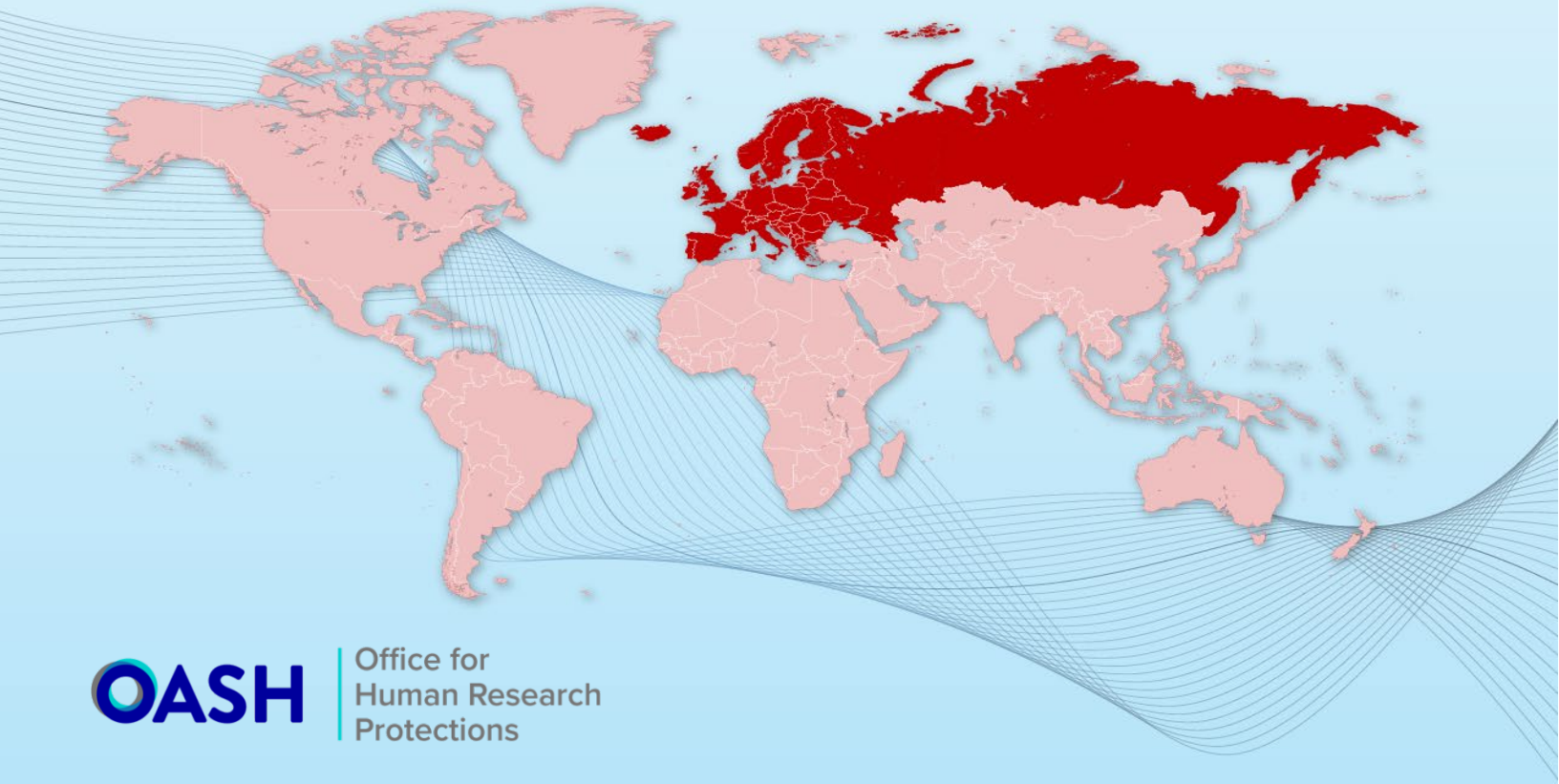
# International Compilation of Human Research Standards
# 2024 Edition

**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 the protection of research participants in more than 130 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 the conduct or oversight of research involving human participants around the world.

## ORGANIZATION

You may jump to a specific country by clicking its name in the Table of Contents.

This document is organized by country in alphabetical order. Before the world regions, there is a section for standards provided by several international organizations. Under each section, you will find the countries or international organizations organized also in alphabetical order. For each country or international organization, 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 as 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 only authorize an agency to promulgate standards, but that they themselves do not include substantive standards
3. Laws, regulations, or guidelines that are disease-specific or focus on research integrity, clinical ethics, products liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, informed consent in clinical practice, radiation, or environmental safety, etc.
4. Ethics codes of academic, medical, or other professional organizations
5. Working papers, drafts, commentaries, or discussion papers

## GENERAL REQUEST FOR PUBLIC INPUT AND COMMENTS

To request that we include a new standard or a new country in the International Compilation, or to let us know of changes to these standards or broken links, please email 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 opinion. In addition, because the standards contained in this Compilation may be created, changed, or revoked on a continuing basis, this Compilation is not an exhaustive source of all current standards, and the information provided may be incomplete or outdated. Users of this compilation must not rely only on the information it provides but should also check with local authorities, legal counsel, and/or research ethics committees before commencing research activities.

# TABLE OF CONTENTS

# EUROPE – Regionwide

## General

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

- European Group on Ethics in Science and New Technologies (EGE), Various Opinions and Statements: https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics_en#ege-opinions-and-statements
- European Commission, Research and Innovation, Law and Regulations, Various: https://ec.europa.eu/info/research-and-innovation/law-and-regulations_en
- How to Complete your Ethics Self-Assessment for Horizon 2020 Proposals (2015): http://ec.europa.eu/ethicsselfassessment/guidance

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

- Oviedo Convention on Human Rightsand Biomedicine and its Protocols: https://www.coe.int/en/web/bioethics/oviedo-convention
- Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (2005): https://rm.coe.int/168008371a
- Various Recommendations: https://www.coe.int/en/web/bioethics/treaties-recommendations
- Various Guides: https://www.coe.int/en/web/bioethics/guides
- Guide for research ethics committee members: https://www.coe.int/en/web/bioethics/guide-for-research-ethics-committees-members

### Uppsala University, CODEX Rules and Guidelines for Research: https://www.codex.uu.se/

## Drugs, Biologics, and Devices

### European Commission, Public Health, Pharmaceuticals: http://ec.europa.eu/health/index_en.htm

***Drugs***

- Legal framework Governing Medicinal Products for Human Use in the EU, various: https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu_en
- Clinical Trials, various regulations, directives, and guidance: https://health.ec.europa.eu/medicinal-products/clinical-trials_en
- EudraLex , Body of European Union Legislation in the Pharmaceutical Sector: https://health.ec.europa.eu/medicinal-products/eudralex_en
- Reform of the EU Pharmaceutical Legislation (2023): https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

***Devices***

- Medical Devices, New regulations, various: https://health.ec.europa.eu/medical-devices-new-regulations_en
- Medical Devices, Directives, various: https://health.ec.europa.eu/medical-devices-sector/directives_en

- Medical Devices, Implementing Measures for Directives, List of Key Documents: https://health.ec.europa.eu/medicaldevices/directives/measures
- Medical Devices, Implementing Measures for Directives, Guidance: https://health.ec.europa.eu/medical-devices-sector/directives_en

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

***Drugs***

- Human Regulatory, Research and development, various: https://www.ema.europa.eu/en/human-regulatory-overview/research-development
- Human Regulatory, Clinical Trials in Human Medicines, various: https://www.ema.europa.eu/clinicaltrialshumanmedicines
- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997): https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e6-r1-guideline-good-clinical-practice_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): https://www.ema.europa.eu/system/files/documents/regulatory-procedural-guideline/reflection_paper_on_ethical_and_gcp_aspects_of_clinical_trials_en.pdf
- Guideline for Good Clinical Practice E6(R2) (2016): https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-good-clinical-practice
- Data Quality Framework for EU Medicines Regulation (2023): https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/data-quality-framework-eu-medicines-regulation_en.pdf

***Devices***

- Human Regulatory, Medical Devices, Various: https://www.ema.europa.eu/en/human-regulatory-overview/medical-devices

## Clinical Trial Registries

**EU Clinical Trials Register:** https://euclinicaltrials.eu/

- Guidance and Q&As: https://euclinicaltrials.eu/guidance-and-q-as/
- FAQs: https://www.clinicaltrialsregister.eu/doc/EU_CTR_FAQ.pdf

## Research Injury

- European Commission, Public Health, Pharmaceuticals: http://ec.europa.eu/health/index_en.htm
- 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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98

- Council of Europe Committee on Bioethics Guide for Reserch Ethis Committee Members: https://rm.coe.int/guideforresearchethicscommitteemembers

## Privacy/Data Protection

***NOTE: The General Data Protection Regulation (GDPR) applies to all countries in the European Economic Area (the EEA). The EEA includes all 27 member countries of the European Union (EU) plus Iceland, Norway, and Liechtenstein.***

***NOTE: Due to the United Kingdom's departure from the European Union (EU), there are notable differences in the UK regarding scope and protections of the General Data Protection Regulation (GDPR).***

### 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/2016/679/personaldataprocessingprotection
- Guidelines on consent under Regulation 2016/679, WP259 rev.01: http://ec.europa.eu/consentguidelines/679/2016
- Various Guidelines, Recommendations, Best Practices: https://www.edpb.europa.eu/our-work-tools/general-guidance/guidelines-recommendations-best-practices_en
- Various Opinions: https://www.edpb.europa.eu/our-work-tools/consistency-findings/opinions_en
- 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-29/1998
- Working Document on Adequacy Referential (2018): https://ec.europa.eu/newsroom/article29
- 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
- Data Quality Framework for EU Medicines Regulation (2023): https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/data-quality-framework-eu-medicines-regulation_en.pdf
- Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European Data Governance and Amending Regulation (EU) 2018/1724 (Data Governance Act): https://eur-lex.europa.eu/datagovernanceact

### 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): https://www.ema.europa.eu/en/documents/report/questions-and-answers-european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.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

**Council of Europe, Data Protection and Cybercrime Division:** http://www.coe.int/dataprotection/

- Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981): https://rm.coe.int/1680078b37
- 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://rm.coe.int/cmrec-97-5-on-the-protection-of-medical-data
- 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: https://ec.europa.eu/justice/article-29/documentation/index_en.htm

## Human Biological Materials

**European Commission, European Group on Ethics in Science and New Technologies:** https://research-and-innovation.ec.europa.eu/european-group-ethics

**European Commission, Public Health, Blood, Tissues, Cells and Organs:** https://health.ec.europa.eu/blood-tissues-cells-and-organs_en

- Blood, Tissues, Cells and Organs: Key Documents: https://health.ec.europa.eu/blood-tissues-cells-and-organs/key-documents
- 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/directive2004/23/EC
- 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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Recommendation Rec (2016) 6 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin: https://search.coe.int/rec/2016/6

## 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/1394/2007

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

- Oviedo Convention, Additional Protocol Concerning Genetic Testing for Health Purposes (CETS No. 203): https://rm.coe.int/1680084824
- Recommendation No. R(92)3 on Genetic Testing and Screening for Health Care Purposes (1992): http://wcd.coe.int/recommendation/R/92/3
- Recommendation CM/Rec(2006)4 of the Committee of Ministers to Members States on Research on Biological Materials of Human Origin: https://search.coe.int/CM/Rec/2006/4
- Recommendation CM/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: https://search.coe.int/CM/Rec/2016/8

## Embryos, Stem Cells, and Cloning

### European Commission, European Group on Ethics in Science and New Technologies: https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics_en

- Statements by the Commission Re: Article 6 (2006)
- Statement of the Commission Related to Research Activities Involving Human Embryonic Stem Cells (2013)
- Commission Staff Working Paper Report on Human Embryonic Stem Cell Research (2003)
- Opinion No. 22 - The Ethics Review of hESC FP7 Research Projects (2007): http://bookshop.europa.eu/ethicsreviewhESCFP7/22/2007

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

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Statement on Genome Editing Technologies by the Committee on Bioethics (2015): https://rm.coe.int/168049034a

# EUROPE – Armenia

***NOTE: For a database of Armenian legislation, see: https://cis-legislation.com/index.fwx***

## Drugs, Biologics, and Devices

### Key Organizations

- The Scientific Center of Drug and Medical Technologies Expertise (SCDMTW): 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/medicalaid/law/1996
- Resolution of the Government of Armenia of January 24, 2002: Procedure for Clinical Trials of New Medications in Armenia: http://www.arlis.am/clinicaltrialsnewmedicationsarmenia/2002
- RA Law on Prevention of Disease Caused by HIV (2012): http://www.arlis.am/preventiondiseaseHIV/law/2012
- Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2013)

## EUROPE – Austria

### General

#### Key Organizations

- 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 (2002) (last amended 2024): http://www.ris.bka.gv.at/universityact/2024
- Hospitals Act (2014): http://www.ris.bka.gv.at/hospitalsact/2014
- Regulation on Leading Ethics Committees (2004): http://www.ris.bka.gv.at/leadingethicscommittees/regulation/2004
- Bioethics Commission, various publications: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html

### Drugs, Biologics, and 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

***Drugs***

- Austrian Drug Law (2013): http://www.ris.bka.gv.at/austriandruglaw/2013
- Various: https://www.basg.gv.at/en/healthcare-professionals/clinical-trials

***Devices***

- Medical Devices Act (2021): https://www.ris.bka.gv.at/medicaldevicesact/2021
- Medical Devices, Various: http://www.basg.at/medizinprodukte/

## 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/austriandruglaw/32/2013

## Privacy/Data Protection

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

### Key Organizations

- Austrian Data Protection Authority: https://www.data-protection-authority.gv.at/

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Data Protection Act No. 165/1999: https://www.ris.bka.gv.at/dataprotectionact/165/1999
- 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/safetyofblood/law/2009
- Law on Quality and Safety of Human Tissue and Cells (2013): http://www.ris.bka.gv.at/qualitysafetyhumantissueandcells/law/2013
- Regulation on Tissue Banks (2014): http://www.ris.bka.gv.at/tissuebanksregulation/2014
- 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/genetechnologyact
- 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/reproductivemedicineact/2010
- Bioethics Commission, various publications: https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html

# EUROPE – Belarus

***NOTE: For a database of Belarusian legislation, see: https://cis-legislation.com/index.fwx***

## General

### Key Organizations

- 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/article25/2004
- Law on Health Care System, Articles 40, 46 (2010): http://pravo.by/healthcaresystem/law
- Ordinance No. 274 on Establishing the National Bioethics Committee (2006)
- Decree No. 55 on Ethics Committees (2008) (Russian): http://www.levonevski.net/no55/2008
- Code of Medical Ethics (1999): http://www.levonevski.net/medicalethics/code/1999
- Guidelines for Ethics Committees on Standard Operational Proceedings (No. 55-0004, 2000): http://www.levonevski.net/no55-0004/2000
- Procedure for the Organization and work of the Ethics Committee of April 21, 2000 (amended 2009): http://www.levonevski.net/pravo/norm2009/num35/d35896/page2.html

## Drugs, Biologics, and Devices

### 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

***Drugs***

- Law on Drugs, Articles 15,16 (2009)
- Law on Health Care System, Article 40 (2010): http://pravo.by/healthcaresystem/law
- Ordinance No. 254 on Clinical Drug Trials and Good Clinical Practice (1999): http://www.levonevski.net/no254/1999
- 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/no161/1999
- Decree No. 55 on Ethics Committees (2008): http://www.levonevski.net/no55/2008
- 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/no55-0504/2004

***Devices***

- Law on Health Care System, Article 40 (2010): http://pravo.by/healthcaresystem/law
- 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/no161/1999
- 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/no55-0504/2004

## 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

## 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/healthcaresystem/law

## 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/healthcaresystem/law
- 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 Organizations

- 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/experimentationonhumans/law
- 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/experimentsonhumans/measures/decree
- 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/experimentsonhumans/measures/decree/modify
- 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/humanexperimentation/law
- 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

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- 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): https://www.health.belgium.be/en/superior-health-council

### 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

## Embryos, Stem Cells, and Cloning

### Key Organizations

- Federal Commission for Medical and Scientific Research on Embryos in Vitro: https://consultativebodies.health.belgium.be/en/advisory-and-consultative-bodies/federal-commission-medical-and-scientific-research-embryos-vitro
- 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

- 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): http://www.ejustice.just.fgov.be/criteriaforreproductivemedicine/decree
- BACB, various: http://www.health.belgium.be/en/belgian-advisory-committee-bioethics

# EUROPE – Bosnia and Herzegovina

## General

### *Federation of Bosnia and Herzegovina*

#### Key Organizations

- 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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Additional Protocol Concerning Biomedical Research, CETS No. 195 (2007)
- Law on Health Protection, MoH Republic of Srpska (2015): http://www.vladars.net/healthprotectionlaw/MOH/srpska
- Law on Health Protection, MoH Federation of Bosnia and Herzegovina, No. 46/10: http://www.mhrr.gov.ba/healthprotectionlaw/46/10
- Other documents: https://almbih.gov.ba/en/documents/

### *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

## 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

- Ministry of Health of Federation of Bosnia and Herzegovina, Clinical Trials: https://almbih.gov.ba/en/clinical-trials/
- Ministry of Health of Federation of Bosnia and Herzegovina, Various Regulations, Drafts, Instructions, and Guidance: https://almbih.gov.ba/en/documents/

### *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: https://almbih.gov.ba/wp-content/uploads/2023/10/medicinal_products_and_medical_devices_act.pdf
- Law on Changes and Amendments of Law on Drugs No. 34/08
- Ordinance on Clinical Trials on Medical Products and Medical Devices (2010): http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf
- Regulation about Medical Devices (2010): https://almbih.gov.ba/wp-content/uploads/2023/10/ordinance_on_medical_devices.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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- 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: https://almbih.gov.ba/ordinance_on_clinical_trials_on_medicinal_products_and_medical_devices.pdf
- Legislation at the state level: https://almbih.gov.ba/en/documents/

### *Republic of Srpska*

#### Key Organizations

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

#### 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/healthinsurancelaw/106/09

- Regulation about Clinical Testing of IMP and Medical Devices, 4/10: https://almbih.gov.ba/wp-content/uploads/2023/10/ordinance_on_clinical_trials_on_medicinal_products_and_medical_devices.pdf

## Social-Behavioral Research

### *Federation of Bosnia and Herzegovina*

#### Key Organizations

- Institute for Public Health FBiH: https://www.zzjzfbih.ba/instituteforpublichealth/FBiH

### *Republic of Srpska*

#### Key Organizations

- Institute for Public Health of the Republika Srpska: https://www.phi.rs.ba/instituteforpublichealth/srpska

## Privacy/Data Protection

#### Key Organizations

- Institute for Public Health of the Republika Srpska: https://www.phi.rs.ba/instituteforpublichealth/srpska

#### Relevant Standards

- Law on the Protection of Personal Data in Bosnia and Herzegovina (2005): https://www.azlp.ba/lawonprotectionofpersonaldata
- 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.azlp.ba/lawonamendmentstolawonprotectionofpersonaldata
- Regulation on the Manner of Keeping the Records of Personal Data Filing Systems and the Pertinent Records Form (2009)
- Compilation of Domestic and International Data Protection Regulations: http://www.azlp.ba/domesticandinternationaldataprotectionregs

## 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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Law on Blood and Blood Components: https://fmoh.gov.ba/bloodandbloodcomponentslaw

## 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

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Law on Transplantation of Organs and Tissues, Official Gazette of Bosnia and Herzegovina No. 75/09: https://fmoh.gov.ba/lawonorganandtissuetransplantation/75/09
- Law on Blood and Blood Products, Official Gazette of Bosnia and Herzegovina No. 09/10: https://fmoh.gov.ba/bloodandbloodproductslaw

### *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/transplantationoforgans
- Law on Transplantation of Human Tissues and Cells (2010): http://www.vladars.net/transplantationhumantissuesandcells
- Rulebook about Testing Procedure for Donor of Transplant Organs in Terms of Diseases Which Can Be Transmitted by Transplantation (2010): http://www.vladars.net/transplantationprocedure and https://www.fmoh.gov.ba/index.php/zakoni-i-strategije/lista-zakonskih-i-podzakonskih-akata

# EUROPE – Bulgaria

## General

#### Key Organizations

- https://www.mh.government.bg/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 (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Law Ratifying the Additional Protocol on Biomedical Research (2006): https://www.mh.government.bg/lawadditionalprotocolbiomedicalresearch
- Medicinal Products in Human Medicine Act (2017): https://www.bda.bg/images/stories/documents/legal_acts/20210208_ZLPHM_English.pdf
- Healthcare Act, Articles 197-206 (2018)

- List of Laws: https://www.mh.government.bg/bg/normativni-aktove/zakoni/

## Drugs, Biologics, and Devices

### Key Organizations

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

### Relevant Standards

***Drugs***

- Medicinal Products in Human Medicine Act, Chapter 4 (2018): https://www.lex.bg/humanmedicineact/ch4
- Regulation No. 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice (2012): http://www.bda.bg/regulation31/2007
- Medical Devices Act: https://www.bda.bg/medicaldevicesact
- Ordinance No. 10 (2008): https://www.bda.bg/Ordinance_Clinical_investigations

***Devices***

- Medical Devices Act (2016): https://www.bda.bg/medicaldevicesact/2016
- Ordinance No. 10 (2008): http://www.bda.bg/Ordinance_Clinical_investigations
- 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/regulation745/2017
- 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/regulation536/2014

## 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/medicinalproducts/humanmedicineact
- Ordinance No. 31 for Determining the Principles of Good Clinical Practice: https://www.bda.bg/goodclinicalpractice/ordinance31

## Research Injury

### Key Organizations

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- 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

## 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

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Bulgarian Commission for Personal Data Protection, EU Legal Framework: https://cpdp.bg/personaldataprotectionEUlegalframework
- Bulgarian Commission for Personal Data Protection, National Legal Framework: https://cpdp.bg/personaldataprotectionlegalframework

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- 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) Genetic Research

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca

- 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)

# EUROPE – Croatia

## General

### Key Organization

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Patient Protection Act, Article 20 (2008): http://www.zakon.hr/patientprotectionact/article20

## Drugs, Biologics, and Devices

### Key Organizations

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

### Relevant Standards

***Drugs***

- Medicinal Product Act (2013): http://narodne-novine.nn.hr/medicinalproductact
- Rule Book on Amendments to Medicinal Product Act (2014): http://narodne-novine.nn.hr/amendmentstomedicinalproductact
- Ordinance on Clinical Trials and Good Clinical Practice (2015): http://narodne-novine.nn.hr/ordinanceonclinicaltrialsandgcp
- Ordinance on Amendments to the Ordinance on Clinical Trials and Good Clinical Practice (2015): https://narodne-novine.nn.hr/ordinanceonamendmentstoclinicaltrialsandgcpordinance

***Devices***

- Medical Devices Act (2013): http://narodne-novine.nn.hr/medicaldevicesact
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: https://eur-lex.europa.eu/745/2017
- 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=1722524150296

## 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/standards
- 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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Law on Mandatory Health Insurance (2013): http://www.hzzo.hr/mandatoryhealthinsurancelaw
- Medicinal Product Act (2013): http://narodne-novine.nn.hr/medicinalproductact
- Rule Book on Amendments to Medicinal Product Act (2014): http://narodne-novine.nn.hr/amendmentstomedicinalproductact
- 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/various

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Implementation Act of the General Data Protection Act (NN 42/18) (2018): https://narodne-novine.nn.hr/42/18/2018

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562

- 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/bloodandbloodproductslawamendments
- Law on the Implementation of Human Tissues and Cells (2012): http://narodne-novine.nn.hr/implementationhumantissuesandcells/2012
- Law on Transplantation of Human Organs for the Purpose of Treatment (2012): http://narodne-novine.nn.hr/transplantationhumanorgansfortreatment/2012
- 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

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Medical Fertilization Act, Article 32: (2012): http://www.hzzo-net.hr/medicalfertilizationact
- Law on the Implementation of Human Tissues and Cells (2012): http://narodne-novine.nn.hr/lawimplementationhumantissuesandcells
- Various Ordinances - Law on the taking and transplantation of parts of the human body for the purpose of treatment: https://zdravlje.gov.hr/transplantationordinances

# EUROPE – Cyprus

## General

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- The Safeguarding and Protection of Patients' Rights Law (2004): http://www.bioethics.gov.cy/Moh/patientsrightslaw/2004

## Drugs, Biologics, and Devices

### Key Organizations

- Ministry of Health, Pharmaceutical Services: https://www.moh.gov.cy/moh/ps
- Ministry of Health, National Bioethics Committee: http://www.bioethics.gov.cy/moh/nbc

### Relevant Standards

- Law for Good Clinical Practice (2004)

## Research Injury

### Key Organizations

- Ministry of Health, Pharmaceutical Services: http://www.moh.gov.cy/moh

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- 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/officeforprotectionpersonaldata

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- 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/law125

## Human Biological Materials

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98

## Embryos, Stem Cells, and Cloning

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca

# EUROPE – Czech Republic

## General

### Key Organizations

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98

- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- 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

### Key Organizations

- Ministry of Health (MOH): http://www.mzcr.cz
- State Institute for Drug Control (SUKL): http://www.sukl.cz/

### Relevant Standards

#### *Drugs*

- 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/536/2014
- 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*

- Act No. 375/2022 Coll, on Medical Devices (the "Act on Medical Devices and In Vitro Diagnostic Medical Devices"): https://www.niszp.cz/cs/legislativa/pravni-predpisy-cr
- Various: http://www.sukl.cz/medical-devices

## Clinical Trial Registries

### Key Organizations

- EU Clinical Trials Register

### Relevant Standards

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

## Research Injury

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Law No. 89/2012 Coll. Civil Code: https://is.muni.cz/civilcode/law89

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Act No. 110/2019 Coll., On Personal Data Processing: https://www.zakonyprolidi.cz/cs/2019-110

## Human Biological Materials

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98

## Genetic Research

### Relevant Standards

- Oviedo Convention, Additional Protocol Concerning Genetic Testing for Health Purposes (CETS No. 203): https://rm.coe.int/1680084824

## 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

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Act of 26 April 2006 on Research on Human Embryonic Stem Cells No. 227/2006 Sb. (Coll.), as amended (2017)

# EUROPE – Denmark

## General

### Key Organizations

- National Scientific Ethics Committee (NVK) and the Scientific Medical Ethics Committees (VMK): http://www.nvk.dk/english
- Danish Research Ethics Committees: https://researchethics.dk/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- 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

- Danish Research Ethics Committees, Various Guidelines: https://researchethics.dk/guidelines
- VMK, Guidance on Hypothesis-Generating Research: https://videnskabsetik.dk/vejledninger/vejledning-om-hypotesegenererende-forskning

## Drugs, Biologics, and Devices

### Key Organizations

- National Scientific Ethics Committee (NVK) and the Scientific Medical Ethics Committees (VMK): http://www.nvk.dk/english
- Danish Research Ethics Committees: https://researchethics.dk/
- Danish Medicines Agency: https://laegemiddelstyrelsen.dk/en/

### Relevant Standards

- Regulation No. 745 on Medical Devices (2017): https://eur-lex.europa.eu/745/2017
- Regulation No. 536 on Clinical Trials on Medicinal Products for Human Use (2014):
- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536&qid=1722524150296
- 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/
- Danish Research Ethics Committees, Various Guidance: https://researchethics.dk/information-for-researchers

## Clinical Trial Registries

### Key Organizations

- National Scientific Ethics Committee (NVK) and the Scientific Medical Ethics Committees (VMK): http://www.nvk.dk/english
- Danish Research Ethics Committees: https://researchethics.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
- Danish Research Ethics Committees, Overview of Mandatory Reporting: https://researchethics.dk/information-for-researchers/overview-of-mandatory-reporting
- Danish Research Ethics Committees, EU Clinical Trials Regulation (CTR) and EU Clinical Trials Information System (CTIS) Q&A: https://researchethics.dk/information-for-researchers/clinical-trials-with-medicinal-products-under-the-ctr/ctr-and-ctis-qanda

## Research Injury

### Key Organizations

- Patient Compensation Association: https://eng.patienterstatningen.dk/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- 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://eng.patienterstatningen.dk/

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Act No. 429 on Processing of Personal Data (2007): https://rm.coe.int/16806af0e6
- Data Protection Act (2018) (amended, 2024): https://www.retsinformation.dk/eli/lta/2018/502
- Health Act No. 903, Chapter 9 (2019): https://www.retsinformation.dk/eli/lta/2019/903

## Human Biological Materials

### Key Organizations

- National Scientific Ethics Committee (NVK) and the Scientific Medical Ethics Committees (VMK): http://www.nvk.dk/english
- Danish Research Ethics Committees: https://researchethics.dk/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- 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 Scientific Ethics Committee (NVK) and the Scientific Medical Ethics Committees (VMK): http://www.nvk.dk/english
- Danish Research Ethics Committees: https://researchethics.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
- Guidance on Genomics and Research in Sensitive Bioinformatics Data (2020): https://researchethics.dk/guidelines/guidance-on-genomics-and-research-in-sensitive-bioinformatics-data

## 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/act440/2004
- Executive Order No. 902 on Medically Assisted Reproduction in Connection with Treatment, Diagnostics and Research, etc. (2019): https://www.retsinformation.dk/assistedreproductionresearchact

# EUROPE – Estonia

## General

### Key Organizations

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- 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/agency-and-contact/about-state-agency-medicines
- 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/medicinalproductsact
- 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/ethicscommitteeforclinicaltrialsprocedure
- MSA, Conditions and Procedure for Conducting Clinical Trials of Medicinal Products. Regulation No. 23 (2005): https://www.riigiteataja.ee/regulation23/2005
- Medical Devices Act (2004): https://www.riigiteataja.ee/medicaldevicesact
- 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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Medicinal Products Act, Section 90: https://www.riigiteataja.ee/medicinalproductsact
- 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/regulation23/2005/

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Personal Data Protection Act (2018): https://www.riigiteataja.ee/personaldataprotectionact and 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

## Human Biological Materials

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562

## 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
- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- 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 Organizations

- Ministry of Social Affairs and Health: http://www.stm.fi/en/frontpage
- National Committee on Medical Research Ethics (TUKIJA): https://tukija.fi/etusivu
- 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://fimea.fi/etusivu
- Various Authorities, Advisory Committees, and Regional Research Ethics Committees: https://tukija.fi/en/cooperation

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- 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

- Report on Children in Medical Research (2003): https://tukija.fi/childrenmedicalresearchreport
- TUKIJA, Legislation ,Various: https://tukija.fi/en/legislation
- Act on Data Protection (1050/2018): https://www.finlex.fi/fi/laki/kaannokset/2018/en20181050.pdf https://www.finlex.fi/en/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 https://www.finlex.fi/en/laki/kaannokset/1889/en18890039.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: https://www.finlex.fi/fi/laki/kaannokset/1999/en19990488.pdf
- Medical Research Act No. 488/1999 (Amended 794/2010): http://www.finlex.fi/en/laki/kaannokset/1999/
- Government Decree on the National Institute for Health and Welfare (668/2008), latest amendment 1122/2015: https://www.finlex.fi/en/laki/kaannokset/2008/
- 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 and https://tenk.fi/en/advice-and-materials/RCR-Guidelines-2012
- The Ethical Principles of Research with Human Participants and Ethical Review in the Human Sciences in Finland (2019): https://tenk.fi/en/advice-and-materials/RCR-Guidelines-2012
- Agreeing on Authorship. Recommendation for Research Publications: https://tenk.fi/sites/tenk.fi/files/TENK_suositus_tekijyys.pdf

## Drugs, Biologics, and Devices

### Key Organizations

- Finnish Medicines Agency (FIMEA): https://fimea.fi/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
- Various Authorities, Advisory Committees, and Regional Research Ethics Committees: https://tukija.fi/en/cooperation
- National Supervisory Authority for Welfare and Health (VALVIRA): https://valvira.fi/

### Relevant Standards

#### *Drugs*

- TUKIJA, Legislation, Various: https://tukija.fi/en/legislation
- Medicines Act 395/1987 (list of amendments and regulations made under the Act): https://www.finlex.fi/medicinesact
- Decree of the National Research Ethics Council of Finland No. 1347/1991: https://www.finlex.fi/fi/laki/alkup/1991/
- 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/
- Decrees on the National Committee on Medical Research Ethics No. 820/2010 and 788/2018: https://finlex.fi/fi/laki/alkup/2010/ , https://www.finlex.fi/fi/laki/alkup/2018/
- Operating Procedures of the National Committee on Medical Research Ethics (2021): https://tukija.fi/operatingproceduresTUKIJA
- Decree of the Ministry of Social Affairs and Health 817/2023 on the Fees Charged for Opinions of the National Medical Research Ethics Committee (2023): https://www.finlex.fi/fi/laki/alkup/2023/
- Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2012
- Finnish Medicines Agency Administrative Regulation on Clinical Trials on Medicinal Products (8/2019): https://fimea.fi/regulationclinicaltrialsonmedicinalproducts
- Report on Children in Medical Research (2003): https://tukija.fi/childrenmedicalresearch

#### *Devices*

- TUKIJA, Legislation ,Various: https://tukija.fi/en/legislation
- Act on Specific Medical Devices Regulated by EU Directive (629/2010, amended 720/2021): https://www.finlex.fi/fi/laki/ajantasa/2010/
- Administrative Regulation. Pharmaceutical Safety and Development Center: Operator and Device Registration Notifications to Authorities Related to Medical Devices: https://finlex.fi/fi/viranomaiset/normi/

## Clinical Trial Registries

### Key Organizations

- Finnish Medicines Agency Fimea: https://fimea.fi/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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Patient Injuries Act (948/2019): https://www.finlex.fi/fi/laki/ajantasa/2019/

- 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
- Act on the Secondary Use of Health and Social Data (552/2019): https://www.finlex.fi/secondaryuseofhealthandsocialdataact

## Privacy/Data Protection

### Key Organizations

- Finnish Social and Health Data Permit Authority (Findata): https://findata.fi/en/
- Office of the Data Protection Ombudsman: https://tietosuoja.fi/en/home

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Data Protection Act (1050/2018): https://www.finlex.fi/en/laki/kaannokset/2018/20181050

## Human Biological Materials

### Key Organizations

- Finnish Medicines Agency Fimea: https://fimea.fi/etusivu
- National Supervisory Authority for Welfare and Health (Valvira): https://valvira.fi/etusivu
- National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Act on the Medical Use of Human Organs, Tissues, and Cells No. 101/2001 (Finnish and Swedish): http://www.finlex.fi/act101/2001
- TUKIJA, Legislation ,Various: https://tukija.fi/en/legislation
- Tukija's Operating Procedures (Regulation and Biobank): https://tukija.fi/regulationandbiobankprocedures
- 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
- Act on the Secondary Use of Health and Social Data (552/2019): https://www.finlex.fi/secondaryuseofhealthandsocialdataact

## 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 39/2023): https://www.finlex.fi/genetechnologyact

## Embryos, Stem Cells, and Cloning

### Key Organizations

- National Supervisory Authority for Welfare and Health: https://valvira.fi/etusivu
- National Committee on Medical Research Ethics (TUKIJA): https://tukija.fi/en/frontpage
- 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

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Medical Research Act No. 488/1999 (amended 295/2004, 749/2010, and 143/2015): http://www.finlex.fi/medicalresearchact
- Act on Assisted Fertility Treatments No. 1237/2006: http://www.finlex.fi/assistedfertilityact
- Criminal Code of Finland (39/1889), Chapter 22, Section 4: Cloning of a Human is Forbidden: https://www.finlex.fi/criminalcodecloning
- Report on Stem Cells, Cloning, and Research (2005): http://tukija.fi/stemcellscloningresearch

# EUROPE – France

## General

### Key Organizations

- 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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- 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: https://www.legifrance.gouv.fr/publichealthcodearticles
- CCNE, Various Legislations and Rights: https://www.ccne-ethique.fr/en/topics/research-legislation-ethics/legislation-rights
- CCNE, Various Bioethics Laws: https://www.ccne-ethique.fr/en/topics/research-legislation-ethics/bioethics-laws

## Drugs, Biologics, and Devices

### Key Organizations

- National Consultative Ethics 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/medicationshumanusedrugsdevices
- Decision on Good Clinical Practices: http://www.legifrance.gouv.fr/decisiononGCP

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- 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/law1321/2016
- Data Protection Act (2018): https://www.legifrance.gouv.fr/dataprotectionact
- 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/decree536/2019

- 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/healthresearchwithconsent
- CNIL, Health Research without Consent (2018): https://www.cnil.fr/healthresearchwithoutconsent
- CNIL, Practical Guide on the Protection of Personal Data: What Framework Applies to Research? (2018): https://www.cnil.fr/guidepersonaldataprotection
- CCNE, Manifesto for Digital Ethics (2023): https://www.ccne-ethique.fr/manifestodigitalethics

## 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 Ethics 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): https://www.legifrance.gouv.fr/codes/article_lc/LEGIARTI000006686056
- 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

## Genetic Research

### Key Organizations

- National Consultative Ethics 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/civilcodearticles
- Article R1131-1 and Subsequent Sections of the Public Health Code: https://www.legifrance.gouv.fr/articleR1131-1

## Embryos, Stem Cells, and Cloning

### Key Organizations

- National Consultative Ethics 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/decree715/2013
- 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/decree155/2015
- Ethical Reflection Concerning Research on Human Embryonic Cells and on Human Embryos in Vitro (2010) : https://www.ccne-ethique.fr/researchethicsembryos

## EUROPE – Georgia

### General

#### Key Organizations

- Bioethics and Health Law Studies Society

#### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- 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/healthcarelaw
- Law on Medicines and Pharmaceutical Activities No. 659 and 1586 (2015): https://matsne.gov.ge/medicinesandpharmaceuticalactivitieslaw

### 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/regulationclinicaltrialsapproval
- 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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Regulation about the Rules and Conditions of Issuing of the Approval of Clinical Trials Approved #176 (2005): https://matsne.gov.ge/regulationclinicaltrialsapproval

## 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/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Law on Data Protection (2018): https://matsne.gov.ge/dataprotectionlaw
- Various: https://personaldata.ge/en

## Human Biological Materials

### Key Organizations

- Bioethics and Health Law Studies Society

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Various: https://matsne.gov.ge/documents

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Law on Health Care, Article 142 (2017): https://matsne.gov.ge/article142
- Law of Georgia on Health Care: https://matsne.gov.ge/healthcarelaw

# EUROPE – Germany

## General

### Key Organizations

- 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/professionalcodephysicians
- DFG, Guidelines for Safeguarding Good Research Practice (2022): https://zenodo.org/records/6472827

## Drugs, Biologics, and Devices

### 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
- German Research Foundation (DFG), Permanent Senate Commission on Key Questions in Clinical Research (SCCR): https://www.dfg.de/

### 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)
- Medical Device Law Implementation Act, Division 4 (2021): https://www.gesetze-im-internet.de/mpdg/
- DFG, Various Recommendations and Statements of the Senate Commission on Key Questions in Clinical Research: https://www.dfg.de/en/dfg-profile/statutory-bodies/senate/clinical-research/statements

## Clinical Trial Registries

### Key Organizations

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

### Relevant Standards

- FAQs: https://www.bfarm.de/DE/Das-BfArM/Aufgaben/Deutsches-Register-Klinischer-Studien/_node.html

## 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

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- 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
- Act on the Improved Use of Health Data (2024): https://www.bundesgesundheitsministerium.de/improveduseofhealthdataact

## 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/

### Relevant Standards

- German Ethics Council, Act of Quality and Security of Human Tissue and Cells (2019): https://www.buzer.de/actqualitysecurityhumantissueandcells
- 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/opinionhumanbiobanksresearch
- ZEKO, Opinion on the (Re)Use of Human Body Material for Medical Research Purposes (2003): https://www.zentrale-ethikkommission.de/stellungnahmen/die-weiter-verwendung-von-menschlichen-koerpermaterialien-fuer-zwecke-medizinischer-forschung
- DGCH, Guidelines on Good Professional Practice (GPP) for the Procurement of Human Tissue and Cells for Drug Production: http://www.dgch.de/GPP

## 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/
- DFG, Various Recommendations and Statements of the Senate Commission on Key Questions in Clinical Research: https://www.dfg.de/en/dfg-profile/statutory-bodies/senate/clinical-research/statements

## Embryos, Stem Cells, and Cloning

### Key Organizations

- Federal Ministry of Education and Research (BMBF): https://www.bmbf.de/
- 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/Committees/StemCell

### 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/Stellungnahme_Stammzellimport.pdf
- German Ethics Council, Cloning for Reproductive Purposes and Cloning for the Purposes of Biomedical Research (2004): https://www.ethikrat.org/Stellungnahme_Klonen.pdf
- German Ethics Council, Should the Stem Cell Law be Amended? (2007): https://www.ethikrat.org/Stn_Stammzellgesetz.pdf
- German Ethics Council, Human-Animal Mixtures in Research (2011): https://www.ethikrat.org/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/recommendation-stem-cell-research.pdf
- German Ethics Council, Germline Intervention in the Human Embryo (2017): https://www.ethikrat.org/recommendation-germline-intervention-in-the-human-embryo.pdf
- German Ethics Council, Intervening in the Human Germline (2019): https://www.ethikrat.org/opinion-intervening-in-the-human-germline-summary.pdf
- ZEKO, Opinion on Stem Cell Research (2002): https://www.zentrale-ethikkommission.de/stellungnahmen/stellungnahme-der-zentralen-ethikkommission-zur-stammzellforschung
- DFG, Various Recommendations and Statements of the Senate Commission on Key Questions in Clinical Research: https://www.dfg.de/en/dfg-profile/statutory-bodies/senate/clinical-research/statements

## EUROPE – Greece

### General

#### Key Organizations

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

#### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Research Ethics for Biological Sciences (2008): https://bioethics.gr/researchethicsbiologicalsciences
- A Guide for Research Ethics Committees for Biological Research (2008): https://bioethics.gr/guidebiologicalresearch

- Opinion on Conflict of Interest in Biomedical Research (2014): https://bioethics.gr/opinionconflictofinterestbiomedicalresearch
- Report on Conflict of Interest in Biomedical Research (2014): https://bioethics.gr/conflictofinterestbiomedicalresearch
- Incidental Findings in Research and Clinical Practice (2015): https://archive.bioethics.gr/incidentalfindingsresearchandclinicalpractice

## Drugs, Biologics, and Devices

### Key Organizations

- National Organization for Medicines (NOM): http://www.eof.gr/NOM
- National Bioethics Commission (NBC): http://www.bioethics.gr/NBC

### 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
- Directive on Clinical Trials for Medicinal Products for Human Use: https://bioethics.gr/directiveclinicaltrialsmedicinalproducts
- NBC, Control of Non-Invasive Clinical Trials for Drugs (2013): https://archive.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/NBC

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- 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

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- 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

## Human Biological Materials

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98

## Genetic Research

### Key Organizations

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

### 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: https://bioethics.gr/biobanks
- Opinion on Prenatal and Pre-Implantation Diagnosis and Embryo Treatment: https://bioethics.gr/prenatalandpreimplantationdiagnosisandembryotreatment
- Opinion on Direct-To-Consumer Genetic Testing (2012): https://archive.bioethics.gr/directtoconsumergenetictesting
- Opinion on Incidental Findings in Research and Clinical Practice (2015): https://archive.bioethics.gr/opinionincidentalfindingsinresearchandclinicalpractice
- Opinion on Advances in Human Genome Editing (2016): https://bioethics.gr/opinionadvancesinhumangenomeediting

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

- National Authority for Medically Assisted Reproduction

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Civil Code (Act 3089/2002, Medically Assisted Reproduction)
- Act 3305/2005 Application of Medically Assisted Reproduction

## EUROPE – Hungary

### General

#### Key Organizations

- Ministry of Human Capacities (EMMI): https://2015-2019.kormany.hu/en/ministry-of-human-resources
- Medical Research Council, Research Ethics Committees (KFEB, TUKEB, HRB): https://ett.aeek.hu/en/secretariat/
- National Center for Public Health and Pharmacy: https://nngyk.gov.hu/

#### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- 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/decree23/2002
- 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/decree35/2005
- 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/decree235/2009
- 1997 CLIV. Law, Healthcare, Chapters VIII and IX

## Drugs, Biologics, and Devices

### Key Organizations

- National Center for Public Health and Pharmacy: https://nngyk.gov.hu/
- Medical Research Council, Ethics Clinical Pharmacology Ethics Committee (KFEB): https://ett.aeek.hu/kfeb/

### Relevant Standards

#### *Drugs*

Clinical Trials:

- Act XCV of 2005 on Medicinal Products for Human Use, Section 3: https://net.jogtar.hu/actXCV/2005
- 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/decree35/2005
- 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%3A32014R0536&qid=1722524150296

Non-Interventional Trials:

- Act CLIV of 1997 on Health Care, Chapter VIII, Section 164/A: http://net.jogtar.hu/actCLIV/1997
- Decree 23/2002. (V. 9) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/decree23/2002
- Act CLIV of 1997 on Health Care, Chapter VIII, Section 159: http://net.jogtar.hu/actCLIV/1197

#### *Devices*

- Authority for Medical Devices, National Healthcare Service System: http://www.enkk.hu/index.php/hun/
- National Center for Public Health and Pharmacy: https://nngyk.gov.hu/
- Medical Research Council, Ethics Committee for Clinical Pharmacology: https://ett.aeek.hu/kfeb/
- Act CLIV of 1997 on Health Care, Chapter VIII, Section 159: http://net.jogtar.hu/actCLIV/1997

Clinical Trials:

- Decree 4/2009. (III. 17.) of the Minister of Health on Medical Devices: http://net.jogtar.hu/decree4/2009

Non-Interventional Trials:

- Decree 23/2002. (V. 9.) of the Minister of Health on Biomedical Research on Human Beings: http://net.jogtar.hu/decree23/2002
- 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/decree235/2009
- Government Decree 27/2015 (II.25.) About the National Health Care Service System: http://njt.hu/decree27/2015

## Research Injury

### Key Organizations

- National Center for Public Health and Pharmacy: https://nngyk.gov.hu/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Register of clinical trials: https://ogyei.gov.hu/clinicaltrialsregister

## Privacy/Data Protection

### Key Organizations

- National Center for Public Health and Pharmacy: https://nngyk.gov.hu/

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Act XCV of 2005 on Medicinal Products for Human Use, Section 3, Paragraph 5: https://net.jogtar.hu/medicinalproductshumanuseact

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- 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
- Various Publications: https://naih.hu/kiadvanyok-publikaciok

## Genetic Research

### Key Organizations

- National Center for Public Health and Pharmacy: https://nngyk.gov.hu/

## Embryos, Stem Cells, and Cloning

### Key Organizations

- Ministry of Human Capacities (EMMI): https://2015-2019.kormany.hu/en/ministry-of-human-resources

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- 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/actlxxx/2006
- 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/decree18/1998

# EUROPE – Iceland

## General

### Key Organizations

- 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/scientificresearchact
- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- 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/regulation520
- NBC, Vulnerable Groups Including Children: https://vsn.is/vidmid/vidkvaemir-hopar/
- NBC, Various Laws and Conventions: https://vsn.is/vidmid/

## Drugs, Biologics, and Devices

### Key Organizations

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

### Relevant Standards

#### *Drugs*

- Medicinal Products Act no. 100/2020: https://www.government.is/medicinalproductsact

- MCA, Regulation on Clinical Trials of Medicinal Products in Humans No. 443/2004 (2010): https://www.government.is/regulation443
- NBC, Various Laws and Regulations: https://vsn.is/vidmid/

***Devices***

- Ministry of Health: https://www.government.is/ministries/ministry-of-health/
- Act on Medical Devices No. 16/2001 (2011): https://www.government.is/regulation16
- Regulation on Medical Devices No. 934/2010 (2010): https://www.government.is/regulation934
- Regulation on Active Implantable Medical Devices No. 320/2011: http://www.stjornartidindi.is/regulation320
- Regulation on In Vitro Diagnostic Medical Devices No. 936/2011: http://stjornartidindi.is/regulation936

## Research Injury

### Key Organizations

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Act on Patient Insurance No. 111/2000 (2011):
- https://www.government.is/publications/legislation/lex/2023/08/09/Act-on-Patient-Insurance-No.-111-2000/
- Act on Health Insurance No. 112/2008 (2012): https://www.government.is/healthinsuranceact
- Regulation on Clinical Trials of Medicinal Products in Humans No. 443/2004, as Amended by Regulations No. 907/2004 and No. 1099/2010: https://www.government.is/regulation443

## Privacy/Data Protection

### Key Organizations

- Data Protection Authority: http://www.personuvernd.is/

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- 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): http://www.vsn.is/en

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- 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

## Embryos, Stem Cells, and Cloning

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No. 55/1996 (2010)
- Regulation on Artificial Fertilization No. 144/2009: https://www.reglugerd.is/reglugerdir/eftir-raduneytum/heilbrigdis/nr/10797

# EUROPE – Ireland

## General

### Key Organizations

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

### Relevant Standards

- Operational Procedures for Research Ethics Committees: Guidance 2004: https://www.drugsandalcohol.ie/Bioethics_Ethical_guidelines_for_research.pdf
- Health Service Executive National Consent Policy, Part 3: https://assets.hse.ie/media/documents/ncr/hse-national-consent-policy.pdf

## 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/
- Health Research Board (HRB): http://www.hrb.ie/

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- 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 Organizations: 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): https://www.lenus.ie/handle/10147/622868

## 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/pharmacogeneticresearchguidelines

# EUROPE – Italy

## General

### Key Organizations

- National Bioethics Committee (CNB): http://www.governo.it/bioetica/eng/index.html

### Relevant Standards

- CNB, Various: https://bioetica.governo.it/it/documenti/pareri/

## Drugs, Biologics, and Devices

### Key Organizations

- Italian Medicines Agency (AIFA): http://www.agenziafarmaco.it/
- AIFA, National Observatory on Clinical Trials (OsSC): https://www.aifa.gov.it/en/osservatorio-nazionale-sperimentazione-clinica
- Ministry of Health, Directorate General for Medicines and Medical Devices: https://www.salute.gov.it/portale/home.html

### Relevant Standards

#### *Drugs*

- AIFA, Various Legislations, Trials: https://www.aifa.gov.it/en/normativa-di-riferimento-sperimentazione
- AIFA, National Coordination Centre of Local Ethics Committees for Clinical Trials Concerning Medicinal Products for Human Use and Medical Devices (CCNCE), Various Forms, Circulars, Regulations, and Related Documents: https://www.aifa.gov.it/centro-coordinamento-comitati-etici
- AIFA, Ethics Committee for Clinical Trials in the Pediatric Field, Various Forms, Circulars, Regulations, and Related Documents: https://www.aifa.gov.it/en/comitato-etico-per-le-sperimentazioni-cliniche-in-ambito-pediatrico
- AIFA, National Ethics Committee for Clinical Trials Relating to Advanced Therapies ("ATMP"): https://www.aifa.gov.it/en/comitato-etico-per-le-sperimentazioni-cliniche-relative-alle-terapie-avanzate-atmp-
- AIFA, Register of Observational Studies: https://www.aifa.gov.it/registro-studi-osservazionali
- AIFA/OsSc, Various Tutorials, Guides, and Manuals: https://www.aifa.gov.it/en/osservatorio-nazionale-sperimentazione-clinica
- MOH, Various Regulations (filter by year and topic on left columns): https://www.salute.gov.it/regulations
- 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 Authorization 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 ProductsDevices
- 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 Labor 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

## Social-Behavioral Research

### Relevant Standards

- National Coordination Center of Ethics Committees (CCNE): Ethical and Regulatory Critical Issues in the Processing of Personal Health Data in Observational Research (2023): https://www.aifa.gov.it/Criticita_etiche_ricerca_osservazionale
- Register of Observational Studies (RSO) (2023): https://www.aifa.gov.it/registro-studi-osservazionali

## Privacy/Data Protection

### Key Organizations

- Italian Data Protection Independent Authority: http://www.garanteprivacy.it/
- AIFA, National Coordination Centre of Local Ethics Committees for Clinical Trials Concerning Medicinal Products for Human Use and Medical Devices (CCNCE): https://www.aifa.gov.it/

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Italian Personal Data Protection Code, Legislative Decree No. 196 of June 30, 2003: https://www.gestaltitaly.com/contents/privacy_note.pdf
- 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/
- CCNE, Ethical and Regulatory Issues in the Processing of Personal Health Data in Observational Research (2023): https://www.aifa.gov.it/personalhealthdataprocessingethics

## 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)
- SIGU, Various Guidelines, Recommendations, and Documents of Interest: https://sigu.net/guidelines

## Embryos, Stem Cells, and Cloning

### Relevant Standards

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

# EUROPE – Latvia

## General

### Key Organizations

- Central Medical Ethics Committee

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Statutes of Central Medical Ethics Committees (1998): http://likumi.lv/

## Drugs, Biologics, and Devices

### Key Organizations

- State Agency of Medicines: http://www.zva.gov.lv/
- Central Medical Ethics Committee

### Relevant Standards

#### *Drugs*

- 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/regulationno.289

### *Devices*

- Medical Treatment Law, Section 34 (2014): https://likumi.lv/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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- 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/regulationno.289
- 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

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Personal Data Processing Law (2014): https://likumi.lv/personal-data-processing-law
- Law on the Rights of Patients, Section 10 (2013): https://likumi.lv/law-on-the-rights-of-patients
- 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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98

- 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/no.1176

## 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/humangenomeresearchlaw
- Law on the Development and Use of the National DNA Database (2006): https://likumi.lv/nationalDNAdatabaselaw
- Regulation of the Cabinet of Ministers: "Procedures for Genetic Research" (2004): http://likumi.lv/geneticresearchprocedures

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Sexual and Reproductive Health Law, Sections 15-20 (2004): https://likumi.lv/sexual-and-reproductive-health-law
- Cabinet Regulation No. 1176 (2013) Procedures for Use of Human Tissues and Cells: http://likumi.lv/no.1176

# EUROPE – Lithuania

## General

### Key Organizations

- 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 (ETS No. 164): https://rm.coe.int/168007cf98
- Law on Ethics of Biomedical Research (2019): https://www.e-tar.lt/biomedicalresearchethicslaw

- Changes of Law on Ethics of Biomedical Research No. 536/2014 (2017): https://www.e-tar.lt/ethicsofbiomedicalresearch
- 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/V-405
- Government of the Republic of Lithuania: Decree No. 1458 on State Fees (2017): https://www.e-tar.lt/no.1458
- 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/V-15
- 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/V-28
- 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/V-1483
- V-235/A1-83, Decree on the Procedure for a Minor's Participation in Biomedical Research (2018): https://www.e-tar.lt/V-235
- V-28, Decree on the Procedure to Conduct Biomedical Research on Medical Documents, No. V-28 (2011): https://www.e-tar.lt/V-28
- 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/V-7
- 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/V-24
- 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/V-4
- Updated Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical Research of the LBEC (2023): https://bioetika.lrv.lt/guidelinesinformedconsent

## Drugs, Biologics, and Devices

### Key Organizations

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

#### *Drugs*

- Law on Ethics of Biomedical Research (2019): https://www.e-tar.lt/biomedicalresearchethicslaw
- Law on Pharmacy of the Republic of Lithuania, Consolidated Version from 01/01/2021 to 31/12/2021: https://www.e-tar.lt/pharmacylaw

- Decree No. 320 on the Rules of Good Clinical Practice (2006): https://www.e-tar.lt/decree320
- Corrections of GCP Terminology in Lithuanian (2006): https://www.e-tar.lt/GCPterminology
- 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/decreeV-6
- 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/decree435

### *Devices*

- Decree No. V-2 on the Procedure to Issue Approvals to Conduct Biomedical Research (2017): https://www.e-tar.lt/decreeV-2
- Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/biomedicalresearchethicslaw
- Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/ethicsofbiomedicalresearch
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: https://eur-lex.europa.eu/no.745
- 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/no.536
- LBEC, Issuance of Permits for Clinical Trials with a Medical Device: https://bioetika.lrv.lt/permitsclinicaltrialsmedicaldevice

## Clinical Trial Registries

### Key Organizations

- Ministry of Health (MOH): http://www.sam.lt/

### Relevant Standards

- Law on Ethics of Biomedical Research (2019): https://www.e-tar.lt/biomedicalresearchethicslaw
- Decree No. 745 on the Rules of Compulsory Civil Liability Insurance for the Principal Investigator and the Sponsor (2016): https://www.e-tar.lt/no.745

## Research Injury

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98

## 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/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Law of the Republic of Lithuania on the Legal Protection of Personal Data: https://www.e-tar.lt/personaldataprotection

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Law on the Re-Use of Health Data: https://www.e-tar.lt/portal/lt/legalAct/0457ba8067e611eca9ac839120d251c4/asr
- LBEC, Protection of Personal Data: https://bioetika.lrv.lt/lt/asmens-duomenu-apsauga/

## Human Biological Materials

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98

## Genetic Research

### Key Organizations

- Ministry of Health (MOH): http://www.sam.lt/

### 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/humanrightsdignitybiologyandmedicine
- Law on Ethics of Biomedical Research (2016): https://www.e-tar.lt/ethicsbiomedicalresearchlaw
- Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/ethicsbiomedicalresearch
- 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/decreeV-660
- 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/decreeV-659

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- 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 Organizations

- National Ethics Consultative Commission: http://www.cne.lu
- Health Ministry: https://msan.gouvernement.lu/en.html
- National Research Ethics Committee (CNER): https://www.cner.lu/en-gb/Home

### Relevant Standards

- National Ethics Commission, Opinion, Various Notices, Reviews, and Opinions: 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, International Framework and Luxembourg Legal Framework: https://cner.gouvernement.lu/en/statuts-legislation.html
- CNER, Various Guidance and Activity Reports: https://cner.gouvernement.lu/en/publications.html

## Privacy/Data Protection

### Key Organizations

- National Data Protection Commission: https://cnpd.public.lu/en.html

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Act of 1 August 2018 on the Organisation of the National Data Protection Commission, Articles 63-65: https://cnpd.public.lu/nationaldataprotectioncommission

## Human Biological Materials

### Relevant Standards

- Law of 1 August 2007 Relating to Human Tissues and Cells Intended for Human Applications: https://legilux.public.lu/humantissuesandcells

## Genetic Research

### Key Organizations

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

### Relevant Standards

- CNER, Various Statutes and Legislations, International Framework and Luxembourg Legal Framework: https://cner.gouvernement.lu/en/statuts-legislation.html
- CNER, Various Guidance and Activity Reports: https://cner.gouvernement.lu/en/publications.html

# EUROPE – Malta

## General

### Key Organizations

- Bioethics Committee: https://healthservices.gov.mt/en/regcounc/Bioethics-Committee/Pages/CommitteeMembers.aspx

### Relevant Standards

- Various: https://healthservices.gov.mt/en/regcounc/Bioethics-Committee/Pages/Opinions.aspx

## Drugs, Biologics, and Devices

### Key Organizations

- Medicines Authority: http://medicinesauthority.gov.mt/
- Malta Competition and Consumer Affairs Authority, Technical Regulations Division: https://mccaa.org.mt/

### Relevant Standards

***Drugs***

- Medicines Act, 2003: https://legislation.mt/eli/cap/458/eng/pdf
- Subsidiary Legislation, 458.43, Clinical Trials Regulations, 2004: https://legislation.mt/eli/sl/458.43/eng/pdf
- Subsidiary Legislation, 458.47, Good Clinical Practice and Requirements for Manufacturing or Import Authorisation of Investigational Medicinal Products (Human Use) Regulations, 2006: https://legislation.mt/eli/sl/458.47/eng/pdf
- Guidance Notes on Good Clinical Practice (2018): https://medicinesauthority.gov/GCP

***Devices***

- Product Safety Act, 2001: https://legislation.mt/eli/cap/427/eng/pdf
- Subsidiary Legislation, 427.16, *In Vitro* Diagnostic Medical Devices Regulations, 2003: https://legislation.mt/eli/sl/427.16/eng
- Subsidiary Legislation, 427.44, Medical Devices Regulations, 2010: https://legislation.mt/eli/sl/427.44/eng
- Subsidiary Legislation, 427.10, Active Implantable Medical Devices Regulations, 2010: https://legislation.mt/eli/sl/427.10/eng

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Data Protection Act, 2018: https://legislation.mt/eli/cap/586/eng/pdf
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/GDPR

# EUROPE – Moldova, Republic of

***NOTE: For a database of Moldovan legislation, see: https://cis-legislation.com/index.fwx***

## General

### Key Organizations

- 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 (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Law No. 1409 Dated 17.12.1997 on Medicines, Articles 11 and 12: http://lex.justice.md/no.1409
- Law No. 263 Dated 27.10.2005 on Patients' Rights and Responsibilities. Articles 9, 10, 11, 12, 13, and 14: https://cis-legislation.com/document.fwx?rgn=11939

## 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/no.1409
- Law No. 263 Dated 27.10.2005 on Patients' Rights and Responsibilities. Articles 9, 10, 11, 12, 13, and 14: https://cis-legislation.com/document.fwx?rgn=11939
- Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Examination of Clinical Trial: https://cis-legislation.com/document.fwx?rgn=89422

## Research Injury

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98

## Privacy/Data Protection

### Key Organizations

- National Center for Personal Data Protection of the Republic of Moldova (NCPDP): 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
- Law No. 982 Dated 11.05.2000 on Access to Information: http://lex.justice.md/no.982
- Law No.133 Dated 08.07.2011 on the Protection of Personal Data: https://cis-legislation.com/document.fwx?rgn=51097
- EU General Data Protection Regulation (2016): https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- 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/no.1123
- 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

- Transplant Agency: https://transplant.gov.md/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Law No. 42 -XVI Dated 06.03.2008 on Transplantation of Organs, Tissues and Human Cells: https://cis-legislation.com/document.fwx?rgn=22702
- LP79 Din 24.05.18, MO195-209/15.06.18 Article 338

## Genetic Research

### Relevant Standards

- Oviedo Convention, Additional Protocol Concerning Genetic Testing for Health Purposes (CETS No. 203): https://rm.coe.int/1680084824

## Embryos, Stem Cells, and Cloning

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- 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/regulation902

# EUROPE – Montenegro

## General

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a

## Drugs, Biologics, and Devices

### Key Organizations

- Ministry of Health of Montenegro: https://www.gov.me/en/mzd
- Institute for Medicines and Medical Devices: https://cinmed.me/en/

### Relevant Standards

- Various, Legislations: https://cinmed.me/en/legislation/
- Various, Good Practice Guidelines: https://cinmed.me/en/legislation/good-practice-guidelines/
- Forms, Medicines: https://cinmed.me/en/legislation/medicines/
- Forms, Devices: https://cinmed.me/en/legislation/medical-devices/
- Various, Instructions: https://cinmed.me/en/laboratory/instructions-and-forms/

## Research Injury

### Key Organizations

- Institute for Medicines and Medical Devices: https://cinmed.me/en/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Law on Medicines, Various Legislations: https://cinmed.me/en/legislation/medicines/

- Law on Medical Devices, Various Legislations: https://cinmed.me/en/legislation/medical-devices/

## Privacy/Data Protection

### Key Organizations

- National Security Agency: https://www.gov.me/en/dztp
- Ministry of Health of Montenegro: https://www.gov.me/en/mzd

### Relevant Standards

- Law on the Protection of Personal Data (Official Gazette of Montenegro No. 79/08, 70/09, 44/12): https://www.afapdp.org/wp-content/uploads/2018/05/Montenegro-Personal-Data-Protection-Law-79-08-and-70-09.pdf
- Ministry of Health, Law on Data Collection in the Field of Health Care (2009): https://www.gov.me/datacollectioninhealthcare

## Human Biological Materials

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562

## Genetic Research

### Key Organizations

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

### Relevant Standards

- Oviedo Convention, Additional Protocol Concerning Genetic Testing for Health Purposes (CETS No. 203): https://rm.coe.int/1680084824
- Law on the Protection of Genetic Data (Official Gazette of Montenegro No. 25/2010)

## Embryos, Stem Cells, and Cloning

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca

# EUROPE – Netherlands

## General

### Key Organizations

- 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
- CCMO, Legal Framework for Medical Scientific Research, Various Standards: https://english.ccmo.nl/investigators/legal-framework-for-medical-scientific-research
- 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
- 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/medicinesact
- VWS, Medicines Act Decree (2007): https://wetten.overheid.nl/medicinesactdecree
- VWS, Medicines Act Regulation (2007): http://wetten.overheid.nl/medicinesactregulation
- CCMO, Clinical Trials with Medicinal Products (CTR), Various Standards and Relevant Information: https://english.ccmo.nl/investigators/clinical-trials-with-medicinal-products-ctr
- CCMO, Clinical Trials with Medical Devices (MDR), Various Standards and Relevant Information: https://english.ccmo.nl/investigators/clinical-investigations-with-medical-devices
- 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: https://www.onderzoekmetmensen.nl/en
- 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
- Central Committee for Research Involving Human Subjects (CCMO): https://english.ccmo.nl/

### Relevant Standards

- Medical Research Involving Human Subjects Act, Article 7 (1998): https://wetten.overheid.nl/article7
- CCMO, Decree of 2014 containing rules for compulsory insurance in medical research involving human subjects and explanatory memorandum: https://english.ccmo.nl/decreecompulsoryinsurancemedicalresearch

## Social-Behavioral Research

### Key Organizations

- National Ethics Council for Social and Behavioural Sciences: http://www.nethics.nl/
- Central Committee for Research Involving Human Subjects (CCMO): https://english.ccmo.nl/

### Relevant Standards

- Netherlands Code of Conduct for Research (2018): https://www.nwo.nl/researchcodeofconduct
- 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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Law for the Protection of Personal Information (2000): http://wetten.overheid.nl/personalinformationprotection

## Human Biological Materials

### Relevant Standards

- Civil Code, Article 467 (1994)
- Human Tissue and Medical Research: Code of Conduct for responsible use (2011): https://www.coreon.org/humantissueresearchcodeofconduct

## Genetic Research

### Key Organizations

- Dutch Health Care Inspectorate (IGZ): http://www.igz.nl/

### Relevant Standards

- Medical Research Involving Human Subjects Act (1998): https://wetten.overheid.nl/medicalresearchhumansubjectsact
- 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

### Relevant Standards

- Fetal Tissue Act (2001) (Dutch): http://wetten.overheid.nl/fetaltissueact
- Embryos Act (2002): https://wetten.overheid.nl/embryosact

# EUROPE – North Macedonia, Republic of

## Drugs, Biologics, and Devices

### Key Organizations

- Drug and Devices Register: https://lekovi.zdravstvo.gov.mk/
- Drug Agency: http://malmed.gov.mk/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Drug and Devices Register, Various Laws: https://lekovi.zdravstvo.gov.mk/laws
- Drug and Devices Register, Medicines, Various Regulations: https://lekovi.zdravstvo.gov.mk/medicines
- Drug and Devices Register, Medical Devices, Various Regulations: https://lekovi.zdravstvo.gov.mk/medicaldevices
- Health Care Law (Official Gazette No. 43/2012) and Laws Amending and Supplementing the Law, Article 275: http://www.fzo.org.mk/article275

## Research Injury

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98

## 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/personaldatalaw and amendments (2021): https://www.dzlp.mk/amendments
- Regulations on Protection of Personal Data: https://dzlp.mk/personaldataregulation
- Rule book for the Manner of Performing Inspection Supervision: https://www.dzlp.mk/inspectionsupervision
- Rulebook on transfer of personal data: https://dzlp.mk/sites/default/files/052e8e10cf2e4bd48e7827e7bc85fb62.pdf

## Human Biological Materials

### Key Organizations

- Health Insurance Fund of Republic of Macedonia: http://www.fzo.org.mk

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- 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): https://www.coe.int/humanrightsdignitybiologyandmedicine
- Health Care Law (Official Gazette No. 43/2012) and Laws Amending and Supplementing the Law (2012-2016): https://zdravstvo.gov.mk/zakon-za-zdravstvenata-zashtita/
- Law on Taking and Transplanting of the Human Body for Treatment (Official Gazette No. 47/2011) and Laws Amending and Supplementing the Law (2011-2016): https://zdravstvo.gov.mk/no.47
- 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/regulationorgansandtissues

## 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/article21

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca

## EUROPE – Norway

### General

#### Key Organizations

- Norwegian Directorate of Health: https://www.helsedirektoratet.no/
- National Committee for Medical and Health Research Ethics (NEM): https://www.forskningsetikk.no/en/about-us/our-committees-and-commission/nem/
- Regional Committees for Medical and Health Research Ethics (REK): https://www.forskningsetikk.no/en/about-us/our-committees-and-commission/rek/
- National Committee for Research Ethics in Science and Technology (NENT): https://www.forskningsetikk.no/en/about-us/our-committees-and-commission/nent/about-nent/

#### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Law regarding Ethics and Integrity in Research (2006): http://www.ub.uio.no/ethicsintegrityresearchlaw
- Act on Health Care Research (2008): http://www.lovdata.no/healthcareresearch
- Organization of Health Research: https://lovdata.no/dokument/orghealthresearch
- Population-Based Health Survey: https://lovdata.no/popbasedhealthsurvey
- Right of Children Between 12-16 Years to Consent to Participate in Health Research: https://lovdata.no/childconsentresearch
- Guidelines for Research on Persons with Impaired Informed Consent Capacity (2005)
- Payment for Research Participants in Medical and Health Research (2009): https://www.forskningsetikk.no/researchparticipantpayment
- 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 Research, Various: https://www.forskningsetikk.no/en/guidelines/
- NENT, Research Ethics Guidelines for Science and Technology (2016): https://www.forskningsetikk.no/en/guidelines/science-and-technology/guidelines-for-research-ethics-in-science-and-technology/

### Drugs, Biologics, and Devices

#### Key Organizations

- Norwegian Medical Products Agency (NOMA): https://www.dmp.no/en

### Relevant Standards

#### *Drugs*

- The Medicines Act: https://lovdata.no/medicinesact
- Act on Health Care Research: https://lovdata.no/healthcareresearch
- Regulation Relating to Clinical Trials on Medicinal Products for Human Use (2009): http://lovdata.no/clinicaltrialsmedicinalproducts
- Regulations Amending the Regulations Relating to Medicinal Products (The Medicines Regulations) (2023): https://lovdata.no/medicinesregulations
- Clinical trials - Regulation EU No 536/2014**:** https://health.ec.europa.eu/clinical-trials

#### *Devices*

- Act of 12 January 1995 No. 6 Relating to Medical Devices (1995): http://lovdata.no/medicaldevicesact
- Act on Health Care Research (2009): https://lovdata.no/healthcareresearch
- Regulations on Medical Devices, No. 1690 (2005): https://lovdata.no/no1690
- Various: https://www.dmp.no/en/medical-devices/guidance-and-regulations

## Research Injury

### Key Organizations

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Act on Patient Injury Compensation (2001): https://lovdata.no/injurycompensation
- Act on Product Liability, Chapter 3: https://lovdata.no/productliability

## Social-Behavioral Research

### Key Organizations

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

### Relevant Standards

- Research Ethics Act (2017): https://lovdata.no/researchethicsact
- Act of Cultural Heritage (1978): https://lovdata.no/culturalheritageact
- NESH, Guidelines for Research Ethics in the Social Sciences, Law, and the Humanities (2016): https://www.forskningsetikk.no/en/guidelines/social-sciences-and-humanities/guidelines-for-research-ethics-in-the-social-sciences-and-the-humanities/

- NESH, Guide to Internet Research Ethics (2018): https://www.forskningsetikk.no/en/guidelines/social-sciences-and-humanities/a-guide-to-internet-research-ethics/
- NCEHR, Guidelines for Research Ethics on Human Remains: https://www.forskningsetikk.no/en/guidelines/human-remains/guidelines-for-research-ethics-on-human-remains/

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Personal Data Act (2018): https://lovdata.no/dokument/personaldataact
- Changes in the authority to make decisions on access to health information and exemption from the duty of confidentiality (2023): https://www.forskningsetikk.no/accesshealthinfo

## Human Biological Materials

### Key Organizations

- Ministry of Health and Care Services: https://www.regjeringen.no/MOHCS

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Act Relating to the Application of Biotechnology in Human Medicine, etc. (Biotechnology Act) (2003, last updated 2021): https://lovdata.no/dokument/NL/lov/2003-12-05-100?q=humanmedisinsk%20bruk
- Act on Health Care Research (2008, last updated 2021): http://www.lovdata.no/cgi-wift/wiftldles?doc=/usr/www/lovdata/all/nl-20080620-044.html&emne=helseforskningslov*&&

## Genetic Research

### Key Organizations

- Norwegian Biotechnology Advisory Board: http://www.bion.no/english/
- Ministry of Health and Care Services: https://www.regjeringen.no/en/dep/hod/id421/
- Directorate of Health: https://www.helsedirektoratet.no/
- National Committee for Research Ethics in Science and Technology (NENT): https://www.forskningsetikk.no/nent/

### Relevant Standards

- Oviedo Convention, Additional Protocol Concerning Genetic Testing for Health Purposes (CETS No. 203): https://rm.coe.int/1680084824
- Genetic Engineering Guidelines, Various: https://www.helsedirektoratet.no/tema/genteknologi

- Act Relating to the Application of Biotechnology in Human Medicine, etc. (2023, last updated 2021): https://lovdata.no/biotechnologyact
- The Gene Technology Act (1993): https://lovdata.no/genetechnologyact
- Guidelines for Research Ethics in Science and Technology (2016): https://www.forskningsetikk.no/en/guidelines/science-and-technology/

### Embryos, Stem Cells, and Cloning

#### Key Organizations

- Ministry of Health and Care Services: https://www.regjeringen.no/

#### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Act Relating to the Application of Biotechnology in Human Medicine, etc. (Biotechnology Act) (2003, last updated 2021): https://lovdata.no/biotechnologyact
- Act on Health Care Research: https://lovdata.no/healthcareresearch

## EUROPE – Poland

### General

#### Key Organizations

- Ministry of Health, Bioethics Appeals Commission (MOH) Bioethics Appeals Commission (MOH): https://www.gov.pl/MOH
- Center of Bioethics, Polish Chamber of Physicians and Dentists (NIL): https://nil.org.pl/
- Association of Good Clinical Practice in Poland (GCPpl): https://www.gcppl.org.pl/

#### Relevant Standards

- Constitution of the Republic of Poland, Article 39 (1997): http://www.sejm.gov.pl/article39
- Medical Profession Act, Articles 21-29 (1996): http://isap.sejm.gov.pl/isap.nsf/medicalprofessionact
- Code of Medical Ethics, Chapter II (2003): http://www.nil.org.pl/medicalethics
- GCPpl, Various Legal Acts and Ethical Standards: https://www.gcppl.org.pl/

### Drugs, Biologics, and Devices

#### Key Organizations

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

#### Relevant Standards

- Various Legal Acts, Regulations, and Other Standards: https://www.urpl.gov.pl/pl/urz%C4%85d/akty-prawne
- Various Regulations of the Republic of Poland: 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

- Order of the Minister of Finance Amending the Regulation Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2005): https://isap.sejm.gov.pl/isap.nsf/civilliability

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Act on the Protection of Personal Data (2018): https://isap.sejm.gov.pl/personaldata

## Human Biological Materials

### Relevant Standards

- Act on the Public Blood Service (2021): https://isap.sejm.gov.pl/publicbloodservice
- Act Regarding Sampling, Storage, and Transplanting of Cells, Tissues, and Organs (2017): http://isap.sejm.gov.pl/isap.nsf/transplanting2017

## 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 amending the regulation on quality standards for medical diagnostic and microbiological laboratories (2015): https://isap.sejm.gov.pl/labqualitystandards
- Act of 27 July 2001 on laboratory diagnosis: https://isap.sejm.gov.pl/labdiagnosis

## Embryos, Stem Cells, and Cloning

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

### Relevant Standards

- Act on Medical and Dental Professions (1996): https://isap.sejm.gov.pl/medicaldentalprof
- Regulation of the Minister of Health on detailed requirements to be met by the documentation concerning reproductive cells and embryos (2015): https://isap.sejm.gov.pl/reproductivecellsembryos
- Act on collection, storage and transplantation of cells, tissues and organs (2005): https://isap.sejm.gov.pl/transplantation
- Regulation of Minister on the export from and import into the territory of the Republic of Poland of germ cells and embryos (2015): https://isap.sejm.gov.pl/isap.nsf/germcellsembryos

# EUROPE – Portugal

## General

### 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 (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- Opinions, Various: http://www.cnecv.gov.pt/cnecv/en/opinions/

## Drugs, Biologics, and Devices

### Key Organizations

- National Authority for Medicines and Health Products: https://www.infarmed.pt/
- National Ethics Committee for Clinical Research (CEIC): https://www.ceic.pt/pagina-inicial
- National Registries of Clinical Trials (CRNEC): https://www.rnec.pt/31a

### Relevant Standards

- Compiled Pharmaceutical Legislation; Title V, Health Products; Chapter II, Medical Devices, Various Standards: https://www.infarmed.pt/web/infarmed/legislacao/legislacao-farmaceutica-compilada/titulo-v-produtos-de-saude/capitulo-ii-dispositivos-medicos
- CEIC, Various Clinical Trials Regulations: https://www.ceic.pt/regulamento-ec
- CRNEC, Various National Legislation: https://www.rnec.pt/portugal

## Clinical Trial Registries

### Key Organizations

- National Registries of Clinical Trials (CRNEC): https://www.rnec.pt/31a

### Relevant Standards

- CRNEC, Various National Legislation: https://www.rnec.pt/portugal

## Research Injury

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Constitution, Article 35 (1997)
- Act on the Protection of Personal Data, No. 58/2019: https://www.pgdlisboa.pt/no.58

## Human Biological Materials

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562

## Genetic Research

### Relevant Standards

- Oviedo Convention, Additional Protocol Concerning Genetic Testing for Health Purposes (CETS No. 203): https://rm.coe.int/1680084824
- Law 12/2005 Regulating the Treatment of Personal Genetic Information and Health Information

## 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, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- 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)

- Opinion 48/CNECV/2006 on Human Cloning (2006)

# EUROPE – Romania

## General

### Key Organizations

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Ordinance on Scientific Research and Technological Development, No. 57/16.08.2002 (2002): https://legislatie.just.ro/Public/DetaliiDocumentAfis/38222

## Drugs, Biologics, and Devices

### 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

- 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
- Clinical Trials, Legislation, Various: https://www.anm.ro/studii-clinice/legislatie/
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use (2014): https://eur-lex.europa.eu/no.536

## Clinical Trial Registries

### Key Organizations

- National Agency for Medicines and Medical Devices, Clinical Studies platform: https://uploaddsc.anm.ro/

## Research Injury

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98

## 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: https://www.dataprotection.ro/

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- 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: https://legislatie.just.ro/Public/DetaliiDocumentAfis/32733

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- 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/directive53

## 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

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Law No. 301 from 2004 Penal Code – Chapter IV – Crimes and Felonies Regarding Genetic Manipulation

# EUROPE – Russia

***NOTE: For a database of Russian legislation, see: https://cis-legislation.com/index.fwx***

## General

### Key Organizations

- 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/article21
- 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/order433n
- Ministry of Health Order 435h "On Ethics Committee of the Ministry of Health of the Russian Federation" (July 10, 2015): http://base.consultant.ru/order435h

## 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 (Rosstandart): http://government.ru/en/department/56/

### 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 on Procedure for Suspension of Use of Medicine for Medical Application, No. 758n (2010): https://cis-legislation.com/no758n
- 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
- Government Decree No. 673 of September 3, 2010 "Approval of Rules for Import and Export of Biological Materials Obtained in Clinical Trials of a Medicinal Product for Medical Use Into and From the Russian Federation": http://acto-russia.org/decree673

## 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 Organizations

- San Marino Bioethics Committee (Italian): http://www.sanita.sm/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Guidelines for the Processing of Personal Data in the Context of Clinical Trials of Medicinal Products, Genetic/Genomic Analyses and Biobanks: https://bioetica.sm/documenti-utili

## Research Injury

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98

## Human Biological Materials

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98

# EUROPE – Serbia

## General

### Key Organizations

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

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Medicines and Medical Devices Agency of Serbia, Laws: https://www.alims.gov.rs/english/regulations/laws/

## Drugs, Biologics, and Devices

### Key Organizations

- Medicines and Medical Devices Agency of Serbia: https://www.alims.gov.rs/english/

### Relevant Standards

- Medicines and Medical Devices Agency of Serbia, Various Laws: https://www.alims.gov.rs/english/regulations/laws/
- Law on Medicines and Medical Devices (2010): https://www.alims.gov.rs/english/wp-content/uploads/2022/01/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/english/wp-content/uploads/2022/01/7-Rules-on-clinical-trials.pdf

## Clinical Trial Registries

### Key Organizations

- Medicines and Medical Devices Agency of Serbia, Search Approved Clinical Trials: https://www.alims.gov.rs/medicinal-products/

## Research Injury

### Key Organizations

- Medicines and Medical Devices Agency of Serbia: https://www.alims.gov.rs/english/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Law on Medicines and Medical Devices, Article 72: https://www.alims.gov.rs/Law-on-Medicines-and-Medical-Devices-2010.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

## 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

### 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/geneticandrarediseases

## Human Biological Materials

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98

## Embryos, Stem Cells, and Cloning

### 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 – Slovak Republic

## General

### Key Organizations

- 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 (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- 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 44Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Act No. 428/2002 Coll. on Protection of Personal Data, as amended by Act No. 90/2005 Coll.
- Act no. 18/2018 On Personal Data Protection and Amending and Supplementing Certain Acts (2018): https://dataprotection.gov.sk/act18

## Human Biological Materials

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- 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

## Embryos, Stem Cells, and Cloning

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- 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

# EUROPE – Slovenia

## General

### Key Organizations

- Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol concerning Biomedical Research (CETS No. 195): https://rm.coe.int/168008371a
- 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/codemedicalethics

## Drugs, Biologics, and Devices

### Key Organizations

- Republic of Slovenia National Medical Ethics Committee (NMEC): https://www.gov.si/NMEC
- 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 (JAZMP): https://www.jazmp.si/en/

### Relevant Standards

- Ministry of Health, Various Legislation (scroll down to "Medicines and medical devices"): https://www.gov.si/drzavni-organi/ministrstva/ministrstvo-za-zdravje/zakonodaja/
- 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
- JAZMP, General Information about Medical Devices, Various Legislation: https://www.jazmp.si/en/medical-devices/general-information-on-medical-devices/legislation/

## Research Injury

### Key Organizations

- Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- 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

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Personal Data Protection Act No. 94/2007: http://pisrs.si/Pis.web/dataact94

## Human Biological Materials

### Key Organizations

- Institute for transplantation of Organs and Tissues of the Republic of Slovenia: https://www.slovenija-transplant.si/en/index.php

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Institute for transplantation of Organs and Tissues of the Republic of Slovenia, Various Laws and Regulations: https://www.slovenija-transplant.si/zakonodaja/#zakoni

## Genetic Research

### Relevant Standards

- Oviedo Convention, Additional Protocol Concerning Genetic Testing for Health Purposes (CETS No. 203): https://rm.coe.int/1680084824

## Embryos, Stem Cells, and Cloning

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- 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

# EUROPE – Spain

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

## General

### Key Organizations

- Spanish Bioethics Committee: https://comitedebioetica.isciii.es/en/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168007cf98
- Spanish Bioethics Committee, Various State and Autonomous Legislation: https://comitedebioetica.isciii.es/en/legal-regime/

## Drugs, Biologics, and Devices

### Key Organizations

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

### Relevant Standards

- AEMPS, Various Standards for Clinical Trials with Medicines for Human Use: https://www.aemps.gob.es/clinicaltrialsmedicineshumanuse
- AEMPS, Various Standards for Clinical Trials with Medical Devices: 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

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Law 14/2007 on Biomedical Research, Article 18: https://www.isciii.es/biomedicalresearch
- 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://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536&qid=1722524150296
- 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/decree1090

## Privacy/Data Protection

### Key Organizations

- Spanish Data Protection Authority: https://www.aepd.es/en/areas/innovation-and-technology
- Spanish Agency of Medicines and Medical Devices (AEMPS): https://www.aemps.gob.es/

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Law 14/2007 on Biomedical Research, Title I, Article 5: https://www.isciii.es/biomedicalresearch
- Organic Law 3/2018 of December 5 on the Protection of Personal Data and Guaranteeing Digital Rights: https://www.boe.es/law3
- Royal Decree 1720/2007 Approving Organic Law 15/1999 for the Protection of Personal Data (2008): 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/AEMPSdataprotection

## Human Biological Materials

### Key Organizations

- Ministry of Science Innovation and Research: https://www.ciencia.gob.es/en/

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: https://www.isciii.es/biomedicalresearch
- Royal Decree 1716/2011 on Biobanks: https://www.boe.es/decree1716
- 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/decree9

## Genetic Research

### Relevant Standards

- Law 14/2007 of July 3 on Biomedical Research, Title I, Articles 6-9; Title V: https://www.isciii.es/biomedicalresearch

## Embryos, Stem Cells, and Cloning

### Key Organizations

- National Biobank Network: https://www.isciiibiobanksbiomodels.es/
- National Bank of Cell Lines: https://www.isciii.es/nbcl

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168
- Law 14/2006 on Methods of Assisted Human Reproduction, Chapters IV and V
- Law 14/2007 of July 3 on Biomedical Research, Title III: https://www.isciii.es/LawonBiomedicalResearch
- 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/decree1527

# EUROPE – Sweden

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

## General

### Key Organizations

- Swedish Ethical Review Authority: https://etikprovningsmyndigheten.se/
- Ethics Review Appeal Board: https://www.onep.se/en/ethicsreviewappealsboard
- Swedish Research Council: http://www.vr.se/english
- National Board of Health and Welfare (Socialstyrelsen): https://www.socialstyrelsen.se/en/

### Relevant Standards

- Act on the Ethical Review of Research Involving Humans (2003:460): https://www.riksdagen.se/act460
- Ordinance Concerning the Ethical Vetting of Research Involving Humans (2003:615): https://www.riksdagen.se/ordinance615
- Statute with Instructions for the Swedish Ethical Review Authority (2018:1879): https://svenskforfattningssamling.se/2018.1879
- Statute with Instructions for the Ethics Review Appeals Board (2007:1068): http://rkrattsbaser.gov.se/2007:1068
- Good Research Practice (2017): https://www.vr.se/goodresearchpractice

## Drugs, Biologics, and Devices

### Key Organizations

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

### Relevant Standards

#### *Drugs*

- Pharmaceuticals Act (2015:315): https://faolex.fao.org/pharmaceuticalsact
- MPA, Various Laws and Regulations (searchable database): https://www.lakemedelsverket.se/laws
- MPA, Regulations on Clinical Drug Trials in Humans (2011:19): http://www.lakemedelsverket.se/19

#### *Devices*

- Swedish Medical Devices Act (1993:584): http://www.notisum.se/act584
- Medical Devices Ordinance (1993:876): http://www.riksdagen.se/ordinance876
- Swedish Implementation of Directive 93/42/EEC (2003:11): https://lakemedelsverket.se/LVFS_2003-11.pdf
- The National Board of Health and Welfare's regulations on the use of medical devices in health care (2021:52): https://www.socialstyrelsen.se/2021.52

## 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) (currently being updated. New report expected in 2024): https://www.vr.se/goodresearchpractice
- Research Review 2023, Humanities and social sciences: https://www.vr.se/humanities-and-social-sciences

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- General Data Protection Regulation (GDPR), Regulation (EU) 2016/679: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679
- Patient Data Act (2008:355): https://www.riksdagen.se/act355
- Publicity and Privacy Act (2009:400): https://www.riksdagen.se/act400
- Act on Certain Health Research Registers (2013:794): https://www.riksdagen.se/act794
- Act Complement to the GDPR (2018:218): https://www.riksdagen.se/act218
- Public Access to Information and Secrecy Ordinance (2009:641): 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/
- Biobank Sweden: http://biobanksverige.se/

### Relevant Standards

- Biobanks in Medical Care Act (2002:297): https://www.riksdagen.se/biobanksno.297
- Regulation on Biobanks in Health Care, etc. (2002:746): http://www.notisum.se/rnp/sls/lag/20020746.htm
- 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. (2018:52) (updated 2021): https://www.socialstyrelsen.se/2018-12-31.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 (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

## Embryos, Stem Cells, and Cloning

### Relevant Standards

- Legal Regulation of Stem Cell Research (2002:119): http://www.regeringen.se/stemcellresearch
- Regulations and Guidelines for the Use of Tissues and Cells in Healthcare and Clinical Research - SOSFS (2009:32): https://www.socialstyrelsen.se/SOSFS

# EUROPE – Switzerland

## General

### Key Organizations

- 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): https://kofam.ch/en
- 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/
- Swiss Academy of Medical Sciences (SAMW): https://www.samw.ch/en.html

### Relevant Standards

- SAMW, Medical-Ethical Guidelines, Various: https://www.samw.ch/de/Ethik/Richtlinien.html
- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164): https://rm.coe.int/168
- Federal Constitution of the Swiss Confederation, RS 101, Article 118b (1999): http://www.admin.ch/opc/en/classified-compilation/19995395/index.html
- Federal Act on Research Involving Human Beings (Human Research Act, HRA), RS 810.30 (2011) (current as of September, 2023): http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance on Clinical Trials in Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301 (2013): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance on Organizational Aspects of the Human Research Act (HRA Organisational Ordinance, OrgO-HRA), RS 810.308 (2013): https://www.admin.ch/opc/en/classified-compilation/20121179/index.html
- Swiss Clinical Trial Organization, Guidelines for Good Operational Practice (GGOP) (2017): https://www.scto.ch/en/publications/guidelines.html

## Drugs, Biologics, and Devices

### Key Organizations

- Swiss Agency for Therapeutic Products (Swissmedic): http://www.swissmedic.ch/

### Relevant Standards

- Clinical Trials, Various Applicable Laws: https://www.swissmedic.ch/clinical-trials

- Clinical trials on medicinal products, Various Applicable laws and guidelines (Swiss Legislation and International Guidelines): https://www.swissmedic.ch/clinical-trials-on-medicinal-products/applicable-laws-and-guidelines.html
- Regulation of Medical Devices, Legal Framework: https://www.swissmedic.ch/regulation-of-medical-devices/

## Clinical Trial Registries

### Key Organizations

- Swiss National Clinical Trials Portal: https://kofam.ch/en/snctp-portal/searching-for-a-clinical-trial

### Relevant Standards

- Federal Act on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 56, 64, 65, and 67 (2011) (current as of September, 2023): https://www.admin.ch/opc/en/classified-compilation/20061313/index.html

## Research Injury

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 24: https://rm.coe.int/168007cf98
- Federal Act on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 19-20 (2011) (current as of September, 2023): http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance 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 (2013): https://www.admin.ch/opc/en/classified-compilation/20121179/index.html
- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance CLinO), RS 810.305, Articles 7, 10-13, 25, and 71, and Annexes 2-3 (2013): 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.html

### Relevant Standards

- Federal Act on Data Protection (FADP), RS 235.1 (1992): http://www.admin.ch/opc/en/classified-compilation/19920153/index.html
- Federal Act 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 (2011): http://www.admin.ch/opc/en/classified-compilation/20061313/index.html

- Ordinance 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 (2013): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance 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 (2013): https://www.admin.ch/opc/en/classified-compilation/20121176/index.html

## Human Biological Materials

### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (ETS No. 164), Articles 21-22: https://rm.coe.int/168007cf98
- Oviedo Convention, Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186): https://rm.coe.int/1680081562
- Federal Act 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 (2011): http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance on Human Genetic Testing, RS 810.122.1 (2007): http://www.admin.ch/opc/fr/classified-compilation/20051790/index.html
- Ordinance 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) (2013): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 7, 9, 12, 16 - 18 and Annex 2 (2013): http://www.admin.ch/opc/en/classified-compilation/20121176/index.html

## Genetic Research

### Relevant Standards

- Federal Constitution of the Swiss Confederation of 18 April 1999, RS 101, Article 119 (1999): http://www.admin.ch/opc/en/classified-compilation/19995395/index.html
- Federal Act on Human Genetic Testing (HGTA), RS 810.12 (2004): http://www.admin.ch/opc/en/classified-compilation/20011087/index.html
- Federal Act on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 3, 32-35, 42, and 49 (2011): http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Ordinance on Human Genetic Testing, RS 810.122.1 (French) (2007): http://www.admin.ch/opc/fr/classified-compilation/20051790/index.html
- Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 28–32 (2013): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305 Articles 22 and 35, and Annexes 3 and 4 (2013): http://www.admin.ch/opc/en/classified-compilation/20121176/index.html

## Embryos, Stem Cells, and Cloning

### Relevant Standards

- Oviedo Convention, Additional Protocol on the Prohibition of Cloning Human Beings (ETS No. 168): https://rm.coe.int/168007f2ca
- Federal Act on Research Involving Human Beings (Human Research Act, HRA), RS 810.30 Articles 2, 25 - 27, 39, 40, 44, and 62 (2011): http://www.admin.ch/opc/en/classified-compilation/20061313/index.html
- Federal Act on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), RS 810.31 (2003): http://www.admin.ch/opc/en/classified-compilation/20022165/index.html
- Ordinance on Research involving Embryonic Stem Cells (Stem Cell Research Ordinance, SCRO), RS 810.311 (2005): http://www.admin.ch/opc/en/classified-compilation/20042542/index.html
- Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 44–46, and Annex 2 (2013): http://www.admin.ch/opc/en/classified-compilation/20121177/index.html
- Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 49, 53, 55, and 56, and Annexes 3 and 4 (2013): 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/no.14

# EUROPE – Ukraine

***MARTIAL LAW IN UKRAINE: Since February 24, 2022, Ukraine has been under martial law due to an attack by the Russian Federation. For information about the work of the Ministry of Health during martial law, as well as news and advice for citizens, doctors, and clarifications for business entities working in the field of health care, visit: https://moz.gov.ua/en/military-state***

***NOTE: For a database of Ukrainian legislation, see: https://cis-legislation.com/index.fwx***

## General

### Key Organizations

- Ministry of Health of Ukraine: http://www.moz.gov.ua/en/
- Ukrainian Institute on Public Health Policy (UIPHP): https://www.uiphp.org.ua/en/

### Relevant Standards

- To search all documents in the Ukraine Legislation database visit: https://zakon.rada.gov.ua/laws/
- Constitution of Ukraine, Article 28 (1996): https://faolex.fao.org/constitutionarticle28
- Civil Code of Ukraine, Article 281 (2003): https://zakon.rada.gov.ua/laws/civilcode
- Criminal Code of Ukraine 2001, Article 141,142 and 321 (2010): https://sherloc.unodc.org/UkraineCriminalCode

## Drugs, Biologics, and Devices

### Key Organizations

- Ministry of Health of Ukraine State Expert Center: http://www.dec.gov.ua

### Relevant Standards

- Law of Ukraine About Medicines, No.22 (1996): https://zakon.rada.gov.ua/laws/no.22
- Preclinical studies, Various Applicable Laws : https://www.dec.gov.ua/materials/preclinicalstudies
- Clinical Trials, Various Applicable Laws, Various: https://www.dec.gov.ua/materials/clinicaltrials
- Various Unofficial Legislation in English: https://www.dec.gov.ua/materials/legislation
- Medicines and Studies, Various Guidelines: https://www.dec.gov.ua/materials/medicines

## Privacy/Data Protection

### Key Organizations

- Ukrainian Parliament Commissioner for Human Rights: www.ombudsman.gov.ua

### Relevant Standards

- The Law of Ukraine on Personal Data Protection (2010): https://zakon.rada.gov.ua/laws/

## Human Biological Materials

### Key Organizations

- Association of Cryobanks of Cord Blood and Other Human Tissues and Cells: https://stemcellbank.org.ua/

### Relevant Standards

- Laws, Decrees, and Regulations, Various: https://stemcellbank.org.ua/regulations

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

- Act on the Banning of Human Reproductive Cloning (2004): https://cis-legislation.com/document

# EUROPE – United Kingdom

***NOTE: For an overview of clinical research regulations in the United Kingdom, see the ClinRegs report: https://clinregs.niaid.nih.gov/country/united-kingdom***

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

## General

### Key Organizations

- 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/
- National Institute for Health Research (NIHR): http://www.nihr.ac.uk/
- UK Research Integrity Office (UKRIO): https://ukrio.org/
- Integrated Research Application System (IRAS): https://www.myresearchproject.org.uk/

## Relevant Standards

- HRA, Various Policies, Standards, and Legislation Applicable to Research and Clinical Trials: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/
- HRA, Governance Arrangements for Research Ethics Committees: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/
- HRA, Policies, Standards & Legislation, Prison Research: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/prison-research/
- HRA, Policies, Standards & Legislation, Research Involving Children: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-involving-children/
- HRA, Policies, Standards & Legislation, Public Health Emergency Research: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/public-health-emergency-research/
- HRA, Policies, Standards & Legislation, Research in Emergency Settings: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-emergency-settings/
- HRA, Guidance for Health and Social Care Researchers at the End of the Transition Period: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/guidance-health-and-social-care-researchers-end-transition-period/
- 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, Good Research Practice, Various Policies and Guidance: https://www.ukri.org/who-we-are/mrc/our-policies-and-standards/research/
- NHS, Participant Information Quality Standards (2023): https://www.hra.nhs.uk/participant-information-quality-standards/
- NHS, Participant Information Design and Review Principles (2023): https://www.hra.nhs.uk/participant-information-design-and-review-principles/
- ABPI, Clinical Trials Best Practice Guide: Helping to Improve Clinical Trial Set-Up Processed in the UK (2024): https://www.abpi.org.uk/publications/clinical-trials-best-practice-guide-2024/

### *Scotland*

#### Key Organizations

- NHS Scotland, 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/RGF-Second-Edition-February-06.pdf

### *Wales*

#### Key Organizations

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

#### Relevant Standards

- Health and Care Research Wales, Support and guidance for researchers: https://healthandcareresearchwales.org/researchers/support-and-guidance-researchers

### *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

- Office for Research Ethics Committees Northern Ireland, Guidance for Applicants: https://bso.hscni.net/guidance-for-applicants/

## Drugs, Biologics, and Devices

#### 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
- Association of British HealthTech Industries (ABHI): https://www.abhi.org.uk/

- Health Research Authority (HRA): http://www.hra.nhs.uk/
- Medical Device Coordination Group (MDCG): https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/medical-device-coordination-group-working-groups_en

### Relevant Standards

- HRA, Policies, Standards & Legislation, Clinical Trials of Investigational Medicinal Products (CTIMPs), Various Currently Applicable Legislation and resources: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/
- HRA, Policies, Standards & Legislation, Phase 1 Clinical Trials: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/phase-1-clinical-trials/
- MDCG, MDCG Endorsed Documents and Other Guidance, Various: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
- The Medical Devices Regulations (2002): https://www.legislation.gov.uk/uksi/2002/618/contents/made

## *Drugs*

- 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
- Medicines for Human Use (Clinical Trials) Amendment Regulations No. 1928 (2006): 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 No. 2984 (2006): http://www.legislation.gov.uk/uksi/2006/2984/pdfs/uksi_20062984_en.pdf
- Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations, No. 941 (2008): http://www.legislation.gov.uk/uksi/2008/941/contents/made
- Genetically Modified Organisms (Deliberate Release) Regulations, No. 2443 (2002): http://www.legislation.gov.uk/uksi/2002/2443/contents/made
- Genetically Modified Organisms (Contained Use) Regulations, No. 1663 (2014) *(*England, Scotland and Wales): http://www.legislation.gov.uk/uksi/2014/1663/part/1/made
- Genetically Modified Organisms (Contained Use) Regulations, No. 339 (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/

## *Devices*

- Medical Devices Regulations, No. 618 (2002): http://www.opsi.gov.uk/si2002.htm
- Medical Devices (Amendment) Regulations, No. 2936 (2008): http://www.legislation.gov.uk/uksi/2008/2936/contents/made
- Various Regulatory Guidance for Medical Devices: https://www.gov.uk/government/collections/regulatory-guidance-for-medical-devices

- Notify MHRA About a Clinical Investigation for a Medical Device, Guidance: https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device
- HRA, Medical Devices and Software Applications: http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/medical-devices-research-2/

## Clinical Trial Registries

### Key Organizations

- International Standard Randomized Controlled Trial Number (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/policies-standards-legislation/research-transparency/

## 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

### 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/publications/clinical-trial-compensation-guidelines/

## Social-Behavioral Research

### Key Organizations

- Economic and Social Research Council (ESRC): https://esrc.ukri.org/
- UK Research Integrity Office: https://ukrio.org/
- Health Research Authority (HRA): http://www.hra.nhs.uk/

### Relevant Standards

- ESRC, Framework for Research Ethics (2015): https://www.gla.ac.uk/media.pdf

- Good Practice in Research: Internet-Mediated Research (2016): http://ukrio.org/wp-content/uploads/UKRIO-Guidance-Note-Internet-Mediated-Research-v1.0.pdf
- HRA, Policies, Standards & Legislation, Social Care Research: https://www.hra.nhs.uk/social-care-research/

## Privacy/Data Protection

***NOTE: Due to the United Kingdom's departure from the European Union (EU), there are notable differences in the UK regarding scope and protections of the General Data Protection Regulation (GDPR).***

### *United Kingdom*

#### Key Organizations

- Information Commissioner's Office (ICO): https://ico.org.uk/
- Confidentiality Advisory Group (CAG): http://www.hra.nhs.uk/about-the-hra/our-committees/section-251

#### Relevant Standards

- Data Protection Act (2018): http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted
- ICO, The UK GDPR: https://ico.org.uk/for-organisations/data-protection-and-the-eu/data-protection-and-the-eu-in-detail/the-uk-gdpr/
- ICO, UK GDPR guidance and resources: 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, Data Protection and Information Governance, Currently Applicable Legislation: https://www.hra.nhs.uk/data-protection-and-information-governance/
- HRA, GDPR Guidance: https://www.hra.nhs.uk/gdpr-guidance/
- HRA, Consent in Research (2018): https://www.hra.nhs.uk/consent-research/
- HRA, Research Tissue Banks and Research Databases: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/
- HRA, Research Data and Tissue Resources: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-data-and-tissue-resources/
- HRA, Confidential Patient Information, Section 251: https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/confidential-patient-information-and-regulations/
- MRC, Using Information About People in Health Research (2017): https://mrc.ukri.org/documents/pdf/using-information-about-people-in-health-research-2017/
- Health Service (Control of Patient Information) Regulations, No. 1438 (2002): http://www.legislation.gov.uk/uksi/2002/1438/made?view=plain

## Human Biological Materials

### *United Kingdom*

#### Key Organizations

- Human Tissue Authority (HTA): http://www.hta.gov.uk/

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

#### Relevant Standards

- The 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
- Regulation 2006 No. 1260, The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) (Applies to England, Wales, and Northern Ireland): http://www.legislation.gov.uk/uksi/2006/1260/contents/made
- Regulation 2006 No. 1659, The Human Tissue Act 2004 (Persons Who Lack Capacity to Consent and Transplants) (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 (2019): https://www.ukri.org/publications/human-tissue-and-biological-samples-for-use-in-research/
- HRA, Use of Human Tissue in Research: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/use-tissue-research/
- HRA, Research Tissue Banks and Research Databases: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/
- HRA, Research Data and Tissue Resources: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-data-and-tissue-resources/

### *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 (HFEA): 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

- Human Fertilisation and Embryology Act (2008): http://www.legislation.gov.uk/ukpga/2008/22/contents
- Human Fertilisation and Embryology Regulation, Guidance: 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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**Dr. Sergio Litewka** and **Dr. Kenneth W. Goodman** of the Institute for Bioethics and Health Policy at University of Miami, Miller School of Medicine

**Dr. Stuart McCully** of Real World Research Limited (RWR-Regs)

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