronology: https://www.hfea.gov.uk/about-us/how-we-regulate/
- HFEA Code of Practice 9th Edition (2018): https://www.hfea.gov.uk/media/2609/june-2018-code-of-practice-9th-edition-draft.pdf

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