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

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 However, not all countries provided corroboration, so some of the information contained in this document may be outdated or incomplete (please see disclaimer below).

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

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

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

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

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

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

1. Standards from the state, provincial, or local levels
2. Enabling legislation, i.e., laws that authorize an agency to promulgate human subjects standards, but do not direct the content of those regulations

3. Laws, regulations, or guidelines that are disease-specific or focus on research integrity, clinical bioethics, product liability, clinical trial inspection procedures, intellectual property, good manufacturing practice, bioequivalence testing, or informed consent in clinical practice

4. Ethics codes of academic, medical, or other professional organizations – see the Ethics Codes Collection: [http://ethics.iit.edu/ecodes/about](http://ethics.iit.edu/ecodes/about)

5. Working papers, drafts, commentaries, or discussion papers

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

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

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

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Various: https://www.who.int/publications/i?healthtopics=487178c1-f124-4085-bf1f-564051f1cd63

World Medical Association: http://www.wma.net/e/


Drugs, Biologics, and Devices

**Drugs**

International Conference on Harmonization (ICH): http://www.ich.org/

- Various guidelines, including Guidelines for Good Clinical Practice E6 (and Integrated Addendums E6(R2)-(R3)): https://www.ich.org/page/efficacy-guidelines

World Health Organization (WHO): http://www.who.int/en/


**Devices**

International Medical Device Regulators Forum (IMDRF): http://www.imdrf.org/

- Various Archived Documents from the Global Harmonization Task Force (GHTF), replaced by the IMDRF in 2012: http://www.imdrf.org/ghtf/ghtf-archived-docs.asp


**Clinical Trial Registries**

International Committee of Medical Journal Editors: http://www.icmje.org/

- Clinical Trial Registration: http://icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

United States, National Institutes of Health, ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/home

• Resolution WHA 58.34 (2005): http://www.wpro.who.int/health_research/policy_documents/ministerial_summit_on_health_research_may2005.pdf?ua=1

World Medical Association: http://www.wma.net/e/

Research Injury

Council for International Organizations of Medical Sciences: http://www.cioms.ch/
• International Ethical Guidelines for Health-related Research Involving Humans (2016), Guideline 14: https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/

International Conference on Harmonization (ICH): http://www.ich.org/
• Various guidelines, including Guidelines for Good Clinical Practice E6 (and Integrated Addendums E6(R2)-(R3)): https://www.ich.org/page/efficacy-guidelines

World Medical Association: https://www.wma.net/

Social-Behavioral Research

UNESCO: http://www.unesco.org/

Privacy/Data Protection

World Medical Association: http://www.wma.net/e/index.htm

Human Biological Materials

International Air Transport Association: http://www.iata.org/
• Infectious Substances and Diagnostic Specimens Shipping Guidelines (2005)

International Society for Biological and Environmental Repositories: https://www.isber.org/
• ISBER Best Practices: Recommendations for Repositories (2019) and Addendums: https://www.isber.org/page/BPR

World Health Organization: http://www.who.int/en/

World Medical Association

Genetic Research
- Human Genome Organization: http://www.hugo-international.org/


Embryos, Stem Cells, and Cloning
- International Society for Stem Cell Research: http://www.isscr.org/
AFRICA – Regionwide

Clinical Trial Registries

Pan African Clinical Trials Registry: http://www.pactr.org/
- PACTR, Terms and Conditions: https://pactr.samrc.ac.za/TermsAndConditions.aspx
- PACTR, FAQs: https://pactr.samrc.ac.za/FAQ.aspx

AFRICA – Algeria

Drugs, Biologics, and Devices

Key Organizations
- Directorate of Pharmacy and Medicine

Relevant Standards
- Order No. 387 of 31 July 2006 Relating to Clinical Trials
- Order No. 00200 of 25 July 2009 Amending Order No. 112 of 22 October 1995 Setting the Rules of Good Clinical Practice

AFRICA – Benin

General

Relevant Standards
- Law No. 2010-40 of 8 December 2010 Regarding the Ethical Code and Duties in Health Research in the Republic of Benin

AFRICA – Botswana

General

Key Organizations
- Ministry of Health and Wellness

Relevant Standards
- Anthropological Research Act 45 (1967):
- Guide for a Consent Form (2005)

Drugs, Biologics, and Devices

Key Organizations
- Ministry of Health and Wellness
Relevant Standards

- Drugs and Related Substances Regulations (1993)
- SADC Guidelines for Regulating Clinical Trials in Human Subjects (2006)
- Guideline for Regulating the Conduct of Clinical Trials Using Medicines in Human Participants (2012)

Social-Behavioral Research

Key Organizations

- Ministry of Health and Wellness

Relevant Standards


AFRICA – Burkina Faso

General

Key Organizations

- Ethics Committee for Health Research

Relevant Standards

- Joint Order 2004-147 / MS / MESSE of 11 May 2004 on the Organization and Functioning of the Ethics Committee for Health Research in Burkina Faso

Drugs, Biologics, and Devices

Relevant Standards

- Joint Order 2004-147 / MS / MESSE of 11 May 2004 on the Organization and Functioning of the Ethics Committee for Health Research in Burkina Faso

AFRICA – Cameroon

General

Key Organizations

- Cameroon Bioethics Initiative: [Website link]

Relevant Standards

- Operational Guidelines for Ethics Committees in Charge of the Evaluation of Biomedical Research

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AFRICA – Congo, Democratic Republic of

NOTE: For an overview of clinical research regulations in the Democratic Republic of the Congo, see the ClinReg report: https://clinregs.niaid.nih.gov/country/DRC

General

Relevant Standards

▪ Decree-Law Framework on Public Health, Title VII: Regarding the National Medical Ethics Committee, Biomedical Research, Transplantation of Organs and Tissues, Genetic Treatment, and Cloning: https://www.mindbank.info/item/2543


AFRICA – Côte-d’Ivoire

Drugs, Biologics, and Devices

Key Organizations

▪ National Committee on Ethics and Research

Relevant Standards

▪ Decree No. 317 / SP / DSPH of 14 July 1987 on the Regulation of Drugs Before and After Marketing in Ivory Coast: http://elearning.trree.org/pluginfile.php/34816/mod_folder/content/0/20_Arrete_Regl_exp_clinique_des_substances_med.pdf?forcedownload=1

AFRICA – Ethiopia

General

Key Organizations

▪ Ethiopian Science and Technology Commission, Health Department

Relevant Standards

▪ Proclamation 60/1999, Section 21


Drugs, Biologics, and Devices

Key Organizations

▪ Food, Medicine, and Health Administration and Control Authority: www.fmhaca.gov.et

Relevant Standards

▪ Drug Administration and Control Proclamation No. 176/1999, Article 21
Human Biological Materials

Key Organizations
- Ethiopian Science and Technology Commission, Health Department

Relevant Standards

AFRICA – Gambia

Genetic Research

Key Organizations
- MRC: Gambia Unit: [http://www.mrc.gm/](http://www.mrc.gm/)

Relevant Standards
- Guidelines of the National DNA Bank (2001)

AFRICA – Ghana


Drugs, Biologics, and Devices

Key Organizations
- Food and Drugs Authority: [http://www.fdaghana.gov.gh](http://www.fdaghana.gov.gh)

Relevant Standards
AFRICA – Guinea

NOTE: For an overview of the clinical research regulations in Guinea, see the ClinRegs report: https://clinregs.niaid.nih.gov/single_country.php?c_id=90

General

Key Organizations
- National Ethics Committee on Health Research (CNERS): http://cners-guinee.org/

Relevant Standards

Research Injury

Key Organizations
- National Ethics Committee on Health Research: http://cners-guinee.org/

Relevant Standards

AFRICA – Kenya


General

Key Organizations
- Ministry of Health (MOH): www.health.go.ke/

Relevant Standards
- Science and Technology Act (2001)

Drugs, Biologics, and Devices

Key Organizations
- Pharmacy and Poisons Board: http://www.pharmacyboardkenya.org/
Relevant Standards

- Pharmacy and Poisons Act, Chapter 244 (2009):
- MOH, Guidelines for Applications to Conduct Clinical Trials in Kenya (2014):
  http://pharmacyboardkenya.org/downloads/?file=Clinical%20Trial%20Guidelines%202014.pdf

**Human Biological Materials**

**Key Organizations**

- Ministry of Health (MOH): www.health.go.ke/

**Relevant Standards**


**AFRICA – Liberia**

*NOTE: For an overview of the clinical research regulations in Liberia, see the ClinRegs report:*


**General**

**Key Organizations**


**Relevant Standards**

- Ethics Committee Guidelines: Procedures for Researchers, Section 1 (2011):
- Operational Guidelines of the National Research Ethics Board (2019):

**Drugs, Biologics, and Devices**

**Key Organizations**

- Liberia Medicines and Health Products Regulatory Authority

**Relevant Standards**

- Guideline for Application to Conduct Clinical Trials in Liberia (2014):

**AFRICA – Madagascar**

**Drugs, Biologics, and Devices**

**Relevant Standards**

- Law No. 2011-002, Article 122 Regarding Clinical Trials:
AFRICA – Malawi

NOTE: For an overview of the clinical research regulations in Malawi, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=129

General

Key Organizations
- National Health Sciences Research Committee (NHSRC): http://www.ncst.mw/national-health-science-research-committee-nhsrc/
- College of Medicine Research and Ethics Committee (COMREC): http://www.medcol.mw/
- Ministry of Health: www.malawi.gov.mw

Relevant Standards
- Presidential Decree on 30th March 1974
- Malawi Government Gazette, June 11, 1976, General Notice No. 398
- NCST, National Policy Measures and Requirements for the Improvement of Health Research Coordination in Malawi (2012)
- NHSRC, Operational Guidelines (2001)
- NHSRC, Summary Guidelines for Writing Research Proposals (2001)

Drugs, Biologics, and Devices

Key Organizations
- Pharmacy, Medicines, and Poisons Board of Malawi

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# AFRICA – Mozambique

## General

### Relevant Standards

- Science and Technology Ethics Code (2007):  
  [http://elearning.trree.org/pluginfile.php/34764/mod_folder/content/0/02-CodigoDeEtica.pdf?forcedownload=1](http://elearning.trree.org/pluginfile.php/34764/mod_folder/content/0/02-CodigoDeEtica.pdf?forcedownload=1)

# AFRICA – Nigeria

## General

### Key Organizations

- National Health Research Ethics Committee:  [https://nhrec.net/](https://nhrec.net/)

### Relevant Standards

- Policy Statement Regarding Enrollment of Children in Research in Nigeria (2016):  
- Guides and Forms, various:  [https://nhrec.net/download-guides-and-forms/](https://nhrec.net/download-guides-and-forms/)

## Drugs, Biologics, and Devices

### Key Organizations

- National Agency for Food, Drug Administration and Control (NAFDAC):  

### Relevant Standards

- Decree No. 15 of 1993

## Clinical Trial Registries

### Key Organizations

- National Health Research Ethics Committee:  [http://nhrec.net/](http://nhrec.net/)

### Relevant Standards

- Frequently Asked Questions:  [http://nctr.nhrec.net](http://nctr.nhrec.net)
### Social-Behavioral Research

**Key Organizations**
- National Health Research Ethics Committee: [http://nhrec.net/](http://nhrec.net/)

**Relevant Standards**

### Human Biological Materials

**Key Organizations**
- National Health Research Ethics Committee: [http://nhrec.net/](http://nhrec.net/)

**Relevant Standards**

### AFRICA – Rwanda

**General**

**Key Organizations**
- Ministry of Health: [https://www.moh.gov.rw/](https://www.moh.gov.rw/)
- National Ethics Committee: [http://www.rnecrwanda.org/](http://www.rnecrwanda.org/)

**Relevant Standards**
- Laws, various: [https://www.moh.gov.rw/publications?tx_filelist_filelist%5Baction%5D=list&tx_filelist_filelist%5Bcontroller%5D=File&tx_filelist_filelist%5Bpath%5D=%2Fuser_upload%2FMoh%2FPublications%2FLaws%2F&cHash=7954b6ed1a3eebee62f86b8f124eab94](https://www.moh.gov.rw/publications?tx_filelist_filelist%5Baction%5D=list&tx_filelist_filelist%5Bcontroller%5D=File&tx_filelist_filelist%5Bpath%5D=%2Fuser_upload%2FMoh%2FPublications%2FLaws%2F&cHash=7954b6ed1a3eebee62f86b8f124eab94)

### AFRICA – Senegal

**General**

**Key Organizations**
- National Committee on Health Research Ethics

**Relevant Standards**
- Law Supporting the Code of Ethics for Health Research (2009)

### AFRICA – Sierra Leone

**NOTE:** For an overview of the clinical research regulations in Sierra Leone, see the ClinRegs report: [https://clinregs.niaid.nih.gov/single_country.php?c_id=193](https://clinregs.niaid.nih.gov/single_country.php?c_id=193)

**General**

**Key Organizations**
- Sierra Leone Ethics and Scientific Review Committee
Relevant Standards


Drugs, Biologics, and Devices

Key Organizations

- Pharmacy Board of Sierra Leone: [http://www.pharmacyboard.gov.sl/](http://www.pharmacyboard.gov.sl/)

Relevant Standards

- Guidelines for Conducting Clinical Trials of Medicines, Food Supplements, Vaccines, and Medical Devices in Sierra Leone, Sections: 3.1.7 and 3.2 (2014): [https://www.medbox.org/pdf/5e148832db60a2044c2d399a](https://www.medbox.org/pdf/5e148832db60a2044c2d399a)

AFRICA – South Africa


General

Key Organizations

- Medical Research Council of South Africa (MRC): [https://www.samrc.ac.za/](https://www.samrc.ac.za/)
- South African Health Products Regulatory Authority: [https://protect.za.mimecast.com/s/5WP2Cr07Vf1mK59tzNft9?domain=sahpra.org.za/](https://protect.za.mimecast.com/s/5WP2Cr07Vf1mK59tzNft9?domain=sahpra.org.za/)

Relevant Standards


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Drugs, Biologics, and Devices

Key Organizations
- Health Products Regulatory Authority: https://www.sahpra.org.za/

Relevant Standards

Clinical Trials Registry

Key Organizations
- South African National Clinical Trials Register: https://sanctr.samrc.ac.za/

Relevant Standards
- FAQs: https://sanctr.samrc.ac.za/FAQ.aspx

Social-Behavioral Research

Key Organizations

Relevant Standards

Human Biological Materials

Key Organizations

Relevant Standards
Genetic Research

Key Organizations
- Medical Research Council of South Africa (MRC): [https://www.samrc.ac.za/](https://www.samrc.ac.za/)

Relevant Standards

Embryos, Stem Cells, and Cloning

Key Organizations
- Medical Research Council of South Africa (MRC): [https://www.samrc.ac.za/](https://www.samrc.ac.za/)

Relevant Standards

AFRICA – Tanzania


General

Key Organizations
- Ministry of Health (MOH)
- National Institute for Medical Research (NIMR): [http://www.nimr.or.tz/](http://www.nimr.or.tz/)
- National Health Research Ethics Committee (NHREC)
- Tanzania Commission for Science and Technology (COSTECH): [https://www.costech.or.tz/](https://www.costech.or.tz/)

Relevant Standards
- Tanzania Commission for Science and Technology, Act No. 7 of 1986: [https://www.costech.or.tz/storage/uploads/mSre0zVqCMimUglsnKrOrRlqHPgNxxwF1rpnkJX0.pdf](https://www.costech.or.tz/storage/uploads/mSre0zVqCMimUglsnKrOrRlqHPgNxxwF1rpnkJX0.pdf)

### Drugs, Biologics, and Devices

#### Drugs

**Key Organizations**
- Tanzania Medicines and Medical Devises Authority: [https://www.tmda.go.tz/](https://www.tmda.go.tz/)

**Relevant Standards**

#### Devices

**Key Organizations**
- Tanzania Medicines and Medical Devises Authority: [https://www.tmda.go.tz/](https://www.tmda.go.tz/)

**Relevant Standards**
- Medical devices, various: [https://www.tmda.go.tz/publications/39](https://www.tmda.go.tz/publications/39)

### Clinical Trials Registry

**Key Organizations**
- Tanzania Commission for Science and Technology (COSTECH): [https://www.costech.or.tz/](https://www.costech.or.tz/)

**Relevant Standards**
- COSTECH, Database, Funded Projects: [https://www.costech.or.tz/funded-projects](https://www.costech.or.tz/funded-projects)
- Various: [https://www.costech.or.tz/documents-and-publications](https://www.costech.or.tz/documents-and-publications)

### AFRICA – Uganda


### General

**Key Organizations**
Relevant Standards


**Drugs, Biologics, and Devices**

**Key Organizations**
- National Drug Authority: [http://www.nda.or.ug/](http://www.nda.or.ug/)

**Relevant Standards**
- National Drug Policy and Authority Act Regulations: [https://www.nda.or.ug/ndpa-act-regulations/](https://www.nda.or.ug/ndpa-act-regulations/)
- Clinical Trial Application Forms: [https://www.nda.or.ug/application-forms/](https://www.nda.or.ug/application-forms/)

**AFRICA – Zambia**

**General**

**Key Organizations**
- Ministry of Health: [https://www.moh.gov.zm/](https://www.moh.gov.zm/)

**Relevant Standards**

**Drugs, Biologics, and Devices**

**Key Organizations**
- Zambia Medicines Regulatory Authority: [http://www.zamra.co.zm/](http://www.zamra.co.zm/)

**Relevant Standards**
- Guidelines on Regulating the Conduct of Clinical Trials in Human Participants: [https://www.who.int/medicines/areas/coordination/zambia_clinical_trials.pdf](https://www.who.int/medicines/areas/coordination/zambia_clinical_trials.pdf)
Human Biological Materials

Relevant Standards

AFRICA – Zimbabwe

General

Key Organizations
- Medical Research Council of Zimbabwe: [http://www.mrcz.org.zw](http://www.mrcz.org.zw)

Relevant Standards
- Research Act (1986)
- Ethics Guidelines for Health Research Involving Human Participants in Zimbabwe

Drugs, Biologics, and Devices

Drugs

Key Organizations
- Medicines Control Authority of Zimbabwe: [http://www.mcaz.co.zw/](http://www.mcaz.co.zw/)

Relevant Standards
- Medicines and Allied Substances Control Act, Chapter 15:03 (1997)
- Medicines and Allied Substances Control Act, General Regulations (1991)
- Statutory Instrument 150 of 1991

Devices

Key Organizations
- Medicines Control Authority of Zimbabwe: [https://www.mcaz.co.zw/](https://www.mcaz.co.zw/)

Relevant Standards
- Medicines and Allied Substances Control Act, Various Regulations: [https://www.mcaz.co.zw/index.php/downloads/category/7-regulations](https://www.mcaz.co.zw/index.php/downloads/category/7-regulations)

Privacy/Data Protection

Key Organizations

Last Updated: November 2021
### Relevant Standards

- Constitution of Zimbabwe of 2013, Section 57:  
- Access to Information and Protection of Privacy Act, Chapter 10:27:  
  http://www.veritaszim.net/node/240#:~:text=An%20Act%20to%20provide%20members%20of%20personal%20information

### Human Biological Materials

**Key Organizations**

- Research Council of Zimbabwe:  [www.rcz.ac.zw](http://www.rcz.ac.zw)

**Relevant Standards**

- Various:  [http://www.rcz.ac.zw/research-registration/](http://www.rcz.ac.zw/research-registration/)

### Genetic Research

**Key Organizations**

- National Biotechnology Authority of Zimbabwe:  [http://www.nba.ac.zw/](http://www.nba.ac.zw/)

**Relevant Standards**

- National Biotechnology Authority Act, Chapter 14:31 (2006):  
  [https://www.nba.ac.zw/books/national_biotechnology_act.pdf](https://www.nba.ac.zw/books/national_biotechnology_act.pdf)
## ASIA/PACIFIC – Australia

**NOTE:** For an overview of clinical research regulations in Australia, see the ClinRegs report: https://clinregs.niaid.nih.gov/country/australia

### General

#### Key Organizations
- Australian Research Council (ARC): [http://www.arc.gov.au](http://www.arc.gov.au)

#### Relevant Standards

### Drugs, Biologics, and Devices

#### Drugs

#### Key Organizations

#### Relevant Standards

#### Devices

#### Key Organizations
Relevant Standards

Clinical Trials Registry

Key Organizations
- National Health and Medical Research Council and the Department of Industry, Innovation, and Science: https://www.australianclinicaltrials.gov.au
- Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/

Relevant Standards

Research Injury

Key Organizations
- Medicines Australia: https://medicinesaustralia.com.au
- National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au

Relevant Standards

Social-Behavioral Research

Key Organizations
- National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au

Relevant Standards
**Privacy/Data Protection**

**Key Organizations**

**Relevant Standards**

**Human Biological Materials**

*NOTE: All Australian states and territories also have laws on human biological materials.*

**Key Organizations**

**Relevant Standards**

**Genetic Research**

**Key Organizations**

**Relevant Standards**
International Compilation of Human Research Standards  
2021 Edition


### Embryos, Stem Cells, and Cloning

#### Key Organizations
- National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/
- National Health and Medical Research Council: Embryo Research Licensing Committee: https://nhmrc.gov.au/embryo-research-licensing-committee

#### Relevant Standards

### ASIA/PACIFIC – Bangladesh

#### General

#### Key Organizations
- Bangladesh Medical Research Council, National Research Ethics Committee: http://www.bmrcbd.org

#### Relevant Standards
- Ethical Guidelines for Conducting Research Studies Involving Human Subjects: https://www.bmrcbd.org/application_form/EthicalGuideline
- Standard Operating Procedures (SOPs): https://www.bmrcbd.org/application_form/SOPs

### Drugs, Biologics, and Devices

#### Key Organizations

#### Relevant Standards
- The Drugs Act (1964)
Human Biological Materials

Key Organizations
- Bangladesh Medical Research Council, National Research Ethics Committee: [http://www.bmrcbd.org](http://www.bmrcbd.org)

Relevant Standards

ASIA/PACIFIC – China, People’s Republic of

NOTE: For an overview of clinical research regulations in China, see the ClinRegs report: [https://clinregs.niaid.nih.gov/country/china](https://clinregs.niaid.nih.gov/country/china)

General

Key Organizations

Relevant Standards

Drugs, Biologics, and Devices

Drugs

Key Organizations

Relevant Standards
▪ Interim Guidelines on International Multi-Regional Drug Clinical Trials (2015)

Devices

Key Organizations
▪ National Medical Products Administration: http://www.nmpa.gov.cn

Relevant Standards
▪ Templates for Medical Device Clinical Trials – Ethical Application and Approval (2016):
  1. Ethical Review Application and Review Form
  2. Informed Consent Form
  3. CRF Template
  4. Protocol Template
  5. Clinical Trial Report Template
  6. Required Documents List for Archiving
### Clinical Trial Registries

#### Key Organizations

#### Relevant Standards

### Privacy/Data Protection

#### Mainland

##### Key Organizations
- Ministry of Industry and Information Technology of People’s Republic of China

##### Relevant Standards

#### Hong Kong

##### Key Organizations
- Privacy Commissioner for Personal Data, Hong Kong: [http://www.pcpd.org.hk](http://www.pcpd.org.hk)

##### Relevant Standards

### Research Injury

#### Key Organizations
Relevant Standards


▪ Guideline on Vaccine Clinical Trials, Part 6 (2004)

▪ Guideline on Ethical Review of Drug Clinical Trials, Appendix 1, Section 6.10 (2010)

Genetic Research

Key Organizations


▪ Ministry of Science and Technology of the People’s Republic of China (MOST): http://www.most.cn/eng/

Relevant Standards


Embryos, Stem Cells, and Cloning

Mainland

Key Organizations


▪ Ministry of Science and Technology of the People’s Republic of China (MOST): http://www.most.cn/eng/

Relevant Standards

▪ Ethical Principles and Conduct Norms for Human Assisted Reproductive Technologies (2003)

▪ Administrative Measures for Clinical Application of Medical Technology (2018)


**Hong Kong**

**Key Organizations**


**Relevant Standards**


**ASIA/PACIFIC – India**

**NOTE:** For an overview of the clinical research regulations in India, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=100

**General**

**Key Organizations**

- Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/

**Relevant Standards**


**Drugs, Biologics, and Devices**

**Drugs**

**Key Organizations**


**Relevant Standards**


**Devices**

**Key Organizations**

- Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/

**Relevant Standards**

- CDSCO, Medical Devices Rules, 2017 General Statutory Rules 78(E) [English from page 146]: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzMzNg== (English from page 143)

**Clinical Trial Registries**

**Key Organizations**

- Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/

**Relevant Standards**

- Clinical Trials Registry – India: http://ctri.nic.in/
- Clinical Trials Registry – India, FAQs: http://ctri.nic.in/Clinicaltrials/faq.php

**Research Injury**

**Key Organizations**

- Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/

**Relevant Standards**

**Social-Behavioral Research**

**Key Organizations**
- Indian Council of Medical Research (ICMR): [http://www.icmr.nic.in/](http://www.icmr.nic.in/)

**Relevant Standards**
- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 9 (2017):

**Privacy/Data Protection**

**Key Organizations**
- Indian Council of Medical Research (ICMR): [http://www.icmr.nic.in/](http://www.icmr.nic.in/)

**Relevant Standards**
- ICMR, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Sections 1, 2, 4, 5, 6, 7, 9, 10, 11 and 12 (2017):
- NACO, Data Protection Guidelines of the National AIDS Control Programme:

**Human Biological Materials**

**Key Organizations**
- Indian Council of Medical Research (ICMR): [http://www.icmr.nic.in/](http://www.icmr.nic.in/)

**Relevant Standards**
- Govt. of India Office Memorandum (O.M. No.19015/53/1997 - IH Pt.) 19th November, 1997 on Exchange of Human Biological Material for Biomedical Research Purposes
- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 11 (2017):

**Genetic Research**

**Key Organizations**
- Department of Biotechnology (DBT): [https://dbtindia.gov.in/](https://dbtindia.gov.in/)
- Indian Council of Medical Research (ICMR): [http://www.icmr.nic.in/](http://www.icmr.nic.in/)

**Relevant Standards**
- DBT, Environmental Protection Act (1986)
- DBT, Recombinant DNA Safety Guidelines (1990)

DBT, Ethical Policies on the Human Genome, Genetic Research, and Services (2002)


### Embryos, Stem Cells, and Cloning

#### Key Organizations

- Indian Council of Medical Research (ICMR): http://www.icmr.nic.in/
- Department of Biotechnology (DBT): https://dbtindia.gov.in/
- Central Drugs Standard Control Organization (CDSCO): https://cdsco.gov.in

#### Relevant Standards

- DBT, Biosafety Programmes, Guidelines, Rules, and Regulations: https://dbtindia.gov.in/regulations-guidelines/programmes/biosafety-programme

### ASIA/PACIFIC – Indonesia

#### General

#### Key Organizations


#### Relevant Standards

- Indonesian Health Act No. 23/1992 Section on Health Research, Article 69
- Regulation No. 39/1995 on Health Research and Development
- Presidential Decree No. 100/1993: Research by Foreigners

### Drugs, Biologics, and Devices

#### Key Organizations

- National Agency of Drug and Food Control: www.pom.go.id

#### Relevant Standards

- Ministry of Health Decree No. 56/2000: Guidelines on Clinical Trials of Traditional Drugs
- Guidelines on Good Clinical Practice (2001)
Human Biological Materials

**Relevant Standards**

- National Guidelines on Use of Stored Biological Materials (2005)

**ASIA/PACIFIC – Japan**

**General**

**Key Organizations**


**Relevant Standards**


**Drugs, Biologics, and Devices**

**Drugs**

**Key Organizations**


**Relevant Standards**


**Devices**

**Key Organizations**


**Relevant Standards**

- Ministerial Ordinance on Good Clinical Practice for Medical Devices (2016): [https://www.mhlw.go.jp/web/t_doc?dataId=81aa6871&dataType=0&pageNo=1](https://www.mhlw.go.jp/web/t_doc?dataId=81aa6871&dataType=0&pageNo=1)
**Clinical Trial Registries**

**Key Organizations**
- Japan Registry of Clinical Trials: [https://jrct.niph.go.jp/](https://jrct.niph.go.jp/)

**Relevant Standards**
- NIPH Clinical Trials Search: [https://rctportal.niph.go.jp/en/](https://rctportal.niph.go.jp/en/)

**Research Injury**

**Key Organizations**

**Relevant Standards**
- Ethics Guidelines for Medical and Health Research Involving Human Subjects, Chapter 2, 3, and No. 6 (2021): [https://www.mhlw.go.jp/content/000757566.pdf](https://www.mhlw.go.jp/content/000757566.pdf)

**Privacy/Data Protection**

**Key Organizations**

**Relevant Standards**

**Human Biological Materials**

**Key Organizations**

**Relevant Standards**

**Genetic Research**

**Key Organizations**

**Relevant Standards**
- Genetic recombination experiments: [https://www.lifescience.mext.go.jp/bioethics/anzen.html#kumikae](https://www.lifescience.mext.go.jp/bioethics/anzen.html#kumikae)
- Genome editing technology: [https://www.lifescience.mext.go.jp/bioethics/anzen.html#chiryo](https://www.lifescience.mext.go.jp/bioethics/anzen.html#chiryo)

**Embryos, Stem Cells, and Cloning**

**Key Organizations**

**Relevant Standards**


Fundamental Philosophy on Handling of Human Embryo (2004)


ASIA/PACIFIC – Kazakhstan


General

Key Organizations


Relevant Standards

- Local Ethics Committees: Policy, Rules and Procedures (2014)
- Guidelines on Ethics in Biomedical Research (2015)
Drugs, Biologics, and Devices

Key Organizations

Relevant Standards
- Order of the MHSD of the RK Dated 12.11.2009 No. 697 on the Approval of Regulations on the Medical-Biological Experiments, Preclinical (Non-Clinical) and Clinical Trials
- Order of the MHSD of the RK dated 19.11.2009 No. 744 on the Approval of Regulations on the Conduct of Clinical Trials and/or Trials on Pharmaceutical and Drug Products, Medical Devices, and Medical Equipment
- Order of the MHSD Dated 20.05.2014 No.272 on the Approval of Regulations on the Implementation of the New Methods of Diagnostic, Treatment, and Rehabilitation

Privacy/Data Protection

Key Organizations

Relevant Standards

ASIA/PACIFIC – Kyrgyzstan

General

Key Organizations
- Ministry of Health
- Ministry of Justice of the Kyrgyz Republic: http://cbd.minjust.gov.kg

Relevant Standards
- Law on Health Protection of the Kyrgyz Republic (Sept. 1, 2005, No. 6), Articles 34 and 72: http://www.pharm.kg/ru/legislation
- Code of Professional Ethics of Medical Worker of the Kyrgyz Republic (2004)
- Code of Administrative Responsibility of the Kyrgyz Republic №114 from 04.08.1998g. (Updated June 11, 2008 N 115 and June 23, 2008 N 136) Chapters 7 and 10
Drugs, Biologics, and Devices

Key Organizations
- Ministry of Health, Department of Drugs and Medical Devices (DDMD): [http://www.pharm.kg](http://www.pharm.kg)
- Ministry of Health, National Bioethics Committee
- Pharmaceutical Union of Kyrgyzstan, Ethics Committee

Relevant Standards

Research Injury

Key Organizations
- Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): [http://www.pharm.kg](http://www.pharm.kg)
- Ministry of Health, National Bioethics Committee

Relevant Standards

Human Biological Materials

Key Organizations
- Ministry of Health, Department of Drug and Medical Devices Provision: [http://www.pharm.kg](http://www.pharm.kg)
- Ministry of Health, National Bioethics Committee

Relevant Standards
Social-Behavioral Research

Key Organizations
- Ministry of Justice of the Kyrgyz Republic: http://minjust.gov.kg/ru/

Relevant Standards

Privacy/Data Protection

Key Organizations
- Ministry of Health, Department of Drug and Medical Devices Provision (DDMDP): http://www.pharm.kg
- Ministry of Health, National Bioethics Committee

Relevant Standards
- DDMD, Technical Regulations on the Safety of Medical Products for Medical Application, Approved by the Governmental Order #74 from February 1, 2012: http://www.pharm.kg/ru/legislation/

ASIA/PACIFIC – Malaysia

General

Key Organizations

Relevant Standards
Malaysian Guideline for Application of Clinical Trial Import License and Clinical Trial Exemption, 7th Edition (2021):

Drugs, Biologics, and Devices

Key Organizations

- Medical Device Authority (MDA), Ministry of Health Malaysia: https://portal.mda.gov.my/
- Clinical Research Malaysia (CRM), Ministry of Health: https://clinicalresearch.my/

Relevant Standards

- Malaysian Guideline for Phase I Unit Inspection and Accreditation Program (2018):
- NIH, Guidelines for Conducting Research in Ministry of Health Institutions and Facilities (2015):
International Compilation of Human Research Standards
2021 Edition


Clinical Trial Registries

Key Organizations

Relevant Standards

Research Injury

Key Organizations
- Attorney General’s Chambers of Malaysia (AGC)
- Department of Occupational Safety and Health (DOSH), Ministry of Human Resources: https://www.dosh.gov.my/index.php/about-us/dosh-profile

Relevant Standards

Social-Behavioral Research

Key Organizations

Relevant Standards
Privacy/Data Protection

**Key Organizations**
- Department of Personal Data Protection: [https://www.pdp.gov.my/jpdpv2/?lang=en](https://www.pdp.gov.my/jpdpv2/?lang=en)

**Relevant Standards**

Human Biological Materials

**Key Organizations**
- Laws of Malaysia. Attorney General’s Chambers of Malaysia (AGC)

**Relevant Standards**

Genetic Research

**Key Organizations**
- Laws of Malaysia. Attorney General’s Chambers of Malaysia (AGC)

**Relevant Standards**
- Biosafety (Approval and Notification) Regulations 2010: [http://bch.cbd.int/database/attachment/?id=17640](http://bch.cbd.int/database/attachment/?id=17640)
Embryos, Stem Cells, and Cloning

Key Organizations
- Ministry of Health, National Stem Cell Research and Ethics Subcommittee (NSCERT)

Relevant Standards

ASIA/PACIFIC – Myanmar

General

Key Organizations
- Ministry of Health, Department of Medical Research (DMR): https://www.dmr.gov.mm/
- Ministry of Health National Ethics Committee on Clinical Research: https://www.moh.gov.mm

Relevant Standards
- DMR, Guideline for Submission to Ethics Review Committee (2016)
## Drugs, Biologics, and Devices

### Key Organizations

### Relevant Standards
- National Drug Law (1992)

## Human Biological Materials

### Relevant Standards

## ASIA/PACIFIC – Nepal

### General

#### Key Organizations

#### Relevant Standards

### Drugs, Biologics, and Devices

#### Key Organizations

#### Relevant Standards

## ASIA/PACIFIC – New Zealand

**NOTE:** All New Zealand acts, bills, and regulations can be found here: [http://www.legislation.govt.nz/](http://www.legislation.govt.nz/)

### General

#### Key Organizations

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- Health and Disability Ethics Committees: http://www.ethics.health.govt.nz/

Relevant Standards
- Health Research Council Act 1990, Sections 24 and 25
- New Zealand Bill of Rights Act, Article 10 (1990)
- Health and Disability Commissioner Act 1994
- New Zealand Public Health and Disability Act 2000, Section 16
- Accident Compensation Act 2001
- HRC, The Role of Ethics (scroll down to Specific Considerations), various: http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval

Drugs, Biologics, and Devices

Drugs

Key Organizations
- New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz
- Medicines New Zealand: http://www.medicinesnz.co.nz/
- Health Research Council (HRC), Standing Committee on Therapeutic Trials: http://www.hrc.govt.nz/about-us/committees/standing-committee-therapeutic-trials-scott

Relevant Standards
- Medicines New Zealand, Guidelines on Clinical Trials, Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial (2015)
Devices

Key Organizations
- New Zealand Medicines and Medical Devices Safety Authority (Medsafe): http://www.medsafe.govt.nz

Relevant Standards
- Conducting Medical Device Clinical Trials in New Zealand, various: http://medsafe.govt.nz/regulatory/DevicesNew/13ConductingClinicalTrials.asp

Clinical Trial Registries

Key Organizations
- Australian New Zealand Clinical Trials Registry: http://www.anzctr.org.au/

Relevant Standards

Privacy/Data Protection

Key Organizations
- Privacy Commissioner: http://www.privacy.org.nz/

Relevant Standards
- Public Records Act (2005)
- Privacy Act 1993 (2012)

Human Biological Materials

Key Organizations
- Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval
- Te Puni Kokiri (TPK): http://www.tpk.govt.nz/

Relevant Standards
- Health Act 1956 (2012)
Human Tissue Act 2008

**Genetic Research**

**Key Organizations**
- Environmental Protection Authority: http://www.epa.govt.nz/

**Relevant Standards**

**Embryos, Stem Cells, and Cloning**

**Key Organizations**
- Advisory Committee on Assisted Reproductive Technology (ACART): http://acart.health.govt.nz/
- Advisory Committee on Assisted Reproductive Technology (ACART): http://ecart.health.govt.nz/
- Ministry of Health: http://www.moh.govt.nz/

**Relevant Standards**
- Human Assisted Reproductive Technology Act 2004 (2009)

**ASIA/PACIFIC – Pakistan**

**General**

**Key Organizations**
- National Bioethics Committee: http://nbcpakistan.org.pk/

**Relevant Standards**
- Various: http://nbcpakistan.org.pk/guidelines.html

**Drugs, Biologics, and Devices**

**Key Organizations**
- National Bioethics Committee: http://nbcpakistan.org.pk/

**Relevant Standards**
Human Biological Materials

**Key Organizations**

**Relevant Standards**

Embryos, Stem Cells, and Cloning

**Key Organizations**

**Relevant Standards**

ASIA/PACIFIC – Philippines

**General**

**Key Organizations**
- Philippine Health Research Ethics Board (PHREB): [www.ethics.healthresearch.ph](http://www.ethics.healthresearch.ph)

**Relevant Standards**

Drugs, Biologics, and Devices

**Drugs**

**Key Organizations**
Relevant Standards

- FDA, Rules and Regulations on the Registration, Including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biologic Products (Administrative Order No. 47-a) (2001)
- FDA, Circular 2015-026: Adoption of the ICH Harmonized Tripartite Guideline, Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products Q5C

**Devices**

**Key Organizations**

- Food and Drug Administration: [http://www.fda.gov.ph/](http://www.fda.gov.ph/)

**Relevant Standards**


**Clinical Trial Registries**

**Key Organizations**

- Philippine Health Research Registry: [http://registry.healthresearch.ph/](http://registry.healthresearch.ph/)

**Relevant Standards**


**Research Injury**

**Key Organizations**

- Philippine Health Research Ethics Board (PHREB): [www.ethics.healthresearch.ph](http://www.ethics.healthresearch.ph)

**Relevant Standards**


**Social-Behavioral Research**

**Key Organizations**

- Philippine Health Research Ethics Board (PHREB): [www.ethics.healthresearch.ph](http://www.ethics.healthresearch.ph)
- Philippine Social Science Council (PSSC): [https://pssc.org.ph/](https://pssc.org.ph/)

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Relevant Standards


Privacy/Data Protection

Relevant Standards


Embryos, Stem Cells, and Cloning

Key Organizations

▪ Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph

Relevant Standards


ASIA/PACIFIC – Singapore

General

Key Organizations

▪ Ministry of Health (MOH): http://www.moh.gov.sg

Relevant Standards


Drugs, Biologics, and Devices

Drugs

Key Organizations

▪ Health Sciences Authority of Singapore (HSA): https://www.hsa.gov.sg/
▪ Ministry of Health (MOH): http://www.moh.gov.sg/
Relevant Standards


Research Injury

Key Organizations

- Health Sciences Authority: http://www.hsa.gov.sg

Relevant Standards


Privacy/Data Protection

Key Organizations


### Relevant Standards


### Human Biological Materials

#### Key Organizations


#### Relevant Standards


### Genetic Research

#### Key Organizations


#### Relevant Standards


### Embryos, Stem Cells, and Cloning

#### Key Organizations

Relevant Standards


ASIA/PACIFIC – South Korea

**General**

**Key Organizations**

**Relevant Standards**

**Drugs, Biologics, and Devices**

**Key Organizations**

**Relevant Standards**
- Pharmaceutical Affairs Act No. 16250 (2019.01.15): [https://www.law.go.kr/LSW/eng/engLsSc.do?menuId=2&section=lawNm&query=%EC%95%BD%EC%82%AC%EB%B2%95&x=0&y=0#liBgcolor15](https://www.law.go.kr/LSW/eng/engLsSc.do?menuId=2&section=lawNm&query=%EC%95%BD%EC%82%AC%EB%B2%95&x=0&y=0#liBgcolor15)
- Act on In Vitro Diagnostic Medical Devices Act No. 16433 (2019.05.01): [https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72621&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1](https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72621&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1)
Regulations for Clinical Trial Personnel Education and Certification for the Educational Institution Notice No.2019-3 (2019.01.17):


Regulation on Medical Device Re-examination No. 2020-29 (2020.05.01):
https://www.law.go.kr/행정규칙/의료기기재심사에관한규정/(2020-29,20200501)

Guidelines on Human Research Protection Program 0053-01 (2014.3) 2017.5.31 고시:
https://nedrug.mfds.go.kr/bbs/38/65

Bioethics and Safety Act No. 16372 (2019.04.23):
https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=208465&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000

Enforcement Decree of Pharmaceutical Affairs Act No. 30141 (2019.10.22):
https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=210861&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000

https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙

Clinical Trial Registries

Key Organizations
- Korea Centers for Disease Control and Prevention (KCDC), Clinical Research Information Service: https://cris.nih.go.kr/cris/index/index.do
- Ministry of Food and Drug Safety (MFDS): https://nedrug.mfds.go.kr/searchClinic

Relevant Standards
- Regulation on Safety of Medicinal Products, No.1576 (2019.12.06):
  https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=71487&srchFr=&srchTo=&srchWord=&srchType=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=2

Research Injury

Key Organizations
Relevant Standards

- Pharmaceutical Affairs Act No.16250 (2019.01.15):
- Regulation on Safety of Pharmaceuticals, etc. No. 1576 (2019.12.12.):
  https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=71487&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=2
- Enforcement Rule of the Medical Devices Act No.1580 (2019.12.23.):
- Guidelines for Clinical Trial Indemnity and Its Process 0052-03 (2021.06.21.):
  https://www.mfds.go.kr/brd/m_1060/view.do?seq=14857&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=103
- Guidance for Sponsors; Safety Reporting Requirements 0785-02 (2020.10.30.):
  https://www.mfds.go.kr/brd/m_1060/view.do?seq=14669&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=4

Social-Behavioral Research

Key Organizations

- Ministry of the Interior and Safety: https://www.mois.go.kr/frt/a01/frtMain.do

Relevant Standards

- Bioethics and Safety Act No.16372(2019.04.):
- Enforcement Decree of the Bioethics and Safety Act No. 30141(2019.10.):
  https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙
- Personal Information Protection Act No.16930 (2020.02.):
- Enforcement Decree of the Personal Information Protection Act No.30892 (2020.08.):

Privacy/Data Protection

Key Organizations

- Ministry of the Interior and Safety (MOIS): http://www.mois.go.kr/eng/a01/engMain.do

Relevant Standards

- Personal Information Protection Act No. 16930 (2020.02.04):
- Standard Personal Information Protection Guidelines (2020.08.11): https://www.law.go.kr/admRulSc.do?menuId=5&subMenuId=41&tabMenuId=183&query=%ED%91%9C%EC%A4%80%EA%B0%9C%EC%9D%B8%EC%A0%95%EB%B3%B4%EB%B3%B4%ED%98%B8%EC%A7%80%EC%B9%A8#liBgcolor0
- Criteria for ensuring the Safety of Personal Information (2020.08.11): https://www.law.go.kr/admRulSc.do?menuId=5&subMenuId=41&tabMenuId=183&query=%ED%91%9C%EC%A4%80%20%EA%B0%9C%EC%9D%B8%EC%A0%95%EB%B3%B4%20%EB%B3%B4%ED%98%B8%EC%A7%80%EC%B9%A8#liBgcolor7

### Human Biological Materials

**Key Organizations**


**Relevant Standards**

- Guidelines on Biological material management in clinical trial (2018.08): https://www.mfds.go.kr/brd/m_218/view.do?seq=33339&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=7

### Genetic Research

**Key Organizations**


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Embryos, Stem Cells, and Cloning

Key Organizations


Relevant Standards

ASIA/PACIFIC – Sri Lanka

**Drugs, Biologics, and Devices**

### Key Organizations
- Cosmetics, Devices, and Drugs Regulatory Authority, Subcommittee on Clinical Trials:

### Relevant Standards
- Legislation, various:
- Guidelines, various:

**Clinical Trial Registries**

### Key Organizations
- Sri Lanka Clinical Trials Registry: [https://slctr.lk/](https://slctr.lk/)

### Relevant Standards
- FAQs: [http://slctr.lk/faq](http://slctr.lk/faq)

ASIA/PACIFIC – Taiwan

**General**

### Key Organizations

### Relevant Standards
- Regulations on Human Trials (2016):
- Enforcement Rules of the Medical Care Act (2017) (Chinese):
- Exempt Review Categories for Human Research (2012):
## Drugs, Biologics, and Devices

### Key Organizations
- Taiwan Food and Drug Administration (FDA): [https://www.fda.gov.tw/ENG/](https://www.fda.gov.tw/ENG/)

### Relevant Standards
- Regulations for Governing the Management of Medical Devices (2014)

## Research Injury

### Key Organizations
- Food and Drug Administration (FDA), MOHW: [https://www.fda.gov.tw/ENG/](https://www.fda.gov.tw/ENG/)

### Relevant Standards

## Social-Behavioral Research

### Key Organizations

### Relevant Standards
### Privacy/Data Protection

#### Key Organizations

#### Relevant Standards

### Human Biological Materials

#### Key Organizations

#### Relevant Standards
- Guidelines for the Collection and Use of Human Specimens for Research (2006) (Chinese): [http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1598&chk=6056f7dd-eb0a-48bf-ae7e-8a2a5875e6e0&mid=46&name=fdContent](http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1598&chk=6056f7dd-eb0a-48bf-ae7e-8a2a5875e6e0&mid=46&name=fdContent)

### Genetic Research

#### Key Organizations
- Food and Drug Administration (FDA): [https://www.fda.gov.tw/ENG/](https://www.fda.gov.tw/ENG/)

#### Relevant Standards

### Embryos, Stem Cells, and Cloning

**Key Organizations**

**Relevant Standards**

### ASIA/PACIFIC – Tajikistan


**General**

**Key Organizations**

**Relevant Standards**
- Order of the Ministry of Public Health of the Republic Tajikistan of 10 March, 2005 No. 118: About the Assertion of the Normative Documents of Republic Committee on Medical Ethics

### ASIA/PACIFIC – Thailand

**NOTE:** For an overview of the clinical research regulations in Thailand, see: [https://clinregs.niaid.nih.gov/single_country.php?c_id=213](https://clinregs.niaid.nih.gov/single_country.php?c_id=213)

**General**

**Key Organizations**

**Relevant Standards**
International Compilation of Human Research Standards
2021 Edition


### Drugs, Biologics, and Devices

#### Drugs

**Key Organizations**

- Food and Drug Administration, Drug Control Division: [https://www.fda.moph.go.th/sites/fda_en/Pages/Main.aspx](https://www.fda.moph.go.th/sites/fda_en/Pages/Main.aspx)
- Medical Council of Thailand (MCT): [https://tmc.or.th/En/](https://tmc.or.th/En/)

**Relevant Standards**

- Consumer Protection Act (2007)
- MCT, Acts and Rules, various: [https://tmc.or.th/En/act_rules_en.php](https://tmc.or.th/En/act_rules_en.php)

#### Devices

**Key Organizations**

- Food and Drug Administration, Medical Device Control Division: [https://www.fda.moph.go.th/sites/fda_en/Pages/Main.aspx](https://www.fda.moph.go.th/sites/fda_en/Pages/Main.aspx)

**Relevant Standards**

- 1988 Medical Device Act
- Laws and Regulations, various: [https://www.fda.moph.go.th/sites/FDA_EN/SitePages/Medical.aspx?IDitem=LawsAndRegulations](https://www.fda.moph.go.th/sites/FDA_EN/SitePages/Medical.aspx?IDitem=LawsAndRegulations)

### Clinical Trial Registries

**Key Organizations**

- Thai Clinical Trials Registry: [http://www.clinicaltrials.in.th/](http://www.clinicaltrials.in.th/)

**Relevant Standards**


### Privacy/Data Protection

**Key Organizations**


**Relevant Standards**


**ASIA/PACIFIC – Uzbekistan**

### General

**Key Organizations**
- Ministry of Health: [https://ssv.uz/en](https://ssv.uz/en)

**Relevant Standards**
- Constitution of Republic of Uzbekistan, Articles 24, 26, 40, 44 (1992)

### Drugs, Biologics, and Devices

**Key Organizations**
- Center for Expertise and standardization of medicines, medical devices and medical equipment: [http://www.minzdrav.uz](http://www.minzdrav.uz)
- Ministry of Health, National Ethics Committee
- Scientific Boards of Medical Institutes

**Relevant Standards**
- Law on Drugs and Pharmaceutical Activity (1997)
- Law on Narcotic and Psychoactive Drugs (2000)
- Guidelines on Conducting Clinical Trials and Determining Clinical Sites (2001)
- National Standard of Uzbekistan: Good Clinical Practice (2013)

### Human Biological Materials

**Key Organizations**
- Ministry of Health, Pharmacological Committee of the Central Department for Quality Control of Pharmaceuticals and Medical Equipment: [https://uzpharm-control.uz/](https://uzpharm-control.uz/)
- Ministry of Health, National Ethics Committee
- Scientific Boards of Medical Institutes

**Relevant Standards**
- Guidelines on Conducting Clinical Trials and Determining Clinical Sites (2001)
### ASIA/PACIFIC – Vietnam


#### General

**Key Organizations**

**Relevant Standards**

#### Drugs, Biologics, and Devices

**Key Organizations**

**Relevant Standards**

Europe
EUROPE – Regionwide

General


Council of Europe, Bioethics Unit: [http://www.coe.int/bioethics](http://www.coe.int/bioethics)

- Guide for research ethics committee members: [https://www.coe.int/en/web/bioethics/guide-for-research-ethics-committees-members](https://www.coe.int/en/web/bioethics/guide-for-research-ethics-committees-members)

Drugs, Biologics, and Devices

Drugs


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

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


**Devices**

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


### Clinical Trial Registries

**EU Clinical Trials Register:** [https://www.clinicaltrialsregister.eu/]

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

### Research Injury

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


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


▪ Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, Article 13, CETS No. 195 (2005):

▪ Council of Europe Committee on Bioethics Guide for research ethics committee members:
https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090001680307e6c

Privacy/Data Protection

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


▪ Guidelines on consent under Regulation 2016/679, WP259 rev.01:
http://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051


https://ec.europa.eu/newsroom/article29/items/614108

▪ Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (2019):


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

International Compilation of Human Research Standards
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- Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (2018): [https://rm.coe.int/16808ae918](https://rm.coe.int/16808ae918)

**Human Biological Materials**


Council of Europe, Bioethics Unit: [http://www.coe.int/bioethics](http://www.coe.int/bioethics)

- Recommendation Rec (2016) 6 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin: [https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff](https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff)

**Genetic Research**


Council of Europe, Bioethics Unit: [http://www.coe.int/bioethics](http://www.coe.int/bioethics)

Recommendation No. R (92) on Genetic Testing and Screening for Health Care Purposes (1992): http://wcd.coe.int/ViewDoc.jsp?id=612007&amp;Site=CM&amp;BackColorInternet=9999CC&amp;BackColorIntranet=FFBB55&amp;BackColorLogged=FFAC75


Recommendation Rec(2016)8 of the Committee of Ministers to Member States on the Processing of Personal Health-Related Data for Insurance Purposes, Including Data Resulting from Genetic Tests (2016): https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016806b2c5f

**Embryos, Stem Cells, and Cloning**


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

- Statement on Genome Editing Technologies by the Committee on Bioethics (2015): https://rm.coe.int/168049034a
EUROPE – Armenia

NOTE: For an overview of human subject protections in Armenia, see “Ethical Review of Biomedical Research in the CIS Countries,” Chapter 3, Section 1:

**Drugs, Biologics, and Devices**

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

**Relevant Standards**
- Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (2013)

EUROPE – Austria

**General**

**Key Organization**
- Ministry of Health: http://www.bmg.gv.at
- Forum of Austrian Ethics Committees: http://www.ethikkommissionen.at

**Relevant Standards**
Drugs, Biologics, and Devices

Drugs

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

Relevant Standards
- Various: https://www.basg.gv.at/en/healthcare-professionals/clinical-trials

Devices

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

Relevant Standards
- Medical Devices, Various: http://www.basg.at/medizinprodukte/formulare/klinische-pruefung/

Research Injury

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

Relevant Standards

Privacy/Data Protection

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

Key Organizations
Relevant Standards

▪ Data Protection Act No. 165/1999: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10001597

Human Biological Materials

Key Organizations

▪ Ministry of Health: http://www.bmg.gv.at

Relevant Standards


Genetic Research

Key Organizations

▪ Ministry of Health: http://www.bmg.gv.at

Relevant Standards


Embryos, Stem Cells, and Cloning

Key Organizations

▪ Ministry of Health: http://www.bmg.gv.at
Relevant Standards


EUROPE – Belarus


General

Key Organization

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

Relevant Standards

- Ordinance No. 274 on Establishing the National Bioethics Committee (2006)

Drugs, Biologics, and Devices

Drugs

Key Organizations

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

Relevant Standards

- Law on Drugs, Articles 15,16 (2009)
▪ Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999): http://www.levonevski.net/pravo/norm2009/num37/d37336.html
▪ Decree No. 50 on Certain Aspects of Clinical Drug Trials (2009)
▪ Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004): http://www.levonevski.net/pravo/norm2009/num24/d24926.html

Devices

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

Relevant Standards
▪ Ordinance No. 161 on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical devices (1999): http://www.levonevski.net/pravo/norm2009/num37/d37336.html
▪ Decree No. 216 on Certain Aspects of Clinical Trials of Medical Devices (2008) (Russian)
▪ Instruction on Accreditation of Health Care Institutions and Attestation of Specialists Involved in Conducting Clinical Trials of Drugs and Medical Devices (No. 55-0504, 2004): http://www.levonevski.net/pravo/norm2009/num24/d24926.html

Clinical Trial Registries

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

Research Injury

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

Social-Behavioral Research

Key Organizations
Privacy/Data Protection

Key Organizations
- National Bioethics Committee
- Center for examinations and tests in health service: https://www.rceth.by/en

Relevant Standards

Human Biological Materials

Key Organizations
- National Bioethics Committee
- State Service of Forensic Medicine (SSFM)
- Center for examinations and tests in health service: https://www.rceth.by/en

Relevant Standards
- Ordinance No. 111 on Further Development of National Pathology Service (1993)
- Ordinance No. 38-c on Rules for Conducting Morphological Examinations (1999)

EUROPE – Belgium


General

Key Organization

Relevant Standards
- 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:
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:

FAMHP, Various Circulars:

BACB, various:

Drugs, Biologics, and Devices

Key Organizations

Federal Agency for Medicines and Health Products (FAMHP), Drugs:

Federal Agency for Medicines and Health Products (FAMHP), Devices:

Belgian Advisory Committee on Bioethics (BACB):

Clinical Trial College:

Relevant Standards

Law Relating to Experimentation on Humans (2004):

Royal Decrees to Experimentation on Humans:

Royal Decrees on Clinical Trials:

BACB, Opinion No. 58: Financing Expensive Medication:

Research Injury

Key Organizations

Federal Agency for Medicines and Health Products (FAMHP):

Relevant Standards

Law Relating to Experimentation on Humans, Chapter XVII (Responsibility and Insurance) Article 29 (2004):
Privacy/Data Protection

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

Relevant Standards
- 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

Relevant Standards
- CSS, various: https://www.health.belgium.be/en/superior-health-council?f%5B0%5D=field_shc_doc%3A1145

Embryos, Stem Cells, and Cloning

Key Organizations

Relevant Standards

▪ Royal Decree Fixing the Criteria for the Program Applicable to the Care Programs ‘Reproductive Medicine’ (15 February 1999): [https://organesdeconcertation.sante.belgique.be/fr/organe-d'avis-et-de-concertation/commission-federale-embryons](https://organesdeconcertation.sante.belgique.be/fr/organe-d'avis-et-de-concertation/commission-federale-embryons)


### EUROPE – Bosnia and Herzegovina

#### General

**Federation of Bosnia and Herzegovina**

**Key Organization**


**Relevant Standards**


▪ Additional Protocol Concerning Biomedical Research, CETS No. 195 (2007)


**Republic of Srpska**

**Key Organization**

▪ Ministry of Health and Social Welfare of Republic of Srpska: [https://www.vladars.net/eng/vlada/ministries/MHSW/Pages/default.aspx](https://www.vladars.net/eng/vlada/ministries/MHSW/Pages/default.aspx)

### Drugs, Biologics, and Devices

**Federation of Bosnia and Herzegovina**

**Key Organizations**


**Relevant Standards**

▪ Law on Changes and Amendments of the Law on Drugs No. 29/05:
▪ Law on Drugs Federation of Bosnia and Herzegovina, No. 109/2012:
▪ Regulation about Clinical testing of IMP and Medical Devices (2010):
▪ Regulation about Medical Devices (2010):
▪ Standards of GCP in Conducting CTs (2012):
▪ Instructions on Manner of Reporting on Safety in the Framework of Clinical Trials (2016):
▪ Other regulations: http://www.almbih.gov.ba/dokumenti/regulative/

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:
▪ Law on Changes and Amendments of Law on Drugs No. 34/08
▪ Regulation about Clinical testing of IMP and Medical Devices (2010):
▪ Regulation about Medical Devices (2010):
▪ Standards of GCP in Conducting CTs (2012):
▪ Instructions on Manner of Reporting on Safety in the Framework of Clinical Trials (2016):

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**
- Law on Health Insurance of the Federation of Bosnia and Herzegovina, Official Gazette No. 46/10

**Republic of Srpska**

**Key Organizations**

**Relevant Standards**
- Medicinal Products and Medicinal Devices Act, Article 52 and 116

**Social-Behavioral Research**

**Federation of Bosnia and Herzegovina**

**Key Organizations**

**Republic of Srpska**

**Key Organizations**

**Privacy/Data Protection**

**Key Organizations**
Relevant Standards

▪ Law on the Protection of Personal Data in Bosnia and Herzegovina (2005): 

▪ 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): 

▪ Regulation on the Manner of Keeping the Records of Personal Data Filing Systems and the Pertinent 
  Records Form (2009)

Human Biological Materials

Federation of Bosnia and Herzegovina

Key Organizations

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

Relevant Standards


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


Genetic Research

Federation of Bosnia and Herzegovina

Key Organizations

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

Relevant Standards


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

Embryos, Stem Cells, and Cloning

**Federation of Bosnia and Herzegovina**

**Key Organizations**

**Relevant Standards**

**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](https://www.vladars.net/eng/vlada/ministries/MHSW/Pages/default.aspx)

**Relevant Standards**

**EUROPE – Bulgaria**

**General**

**Key Organization**

**Relevant Standards**
Drugs, Biologics, and Devices

Drugs

Key Organizations

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

Relevant Standards


Devices

Key Organizations


Relevant Standards


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### Clinical Trial Registries

**Key Organizations**

**Relevant Standards**
- Ordinance No. 31 for Determining the Principles of Good Clinical Practice: [https://www.bda.bg/images/stories/documents/regulations/naredbi/20210415/31-D0%9D%D0%90%D0%A0%D0%95%D0%94%D0%91%D0%90%208%2B%84%96%2031%208E%D0%A2%2B12%20D0%90%2092%20%3D%20%A1%D0%A2%20%2072%20%93.pdf](https://www.bda.bg/images/stories/documents/regulations/naredbi/20210415/31-D0%9D%D0%90%D0%A0%D0%95%D0%94%D0%91%D0%90%208%2B%84%96%2031%208E%D0%A2%2B12%20D0%90%2092%20%3D%20%A1%D0%A2%20%2072%20%93.pdf)

### Research Injury

**Key Organizations**

**Relevant Standards**
- Others: [https://www.mh.government.bg/media/filer_public/2021/03/08/zakon_za_lekarstvenite_produkti_v_humannata_medicina.pdf](https://www.mh.government.bg/media/filer_public/2021/03/08/zakon_za_lekarstvenite_produkti_v_humannata_medicina.pdf)
  [https://www.bda.bg/images/stories/documents/regulations/naredbi/20210415/31-D0%9D%D0%90%D0%A0%D0%95%D0%94%D0%91%D0%90%208%2B%84%96%2031%208E%D0%A2%2B12%20D0%90%2092%20%3D%20%A1%D0%A2%20%2072%20%93.pdf](https://www.bda.bg/images/stories/documents/regulations/naredbi/20210415/31-D0%9D%D0%90%D0%A0%D0%95%D0%94%D0%91%D0%90%208%2B%84%96%2031%208E%D0%A2%2B12%20D0%90%2092%20%3D%20%A1%D0%A2%20%2072%20%93.pdf)

### Privacy/Data Protection

**Key Organizations**
- Ombudsman: [www.ombudsman.bg](http://www.ombudsman.bg)

**Relevant Standards**

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Human Biological Materials

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

Relevant Standards
- Regulation No. 13 of 4 April 2007 for the Terms and Conditions of Informing Bulgarian Citizens on the Activities regarding the Transplantation of Organs, Tissues and Cells: http://www2.bgtransplant.bg/sites/default/files/docs/naredbi/Naredba_no13_ot_04_april_2007_g.rtf

Genetic Research

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

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

Embryos, Stem Cells, and Cloning

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

Relevant Standards


EUROPE – Croatia

General

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

Relevant Standards
- Patient Protection Act, Article 20 (2008): http://www.zakon.hr/z/255/Zakon-o-za%C5%A1atiti-prava-pacijenata

Drugs, Biologics, and Devices

Drugs

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

Relevant Standards

Devices

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

Clinical Trial Registries
Key Organizations
- Ministry of Health: [https://zdravlje.gov.hr/](https://zdravlje.gov.hr/)
- Agency for Medicinal Products and Medical Devices: [http://www.halmed.hr/](http://www.halmed.hr/)

Relevant Standards
- HALMED Front Page for Industry Representatives: [https://www.halmed.hr/Predstavnici-industrije/](https://www.halmed.hr/Predstavnici-industrije/)

Research Injury
Key Organizations
- Agency for Medicinal Products and Medical Devices of Croatia: [http://www.halmed.hr/](http://www.halmed.hr/)
- Ministry of Health: [https://zdravlje.gov.hr/](https://zdravlje.gov.hr/)
- Croatian Health Insurance Fund: [http://www.hzzo.hr/en/](http://www.hzzo.hr/en/)

Relevant Standards
- Various: [https://zdravlje.gov.hr/arkiva-80/zakonodavstvo/zakoni-i-pravilnici/pravilnici/pravilnici/zakon-o-lijekovima/1061](https://zdravlje.gov.hr/arkiva-80/zakonodavstvo/zakoni-i-pravilnici/pravilnici/pravilnici/zakon-o-lijekovima/1061)

Privacy/Data Protection
Key Organizations
- Croatian Personal Data Protection Agency: [http://www.azop.hr/](http://www.azop.hr/)

Last Updated: November 2021
Relevant Standards


**Human Biological Materials**

**Key Organizations**

- Ministry of Health: [https://zdravlje.gov.hr/](https://zdravlje.gov.hr/)

**Relevant Standards**

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

**Genetic Research**

**Key Organizations**

- Ministry of Health: [https://zdravlje.gov.hr/](https://zdravlje.gov.hr/)

**Relevant Standards**

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

**Relevant Standards**


## EUROPE – Cyprus

### General

#### Relevant Standards


### Drugs, Biologics, and Devices

#### Key Organizations


#### Relevant Standards


### Research Injury

#### Key Organizations


#### Relevant Standards

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

Key Organizations
- Commissioner's Office for the Protection of Personal Data:
  #:~:text=The%20Commissioner%20for%20personal%20data,processing%20of%20their%20personal%20data

Relevant Standards
- Protection of Natural Persons Against the Processing of Personal Data and the Free Circulation of such Data Act of 2018 (Law 125 (I)):
  http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/all/DE97F6F59835A03AC22582DD003D895E/$file/%CE%9D%CF%8C%CE%BC%CE%BF%CF%82%20125(%CE%99)_2018.pdf?openelement

Embryos, Stem Cells, and Cloning

Relevant Standards

EUROPE – Czech Republic

General

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

Relevant Standards
- Act No. 130/2002 Collection on Research and Development Support, as Amended (2018)

Drugs, Biologics, and Devices

Drugs

Key Organizations
- Ministry of Health (MOH): http://www.mzcr.cz

Relevant Standards

### Devices

**Key Organizations**

**Relevant Standards**
- Act No. 89/2021 Coll., on Medical Devices:
- Act No. 90/2021 Coll, on Medical Devices (the “Act on In Vitro Diagnostic Medical Devices”)

### Clinical Trial Registries

**Key Organizations**
- EU Clinical Trials Register

**Relevant Standards**
- EU Clinical Trials Register: [https://www.clinicaltrialsregister.eu/](https://www.clinicaltrialsregister.eu/)

### Research Injury

**Relevant Standards**

### Privacy/Data Protection

**Key Organizations**

**Relevant Standards**
Embryos, Stem Cells, and Cloning

Key Organizations

Relevant Standards

EUROPE – Denmark

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

Relevant Standards

Drugs, Biologics, and Devices

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

Relevant Standards
- 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/lt/2021/965

Last Updated: November 2021

### Clinical Trial Registries

**Key Organizations**
- National Committee on Health Research Ethics (NVK): [https://en.nvk.dk/](https://en.nvk.dk/)

**Relevant Standards**
- 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/lt/a/2021/965](https://www.retsinformation.dk/eli/lt/a/2021/965)

### Research Injury

**Key Organizations**

**Relevant Standards**

### Privacy/Data Protection

**Key Organizations**
- Danish Data Protection Agency (DPA): [https://www.datatilsynet.dk/english/](https://www.datatilsynet.dk/english/)

**Relevant Standards**
- Health Act No. 903, Chapter 9 (2019): [https://www.retsinformation.dk/Forms/R0710.aspx?id=210110#id56770dec-1ec6-44de-9fb0-8fabecc8f4a62](https://www.retsinformation.dk/Forms/R0710.aspx?id=210110#id56770dec-1ec6-44de-9fb0-8fabecc8f4a62)

### Human Biological Materials

**Key Organizations**
- National Committee on Health Research Ethics (NVK): [http://www.nvk.dk/english](http://www.nvk.dk/english)
Relevant Standards


Genetic Research

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

Relevant Standards

- 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/lt/2021/965](https://www.retsinformation.dk/eli/lt/2021/965)

Embryos, Stem Cells, and Cloning

Key Organizations
- Danish Council of Ethics: [http://www.etiskraad.dk/english](http://www.etiskraad.dk/english)

Relevant Standards


EUROPE – Estonia

General

Key Organization

Relevant Standards

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards

- Medicinal Products Act, Section 90: https://www.riigiteataja.ee/en/eli/ee/525112013005/consolide/current

Privacy/Data Protection

Key Organizations

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

Relevant Standards

International Compilation of Human Research Standards  
2021 Edition


### Genetic Research

**Relevant Standards**


### Embryos, Stem Cells, and Cloning

**Relevant Standards**


### EUROPE – Finland

**General**

**Key Organization**

- Findata: [https://findata.fi/en/](https://findata.fi/en/)

**Relevant Standards**

- Decree of the National Research Ethics Council of Finland No. 1347/1991
- Decrees on the National Committee on Medical Research Ethics No. 820/2010 and 788/2018
- Operating Procedures of the National Committee on Medical Research Ethics (2019)
- Decree on Fees, No. 1287/2018


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**Drugs, Biologics, and Devices**

**Drugs**

**Key Organizations**


▪ Ministry of Social Affairs and Health (MSAH): http://stm.fi/en/frontpage

▪ National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en

▪ Regional Medical Ethics Committees: https://tukija.fi/alueelliset-eettiset-toimikunnat

**Relevant Standards**


▪ Operating Procedures of the National Committee on Medical Research Ethics (2021): https://tukija.fi/documents/1481661/0/TUKIJAn+toimintaohje_07062021_EN.pdf/5a2a86df-6a18-d68b-56d8-8dbba3ce5ba2/TUKIJAn+toimintaohje_07062021_EN.pdf?t=1623235604734

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Last Updated: November 2021
Decree on Fees, No. 1171/2020: https://tukija.fi/documents/1481661/0/Maksuasetus+20201171+(3).pdf/e7e9dc90-f06f-47b3-98ee-e3beb7253d87/Maksuasetus+20201171+(3).pdf?r=1610024226291

Decree on Clinical Trials on Medicinal Products No. 841/2010


Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2012

Templates for Clinical Trial Information Leaflet and Consent Form (2018): https://tukija.fi/lomakkeet-ja-asiakirjamallit

Templates for Clinical Trial Information Leaflet and Consent Form (2018): http://tukija.fi/en/publications1


Various Guidelines: http://tukija.fi/en/publications1


Devices

Key Organizations


Relevant Standards


Clinical Trial Registries

Key Organizations

Research Injury

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

Relevant Standards

Social-Behavioral Research

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

Relevant Standards

Privacy/Data Protection

Key Organizations

Relevant Standards

Human Biological Materials

Key Organizations

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

Key Organizations
- National Committee on Medical Research Ethics (TUKIJA): http://www.tukija.fi/en

Relevant Standards

Embryos, Stem Cells, and Cloning

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

Relevant Standards

EUROPE – France

General

Key Organization
- Ministry of Social affairs and Health: http://www.sante.gouv.fr/

Relevant Standards
Drugs, Biologics, and Devices

Key Organizations

Relevant Standards
- Medications for Human Use, Articles 5111-1 and Subsequent Sections for Drugs and Medical Devices: [https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665](https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665)

Social-Behavioral Research

Key Organizations
- National Consultative Ethics Committee

Relevant Standards

Privacy/Data Protection

Key Organizations

Relevant Standards
Human Biological Materials

Key Organizations

- Protection of Persons Committee (CPP)

Relevant Standards

- CCNE, various: http://www.ccne-ethique.fr/en/type_publication/avis

Genetic Research

Key Organizations

- Biomedicine Agency: https://www.agence-biomedecine.fr/About-us

Relevant Standards

- Civil Code Articles 16-10 to 16-13: http://www.legifrance.gouv.fr/affichCode.do?id=LEGISCTA000006136513&cidTexte=LEGITEXT000006070721&dateTexte=20131006
■ Article R1131-1 and Subsequent Sections of the Public Health Code: https://www.legifrance.gouv.fr/affichCode.do?idArticle=LEGIARTI000018615563&idSectionTA=LEGISCTA000006196158&cidTexte=LEGITEXT000006072665&dateTexte=20191011
■ CCNE, various: http://www.ccne-ethique.fr/en/type_publication/avis

**Embryos, Stem Cells, and Cloning**

**Key Organizations**
- Biomedicine Agency: http://www.enseignementsup-recherche.gouv.fr/

**Relevant Standards**
- CCNE, various: http://www.ccne-ethique.fr/en/type_publication/avis

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**EUROPE – Georgia**

*NOTE: For an overview of human subject protections in Georgia, see “Ethical Review of Biomedical Research in the CIS Countries,” Chapter 3, Section 4:*

**General**

**Key Organization**
- Bioethics and Health Law Studies Society

**Relevant Standards**
- Additional Protocol to the Convention’s on Human Rights and Biomedicine, concerning Biomedical Research, ETS No. 195 (2010)
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

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

Social-Behavioral Research

Key Organizations
- Social and Psychological Agency

Relevant Standards

Privacy/Data Protection

Key Organizations
- Office of the Personal Data Protection Inspector: https://personaldata.ge/en
Relevant Standards

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

Human Biological Materials

Key Organizations

- Bioethics and Health Law Studies Society

Relevant Standards


Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards


EUROPE – Germany

General

Key Organization

- German Medical Association (BÄK): https://www.bundesaerztekammer.de/weitere-sprachen/english/german-medical-association/
- Central Ethics Committee of the German Medical Association (ZEKO): https://www.zentrale-ethikkommission.de/
- Permanent Working Party of Research Ethics Committees in Germany: http://www.ak-med-ethikkomm.de/
- German Ethics Council: https://www.ethikrat.org/en/
- 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


Drugs, Biologics, and Devices

Drugs

Key Organizations

▪ Federal Institute for Drugs and Medical Devices (BfArM): https://www.bfarm.de/EN/Home/_node.html
▪ Paul-Ehrlich-Institut (PEI): https://www.pei.de/EN/home/home-node.html

Relevant Standards

▪ Second Promulgation on the Clinical Trial of Drugs in Human (1997)

Devices

Key Organizations

▪ Federal Institute for Drugs and Medical Devices (BfArM): http://www.bfarm.de/EN/Home/home_node.html
▪ Paul-Ehrlich-Institut (PEI): http://www.pei.de/EN/home/node.html

Relevant Standards


Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

Relevant Standards

Privacy/Data Protection

Key Organizations
- Datenschutzkonferenz (DSK): https://www.datenschutzkonferenz-online.de/

Relevant Standards
- Data Protection Laws in German States: http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html
- DSK, Short Paper No. 4: Data Transmission to Third Countries: https://www.datenschutzkonferenz-online.de/media/kp/dsk_kpnr_4.pdf

Human Biological Materials

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

Relevant Standards
International Compilation of Human Research Standards
2021 Edition


- DGCH, Guidelines on Good Professional Practice (GPP) for the Procurement of Human Tissue and Cells for Drug Production:

### Genetic Research

**Key Organizations**

- German Society of Human Genetics (GfH): [https://gfhev.de/en/home.html](https://gfhev.de/en/home.html)

**Relevant Standards**


### Embryos, Stem Cells, and Cloning

**Key Organizations**

- German Ethics Council: [https://www.ethikrat.org/en/](https://www.ethikrat.org/en/)
- Central Ethics Committee of the German Medical Association (ZEKO): [http://www.zentrale-ethikkommission.de/](http://www.zentrale-ethikkommission.de/)

**Relevant Standards**


EUROPE – Greece

Key Organization

Relevant Standards

Drugs, Biologics, and Devices

Key Organizations
Relevant Standards

- Act 3418/2005 Code on Medical Ethics

Research Injury

Key Organizations


Relevant Standards

- Act 3418/2005 Code on Medical Ethics

Privacy/Data Protection

Key Organizations


Relevant Standards

- Greek Constitution 1975/1986/2001 Article 9.1
- Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998)
- Act 3418/2005 Code on Medical Ethics

Genetic Research

Key Organizations

Relevant Standards

- Greek Constitution 1975/1986/2001, Article 5.5
- Act 3418/2005 Code on Medical Ethics
- Opinion on Prenatal and Pre-Implantation Diagnosis and Embryo Treatment: http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/1_pd_pgd_opin_eng2.pdf

Embryos, Stem Cells, and Cloning

Key Organizations

- National Authority for Medically Assisted Reproduction

Relevant Standards

- Act 3305/2005 Application of Medically Assisted Reproduction
- NBC, various: http://www.bioethics.gr/index.php/gnomes

EUROPE – Hungary

General

Key Organization

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

- Fundamental Law of Hungary, Updated with the Fifth Amendment (2016), Articles II-III: http://njt.hu/cgi_bin/njt_doc.cgi?docid=140968.322953
- Act CLIV of 1997 on Health Care, Chapters VIII and IX: http://njt.hu/cgi_bin/njt_doc.cgi?docid=30903.339193
- Act 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 35/2005 (VIII.26.) of the Minister of Health on the Clinical Trials of Investigational Medicinal Products for Human Use and on the Application of Good Clinical Practice: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM
- Decree No. 235/2009 (X.20.) from the Hungarian Government on the Regulations of Giving Permission for Human Medical Experiments, for Clinical Studies of Experimental Medicinal Products, and for the Clinical Studies of the Medical Devices: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0900235.KOR&celpara=#xcelparam
- 1997 CLIV. Law, Healthcare, Chapters VIII and IX: http://njt.hu/cgi_bin/njt_doc.cgi?docid=30903.339193

Drugs, Biologics, and Devices

Drugs

Key Organizations

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

Relevant Standards

Clinical Trials:

- Act XCV of 2005 on Medicinal Products for Human Use, Section 3: https://net.jogtar.hu/jogszabaly?docid=A0500095.TV&searchUrl=/gyorskereso%3Fextraparams%3D%7B%252B%252BYear%2522%253A%25222005%2522%252C%2522SerialNumber%2522%253A%252295%2522%252C%2522ID%2522%253A%2522FullTextSearch%2522%257D
- Decree 35/2005 (VIII. 26) of the Minister of Health on the Clinical Trial and Application of Correct Clinical Practices of Investigational Medicinal Products Intended for Use in Humans: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM&celpara=#xcelparam
Non-Interventional Trials:

Devices

Key Organizations
- Medical Research Council, Ethics Committee for Clinical Pharmacology: [https://ett.aeek.hu/kfeb/](https://ett.aeek.hu/kfeb/)

Relevant Standards

Clinical Trials:

Non-Interventional Trials:
- Government Decree 27/2015 (II.25.) About the National Health Care Service System: [http://njt.hu/cgi_bin/njt_doc.cgi?docid=174246.343548](http://njt.hu/cgi_bin/njt_doc.cgi?docid=174246.343548)

Research Injury

Key Organizations

Relevant Standards
- Register of clinical trials: [https://ogyei.gov.hu/klinikai_vizsgalatok_nyilvantartasa](https://ogyei.gov.hu/klinikai_vizsgalatok_nyilvantartasa)

Privacy/Data Protection

Key Organizations
Relevant Standards

▪ Act XCV of 2005 on Medicinal Products for Human Use, Section 3, Paragraph 5: [link]

Human Biological Materials

Key Organizations

▪ Hungarian National Authority for Data Protection and Freedom of Information: [link]

Relevant Standards

▪ Act XLVII of 1997 on the Handling of Medical and Other Related Data: [link]
▪ Act CXII of 2011 on Right of Informational Self-Determination and Freedom of Information: [link]
▪ EU General Data Protection Regulation (2016): [link]
▪ Preparing to Apply the Privacy Policy in 12 Steps: Guidance for Data Controllers and Data Processors (2018): [link]

Genetic Research

Key Organizations

▪ The National Center for Public Health: [link]

Embryos, Stem Cells, and Cloning

Key Organizations

▪ Ministry of Human Capacities (EMMI): [link]

Relevant Standards

▪ Act LXXX of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Transplantation of Organs and Tissues of Human Origin: [link]
▪ 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: [link]

EUROPE – Iceland

General

Key Organization

▪ Ministry of Health: [link]
▪ National Bioethics Committee (NBC): [link]
Relevant Standards

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

Drugs, Biologics, and Devices

Drugs

Key Organizations

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

Relevant Standards

- MCA, Regulation on Clinical Trials of Medicinal Products in Humans No. 443/2004 (2010):
- NBC, various: http://www.vsn.is/en/content/clinical-trials

Devices

Key Organizations

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

Relevant Standards

International Compilation of Human Research Standards  
2021 Edition

- Regulation on Active Implantable Medical Devices No. 320/2011: [http://www.stjornartidindi.is/Advert.aspx?ID=e50d676c-4651-46c2-83b5-ad946f3deeeaa](http://www.stjornartidindi.is/Advert.aspx?ID=e50d676c-4651-46c2-83b5-ad946f3deeeaa)
- Regulation on In Vitro Diagnostic Medical Devices No. 936/2011: [http://stjornartidindi.is/Advert.aspx?ID=f20b3e4e-ab25-44d3-8e32-e5f42a7b02f0](http://stjornartidindi.is/Advert.aspx?ID=f20b3e4e-ab25-44d3-8e32-e5f42a7b02f0)

### Research Injury

#### Key Organizations
- Icelandic Health Insurance Agency (MCA): [http://www.sjukra.is/english](http://www.sjukra.is/english)

#### Relevant Standards

### Privacy/Data Protection

#### Key Organizations
- Data Protection Authority: [http://www.personuvernd.is/information-in-english/](http://www.personuvernd.is/information-in-english/)

#### Relevant Standards

### Human Biological Materials

#### Key Organizations
- Ministry of Health: [https://www.government.is/ministries/ministry-of-health/](https://www.government.is/ministries/ministry-of-health/)
- National Bioethics Committee (NBC): [www.visindasidane.is/en](http://www.visindasidane.is/en)

#### Relevant Standards
- Regulations on the Keeping and Utilization of Biological Samples in Biobanks No. 1146/2010: [https://www.reglugerdir.is/reglugerdir/eftir-raduneytum/heilbrigdisraduneyti/nr/16910](https://www.reglugerdir.is/reglugerdir/eftir-raduneytum/heilbrigdisraduneyti/nr/16910)
- NBC, Biobanks: [http://www.vsn.is/en/content/biobanks](http://www.vsn.is/en/content/biobanks)
## Embryos, Stem Cells, and Cloning

### Relevant Standards

- Regulation on Artificial Fertilization No. 144/2009: [https://www.reglugerdir.is/reglugerdir/eftirraduneytum/heilbrigdis/nr/10797](https://www.reglugerdir.is/reglugerdir/eftirraduneytum/heilbrigdis/nr/10797)

### EUROPE – Ireland

#### General

**Key Organization**

**Relevant Standards**

#### Drugs, Biologics, and Devices

**Key Organizations**
- Health Products and Regulatory Authority: [https://www.hpra.ie/](https://www.hpra.ie/)

**Relevant Standards**

#### Research Injury

**Key Organizations**
- Health Products and Regulatory Authority: [https://www.hpra.ie/](https://www.hpra.ie/)

**Relevant Standards**
Privacy/Data Protection

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

Relevant Standards
- Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018: http://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/health-research-regulations-2018/
- DPC, For Organisations: http://gdprandyou.ie/organisations/

Human Biological Materials

Key Organizations
- Health Products and Regulatory Authority: https://www.hpра.ie/

Relevant Standards

Genetic Research

Key Organizations
- Health Products and Regulatory Authority: https://www.hpра.ie/

Relevant Standards

EUROPE – Italy

General

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

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

**Drugs**

**Key Organizations**

- Italian Medicines Agency: http://www.agenziafarmaco.it/
- Ministry of Health (MOH): http://www.ministerosalute.it

**Relevant Standards**

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

**Devices**

**Key Organizations**

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

**Relevant Standards**

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

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

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

Privacy/Data Protection

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

Relevant Standards
- Administrative Decree: Electronic Data Transmission Pertaining to Clinical Medical Experimentation (May 25, 2000)
- Regulation for the Implementation of Articles No. 20 and 21 of the Legislative Decree No. 196 of June 30, 2003
- Ministerial Decree No. 277 (2007)
- General Principles of Processing Personal Data (2018): https://www.garanteprivacy.it/home/doveri#2

Genetic Research

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

Relevant Standards
- SIGU, various: http://www.sigu.net/show/documenti/5/1/linee%20guida

Embryos, Stem Cells, and Cloning

Relevant Standards
EUROPE – Latvia

**General**

**Key Organization**
- Central Medical Ethics Committee

**Relevant Standards**

**Drugs, Biologics, and Devices**

**Drugs**

**Key Organizations**
- Central Medical Ethics Committee

**Relevant Standards**

**Devices**

**Key Organizations**

**Relevant Standards**

**Research Injury**

**Key Organizations**
Relevant Standards


Privacy/Data Protection

Key Organizations


Relevant Standards


Human Biological Materials

Key Organizations

▪ Central Medical Ethics Committee

Relevant Standards


Genetic Research

Key Organizations


▪ Central Medical Ethics Committee
Relevant Standards


**Embryos, Stem Cells, and Cloning**

**Key Organizations**

- Central Medical Ethics Committee

**Relevant Standards**


**EUROPE – Lithuania**

**General**

**Key Organization**


**Relevant Standards**

- Changes of Law on Ethics of Biomedical Research No. 536/2014 (2017): [https://www.etar.lt/portal/lt/legalAct/43db5e50d05f11e7910a89ac20768b0f](https://www.etar.lt/portal/lt/legalAct/43db5e50d05f11e7910a89ac20768b0f)
- 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.etar.lt/portal/lt/legalAct/2a0242a0b5fe11e5a6588fb85a3cc84b/ILdhwnkYPP](https://www.etar.lt/portal/lt/legalAct/2a0242a0b5fe11e5a6588fb85a3cc84b/ILdhwnkYPP)
- V-28, Decree on the Detailed Requirements for the Content of a Person’s Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent (2018): https://www.e-tar.lt/portal/lt/legalAct/0f2f1b70b9db11e5a6588fb85a3cc84b/asr
- V-7, Decree on the Sample Form of the Biomedical Research Protocol, Summary of the Protocol and the CV of Investigator (2017): https://www.e-tar.lt/portal/legalAct/352d55b0c4411e5a6588fb85a3cc84b
- V-24, Decree on the Procedure for Submission of the Documents to the Lithuanian Bioethics Committee to Issue Favorable Opinion to Conduct a Clinical Trial on Medicinal Products or Approval to Conduct Biomedical Research by the Sponsor of the Clinical Trial on Medicinal Product or Other Type of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/3790a050be7e11e4bb408bababdbff3/UqqJXDRUqi
- V-4, Decree on the Request to Issue Approval to Conduct Biomedical Research, the Application Form and the Biomedical Research Ethical Assessment Form (2016): https://www.e-tar.lt/portal/legalAct/27a3460090f011e4bb408bababdbff3/UqqJXDRUqi
- Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical Research of the LBEC (2018): http://bioetika.sam.lt/get_file.php?file=bnNlV3pKeWhhWjJlcW1xZ2xxQnNrwWlpbrXM2VWttKbJ5Wlp1ekptZGlhV2V5c3JXbUdGa3lzR2NrNkb1pxVng2aVprR2ZIWk0yWG81ekxrMn1YY2ltV3Iw5e6tvbWFjbkp4bWwceCUyQmNTZ2FmJdUWThaono4ZWriTiHbBNlbnJzbVZ4SjJWYWFHZW9HYW1tNmhvajVobmFwR1Zrkw1jbFds2xwdGxsR1pzr5B5WnlXQmdxRzZhWVoRmNKMXJuZyUzRCUzRA==&view=1

**Drugs, Biologics, and Devices**

**Drugs**

- Key Organizations

**Relevant Standards**

- Law on Pharmacy of the Republic of Lithuania, Consolidated Version from 01/01/2021 to 31/12/2021: https://www.e-tar.lt/portal/lt/legalAct/TAR.FF33B3BF23DD/asr

Decree No. V-6 on the Sample Form of the Request for Favorable Opinion to Conduct Clinical Trial on Medicinal Product Form and the Ethical Assessment Form (2016): https://www.e-tar.lt/portal/lt/legalAct/b65b5ca0c44011e583a295d9366ec7ab3/qcerDrSCSCJ


Guidelines to Advertise Clinical Trials, Adopted by the Group of Experts on Biomedical Research of the LBEC (2018): http://bioetika.sam.lt/get_file.php?file=bXRIVnpKV2hacDJkcXBPZ3ILQnhrY1prbXM1c2tHalJ5SmFlekpLZh2Vnl5c3lJXeDJGa3lybWNscUNYb1oyVmxxaHJrR1RIYmMzTG8yN0xtbTJaYTJ1Vm1wSElvcFdjblp4bGNweDVucFdXb1d6VGJNWNb6OHFqbkm1mR29jYWlidFBlekp5bllLDWNvW1NjbbkHYwTwZWVhvYzVqMW1tMG5iaWN1cHVLDeDRLYnQ1VzNuWHVTaGIxS1puaVReV2xobmladWwyeVBsOVNjbTU3TWwyJTJCWmRKbyUzRA==&view=1

**Devices**

**Key Organizations**

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

**Relevant Standards**

- Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/43db5e50d50f11e7910a89ac20768b0f

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**Clinical Trial Registries**

**Key Organizations**

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

**Relevant Standards**

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

### Research Injury

#### Key Organizations


### Social-Behavioral Research

#### Key Organizations

- State Data Protection Inspectorate: [https://www.ada.lt/go.php/eng](https://www.ada.lt/go.php/eng)

#### Relevant Standards


### Privacy/Data Protection

#### Key Organizations


#### Relevant Standards

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

### Human Biological Materials

#### Key Organizations


#### Relevant Standards


### Genetic Research

#### Key Organizations


#### Relevant Standards


▪ Changes of Law on Ethics of Biomedical Research (2017): https://www.e-tar.lt/portal/lt/legalAct/43db5e50d05f11e7910a89ac20768b0f


▪ Decree No. V-659 on the Procedure for Importing of the Stem Cells Taken from the Umbilical Cord or Placenta after the Birth of a Child and the Samples Taken for Genetic Research into the Territory of the Republic of Lithuania and Exporting Therefrom (2017): https://www.e-tar.lt/portal/lt/legalAct/TAR.E2473B1958CA/gEtbNSRzzc

**Embryos, Stem Cells, and Cloning**

**Key Organizations**

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

**Relevant Standards**

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

**EUROPE – Luxembourg**

**General**

**Key Organization**

▪ National Ethics Consultative Commission: http://www.cne.lu


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

**Relevant Standards**


Drugs, Biologics, and Devices

Key Organizations


Relevant Standards

- CNER, Publications and Guidance, various: [https://www.cner.lu/en-gb/Publications](https://www.cner.lu/en-gb/Publications)

Clinical Trial Registries

Key Organizations


Privacy/Data Protection

Key Organizations


Relevant Standards

Human Biological Materials

Key Organizations

Relevant Standards

Genetic Research

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

Relevant Standards

EUROPE – Malta

General

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

Relevant Standards

Drugs, Biologics, and Devices

Drugs

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

Relevant Standards

**Devices**

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

**Relevant Standards**

**Privacy/Data Protection**

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

**Relevant Standards**

**EUROPE – Moldova**

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

**General**

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

**Relevant Standards**

### 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**

- Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Expertise of Clinical Trial: http://lex.justice.md/md/362783/
- Order No.648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in the Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf

### Research Injury

**Key Organizations**

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

**Relevant Standards**

- Government Decision No. 5/18.01.2016 Regarding the National Committee for Ethical Expertise of Clinical Trials: http://lex.justice.md/md/362783/
- Order No. 648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in the Republic of Moldova: http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf

### Privacy/Data Protection

**Key Organizations**


**Relevant Standards**

International Compilation of Human Research Standards  
2021 Edition

- LP143 Din 19.07.18, MO309-320/17.08.18 Article 482

### Human Biological Materials

**Key Organizations**

- Transplant Agency: [http://lex.justice.md/md/334622](http://lex.justice.md/md/334622)

**Relevant Standards**

- LP79 Din 24.05.18, MO195-209/15.06.18 Article 338
- Order No.648/12.08.2016 Concerning the Regulation of Authorizing the Conduct of Clinical Trials in Republic of Moldova: [http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf](http://amed.md/sites/default/files/Legislatie/Ordine%20ale%20MS/Ordinul%20MS%20nr.%20648.pdf)

### Embryos, Stem Cells, and Cloning

**Key Organizations**


**Relevant Standards**

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

### EUROPE – Montenegro

**Drugs, Biologics, and Devices**

**Key Organizations**

- Institute for Medicines and Medical Devices: [https://www.cinmed.me/Portal/faces/glavna.jspx?_adf-state=ye0txrsh1_4](https://www.cinmed.me/Portal/faces/glavna.jspx?_adf-state=ye0txrsh1_4)
Relevant Standards

▪ Various, Legislations: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967271693989170&paramPut=Laws&paramRender=2&paramS=94&_adf.ctrl-state=ye0txrsh1_122

▪ Various, Rulebooks: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967358763502102&paramPut=Rulebooks&paramRender=2&paramS=95&_adf.ctrl-state=ye0txrsh1_161

▪ Various, Decrees and Orders: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967402452526204&paramPut=Decrees+and+Orders&paramRender=2&paramS=98&_adf.ctrl-state=ye0txrsh1_195

▪ Various, Good Practice Guidelines: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967427083926799&paramPut=Good+Practice+guidelines&paramRender=2&paramS=99&_adf.ctrl-state=ye0txrsh1_229

▪ Forms, Medicines: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967477611251621&paramPut=Forms+%26+Medicines&paramRender=2&paramS=62&_adf.ctrl-state=ye0txrsh1_297

▪ Forms, Devices: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=96752569520403&paramPut=Forms++Medical+Devices&paramRender=2&paramS=100&_adf.ctrl-state=ye0txrsh1_331

▪ Various, Instructions: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967545352596410&paramPut=Instructions&paramRender=2&paramS=96&_adf.ctrl-state=ye0txrsh1_365

Research Injury

Key Organizations

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

▪ Institute for Medicines and Medical Devices: https://www.cinmed.me/Portal/faces/glavna.jspx?_adf.ctrl-state=ye0txrsh1_4

Relevant Standards

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

▪ Law on Medical Devices, see various, Legislations: https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967271693989170&paramPut=Laws&paramRender=2&paramS=94&_adf.ctrl-state=ye0txrsh1_122
Privacy/Data Protection

Key Organizations

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

Human Biological Materials

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

Relevant Standards
- Law on the Collection and Use of Biological Samples (Official Gazette of Montenegro No. 14/2010): http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=57491&rType=2&file=ZAKON%20O%20UZIMANJU%20I%20KORI%C5%A0%C4%86ENJU%20BIOLO%C5%A0IH%20UZORAKA.pdf

Genetic Research

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

Relevant Standards

Embryos, Stem Cells, and Cloning

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

Relevant Standards

EUROPE – Netherlands

General

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

- 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

- Central Committee for Research Involving Human Subjects (CCMO): https://english.ccmo.nl/
- Medicines Evaluation Board (MEB): http://english.cbg-meb.nl/

Relevant Standards


Clinical Trial Registries

Key Organizations

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

Research Injury

Key Organizations


Relevant Standards


### Social-Behavioral Research

**Key Organizations**

**Relevant Standards**

### Privacy/Data Protection

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

**Relevant Standards**

### Human Biological Materials

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

**Relevant Standards**
- Civil Code, Article 467 (1994)

### Genetic Research

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

**Relevant Standards**
- Guidelines for Researchers and Sponsors with Regard to the Assessment by Official Bodies of Clinical Research Involving Gene Therapeutics in the Netherlands (2012)
Embryos, Stem Cells, and Cloning

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

Relevant Standards

EUROPE – North Macedonia, Republic of

Drugs, Biologics, and Devices

Drugs

Key Organizations
- Ministry of Health of Republic of Macedonia: www.zdravstvo.gov.mk
- Drug and Devices Register: https://lekovi.zdravstvo.gov.mk/

Relevant Standards
- Health Care Law (Official Gazette No. 43/2012) and Laws Amending and Supplementing the Law, Article 275: http://www.fzo.org.mk/default.asp?ItemID=37115BDC6DEF524D877A8C36F95A85F6
- Rulebook on Amending and Supplementing the Rulebook on the Manner and the Procedure for Clinical Trials on Medicinal Products and the Documentation Contents and Annex No.3 (Guideline for the Clinical Trial Applicant ) (Document No. 23.3) (2012): https://lekovi.zdravstvo.gov.mk/documents/1/1


Devices

Key Organizations
- Drug and Devices Register: [https://lekovi.zdravstvo.gov.mk/](https://lekovi.zdravstvo.gov.mk/)

Relevant Standards
- Rulebook on the Manner of Reporting Adverse Effects During the Use of Medical Devices, Types of Reactions they Cause, the Actions of Health Workers and Suppliers, As Well as the Manner of Organizing the System of Monitoring Adverse Effects and Reactions to Medical Devices (Official Gazette No.100/2016) (Document No.8): [https://lekovi.zdravstvo.gov.mk/documents/1/2](https://lekovi.zdravstvo.gov.mk/documents/1/2)

Research Injury

Key Organizations

Relevant Standards

Social-Behavioral Research

Key Organizations
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)
- Regulations on Protection of Personal Data: https://dzlp.mk/sites/default/files/77121008d1284263a9e519ae9b24f80c.pdf
- Rulebook on transfer of personal data: https://dzlp.mk/sites/default/files/052e8e10cf2e4bd48e7827e7bc85fb62.pdf

Human Biological Materials

Key Organizations

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

Relevant Standards


### Genetic Research

**Key Organizations**


**Relevant Standards**


### Embryos, Stem Cells, and Cloning

**Key Organizations**


**Relevant Standards**


### EUROPE – Norway

#### General

**Key Organization**

- Regional Committees for Medical and Health Research Ethics (REK): [https://helseforskning.etikkom.no/forside?_ikbLanguageCode=us](https://helseforskning.etikkom.no/forside?_ikbLanguageCode=us)

**Relevant Standards**

International Compilation of Human Research Standards
2021 Edition

- Right of Children Between 12-16 Years to Consent to Participate in Health Research: [https://lovdata.no/dokument/SF/forskrift/2017-06-28-1000](https://lovdata.no/dokument/SF/forskrift/2017-06-28-1000)
- Payment for Research Participants in Medical and Health Research (2009)
- Guidelines for Research Ethical and Scientific Evaluation of Qualitative Research Projects in Medical and Health Research (2009): [https://www.etikkom.no/forskningsetiske-retningslinjer/Medisin-og-helse/Kvalitativ-forskning/](https://www.etikkom.no/forskningsetiske-retningslinjer/Medisin-og-helse/Kvalitativ-forskning/)

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Norwegian Medicines Agency: [https://legemiddelverket.no/english](https://legemiddelverket.no/english)

Relevant Standards

Devices

Key Organizations

- Norwegian Medicines Agency: [https://legemiddelverket.no/english](https://legemiddelverket.no/english)

Relevant Standards

- Various: [https://legemiddelverket.no/english/medical-devices/regulatory-information-regarding-medical-devices](https://legemiddelverket.no/english/medical-devices/regulatory-information-regarding-medical-devices)

Research Injury

Key Organizations


Relevant Standards


Social-Behavioral Research

Key Organizations


Relevant Standards


### Privacy/Data Protection

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

#### Relevant Standards

### Human Biological Materials

#### Key Organizations
- Regional Committees for Medical and Health Research Ethics (REK): https://helseforskning.etikkom.no/forside?_ikbLanguageCode=us

#### Relevant Standards
- Act Relating to the Application of Biotechnology in Human Medicine, etc. (Biotechnology Act) (December 5, 2003, No. 100): https://lovdata.no/dokument/NL/lov/2003-12-05-100?q=humanmedisinsk%20bruk

### Genetic Research

#### Key Organizations
- Norwegian Directorate of Health: https://www.helsedirektoratet.no/tema/genteknologi
- Norwegian Biotechnology Advisory Board: http://www.bion.no/english/
- Regional Committees for Medical and Health Research Ethics (REK): https://helseforskning.etikkom.no/forside?_ikbLanguageCode=us

#### Relevant Standards

### Embryos, Stem Cells, and Cloning

**Key Organizations**
- Norwegian Directorate of Health: https://www.helsedirektoratet.no/tema/genteknologi
- Regional Committees for Medical and Health Research Ethics (REK): https://helseforskning.etikkom.no/forside?_ikbLanguageCode=us

**Relevant Standards**
- Act Relating to the Application of Biotechnology in Human Medicine, etc. (Biotechnology Act) (December 5, 2003, No. 100): https://lovdata.no/dokument/NL/lov/2003-12-05-100?q=humanmedisinsk%20bruk

### EUROPE – Poland

**General**

**Key Organization**
- Center of Bioethics, Polish Chamber of Physicians and Dentists (NIL): https://nil.org.pl/dzialalnosc/osrodki/osrodek-bioetyki

**Relevant Standards**
Drugs, Biologics, and Devices

**Drugs**

**Key Organizations**

**Relevant Standards**

**Devices**

**Key Organizations**

**Relevant Standards**

**Clinical Trial Registries**

**Key Organizations**

**Relevant Standards**
- The Central Register of Clinical Trials: [https://bkwp.pl/](https://bkwp.pl/)
### Research Injury

**Key Organizations**
- Minister of Finance: [https://www.gov.pl/web/finance](https://www.gov.pl/web/finance)

**Relevant Standards**

### Social-Behavioral Research

**Key Organizations**

**Relevant Standards**

### Privacy/Data Protection

**Key Organizations**

**Relevant Standards**

### Human Biological Materials

**Key Organizations**

**Relevant Standards**
Geneic Research

Key Organizations

Relevant Standards

Embryos, Stem Cells, and Cloning

Key Organizations

Relevant Standards
- Regulation of the Minister of Health of 15 October 2015 on detailed requirements to be met by the documentation on germ cells and embryos: http://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001686

EUROPE – Portugal

General

Key Organization

Relevant Standards
## Drugs, Biologics, and Devices

### Drugs

**Key Organizations**

**Relevant Standards**
- Approval of the Applicable Legal Standards for the Conduct of Clinical Trials of Medicines for Human Use, Law No. 46/2004
- Decree-Law No. 102/2007 of April 2

### Devices

**Key Organizations**

**Relevant Standards**

### Research Injury

**Relevant Standards**

### Privacy/Data Protection

**Key Organizations**

**Relevant Standards**
- Constitution, Article 35 (1997)

**Genetic Research**

**Key Organizations**

**Relevant Standards**
- Law 12/2005

**Embryos, Stem Cells, and Cloning**

**Key Organizations**

**Relevant Standards**
- Portuguese Law on Assisted Reproductive Technologies, Articles 7 and 9 (2006)
- Opinion 15/CNECV/95 on Embryo Research (1995)

**EUROPE – Romania**

**General**

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

**Relevant Standards**
  https://www.coe.int/en/web/bioethics/oviedo-convention

**Drugs, Biologics, and Devices**

**Key Organizations**
- Ministry of Health (MOH): http://www.ms.ro
National Agency for Medicines and Medical Devices: https://www.anm.ro/en/
National Bioethics Committee for Medicines and Medical Devices: http://www.bioetica-medicala.ro/

Relevant Standards
- Order 904/25July 2006 on Approval of Rules Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use -- Transposition of 2001/20/EC Directive, and various legislation for CTs

Clinical Trial Registries
Key Organizations
- National Agency for Medicines and Medical Devices: https://www.anm.ro/en/

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

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

Relevant Standards

Social-Behavioral Research
Key Organizations

Privacy/Data Protection
Key Organizations
Relevant Standards


### Human Biological Materials

**Key Organizations**


**Relevant Standards**


### Genetic Research

**Key Organizations**


**Relevant Standards**


### Embryos, Stem Cells, and Cloning

**Relevant Standards**

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

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

General

Key Organization

- Russian Committee for Bioethics: http://www.bioethics.ru/eng/

Relevant Standards

- Ministry of Health Order 433n (July 10, 2015) “On Adoption of the Regulations on Organization of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation (Including Order of Patients’ Assignment for Administering Such Medical Help), Standard Form of Protocol for Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment, and Rehabilitation”: http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=183847

Drugs, Biologics, and Devices

Key Organizations


Relevant Standards

- Ministry of Health Order No. 753n (August 26, 2010)


### Research Injury

#### Relevant Standards

### Privacy/Data Protection

#### Relevant Standards

### Genetic Research

#### Key Organizations
- Interdepartmental Commission on Genetic-Engineering Activity

#### Relevant Standards

### Embryos, Stem Cells, and Cloning

#### Relevant Standards

### EUROPE – San Marino

#### General

#### Key Organization

#### Relevant Standards
Research Injury

Relevant Standards


EUROPE – Serbia

General

Key Organization

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

Relevant Standards

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

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Clinical Trial Registries

Key Organizations

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

Relevant Standards

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

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

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

Social-Behavioral Research

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

Privacy/Data Protection

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

Relevant Standards

Genetic Research

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

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

Embryos, Stem Cells, and Cloning

Key Organizations
- Ministry of Health (MOH): http://www.zdravlje.gov.rs/
▪ National Health Insurance Fund: http://www.rfzo.rs/

**Relevant Standards**

**EUROPE – Slovakia**

**General**

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

**Relevant Standards**
▪ Additional Protocol on Biomedical Research (2005)

**Drugs, Biologics, and Devices**

**Key Organizations**
▪ State Institute for Drug Control: http://www.sukl.sk/en

**Relevant Standards**
▪ Ministerial Regulation No. 239/2004 Coll. on Requirements for Clinical Trials and Good Clinical Practice, as Amended by Ministerial Regulation No. 148/2009 Coll.

**Research Injury**

**Relevant Standards**
▪ Law 277/1994 on Health Care, Section 44

**Privacy/Data Protection**

**Key Organizations**
▪ Office for Personal Data Protection: https://dataprotection.gov.sk/uoou/en

**Relevant Standards**

### Human Biological Materials

**Relevant Standards**

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

### Embryos, Stem Cells, and Cloning

**Relevant Standards**

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

### EUROPE – Slovenia

#### General

**Key Organization**

• Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/
• Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/

**Relevant Standards**

• Health Services Act: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO214
• Decree Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research (2005): http://pisrs.si/Pis.web/pregledPredpisa?id=URED3728

Last Updated: November 2021
Mental Health Act, Official Gazette Nos. 77/2008 and 46/2015: [http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO2157]


**Drugs, Biologics, and Devices**

**Drugs**

**Key Organizations**

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

**Relevant Standards**

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

**Devices**

**Key Organizations**

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

**Relevant Standards**

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

**Clinical Trial Registries**

**Key Organizations**

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

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Research Injury

Key Organizations
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/

Relevant Standards
- Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research (2005)
- Decree ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research: http://pisrs.si/Pis.web/pregledPredpisa?id=URED3728

Social-Behavioral Research

Key Organizations
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/
- National Institute of Public Health: https://www.nijz.si/en

Privacy/Data Protection

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

Relevant Standards
- Personal Data Protection Act No. 94/2007: http://pisrs.si/Pis.web/pregledPredpisa?id=ZAKO3906
Human Biological Materials

Key Organizations

▪ Ministry of Health of the Republic of Slovenia: http://www.mz.gov.si/
▪ Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/
▪ Institute Service of Slovenia for Transfusion Medicine: http://www.ztm.si/en/

Relevant Standards

▪ On Interventions into the Human Corpse Which are Not Part of the Routine Autopsy and on Handling with Biologic Material of Human Origin (2004)

Genetic Research

Key Organizations


Relevant Standards


Embryos, Stem Cells, and Cloning

Key Organizations

▪ Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: https://www.jazmp.si/en/
Relevant Standards


EUROPE – Spain

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

**General**

**Key Organization**

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

**Relevant Standards**


**Drugs, Biologics, and Devices**

**Drugs**

**Key Organizations**

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

**Relevant Standards**

▪ Royal Decree 577/2013 Regulating Pharmacovigilance in Human Use Medicines: 

▪ Royal Decree 1090/2015 Regulating Clinical Trials with Medicinal Products, Ethics Committees for 
  Investigation with Medicinal Products and the Spanish Clinical Studies Registry:
  http://noticias.juridicas.com/base_datos/Admin/565124-rd-1090-2015-de-4-dic-regula-los-ensayos- 
  clinicos-con-medicamentos-los-comites.html

**Devices**

**Key Organizations**

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

**Relevant Standards**

▪ Royal Decree 1591/2009, Regulating Sanitary Devices:

▪ Various: https://www.aemps.gob.es/productos-sanitarios/prodsanitarios/

**Research Injury**

**Key Organizations**

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

**Relevant Standards**

▪ Law 14/2007 on Biomedical Research, Article 18:
  http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearc 
  hEnglish.pdf

▪ Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on 
  content/EN/TXT/HTML/?uri=CELEX:32014R0536&from=EN

▪ Royal Decree 1090/2015 Regulating Clinical Trials with Medicinal Products, Ethics Committees for 
  Investigation with Medicinal Products and the Spanish Clinical Studies Registry:
  https://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/Royal-Decree-1090- 
  2015_4-December.pdf

**Privacy/Data Protection**

**Key Organizations**

▪ Spanish Data Protection Authority: https://www.agpd.es/portalweb/index-ides-idphp.php

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

**Relevant Standards**

▪ Law 14/2007 on Biomedical Research, Title I, Article 5:
  http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearc 
  hEnglish.pdf


▪ Organic Law 3/2018 of December 5 on the Protection of Personal Data and Guaranteeing Digital 
  Rights:
Human Biological Materials

Key Organizations

Relevant Standards
- Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf
- Royal Decree 1723/2012 Regarding Activities of Collection, Clinical Use and Territorial Coordination of Human Organs for Transplants and Establishing Their Quality and Safety Requirements: http://noticias.juridicas.com/base_datos/Admin/rd1716-2011.html

Genetic Research

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

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

Embryos, Stem Cells, and Cloning

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

National Biobank Network: https://redbiobancos.es/


**Relevant Standards**

- Law 14/2006 on Methods of Assisted Human Reproduction, Chapters IV and V
- National Biobank Network, various, Documents of Interest: https://redbiobancos.es/valor-anadido-de-la-rnbb/documentos-de-interes/

**EUROPE – Sweden**

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

**General**

**Key Organization**

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

**Relevant Standards**


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Drugs, Biologics, and Devices

Drugs

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

Relevant Standards
- Pharmaceuticals Act No. No. 2015:315: https://open.karnovgroup.se/halso-och-sjukvard/lakemedelslagen

Devices

Key Organizations

Relevant Standards

Social-Behavioral Research

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

Relevant Standards

Privacy/Data Protection

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

Relevant Standards
International Compilation of Human Research Standards
2021 Edition


Human Biological Materials

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

Relevant Standards

Genetic Research

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

Relevant Standards

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Embryos, Stem Cells, and Cloning

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

Relevant Standards

EUROPE – Switzerland

General

Key Organization
- Swiss Association of Research Ethics Committees: https://swissethics.ch/en/

Relevant Standards
Drugs, Biologics, and Devices

**Drugs**

**Key Organizations**

**Relevant Standards**

**Devices**

**Key Organizations**

**Relevant Standards**
▪ Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Article 7: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html


Clinical Trial Registries

Key Organizations


Relevant Standards


Research Injury

Key Organizations


Relevant Standards


▪ Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance HRO), RS 810.301, Articles 8, 12, 13, and 15, and Annexes 1-2: https://www.admin.ch/opc/en/classified-compilation/20121179/index.html


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


Relevant Standards

- Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305 Articles 5, 7, 9, 12, 16-18, and 25, and Annexes 2-3: https://www.admin.ch/opc/en/classified-compilation/20121176/index.html

Human Biological Materials

Key Organizations

- Swiss Academy of Medical Sciences (SAMS): http://www.samw.ch/en/News/News.html

Relevant Standards


Genetic Research

Key Organizations


Relevant Standards


### Embryos, Stem Cells, and Cloning

#### Key Organizations


#### Relevant Standards


### EUROPE – Ukraine

#### General

#### Key Organization

▪ Ukrainian Ministry of Health: http://www.moz.gov.ua/en/
Relevant Standards

- To search all documents in the Ukraine Legislation database visit: https://zakon.rada.gov.ua/laws/main/av2021
- Constitution of Ukraine Art. 28 (1996)
- Health Care Law, Article 45 (1992)
- Criminal Code of Ukraine 2001, Article 141 and 142

Drugs, Biologics, and Devices

Key Organizations

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

Relevant Standards

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

Research Injury

Key Organizations

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

Relevant Standards


Privacy/Data Protection

Key Organizations

- State Service of Ukraine on Personal Data Protection
- Ukrainian Parliament Commissioner for Human Rights: www.ombudsman.gov.ua
Relevant Standards
- Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2010)
- On Protection of Personal Data Act, 01.06.2010 with changes from 19.10.2017

**Human Biological Materials**

**Key Organizations**

**Relevant Standards**
- Cabinet Ministry of Ukraine Act No. 286 on 02.03.2016 License Conditions on Providing Activities of Banks of Cord Blood and Other Human Tissues and Cells
- Ministry of Health Act 20.04.12 No. 276 On Approving the List of Human Tissues and Cells, Allowing the Use of Banks of Cord Blood and Other Human Tissues and Cells
- Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007) with Changes from 23.09.2009 No. 690

**Embryos, Stem Cells, and Cloning**

**Key Organizations**
- National Academy of Sciences Bioethics Committee

**Relevant Standards**
- Ukrainian Ministry of Health Order No. 630 Regarding Approval of the Procedure for the Conduct of Clinical Trials of Tissue and Cell Transplants and Expert Evaluation of Materials of Clinical Trials (2007)
- Ukrainian Ministry of Health Order No. 787 on Approval of the Use of Reproductive Technologies in Ukraine 09.09.2013

**EUROPE – United Kingdom**


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

**England**

**Key Organization**
- Medical Research Council (MRC): [https://www.mrc.ac.uk/](https://www.mrc.ac.uk/)

**Relevant Standards**
- HRA, Guidance: [https://www.hra.nhs.uk/planning-and-improving-research/](https://www.hra.nhs.uk/planning-and-improving-research/)
- HRA, Integrated Research Application System: [https://www.myresearchproject.org.uk/](https://www.myresearchproject.org.uk/)

**Scotland**

**Key Organizations**

**Relevant Standards**

Wales

Key Organizations
• Health and Care Research Wales: http://www.healthandcareresearchwales.org/

Relevant Standards

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

Drugs, Biologics, and Devices

Drugs

Key Organizations
• Administration of Radioactive Substances Advisory Committee (ARSAC) (UK): https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee
• Health and Safety Executive (HSE): http://www.hse.gov.uk/
• Association of the British Pharmaceutical Industry (ABPI): http://www.abpi.org.uk
• National Institute for Health Research: http://www.nihr.ac.uk/
• Health Research Authority (HRA): http://www.hra.nhs.uk/

Relevant Standards


National Institute for Health Research, Clinical Trials Toolkit: [http://www.ct-toolkit.ac.uk/](http://www.ct-toolkit.ac.uk/)


### Devices

#### Key Organizations


#### Relevant Standards

- Clinical Trials for Medical Devices: [https://www.gov.uk/government/collections/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: [https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device](https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device)

### Clinical Trial Registries

#### Key Organizations

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

Research Injury
Key Organizations

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

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

Relevant Standards

Privacy/Data Protection
United Kingdom
Key Organization
- Information Commissioner’s Office: https://ico.org.uk/
International Compilation of Human Research Standards
2021 Edition

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

Relevant Standards

England and Wales

Key Organizations

Relevant Standards
- HRA, Research Data and Tissue Resources: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-data-and-tissue-resources/
- Section 251 and the Confidentiality Advisory Group (CAG): http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/

Human Biological Materials

United Kingdom

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

Relevant Standards

▪ HTA, Guidance for Professionals: https://www.hta.gov.uk/guidance-professionals


**Scotland**

**Key Organizations**

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

**Relevant Standards**


**Genetic Research**

**Key Organizations**

▪ Public Health Genetics Foundation: http://www.phgfoundation.org/

▪ Gene Therapy Advisory Committee: http://www.hra.nhs.uk/resources/applying-to-recs/gene-therapy-advisory-committee-gtac/

▪ Genomics England: https://www.genomicsengland.co.uk/

**Embryos, Stem Cells, and Cloning**

**Key Organizations**

▪ Human Fertilisation and Embryology Authority: http://www.hfea.gov.uk/

▪ Human Tissue Authority (HTA): https://www.hta.gov.uk/

**Relevant Standards**


▪ Human Fertilisation and Embryology Regulation and Chronology: https://www.hfea.gov.uk/about-us/how-we-regulate/

LATIN AMERICA AND THE CARIBBEAN – Regionwide

General

Caribbean Public Health Agency: http://carPHA.org/What-We-Do/Research-Training-and-Policy-Development

Pan American Health Organization: http://www.paho.org/
  ▪ PAHO, Regional Program on Bioethics, various resources: https://www.paho.org/en/bioethics

Drugs, Biologics, and Devices

Pan American Health Organization (PAHO): http://www.paho.org/

LATIN AMERICA AND THE CARIBBEAN – Argentina

NOTE: Several provinces have their own regulations pertaining to human subjects research.

General

Key Organization
  ▪ Ministry of Health: https://www.argentina.gob.ar/salud

Relevant Standards

Drugs, Biologics, and Devices

Drugs

Key Organizations
  ▪ National Administration of Drugs, Foods, and Medical Devices (ANMAT): https://www.argentina.gob.ar/anmat

Relevant Standards
International Compilation of Human Research Standards
2021 Edition


**Devices**

**Key Organizations**
- National Administration of Drugs, Foods, and Medical Devices (ANMAT): https://www.argentina.gob.ar/anmat

**Relevant Standards**

**Clinical Trial Registries**

**Key Organizations**
- National Registry of Health Research: https://www.argentina.gob.ar/salud/registroinvestigaciones

**Relevant Standards**
- FAQs: https://sisa.msal.gov.ar/sisa/#Renis

**Privacy/Data Protection**

**Key Organizations**
- National Directorate for the Protection of Personal Data: https://www.argentina.gob.ar/aaip/datospersonales

**Relevant Standards**
### Human Biological Materials

**Key Organizations**
- Ministry of Health: [https://www.argentina.gob.ar/salud](https://www.argentina.gob.ar/salud)

**Relevant Standards**

### LATIN AMERICA AND THE CARIBBEAN – Barbados

**General**

**Key Organization**
- University of the West Indies – Cave Hill / Ministry of Health: [http://www.cavehill.uwi.edu/researchethics/home.aspx](http://www.cavehill.uwi.edu/researchethics/home.aspx)

**Relevant Standards**
- Research Ethics Policy and Guidelines: [https://www.cavehill.uwi.edu/researchethics/docs/uwi_policy_research_ethics_oct.aspx](https://www.cavehill.uwi.edu/researchethics/docs/uwi_policy_research_ethics_oct.aspx)

### LATIN AMERICA AND THE CARIBBEAN – Bermuda

**General**

**Key Organization**
- Department of Health: [https://www.gov.bm/department/health](https://www.gov.bm/department/health)

**Relevant Standards**

### LATIN AMERICA AND THE CARIBBEAN – Bolivia

**General**

**Key Organization**
- Ministry of Health and Sport (MHS): [https://www.minsalud.gob.bo/](https://www.minsalud.gob.bo/)
- National Bioethics Committee (NBC)

**Relevant Standards**
- Legal Decree No. 15.629 of July 18, 1978, Articles 147 and 148
- Regulations on Public Health Research, Chapter V (1978)
International Compilation of Human Research Standards
2021 Edition

- Rules and Regulations of the National Bioethics Committee
- MHS, Guidelines for the Development of Health Research and Ethical Norms (2002)
- NBC, Requirements for the Evaluation of Research Projects NBC, Code of Ethics and Medical Deontology

**Drugs, Biologics, and Devices**

**Key Organization**
- State Agency of Drugs and Medical Technology: [https://www.agemed.gob.bo/](https://www.agemed.gob.bo/)
- National Bioethics Committee (NBC)

**Relevant Standards**
- National Norms, various: [https://www.agemed.gob.bo/#regulacion/normas_nacionales](https://www.agemed.gob.bo/#regulacion/normas_nacionales)
- MHS, Rule on Clinical Studies with Medicines or Products in the Clinical Investigation Stage (2005)
- NBC, Projects that Involve Drugs or Therapeutic Products
- Drugs, various laws: [https://www.agemed.gob.bo/#regulacion/legislacion_medicamentos](https://www.agemed.gob.bo/#regulacion/legislacion_medicamentos)

**LATIN AMERICA AND THE CARIBBEAN – Brazil**

*NOTE: For an overview of clinical research regulations in Brazil, see the ClinRegs report:*

**General**

**Key Organization**

**Relevant Standards**
International Compilation of Human Research Standards  
2021 Edition


Drugs, Biologics, and Devices

**Drugs and Biologics**

**Key Organizations**


**Relevant Standards**

- Law No. 9782/99 Defining the National Health Surveillance System: [http://www.planalto.gov.br/ccivil_03/leis/L9782.htm](http://www.planalto.gov.br/ccivil_03/leis/L9782.htm)


**Devices**

**Key Organizations**

▪ Brazilian Health Surveillance Agency (ANVISA): http://portal.anvisa.gov.br/english

**Relevant Standards**


**Clinical Trial Registries**

**Key Organizations**

▪ Brazilian Clinical Trials Registry: http://www.ensaiosclinicos.gov.br/

**Relevant Standards**

▪ FAQs: https://ensaiosclinicos.gov.br/faq

**Research Injury**

**Key Organizations**

▪ Brazilian Health Surveillance Agency: http://portal.anvisa.gov.br/english

▪ National Health Council (CNS): http://www.conselho.saude.gov.br/

Relevant Standards

- Law No. 6360/76: http://www.planalto.gov.br/ccivil_03/leis/l6360.htm
- Circular Letter 13/2020-CONEP/SECNS/MS for the processing of adverse events in the CEP/Conep System: https://drive.google.com/file/d/12zhLX2RB3o7gkCzjD_18FYG1AB05F_db/view

Social-Behavioral Research

Key Organizations


Relevant Standards


Privacy/Data Protection

Key Organizations

- National Health Council (CNS): http://www.conselho.saude.gov.br/
- Federal Council of Medicine (CFM): http://portal.cfm.org.br

Relevant Standards

- Law No. 13.853 of July 8, 2019 - Amends Law No. 13.709, of August 14, 2018, to provide for the protection of personal data and to create the National Data Protection Authority; and other provisions: http://www.planalto.gov.br/ccivil_03/_Ato2019-2022/2019/Lei/L13853.htm#art1
Human Biological Materials

Key Organizations

- National Health Council (CNS): http://www.conselho.saude.gov.br/
- Brazilian Health Surveillance Agency: http://portal.anvisa.gov.br/english

Relevant Standards

- Resolution of the Collegiate Board - RDC No. 504 of 05/26/2021 - provides Good Practices for the transport of human biological material. Revokes RDC No. 20 of April 10, 2014: https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-504-de-27-de-maio-de-2021-323008631

Genetic Research

Key Organizations

- National Health Council (CNS): http://www.conselho.saude.gov.br/

Relevant Standards


- Normative Resolution No. 33, of August 2, 2021: [http://ctnbio.mctic.gov.br/resolucoes-normativas/-/asset_publisher/OgW431Rs9dQ6/content/resolucao-normativa-n%2C2%BA-33-de-02-de-agosto-de-2021?redirect=http%3A%2F%2Fctnbio.mctic.gov.br%2Fresolucoes-normativas%3Fp_id%3D101_INSTANCE_OgW431Rs9dQ6%26p_life%2Cycle%3D0%26p_state%3Dnormal%26p_mode%3Dview%26p_col_id%3Docloum-2%26p_col_count%3D3](http://ctnbio.mctic.gov.br/resolucoes-normativas/-/asset_publisher/OgW431Rs9dQ6/content/resolucao-normativa-n%2C2%BA-33-de-02-de-agosto-de-2021?redirect=http%3A%2F%2Fctnbio.mctic.gov.br%2Fresolucoes-normativas%3Fp_id%3D101_INSTANCE_OgW431Rs9dQ6%26p_life%2Cycle%3D0%26p_state%3Dnormal%26p_mode%3Dview%26p_col_id%3Docloum-2%26p_col_count%3D3)

### Embryos, Stem Cells, and Cloning

**Key Organizations**


**Relevant Standards**


### LATIN AMERICA AND THE CARIBBEAN – Chile

#### General

**Key Organization**
- Ministry of Health: [http://www.minsal.cl](http://www.minsal.cl)
- Institute of Public Health: [http://www.ispch.cl](http://www.ispch.cl)

**Relevant Standards**
- Law No. 21.331, modifying law 20.584 and establishing that children or adolescents can refuse to participate in research. Also, adults who are physically or mentally unable to express their consent or preferences cannot be included in research: [https://www.bcn.cl/leychile/navegar?idNorma=1159383](https://www.bcn.cl/leychile/navegar?idNorma=1159383)

#### Drugs, Biologics, and Devices

**Key Organizations**
- Ministry of Health: [http://www.minsal.cl](http://www.minsal.cl)
- Institute of Public Health: [http://www.ispch.cl](http://www.ispch.cl)

**Relevant Standards**
International Compilation of Human Research Standards
2021 Edition


Research Injury

Key Organizations
- Ministry of Health: http://www.minsal.cl
- Institute of Public Health: http://www.ispch.cl

Relevant Standards

Privacy/Data Protection

Key Organizations
- Ministry of Health: http://www.minsal.cl
- Ministry of the Secretary General of the Government: http://www.msgg.gob.cl

Relevant Standards
- Law No. 20584. Regulating the Rights and Duties Incumbent upon Persons in Connection with Actions Linked to their Health Care (2012): http://www.leychile.cl/Navegar?idNorma=1039348

Genetic Research

Key Organizations
- Ministry of Health: http://www.minsal.cl
Relevant Standards


Embryos, Stem Cells, and Cloning

Key Organizations

▪ Ministry of Health: http://www.minsal.cl

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Colombia

General

Key Organization

▪ Ministry of Health and Social Protection: https://www.minsalud.gov.co/Paginas/default.aspx
▪ Administrative Department of Science, Technology, and Innovation (COLCIENCIAS): http://www.colciencias.gov.co/

Relevant Standards

Drugs, Biologics, and Devices

Drugs

Key Organizations


Relevant Standards

- Resolution No. 2011020764 of June 10th, 2011: Regulation Related to the Content and Frequency of Adverse Event Reports in Clinical Investigation in Humans: https://normograma.invima.gov.co/docs/resolucion_invima_20764_2011.htm?q=resolution+2011020764
- Resolution 1403 of 2007 - Which determines the Pharmaceutical Service Management Model, adopts the Essential Conditions and Procedures Manual and establishes other provisions: https://www.invima.gov.co/documents/20143/453029/Resoluci%C3%B3n+1403+de+2007.pdf/6b2e1ce1-bb34-e17f-03ef-34e35c126949
- Decree 780 of 2016 - By which the Sole Regulatory Decree of the Health and Social Protection Sector is issued. Chapter 10 Drugstores and pharmaceutical service: https://www.invima.gov.co/documents/20143/453029/Decreto+0780+de+2016.pdf/1a19484b-e3f1-f7f8-8b66-aacc81849a7a
- Resolution 839 of 2017 - By which Resolution 1995 of 1999 is amended: https://www.invima.gov.co/documents/20143/453029/Resoluci%C3%B3n%C3%B3n+839+de+2017.pdf/9b129f5f-d943-fde8-78f7-0f073f4753af?t=1540842229176
- Resolution 3100 of 2019 - By which the procedures and conditions for the registration of Health Service Providers and the authorization of health services are defined and the Health Service Provider Registration and Authorization Manual is adopted: https://normograma.invima.gov.co/docs/resolucion_minsaludps_3100_2019.htm?q=resolution+3100
- Circular 600-9915-15 - Research Ethics Committees October 2015: https://www.invima.gov.co/documents/20143/453029/Circular_600-9915-15_Comit%C3%A9s+-&C3%89tica_en_investigaci%C3%B3n%20octubre2015.pdf/1c5049a4-e2c2-6825-1aff-811b09c61e3f


External Circular No. 600-1414-16: Notification of Deviations (2016): https://www.invima.gov.co/documents/20143/453029/Circular+600-1414-16+Notificaci%C3%B3n+B3n+de+desviaciones.pdf/e03d7820-8839-061e-b7aa-480e3de4a79c


Circular 600-4167-16 - Protocol Evaluation May 2016: https://www.invima.gov.co/documents/20143/453029/Circular_600-4167-16.pdf/1330a354-0eb7-efd4-ac77-302812e50d0c

Circular 600-3950-17 - National Adverse Event Reporting May 2017: https://www.invima.gov.co/documents/20143/453029/Circular-Externa-600-3950-17.pdf/7f033df3-1c1f-e2a3-a6d3-6f75d1e29ae6


Exceptional clinical research measures applicable under the national contingency for COVID-19 to reduce risks to subjects participating in clinical trials: https://www.invima.gov.co/documents/20143/1251430/Circular+Medidas+excepcionales+investigacion%C3%B3n+cl%C3%ADnica.pdf

Instruction for online tool management and industry reporting, Version 1 (2021)

Coronavirus (COVID-19) clinical research guidelines, March (2020)

Devices

Key Organizations

- National Institute of Drug and Food Surveillance: http://www.invima.gov.co/
Relevant Standards

Clinical Trial Registries

Key Organizations

Relevant Standards

Research Injury

Key Organizations
- Ministry of Health and Social Protection: [https://www.minsalud.gov.co/Paginas/default.aspx](https://www.minsalud.gov.co/Paginas/default.aspx)

Relevant Standards

Privacy/Data Protection

Key Organizations
- Ministry of Health and Social Protection: [https://www.minsalud.gov.co/Paginas/default.aspx](https://www.minsalud.gov.co/Paginas/default.aspx)

Relevant Standards
Human Biological Materials

Key Organizations
- Ministry of Health and Social Protection: https://www.minsalud.gov.co/Paginas/default.aspx

Relevant Standards

Genetic Research

Key Organizations
- Ministry of Health and Social Protection: https://www.minsalud.gov.co/Paginas/default.aspx

Relevant Standards

LATIN AMERICA AND THE CARIBBEAN – Costa Rica

General

Key Organization
- Ministry of Health: https://www.ministeriodesalud.go.cr/

Relevant Standards
- Reform Regulation to the Biomedical Research Regulatory Law: http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NR_TC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC

Drugs, Biologics, and Devices

Key Organizations
- National Health Research Council: https://www.ministeriodesalud.go.cr/conis/
Relevant Standards

▪ Regulatory Law of Biomedical Research No. 9234 (2014):
  TC&nValor1=1&nValor2=77070&nValor3=96424&strTipM=TC

▪ Regulatory Decree NO. 39061-S (2016) on the Regulatory Law of Biomedical Research No. 39533-S:
  C&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC

▪ Reforms to the Regulatory Decree No. 39533-S (2016) Regulatory Law of Biomedical Research No. 9234:
  TC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC

▪ Requirements for Accreditation, various:
  https://www.ministeriodesalud.go.cr/conis/index.php/servicios/requisitos-de-acreditaciones

▪ Good Practices for Biomedical Research, various:
  https://www.ministeriodesalud.go.cr/conis/index.php/servicios/buenas-practicas-en-investigacion-
  biomedica

Clinical Trial Registries

Key Organizations

▪ National Health Research Council: https://www.ministeriodesalud.go.cr/conis/

Relevant Standards

▪ Registered Studies: https://www.ministeriodesalud.go.cr/conis/index.php/servicios/investigaciones-
  registradas

LATIN AMERICA AND THE CARIBBEAN – Cuba

Drugs, Biologics, and Devices

Key Organizations

▪ Center for State Control of Medications: http://www.cecmed.cu/

Relevant Standards

▪ Various: http://www.cecmed.cu/ensayos-clinicos/autorizados

Clinical Trial Registries

Key Organizations

▪ Public Cuban Registry of Clinical Trials: https://rpccc.sld.cu/

LATIN AMERICA AND THE CARIBBEAN – Dominica

General

Key Organization

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Dominican Republic

General

Key Organization


Relevant Standards

- CONABIOS, Legal Basis, various: http://conabios.gob.do/base-legal-del-conabios/

LATIN AMERICA AND THE CARIBBEAN – Ecuador

General

Key Organization

- Ministry of Public Health: http://www.salud.gob.ec/

Relevant Standards

- Regulation for the Approval of Ethics Committees (2014): https://www.salud.gob.ec/aprobacion-de-comites-de-etica/
- Approval of Ethics Committees: https://www.salud.gob.ec/aprobacion-de-comites-de-etica/
- Approval of Health Research: https://www.salud.gob.ec/autorizacion-de-investigaciones-en-salud/

Drugs, Biologics, and Devices

Key Organizations

- Ministry of Public Health: http://www.salud.gob.ec/
- National Health Agency for Regulation, Control, and Oversight: http://www.controlsanitario.gob.ec/ensayos-clinicos/
Relevant Standards

- Approval of Clinical Trials: https://www.controlsanitario.gob.ec/ensayos-clinicos/

Privacy/Data Protection

Key Organizations

- Ministry of Public Health: http://www.salud.gob.ec/

Relevant Standards

- Ministerial Agreement No. 005216, Public Registry No. 427, Confidential Information in National Health System (January 29, 2015)

Human Biological Materials

Key Organizations

- National Institute on Donation and Transplantation of Organs, Tissues, and Cells: http://www.donaciontrasplante.gob.ec/indot/

Relevant Standards

- Import and Export of Human Biological Samples for research. Ministerial Agreement No. 0088, Public Registry No. 34, (July 12, 2017): http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/08/Acuerdo-Ministerial-0088-2017_Autorizaci%C3%B3n-de-importaci%C3%B3n-de-muestras-biol%C3%B3gicas.pdf
- Authorization of Import and Export of Human Biological Samples for Research and Health: https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/10/IE-B.3.3.2-EC-01-Instructivo-Externo-Autorizaci%C3%B3n-Muestras-Biol%C3%B3gicas.pdf

Genetic Research

Key Organizations

- Ministry of Public Health: http://www.salud.gob.ec/
Relevant Standards

Embryos, Stem Cells, and Cloning

Key Organizations
- Ministry of Public Health: http://www.salud.gob.ec/

Relevant Standards

LATIN AMERICA AND THE CARIBBEAN – El Salvador

General

Key Organization
- National Health Research Ethics Committee: http://www.cneis.org.sv/

Relevant Standards

Drugs, Biologics, and Devices

Key Organizations
Relevant Standards

▪ Medication Law, Articles 29 and 66 (2012):  
cumento_legislativo.pdf

▪ User’s Guide for the Application of Clinical Investigation Protocols:
  http://www.medicamentos.gob.sv/index.php/es/servicios-m/descargables/ensayos-clinicos

LATIN AMERICA AND THE CARIBBEAN – Grenada

General

Key Organization

▪ St. George’s University/Windward Islands Research and Education Foundation:
  http://www.sgu.edu/school-of-medicine/institutional-review-board.html

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Guyana

General

Key Organization

▪ Ministry of Health: https://www.health.gov.gy/

Relevant Standards

▪ Medical Research Involving Human Subjects Regulations (2007):

LATIN AMERICA AND THE CARIBBEAN – Guatemala

General

Key Organization

▪ Ministry of Public Health and Social Assistance: http://www.mspas.gob.gt/

Relevant Standards

▪ Ministerial Accords and Amendments, various:
  https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/acuerdos

▪ Internal Regulations of the National Committee on Health Ethics (2018):
ativaCNES.pdf

Drugs, Biologics, and Devices

Key Organizations

▪ Ministry of Public Health and Social Assistance, Department of Regulation and Control of
  Pharmaceutical Products: https://medicamentos.mspas.gob.gt/
Relevant Standards
- Ministerial Accords and Amendments, various: https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/acuerdos
- Clinical Trials, various: https://medicamentos.mspas.gob.gt/index.php/formularios/formensayos

LATIN AMERICA AND THE CARIBBEAN – Haiti

General

Key Organization

Relevant Standards
- Internal Regulations (2010)

LATIN AMERICA AND THE CARIBBEAN – Honduras

General

Key Organization
- Secretariat of Health: http://www.salud.gob.hn/

Relevant Standards
- Health Code, Decree No. 65-91, Articles 175 and 176

Drugs, Biologics, and Devices

Key Organizations
- Secretariat of Health: http://www.salud.gob.hn/

Relevant Standards

Human Biological Materials

Relevant Standards
### Embryos, Stem Cells, and Cloning

**Relevant Standards**


### LATIN AMERICA AND THE CARIBBEAN – Jamaica

**General**

**Key Organization**


**Relevant Standards**


### Drugs, Biologics, and Devices

**Key Organizations**


**Relevant Standards**


### LATIN AMERICA AND THE CARIBBEAN – Mexico

*NOTE: For an overview of clinical research regulations in Mexico, see the ClinRegs report: [https://clinregs.niaid.nih.gov/country/mexico](https://clinregs.niaid.nih.gov/country/mexico)*

**General**

**Key Organization**

- Ministry of Health: [https://www.gob.mx/salud](https://www.gob.mx/salud)
- Federal Commission for Protection Against Health Risks (Cofepris): [https://www.gob.mx/cofepris](https://www.gob.mx/cofepris)

**Relevant Standards**


**Drugs, Biologics, and Devices**

**Relevant Standards**


**Privacy/Data Protection**

**Key Organizations**


**Relevant Standards**

Human Biological Materials

Key Organizations
- Secretariat of Health: https://www.gob.mx/salud

Relevant Standards

Genetic Research

Key Organizations
- National Institute of Genomic Medicine: http://www.inmegen.gob.mx/

Relevant Standards
- Modifications to the General Health Law to Protect Genomic Sovereignty (2008)
- Regulations to the General Health Law on Health Research, Title Four, Chapter Two (2014): http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf

LATIN AMERICA AND THE CARIBBEAN – Nicaragua

General

Key Organization
- Ministry of Health (MINSA) Nicaragua: http://www.minsa.gob.ni
- Institutional Ethical Review Committee (CIRE)

Relevant Standards
Drugs, Biologics, and Devices

Key Organization
- Ministry of Health, Directorate of Sanitary Regulations: [http://www.minsa.gob.ni](http://www.minsa.gob.ni)

Relevant Standards
- Normative-064, Standard for the registration of medical devices: [http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Normativa-064%E2%80%9CNorma-para-el registro-de-dispositivos-%C3%A9dicos%E2%80%9D/](http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Normativa-064%E2%80%9CNorma-para-el registro-de-dispositivos-%C3%A9dicos%E2%80%9D/)

Clinical Trial Registries

Key Organization
- Ministry of Health, Directorate of Sanitary Regulations: [http://www.minsa.gob.ni](http://www.minsa.gob.ni)

Relevant Standards
- Clinical Trial Standards: [http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Direcci%C3%B3n-de-Farmacia/Ensayos-Cl%C3%ADnicos/Norma-de-Ensayos-Clinicos/](http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Direcci%C3%B3n-de-Farmacia/Ensayos-Cl%C3%ADnicos/Norma-de-Ensayos-Clinicos/)

LATIN AMERICA AND THE CARIBBEAN – Panama

General

Key Organization
- National Committee of Research Bioethics: [https://cnbi.senacyt.gob.pa](https://cnbi.senacyt.gob.pa)

Relevant Standards

Drugs, Biologics, and Devices

Relevant Standards
Privacy/Data Protection

Relevant Standards

- Law No. 81, March 26, 2019: [https://www.gacetaoficial.gob.pa/pdfTemp/28743_A/GacetaNo_28743a_20190329.pdf](https://www.gacetaoficial.gob.pa/pdfTemp/28743_A/GacetaNo_28743a_20190329.pdf)

Human Biological Materials

Relevant Standards


Embryos, Stem Cells, and Cloning

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Paraguay

General

Key Organization


Relevant Standards


Drugs, Biologics, and Devices

Key Organization


Relevant Standards

- Law 1119/97 Regarding Health Products and Other Products, Article 30: [https://www.mspbs.gov.py/dependencias/dnvs/adjunto/1d0e83-LEYN11191997DEPRODUCTOSPARALASALUDYOTROS.pdf](https://www.mspbs.gov.py/dependencias/dnvs/adjunto/1d0e83-LEYN11191997DEPRODUCTOSPARALASALUDYOTROS.pdf)
LATIN AMERICA AND THE CARIBBEAN – Peru

NOTE: For an overview of clinical research regulations in Peru, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=170

General

Key Organization

▪ National Institute of Health: http://www.ins.gob.pe/

Relevant Standards


Drugs, Biologics, and Devices

Key Organization

▪ National Institute of Health (INS) General Office on Research and Technology Transfer (OGITTT): http://www.ins.gob.pe/
▪ National Directorate of Drugs and Medical Devices (MINSA): www.digemid.minsa.gob.pe

Relevant Standards

▪ Procedures Manual for Clinical Trials (2017)

Clinical Trial Registries

Key Organization

▪ Peruvian Registry of Clinical Trials: https://ensayosclinicos-repec.ins.gob.pe/

Relevant Standards

▪ Various regulations: https://ensayosclinicos-repec.ins.gob.pe/regulacion/normatividad-vigente

Research Injury

Key Organizations

▪ National Institute of Health: http://www.ins.gob.pe/
Relevant Standards


Privacy/Data Protection

Key Organizations

- National Directorate of Drugs and Medical Devices: www.digemid.minsa.gob.pe

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Saint Lucia

Drugs, Biologics, and Devices

Relevant Standards


LATIN AMERICA AND THE CARIBBEAN – Trinidad and Tobago

General

Key Organization

- Ministry of Health: http://www.health.gov.tt/
- University of the West Indies (UWI), St. Augustine: https://sta.uwi.edu/research/ethics.asp

Relevant Standards

- UWI, Research Ethics, various: https://sta.uwi.edu/research/campus-ethics

LATIN AMERICA AND THE CARIBBEAN – Uruguay

General

Key Organization

- Ministry of Public Health: http://www.msp.gub.uy/
Relevant Standards


Drugs, Biologics, and Devices

Key Organization

- Ministry of Public Health: http://www.msp.gub.uy/

Relevant Standards


Research Injury

Key Organizations

- Ministry of Public Health: http://www.msp.gub.uy/

Relevant Standards


Privacy/Data Protection

Key Organizations

- Ministry of Public Health: http://www.msp.gub.uy/

Relevant Standards


Human Biological Materials

Key Organizations

- Ministry of Public Health: http://www.msp.gub.uy/
### LATIN AMERICA AND THE CARIBBEAN – Venezuela

#### General

**Key Organization**
- National Fund on Science and Technology, Commission on Bioethics and Biosecurity (FONACIT): [www.fonacit.gob.ve](http://www.fonacit.gob.ve)
- Venezuelan Institute of Scientific Research (IVIC): [https://www.ivic.gob.ve](https://www.ivic.gob.ve)

**Relevant Standards**
- Resolution No. 48 (1998)

#### Drugs, Biologics, and Devices

**Key Organization**
- National Institute of Hygiene “Rafael Rangel”: [http://www.inhrr.gob.ve](http://www.inhrr.gob.ve)

**Relevant Standards**
- Medicines Act, Title III, Chapter II

#### Genetic Research

**Key Organizations**
- Venezuelan Institute of Scientific Research (IVIC): [https://www.ivic.gob.ve](https://www.ivic.gob.ve)

**Relevant Standards**
- Contract for Accessing Genetic Resources (2003)
### MIDDLE EAST/NORTH AFRICA – Egypt

#### General

**Key Organization**
- Medical Professionals Union

**Relevant Standards**
- Professional Ethics Regulations, Conducting Medical Research on Human Beings, Articles 52-61 (2003)

#### Drugs, Biologics, and Devices

**Key Organization**
- Egyptian Drug Authority: [https://www.edaegypt.gov.eg/](https://www.edaegypt.gov.eg/)

**Relevant Standards**
- Ministerial Resolutions, various: [https://www.edaegypt.gov.eg/ar/%D8%A7%D9%84%D9%82%D9%88%D8%A7%D9%86%D9%8A%D9%86-%D9%88%D8%A7%D9%84%D9%82%D8%B1%D8%A7%D8%B1%D8%A7%D8%AA-%D9%88%D8%A7%D9%84%D9%82%D8%B9%D8%AF-%D8%A7%D9%84%D9%85%D9%86%D8%B8%D9%85%D8%A9/%D8%A7%D9%84%D9%82%D8%B1%D8%A7%D8%AA-%D8%A7%D9%84%D8%B2%D8%A7%D8%B1%D9%8A%D8%A9/](https://www.edaegypt.gov.eg/ar/%D8%A7%D9%84%D9%82%D9%88%D8%A7%D9%86%D9%8A%D9%86-%D9%88%D8%A7%D9%84%D9%82%D8%B1%D8%A7%D8%B1%D8%A7%D8%AA-%D9%88%D8%A7%D9%84%D9%82%D8%B9%D8%AF-%D8%A7%D9%84%D9%85%D9%86%D8%B8%D9%85%D8%A9/%D8%A7%D9%84%D9%82%D8%B1%D8%A7%D8%AA-%D8%A7%D9%84%D8%B2%D8%A7%D8%B1%D9%8A%D8%A9/)
### Relevant Standards
- Trial Registration: [https://www.irct.ir/page/help](https://www.irct.ir/page/help)

### MIDDLE EAST/NORTH AFRICA – Israel

#### General

**Key Organization**

**Relevant Standards**
- Public Health Regulations (Medical Experiments Involving Human Subjects) (1999)

#### Drugs, Biologics, and Devices

**Key Organization**
- Ministry of Health, Pharmaceutical Administration: [http://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/Drugs/Pages/default.aspx](http://www.health.gov.il/English/MinistryUnits/HealthDivision/MedicalTechnologies/Drugs/Pages/default.aspx)

**Relevant Standards**
- Public Health Order (1940)
- Public Health Regulations (Clinical Studies in Human Subjects) (1980) (as subsequently amended)
- Various procedures, [https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/ClinicalTrials/Pages/CTH.aspx](https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/ClinicalTrials/Pages/CTH.aspx)

#### Privacy/Data Protection

**Key Organizations**

**Relevant Standards**

#### Genetic Research

**Key Organizations**

**Relevant Standards**
- Instruction of the Supreme Committee for Clinical Studies on Humans Regarding Establishment and Usage of Genetic Samples Reservoir (2005)
- Amendment (2007)
Embryos, Stem Cells, and Cloning

Relevant Standards

▪ Genetic Intervention Prohibition Law (Human Cloning and Genetic Changes in Reproduction Cells) (1999)

MIDDLE EAST/NORTH AFRICA – Jordan

Drugs, Biologics, and Devices

Key Organization


Relevant Standards

▪ Drug and Pharmacy Law No. 12 (2013): http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugDirectorate/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D8%AF%D9%88%D8%A7%D8%A1%20%D9%88%D8%A7%D9%84%D8%B5%D9%8A%D8%AF%D9%84%D8%A9.pdf
▪ Narcotic and Psychotropic Law No. 23 (2016): http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugsAndPsychotropicSubstances/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D9%85%D8%AE%D8%AF%D8%B1%D8%A7%D8%AA%20%D9%88%D8%A7%D9%84%D9%85%D8%A4%D8%AB%D8%B1%D8%A7%D8%AA%20%D8%A7%D9%84%D8%B9%D9%82%D9%84%D8%A8%D9%8A%D8%A9.pdf

Research Injury

Relevant Standards


Embryos, Stem Cells, and Cloning

Relevant Standards

▪ Stem Cell By-law No. 10 (2014)

MIDDLE EAST/NORTH AFRICA – Kuwait

General

Key Organization

▪ Ministry of Health, Kuwait Institute for Medical Specialization: http://www.kims.org.kw/
Relevant Standards
- Ethical Guidelines for Biomedical Research

**MIDDLE EAST/NORTH AFRICA – Qatar**

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<td>- Ministry of Public Health, Health Research Governance Department: <a href="https://www.moph.gov.qa/english/derpartments/policyaffairs/healthresearchgovernance/Pages/default.aspx">Link</a></td>
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<td>- Clinical trials, various: <a href="https://research.moph.gov.qa/en/Pages/ClinicalTrials.aspx?csrt=16566705229134832818">Link</a></td>
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<td>- Ministry of Public Health, Health Research Governance Department: <a href="https://www.moph.gov.qa/english/derpartments/policyaffairs/healthresearchgovernance/Pages/default.aspx">Link</a></td>
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Relevant Standards

- Guidance for the Design, Ethical Review, and Conduct of Genomic Research in Qatar:
- Guidelines for Gene Transfer Research in Humans:
- Human Research Policies & Regulations, various:

Embryos, Stem Cells, and Cloning

Key Organizations

- Ministry of Public Health, Health Research Governance Department:

Relevant Standards

- Human Research Policies & Regulations, various:

MIDDLE EAST/NORTH AFRICA – Saudi Arabia

General

Key Organization


Relevant Standards


Social-Behavioral Research

Key Organization


Relevant Standards

- Implementing Regulations of the Law of Ethics of Research on Living Creatures, Expedited Research (Article 10.18g) and Categories of Social-Behavioral Research That do not Require Continuing Review (Article 10.32) (2016):
MIDDLE EAST/NORTH AFRICA – Sudan

General

Key Organization
- Federal Ministry of Health: http://www.fmoh.gov.sd/

Relevant Standards
- Operation Guidelines, Functions, and Procedures (2016)

Drugs, Biologics, and Devices

Key Organization

Relevant Standards

Human Biological Materials

Key Organizations
- Federal Ministry of Health: http://www.fmoh.gov.sd/
- National Council on Biosafety

Relevant Standards
- Human Organs and Tissues Transplant Legislation, Chapter 2, Articles 3 and 4 (1978)
- Act on Biosafety (2010)

Genetic Research

Key Organizations

Relevant Standards
- Guidelines for Genetics Research on Sudanese Subjects (2005)

MIDDLE EAST/NORTH AFRICA – Tunisia

Drugs, Biologics, and Devices

Key Organization
- Ministry of Public Health, Institut Pasteur: www.pasteur.tn
Relevant Standards

- Conditions of Contract and Specifications Related to Medical or Scientific Experimentation of Medicines Intended for Humans
- Disposals and Director’s Principles Related to Good Practices in Clinical Trials

MIDDLE EAST/NORTH AFRICA – Turkey

General

Key Organization


Relevant Standards

- Turkish Constitution, Article 172. Health Services Basic Law No. 3359 (1987)
- Regulation on Medical Deontology, Article 11 (1960)
- Bylaw on Patient Rights No. 23420 (1998)

Drugs, Biologics, and Devices

Drugs

Key Organizations

- Turkey Pharmaceuticals and Medical Devices Agency (Turkish) (TITCK): [http://www.titck.gov.tr](http://www.titck.gov.tr)
- Clinical Research Association (CRA): [www.klinikarastirmalar.org](http://www.klinikarastirmalar.org)

Relevant Standards

- Turkish Penal Law, Article 90 (2005)
- Fundamental Law #3359 on Health Services, Supplemental Article 10 (2011)
- Various TMMDA legislation: [https://www.titck.gov.tr/mevzuat](https://www.titck.gov.tr/mevzuat)
- Regulation on Efficacy, Safety, and Clinical Trials of Cosmetic Products (2015)


Guideline on the Audit of Pharmacovigilance: [https://titck.gov.tr/storage/Archive/2019/legislation/05ef1188-6756-4165-b0d5-bb0a28bbebb3.pdf](https://titck.gov.tr/storage/Archive/2019/legislation/05ef1188-6756-4165-b0d5-bb0a28bbebb3.pdf)

Bylaw on Medical Devices aimed for In Vitro Diagnostics: [https://www.resmigazete.gov.tr/ eskiler/2021/06/20210602M1-1.pdf](https://www.resmigazete.gov.tr/ eskiler/2021/06/20210602M1-1.pdf)

### Devices

#### Key Organizations

- Turkey Pharmaceuticals and Medical Devices Agency (TITCK): [http://www.titck.gov.tr](http://www.titck.gov.tr)

#### Relevant Standards


### Research Injury

#### Key Organizations

- Turkish Medicines and Medical Devices Agency (TMMDA): [https://www.titck.gov.tr/mevzuat](https://www.titck.gov.tr/mevzuat)

#### Relevant Standards


- Various other guidance: [https://www.titck.gov.tr/mevzuat/liste/k%C4%B1lavuz?page=6](https://www.titck.gov.tr/mevzuat/liste/k%C4%B1lavuz?page=6)

### Social-Behavioral Research

#### Key Organizations

- Yıldırım Beyazıt University Psychiatry and Behavioral Neuroscience Application and Research Center: [https://aybu.edu.tr/pdnam](https://aybu.edu.tr/pdnam)

- Istanbul University Consumer Behavior and Behavioral Economics Application and Research Center: [https://www.istanbul.edu.tr/tr/](https://www.istanbul.edu.tr/tr/)

#### Relevant Standards

Privacy/Data Protection

**Key Organizations**
- Personal Data Protection Authority: [https://www.kvkk.gov.tr/](https://www.kvkk.gov.tr/)

**Relevant Standards**
- Personal Data Protection Law: [https://www.kvkk.gov.tr/Icerik/6649/Personal-Data-Protection-Law](https://www.kvkk.gov.tr/Icerik/6649/Personal-Data-Protection-Law)

Human Biological Materials

**Key Organizations**

**Relevant Standards**
- Law on Procurement, Preservation, Grafting, and Transplantation of Organs and Tissues, No. 2238 (1979)
- Law on Blood and Blood Products, No. 2857 (1983)
- Regulation on Blood and Blood Products, No. 7314 (1983)
- Good Clinical Practice Guidelines for Advanced Therapy Medicinal Products (2011)

Genetic Research

**Key Organizations**

**Relevant Standards**

Embryos, Stem Cells, and Cloning

**Key Organizations**

**Relevant Standards**
- Regulation on Centers for Medically Assisted Procreation, No. 19551 (1987)
- Regulation on Cordon Blood Banks (2005)
- Circular on Research of Embryonic Stem Cells (2005)
Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)


### MIDDLE EAST/NORTH AFRICA – United Arab Emirates

#### General

**Key Organization**

- Health Authority - Abu Dhabi: [http://www.haad.ae/haad/](http://www.haad.ae/haad/)

**Relevant Standards**

North America
NORTH AMERICA – Canada

NOTE: Several Canadian provinces and territories also have human subject research standards. For an overview of clinical research regulations in Canada, see the ClinRegs report: https://clinregs.niaid.nih.gov/country/canada

General

Key Organizations

Relevant Standards

Drugs, Biologics, and Devices

Drugs

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Clinical Trial Registries

Key Organizations

Relevant Standards

Research Injury

Key Organizations

Relevant Standards

Social-Behavioral Research

Key Organizations

Relevant Standards

Privacy/Data Protection

NOTE: Each of the Canadian provinces and territories also has enacted privacy legislation.

Key Organizations
- Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca/e/193.html

Relevant Standards
- OPC: SOR/2001-6, SOR/2001-7, and SOR/2001-8 (September 29, 2014)
Human Biological Materials

Key Organizations

Relevant Standards

Genetic Research

Key Organizations

Relevant Standards

Embryos, Stem Cells, and Cloning

Key Organizations

Relevant Standards

NORTH AMERICA – United States

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

General

Key Organization and Relevant Standards

Last Updated: November 2021
HHS, Food and Drug Administration (FDA) (FDA is not a Common Rule agency): [https://www.fda.gov/](https://www.fda.gov/)


Subpart A of the HHS regulations for the protection of research participants at 45 CFR 46 is often referred to as the Common Rule because various Federal departments and agencies have adopted the same regulations. For a list of U.S. Federal departments and agencies that have adopted the Common Rule and citations to their relevant regulations see: [https://www.hhs.gov/ohrp/compliance-and-reporting/common-rule-agencies-contacts/index.html](https://www.hhs.gov/ohrp/compliance-and-reporting/common-rule-agencies-contacts/index.html)

Other relevant standards by U.S. Federal departments and agencies include:


   a. Executive Order 12333, adopting 45 CFR 46 Subparts A, B, C, and D


   a. United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects


   c. 34 CFR 98 (1984)

   d. 34 CFR 99 (2000)

   e. 34 CFR 350.4(c) (1991)

   f. 34 CFR 356.3(c) (1991)


   a. DOE Order 443.1B

   b. DOE Order 481.1


   a. Public Law 108-458, Section 8306

   c. 28 CFR 46 (1991), Subpart A: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr46_main_02.tpl

8. Department of Veterans Affairs:

9. Environmental Protection Agency, Program in Human Research Ethics: https://www.epa.gov/osa/basic-information-about-human-subjects-research-0
   a. Subpart A: Basic EPA Policy for Protection of Subjects in Human Research Conducted or Supported by EPA (Common Rule)
   b. Subpart B: Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women (2006)
   c. Subpart C: Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA (2006)
   d. Subpart D: Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA (2006)
   e. Subpart K: Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults (2013)
   f. Subpart L: Prohibition of Third-Party Research Involving Intentional Exposure to a Pesticide of Human Subjects who are Children or Pregnant or Nursing Women (2013)
   g. Subpart M: Requirements for Submission of Information on the Ethical Conduct of Completed Human Research (2013)
   h. Subpart O: Administrative Actions for Noncompliance (2013)

Drugs, Biologics, and Devices

Drugs and Biologics

Key Organizations

▪ Food and Drug Administration: https://www.fda.gov/Drugs and https://www.fda.gov/vaccines-blood-biologics

Relevant Standards


▪ FDA, Drugs, Guidance, various: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs

▪ FDA, Biologics, Guidance, various: https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics

Devices

Key Organizations

▪ Food and Drug Administration, Center for Devices and Radiological Health: https://www.fda.gov/Medical-Devices

Relevant Standards


Clinical Trial Registries

Key Organizations

- National Institutes of Health ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/home
- Office of Research Oversight (ORO): http://www1.va.gov/oro/

Relevant Standards

- FAQs on ClinicalTrials.gov: https://www.clinicaltrials.gov/ct2/manage-recs/faq
- Department of Veterans Affairs, FAQ: http://www.research.va.gov/resources/ORD_Admin/clinical_trials/registration-faq.pdf

Research Injury

Key Organizations

- Various

Relevant Standards

- Department of Health and Human Services, Sections 116(a)(6) and (7) of the Common Rule: https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf
- Department of Veterans Affairs, Handbook 1200.5, Appendix F, Paragraph 2a(11)
Social-Behavioral Research

Key Organizations
- Various

Relevant Standards
- National Science Foundation, FAQs and Vignettes: https://www.nsf.gov/bfa/dias/policy/hsfqas.jsp

Privacy/Data Protection

Key Organizations
- Various

Relevant Standards
Human Biological Materials

Key Organizations
- Department of Health and Human Services, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/

Relevant Standards

Genetic Research

Key Organizations
- FDA, Center for Biologics Research and Evaluation (CBER): https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber
- HHS, Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/
- HHS, NIH, Office of Science Policy, Biosafety, Biosecurity, and Emerging Biotechnology Policy Division: https://osp.od.nih.gov/biosafety-biosecurity-and-emerging-biotechnology/

Relevant Standards
Embryos, Stem Cells, and Cloning

Key Organizations

Relevant Standards
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- The European Council

**Africa:**
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**Europe:**
- Global Regulatory Affairs team at Comac Medical Ltd.
- Finland: Marko Ahteensuu
- Germany: Claudia Leuker
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**Latin America and the Caribbean:**
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