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 However, not all countries provided corroboration, so some of the information contained in this document may be outdated or incomplete (please see disclaimer below).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 country, 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

Last Updated: November 2021
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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International Organizations
INTERNATIONAL ORGANIZATIONS

General


International Committee of the Red Cross (ICRC): [www.icrc.org](http://www.icrc.org)
- Geneva Convention Relative to the Treatment of Prisoners of War, Articles 13 and 130 (1950): [https://www.icrc.org/applic/ihl/ihl.nsf/7c4d08d9b287a42141256739003e636b/6fe8f54a3517b75ac125641e004a9e68](https://www.icrc.org/applic/ihl/ihl.nsf/7c4d08d9b287a42141256739003e636b/6fe8f54a3517b75ac125641e004a9e68)
- Additional Protocol I Relating to the Protection of Victims of International Armed Conflicts, Article 11 (1977): [http://www.icrc.org/ihl.nsf/7c4d08d9b287a42141256739003e636b/f6c8b9fee14a77fdec125641e0052b079](http://www.icrc.org/ihl.nsf/7c4d08d9b287a42141256739003e636b/f6c8b9fee14a77fdec125641e0052b079)


TRUST Project: [http://www.globalcodeofconduct.org](http://www.globalcodeofconduct.org)


- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011): [https://www.who.int/publications/i/item/9789241502948](https://www.who.int/publications/i/item/9789241502948)


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

**World Medical Association:** [http://www.wma.net/e/](http://www.wma.net/e/)


### Drugs, Biologics, and Devices

**Drugs**


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

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


**Devices**

**International Medical Device Regulators Forum (IMDRF):** [http://www.imdrf.org/](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](http://www.imdrf.org/ghtf/ghtf-archived-docs.asp)

**International Standards Organization:** [http://www.iso.org/iso/home.html](http://www.iso.org/iso/home.html)


### Clinical Trial Registries

**International Committee of Medical Journal Editors:** [http://www.icmje.org/](http://www.icmje.org/)

- Clinical Trial Registration: [http://icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html](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](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](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/](http://www.wma.net/e/)

**Research Injury**

**Council for International Organizations of Medical Sciences:** [http://www.cioms.ch/](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/](https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/)

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

**World Medical Association:** [https://www.wma.net/](https://www.wma.net/)

**Social-Behavioral Research**

**UNESCO:** [http://www.unesco.org/](http://www.unesco.org/)

**Privacy/Data Protection**

**World Medical Association:** [http://www.wma.net/e/index.htm](http://www.wma.net/e/index.htm)

**Human Biological Materials**

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

**International Society for Biological and Environmental Repositories:** [https://www.isber.org/](https://www.isber.org/)

**World Health Organization:** [http://www.who.int/en/](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/](http://www.pactr.org/)
- PACTR, Terms and Conditions: [https://pactr.samrc.ac.za/TermsAndConditions.aspx](https://pactr.samrc.ac.za/TermsAndConditions.aspx)
- PACTR, FAQs: [https://pactr.samrc.ac.za/FAQ.aspx](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**
  - 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: www.cambin.org

Relevant Standards
- Operational Guidelines for Ethics Committees in Charge of the Evaluation of Biomedical Research
AFRICA – Congo, Democratic Republic of the Congo

**NOTE:** For an overview of clinical research regulations in the Democratic Republic of the Congo, see the ClinRegs report: [https://clinregs.niaid.nih.gov/country/DRC](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](https://www.mindbank.info/item/2543)
- Proposal for Ministerial Order No. 1250 Establishing the National Advisory Committee on Ethics Health (2004): [https://healthresearchweb.org/?action=download&file=DRCPOlicy.pdf](https://healthresearchweb.org/?action=download&file=DRCPOlicy.pdf)

AFRICA – Côte-d’Ivoire

### Drugs, Biologics, and Devices

**Key Organizations**

- National Committee on Ethics and Research

**Relevant Standards**


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](http://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/

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

AFRICA – Ghana

NOTE: For an overview of the clinical trial information in Ghana, see:

Drugs, Biologics, and Devices

Key Organizations
- Food and Drugs Authority: http://www.fdaghana.gov.gh

Relevant Standards
- Act 851, Public Health Act, 2012:
- Applications for Clinical Trials as Defined Under Section 150-166 (Part 8) of the Public Health Act 2012, Act 851:
- Clinical Trials, Biological Products, Devices, and More, Guidelines and Forms, various:
- Clinical Trials, Biological Products, Devices, and More, Operational Guidelines, various:
AFRICA – Guinea

NOTE: For an overview of the clinical research regulations in Guinea, see the ClinReg 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


▪ CNERS, Frequently Asked Questions: http://cners-guinee.org/faq/

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

### Human Biological Materials

#### Key Organizations

#### Relevant Standards

### AFRICA – Liberia

**NOTE:** For an overview of the clinical research regulations in Liberia, see the ClinRegs report: [https://clinregs.niaid.nih.gov/single_country.php?c_id=122](https://clinregs.niaid.nih.gov/single_country.php?c_id=122)

#### General

#### Key Organizations

#### Relevant Standards

### Drugs, Biologics, and Devices

#### Key Organizations
- Liberia Medicines and Health Products Regulatory Authority

#### Relevant Standards

### AFRICA – Madagascar

#### Drugs, Biologics, and Devices

#### Relevant Standards
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

Relevant Standards

Social-Behavioral Research

**Key Organizations**
- National Committee on Research in the Social Sciences and Humanities

**Relevant Standards**
- Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011):

Human Biological Materials

**Key Organizations**
- National Commission for Science and Technology: [www.ncst.mw](http://www.ncst.mw)

**Relevant Standards**

Genetic Research

**Key Organizations**

**Relevant Standards**
- Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi (2002)

AFRICA – Mali

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

Drugs, Biologics, and Devices

**Key Organizations**
- Directorate of Pharmacy and Medicine

**Relevant Standards**
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

AFRICA – Nigeria

General

Key Organizations
- National Health Research Ethics Committee: 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/

Drugs, Biologics, and Devices

Key Organizations
- National Agency for Food, Drug Administration and Control (NAFDAC):
  http://www.nafdac.gov.ng/

Relevant Standards
- Decree No. 15 of 1993

Clinical Trial Registries

Key Organizations
- National Health Research Ethics Committee: http://nhrec.net/

Relevant Standards
- Frequently Asked Questions: 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


General

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


Drugs, Biologics, and Devices

Key Organizations

- Ministry of Health: http://www.sante.gov.bf/
- Pharmacy Board of Sierra Leone: 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
- Clinical Trials, various: http://www.pharmacyboard.gov.sl/Resources/ClinicalTrials.aspx

AFRICA – South Africa


General

Key Organizations

- Medical Research Council of South Africa (MRC): https://www.samrc.ac.za/
- Human Sciences Research Council (HSRC): http://www.hsrc.ac.za/en/about/research-ethics
- South African Health Products Regulatory Authority: https://protect.za.mimecast.com/s/5WP2Cr07VKf1mK59tzNft9?domain=sahpra.org.za/

Relevant Standards

Drugs, Biologics, and Devices

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

Relevant Standards
- South African Good Clinical Practice: Clinical Trial Guidelines (2020)

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
- Ethics in Health Research: Principles, Processes, and Structures, Section 3.3.7(i) (2015):

Human Biological Materials

Key Organizations

Relevant Standards
- National Health Act No. 61, Chapter 8, Sections 53-68 (2003):
- Regulations Relating to the Use of Human Biological Material, 2 March 2012:
- Regulations Regarding General Control of Human Bodies, Tissues, Blood Products and Gametes, 2 March 2012

### 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/mSre0zVqCMimUglSnKrOrRLqHPgNxwwF1rpnkjX0.pdf


### Drugs, Biologics, and Devices

#### Drugs

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

**Relevant Standards**

#### Devices

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

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

### Clinical Trials Registry

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

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

### AFRICA – Uganda

**NOTE:** For an overview of the clinical research regulations in Uganda, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=223

### 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

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/

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/

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

Privacy/Data Protection

Key Organizations
- Registrar General: http://www.rg.gov.zw/
- Zimbabwe National Statistics Agency: http://www.zimstat.co.zw/
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,or%20discl osure%20of%20personal%20information

Human Biological Materials

Key Organizations

▪ Research Council of Zimbabwe: www.rcz.ac.zw

Relevant Standards


▪ Various: http://www.rcz.ac.zw/research-registration/

Genetic Research

Key Organizations

▪ National Biotechnology Authority of Zimbabwe:  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
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

▪ National Health and Medical Research Council (NHMRC): http://www.nhmrc.gov.au/
▪ Australian Research Council (ARC): http://www.arc.gov.au
▪ Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS): http://aiatsis.gov.au/

Relevant Standards


Drugs, Biologics, and Devices

Drugs

Key Organizations

▪ Therapeutic Goods Administration (TGA): http://www.tga.gov.au

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

Embryos, Stem Cells, and Cloning

Key Organizations


Relevant Standards


ASIA/PACIFIC – Bangladesh

General

Key Organizations

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

Relevant Standards

- Ethical Guidelines for Conducting Research Studies Involving Human Subjects: [https://www.bmrcbd.org/application_form/EthicalGideline](https://www.bmrcbd.org/application_form/EthicalGideline)
- Standard Operating Procedures (SOPs): [https://www.bmrcbd.org/application_form/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**
• Guideline for HIV Vaccine Research Technology (2003)
• Interim Guidelines on International Multi-Regional Drug Clinical Trials (2015)

Devices

Key Organizations

• National Medical Products Administration: http://www.nmpa.gov.cn

Relevant Standards

• Regulations on the Supervision and Administration of Medical Devices (revised 2017): http://www.nmpa.gov.cn/WS04/CL2076/331389.html
• Amendment of Measures for the Registration and Administration of In Vitro Diagnostic Reagents (updated Art.20 in 2017): http://www.nmpa.gov.cn/WS04/CL2077/300690.html
• 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
- Chinese Clinical Trial Registry: http://www.chictr.org.cn/enIndex.aspx

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

Relevant Standards

Research Injury

Key Organizations
- National Medical Products Administration: http://www.nmpa.gov.cn
International Compilation of Human Research Standards 2021 Edition

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)


Last Updated: November 2021


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

**Relevant Standards**
CDSCO, New Drugs and Clinical Trials Rules (2019): 

CDSCO, Good Clinical Practice Guidelines for Clinical Research in India (2001): 

ICMR, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 7 (2017): 

### Devices

**Key Organizations**

- Central Drugs Standard Control Organization, Office of Drugs Controller General of India (DCGI): 
  https://cdsco.gov.in/opencms/opencms/en/Home/

- 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)

- ICMR, National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 7.7 (2017): 

### 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**

- Central Drugs Standard Control Organization (CDSCO): 
  https://cdsco.gov.in/opencms/opencms/en/Home/

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

**Relevant Standards**

- CDSCO, New Drugs and Clinical Trials Rules (2019): 

- ICMR, National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 2.6 (2017): 
## Social-Behavioral Research

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

**Relevant Standards**

## 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): [https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)

## 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

## 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)
Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- DBT, Biosafety Programme, Guidelines, Rules, and Regulations: [https://dbtindia.gov.in/regulations-guidelines/regulations/biosafety-programme](https://dbtindia.gov.in/regulations-guidelines/regulations/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](http://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
- Genome editing technology: https://www.lifescience.mext.go.jp/bioethics/anzen.html#chiryo

### Embryos, Stem Cells, and Cloning

#### Key Organizations

#### Relevant Standards
▪ Rules for Enforcement of Act on Safety of Regenerative Medicine (2018): [https://www.mhlw.go.jp/content/000452630.pdf](https://www.mhlw.go.jp/content/000452630.pdf)
▪ Fundamental Philosophy on Handling of Human Embryo (2004)

**ASIA/PACIFIC – Kazakhstan**

*NOTE: For an overview of human subject protections in Kazakhstan, see “Ethical Review of Biomedical Research in the CIS Countries,” Chapter 3, Section 5:

**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 04.08.1998r. (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

Relevant Standards

Privacy/Data Protection

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

ASIA/PACIFIC – Malaysia

General

Key Organizations

Relevant Standards
International Compilation of Human Research Standards
2021 Edition

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

**Drugs, Biologics, and Devices**

**Key Organizations**

- Ministry of Health Malaysia, National Pharmaceutical Regulatory Agency (NPRA):
- 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**
- National Medical Research Register (NMRR): [https://nmrr.gov.my/](https://nmrr.gov.my/)

**Relevant Standards**

### Research Injury

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

**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
- Act 709: Personal Data Protection Act (2010): Section 38, 39 and 40

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

Drugs, Biologics, and Devices

Key Organizations
- Ministry of Health, Food and Drug Administration: http://www.fdamyanmar.gov.mm/

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/

General

Key Organizations
- Health Research Council (HRC) Ethics Committee: http://www.hrc.govt.nz/
Ministry of Health (MOH): http://www.moh.govt.nz/
Health and Disability Commissioner (HDC): http://www.hdc.org.nz/
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)
International Compilation of Human Research Standards
2021 Edition

- Human Tissue Act 2008

### Genetic Research

**Key Organizations**
- Environmental Protection Authority: [http://www.epa.govt.nz/](http://www.epa.govt.nz/)

**Relevant Standards**

### Embryos, Stem Cells, and Cloning

**Key Organizations**

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

### ASIA/PACIFIC – Pakistan

#### General

**Key Organizations**

**Relevant Standards**

#### Drugs, Biologics, and Devices

**Key Organizations**

**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, Guidelines: Regulation of Clinical Trials in the Philippines: http://www.pcrp.org.ph/pdf/GuidelinesversionLR_PDF
- 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/

Relevant Standards

- FDA, Guidelines: Regulation of Clinical Trials in the Philippines: http://www.pcrp.org.ph/pdf/GuidelinesversionLR_PDF

Clinical Trial Registries

Key Organizations

- Philippine Health Research Registry: http://registry.healthresearch.ph/

Relevant Standards

- PHREB, National Ethical Guidelines for Health and Health-Related Research: https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4

Research Injury

Key Organizations

- Department of Science and Technology (DOST): http://www.dost.gov.ph/
- Philippine Health Research Ethics Board (PHREB): www.ethics.healthresearch.ph

Relevant Standards

- PHREB, National Ethical Guidelines for Health and Health-Related Research: https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4

Social-Behavioral Research

Key Organizations

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


Relevant Standards


Drugs, Biologics, and Devices

Drugs

Key Organizations

- Health Sciences Authority of Singapore (HSA): https://www.hsa.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
- 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
- Regulation on Medical Device Re-examination No. 2020-29 (2020.05.01): https://www.law.go.kr/행정규칙/의료기기재심사에관한규정/(2020-29,20200501)

**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**
International Compilation of Human Research Standards
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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/eng/a01/engMain.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 (2020.02.04):

▪ 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):

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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&srchFrm=&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
International Compilation of Human Research Standards
2021 Edition


### Relevant Standards


### Embryos, Stem Cells, and Cloning

### Key Organizations


### Relevant Standards

ASIA/PACIFIC – Sri Lanka

Drugs, Biologics, and Devices

Key Organizations


Relevant Standards


Clinical Trials Registries

Key Organizations

- Sri Lanka Clinical Trials Registry: https://slctr.lk/

Relevant Standards

- FAQs: http://slctr.lk/faq

ASIA/PACIFIC – Taiwan

General

Key Organizations


Relevant Standards

Drugs, Biologics, and Devices

Key Organizations
- Taiwan Food and Drug Administration (FDA): 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/

Relevant Standards

Social-Behavioral Research

Key Organizations

Relevant Standards

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Privacy/Data Protection

**Key Organizations**
- Ministry of Justice: https://www.moj.gov.tw/2832/

**Relevant Standards**

Human Biological Materials

**Key Organizations**

**Relevant Standards**

Genetic Research

**Key Organizations**
- Food and Drug Administration (FDA): https://www.fda.gov.tw/ENG/
- Ministry of Science and Technology: https://www.most.gov.tw/en/public

**Relevant Standards**

Embryos, Stem Cells, and Cloning

Key Organizations

Relevant Standards

ASIA/PACIFIC – Tajikistan


General

Key Organizations
- Ministry of Public Health: http://www.health.tj/

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

General

Key Organizations
- Medical Council of Thailand (MCT): http://www.tmc.or.th/en_home.php

Relevant Standards

Last Updated: November 2021
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**

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ASIA/PACIFIC – Uzbekistan

Key Organizations
- Ministry of Health: 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
- 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/
- 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 – Regionwide

General


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

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

Drugs, Biologics, and Devices

Drugs


### Devices


### Clinical Trial Registries

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

▪ FAQs: [https://www.clinicaltrialsregister.eu/doc/EU_CTR_FAQ.pdf](https://www.clinicaltrialsregister.eu/doc/EU_CTR_FAQ.pdf)

### Research Injury


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


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- 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

- Transfers of Personal Data to Third Countries: Applying Articles 25 and 26 of the EU Data Protection Directive (1998):

  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):


- European Medicines Agency policy on publication of clinical data for medicinal products for human use:


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

- Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981):
- Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (2018): https://rm.coe.int/16808ae918

**Human Biological Materials**


Council of Europe, Bioethics Unit: 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

**Genetic Research**


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

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- 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](https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016806b2c5f)

### Embryos, Stem Cells, and Cloning

**European Commission, European Group on Ethics in Science and New Technologies:**

- Statements by the Commission Re: Article 6 (2006): [http://www.uv.es/operuv/docs_7pm/FP7ECStatementsComm_Ethical.pdf](http://www.uv.es/operuv/docs_7pm/FP7ECStatementsComm_Ethical.pdf)

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

- Statement on Genome Editing Technologies by the Committee on Bioethics (2015): [https://rm.coe.int/168049034a](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/](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](http://www.bmg.gv.at)
- Forum of Austrian Ethics Committees: [http://www.ethikkommissionen.at](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](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](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:
Drugs, Biologics, and Devices

Key Organizations


Relevant Standards


Research Injury

Key Organizations


Relevant Standards

**Privacy/Data Protection**

**Key Organizations**
- Belgian Data Protection Authority: [https://www.dataprotectionauthority.be/](https://www.dataprotectionauthority.be/)

**Relevant Standards**
- Act on the Protection of Natural Persons with Regard to the Processing of Personal Data (30 July 2018)

**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](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


**EUROPE – Bosnia and Herzegovina**

### General

#### Federation of Bosnia and Herzegovina

**Key Organization**

▪ Agency for drugs and medical devices of Bosnia and Herzegovina: http://www.almbih.gov.ba/

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

#### Relevant Standards


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


▪ Other documents: http://www.almbih.gov.ba/dokumenti/

#### Republic of Srpska

**Key Organization**

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

### Drugs, Biologics, and Devices

#### Federation of Bosnia and Herzegovina

**Key Organizations**

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

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

#### Relevant Standards

▪ 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 Changes and Amendments of Law on Drugs No. 34/08

**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**

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

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

Relevant Standards

Republic of Srpska

Key Organizations

Relevant Standards
- Rulebook about Testing Procedure for Donor of Transplant Organs in Terms of Diseases Which can be Transmitted by Transplantation (2010): http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/%d0%9f%d1%80%d0%b0%d0%b2%d0%b3%d0%bd%d0%b8%d0%ba_%d0%be%d0%ba%d1%80%d0%b8%d1%82%d0%b5%d1%80%d0%b8%d1%81%d1%82%d0%b8%d0%b7%d0%b0%d1%82%d0%b5%d1%81%d1%82%d0%b8%d1%80%d0%b0%d1%9a%d0%b5_%d0%b4%d0%b0%d0%b2%d0%b0%d0%bb%d0%b0%d1%86%d0%b4%d0%b2%d0%ba%d0%b8%d0%b2%d0%be%d1%80%d0%b3%d0%b0%d0%bd%d0%b0_64_10.pdf

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

**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/%D0%9D%D0%90%D0%A0%D0%95%D0%94%D0%91%D0%90%20E2%84%96%2031%20%D0%9E%D0%A2%2012%20%D0%90%D0%92%D0%93%D0%A3%D0%A1%D0%A2%202007%20%D0%93.pdf](https://www.bda.bg/images/stories/documents/regulations/naredbi/20210415/%D0%9D%D0%90%D0%A0%D0%95%D0%94%D0%91%D0%90%20E2%84%96%2031%20%D0%9E%D0%A2%2012%20%D0%90%D0%92%D0%93%D0%A3%D0%A1%D0%A2%202007%20%D0%93.pdf)

**Research Injury**

**Key Organizations**

**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/%D0%9D%D0%90%D0%A0%D0%95%D0%94%D0%91%D0%90%20%20E2%84%96%2031%20%D0%9E%D0%A2%2012%20%D0%90%D0%92%D0%93%D0%A3%D0%A1%D0%A2%202007%20%D0%93.pdf](https://www.bda.bg/images/stories/documents/regulations/naredbi/20210415/%D0%9D%D0%90%D0%A0%D0%95%D0%94%D0%91%D0%90%20%20E2%84%96%2031%20%D0%9E%D0%A2%2012%20%D0%90%D0%92%D0%93%D0%A3%D0%A1%D0%A2%202007%20%D0%93.pdf)

**Privacy/Data Protection**

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

**Relevant Standards**
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**

- 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**

- Patient Protection Act, Article 20 (2008): [http://www.zakon.hr/z/255/Zakon-o-za%C5%A1titii-prava-pacijenata](http://www.zakon.hr/z/255/Zakon-o-za%C5%A1titii-prava-pacijenata)

### Drugs, Biologics, and Devices

**Drugs**

**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**


**Devices**

**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


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/arhiva-80/zakonodavstvo/zakoni-i-pravilnici/pravilnici/pravilnici-zakon-o-lijekovima/1061](https://zdravlje.gov.hr/arhiva-80/zakonodavstvo/zakoni-i-pravilnici/pravilnici/pravilnici-zakon-o-lijekovima/1061)

Privacy/Data Protection

Key Organizations

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

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Relevant Standards

- General (2018): http://azop.hr/info-servis/detaljnije/smjernice

Human Biological Materials

Key Organizations

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

Relevant Standards

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

Genetic Research

Key Organizations

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards


**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: http://www.dataprotection.gov.cy/dataprotection/dataprotection.nsf/home_el/home_el?opendocument#:~:text=The%20Commissioner%20for%20personal%20data,processing%20of%20their%20personal%20data

Relevant Standards
- 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/DE97F6F59835A03AC225822DD03D895E/$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/

**Research Injury**

**Relevant Standards**

**Privacy/Data Protection**

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

**Relevant Standards**

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### Embryos, Stem Cells, and Cloning

**Key Organizations**

**Relevant Standards**

### EUROPE – Denmark

**General**

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

**Relevant Standards**

### Drugs, Biologics, and Devices

**Key Organizations**
- Committees on Medicine Research Ethics (VMK): [https://www.dvmk.dk/](https://www.dvmk.dk/)
- Danish Medicines Agency: [https://laegemiddelstyrelsen.dk/en/](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/a/2021/965](https://www.retsinformation.dk/eli/lt/a/2021/965)

### 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/2021/965](https://www.retsinformation.dk/eli/lt/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-9fb0-8fabec8f4a62](https://www.retsinformation.dk/Forms/R0710.aspx?id=210110#id56770dec-1ec6-44de-9fb0-8fabec8f4a62)

### Human Biological Materials

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

- Minister of Social Affairs (MSA): [https://www.sm.ee/en](https://www.sm.ee/en)

Relevant Standards

- 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](https://www.sm.ee/en)
- Estonian Health Insurance Fund: [https://www.haigekassa.ee/en](https://www.haigekassa.ee/en)

Relevant Standards


Privacy/Data Protection

Key Organizations


Relevant Standards

### International Data Transfer (2018)


### 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


Drugs, Biologics, and Devices

Drugs

Key Organizations

- 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
Decree on Fees, No. 1171/2020: https://tukija.fi/documents/1481661/0/Maksuasetus+20201171+(3).pdf/e7e9de90-f06f-47b3-98ee-e3beb7253d87/Maksuasetus+20201171+(3).pdf?t=161002422691

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-asiarjamallit

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


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

### Drugs, Biologics, and Devices

**Key Organizations**
- National Health Products Safety Agency (ANSM): http://ansm.sante.fr/

**Relevant Standards**
- Medications for Human Use, Articles 5111-1 and Subsequent Sections for Drugs and Medical Devices: https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665
- CCNE, various: http://www.ccne-ethique.fr/en/type_publication/avis

### Social-Behavioral Research

**Key Organizations**
- National Consultative Ethics Committee

**Relevant Standards**

### Privacy/Data Protection

**Key Organizations**

**Relevant Standards**


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

### 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;jsessionid=D2DE023194483D3384DE19DE8959BDDA.tpdjio17v_3?idSectionTA=LEGISCTA0000006136513&cidTexte=LEGITEXT000006070721&dateTexte=20131006
Embryos, Stem Cells, and Cloning

Key Organizations

Relevant Standards

EUROPE – Georgia


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

- Promulagation on the Principles of the Conduct of Clinical Trials of Drugs According to the Rules (1987)
- Second Promulagation 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**
- Federal Commissioner for Data Protection and Freedom of Information: [https://www.bfdi.bund.de/EN/](https://www.bfdi.bund.de/EN/)
- Datenschutzkonferenz (DSK): [https://www.datenschutzkonferenz-online.de/](https://www.datenschutzkonferenz-online.de/)

**Relevant Standards**
- DSK, Short Paper No. 4: Data Transmission to Third Countries: [https://www.datenschutzkonferenz-online.de/media/kp/dsk_kpnr_4.pdf](https://www.datenschutzkonferenz-online.de/media/kp/dsk_kpnr_4.pdf)

**Human Biological Materials**

**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**
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

General

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

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

Relevant Standards

- Greek Constitution 1975/1986/2001 Article 9.1
- Act 2619/98 (Biomedicine Convention of the Council of Europe) (1998)
- Act 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
- Recommendation on Banks of Biological Material of Human Origin (Biobanks) in Biomedical Research:
- Recommendation on the Collection and Use of Genetic Data:
- Opinion on Prenatal and Pre-Implantation Diagnosis and Embryo Treatment:
- Opinion on Direct-To-Consumer Genetic Testing (2012):
- Opinion on Incidental Findings in Research and Clinical Practice (2015):
- Opinion on Advances in Human Genome Editing (2016):

Embryos, Stem Cells, and Cloning

Key Organizations

- National Authority for Medically Assisted Reproduction

Relevant Standards

- Act 3305/2005 Application of Medically Assisted Reproduction

EUROPE – Hungary

General

Key Organization

- Medical Research Council, Research Ethics Committees (KFEB, TUKEB, HRB):

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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&celparam=##xcelparam
- 1997 CLIV. Law, Healthcare, Chapters VIII and IX: http://njt.hu/cgi_bin/njt_doc.cgi?docid=30903.339193

Drugs, Biologics, and Devices

Drugs

Key Organizations

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

Relevant Standards

Clinical Trials:

- Act XCV of 2005 on Medicinal Products for Human Use, Section 3: https://net.jogtar.hu/jogszabaly?docid=A0500095.TV&searchUrl=/gyorskereso%3Fextraparams%3D%7B%2522Year%2522%3A%25222005%2522%2C%2522%252C%2522SerialNumber%2522%3A%252295%2522%2C%2522%2522ID%2522%3A%2522FullTextSearch%2522%7D
Non-Interventional Trials:
- Act CLIV of 1997 on Health Care, Chapter VIII, Section 164/A: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV
- Act CLIV of 1997 on Health Care, Chapter VIII, Section 159: http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700154.TV

Devices

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

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

Clinical Trials:

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

Research Injury

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

Relevant Standards
- Register of clinical trials: https://ogyei.gov.hu/klinikai_vizsgalatokNyilvantartasa

Privacy/Data Protection

Key Organizations
- National Institute of Pharmacy and Nutrition: http://www.ogyei.gov.hu
Relevant Standards

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

Human Biological Materials

Key Organizations

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

Relevant Standards

- Act XLVII of 1997 on the Handling of Medical and Other Related Data:
  http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99700047.TV&celpara=#xcelparam

- Act CXII of 2011 on Right of Informational Self-Determination and Freedom of Information:
  http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A1100112.TV&celpara=#xcelparam


- Preparing to Apply the Privacy Policy in 12 Steps: Guidance for Data Controllers and Data Processors (2018):
  http://www.naih.hu/felkeszueles-az-adatvedelmi-rendelet-alkalmazasara.html

Genetic Research

Key Organizations

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- Act LXXX of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Transplantation of Organs and Tissues of Human Origin:
  http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0600080.TV&celpara=#xcelparam

- Decree 18/1998 (XII 27) EüM on Implementing Act CLIV of 1997 on Health Care as Regards Transplantation and Storage of Organs and Tissues and Certain Histopathology Examinations:
  http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam

EUROPE – Iceland

General

Key Organization

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

- Act on Scientific Research in the Health Sector No. 44/2014:
  https://www.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.reglugerdir.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=c50d676c-4651-46c2-83b5-ad946f3deeaa
- Regulation on In Vitro Diagnostic Medical Devices No. 936/2011:
  http://stjornartidindi.is/Advert.aspx?ID=f20b3e4e-ab25-44d3-8e32-e5f42a7b02f0

Research Injury

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

Relevant Standards
  https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Act-on-Patient-Insurance-as-amended.pdf
- Act on Health Insurance No. 112/2008 (2012):
- Regulation on Clinical Trials of Medicinal Products in Humans No. 443/2004 (2010):

Privacy/Data Protection

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

Relevant Standards
- Act No. 90/2018 on Data Protection and the Processing of Personal Data:

Human Biological Materials

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

Relevant Standards
- Regulations on the Keeping and Utilization of Biological Samples in Biobanks No. 1146/2010:
  https://www.reglugerdir.is/reglugerdir/eftir-raduneytum/heilbrigdisraduneyti/nr/16910
- NBC, Access to and Utilisation of Health Data and Bio-Samples:
  http://www.vsn.is/en/content/access-and-utilisation-health-data-and-bio-samples
- NBC, Biobanks: http://www.vsn.is/en/content/biobanks
**Embryos, Stem Cells, and Cloning**

**Relevant Standards**

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

**EUROPE – Ireland**

**General**

**Key Organization**


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**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.hpra.ie/

Relevant Standards

Genetic Research

Key Organizations
- Health Products and Regulatory Authority: https://www.hpra.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**

**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**

**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](https://www.garanteprivacy.it/home/doveri#2)

**Genetic Research**

**Key Organizations**
- Instituto Superiore di Sanita (ISS): [https://www.iss.it/](https://www.iss.it/)

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

**Embryos, Stem Cells, and Cloning**

**Relevant Standards**
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▪ Central Medical Ethics Committee

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Embryos, Stem Cells, and Cloning

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- Central Medical Ethics Committee

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EUROPE – Lithuania

General

Key Organization

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

Relevant Standards

- Changes of Law on Ethics of Biomedical Research No. 536/2014 (2017): 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/ILdhwknYPP
▪ V-28, Decree on the Detailed Requirements for the Content of a Person’s Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent (2018): https://www.e-tar.lt/portal/lt/legalAct/0f2f1b70b9db11e5a6588fb85a3cc84b/asr


▪ V-24, Decree on the Procedure for Submission of the Documents to the Lithuanian Bioethics Committee to Issue Favorable Opinion to Conduct a Clinical Trial on Medicinal Products or Approval to Conduct Biomedical Research by the Sponsor of the Clinical Trial on Medicinal Product or Other Type of Biomedical Research (2016): https://www.e-tar.lt/portal/lt/legalAct/3790a050be7e11e5a6588fb85a3cc84b

▪ V-4, Decree on the Request to Issue Approval to Conduct Biomedical Research, the Application Form and the Biomedical Research Ethical Assessment Form (2016): https://www.e-tar.lt/portal/legalAct/27a3460090f011e4bb408baba2bdddf3/UqgJXDRUqi

▪ Guidelines for Patient Information Sheet and Informed Consent Form, Adopted by the Group of Experts on Biomedical Research of the LBEC (2018): http://bioetika.sam.lt/get_file.php?file=bnNIV3pKeWhhWjJlcW1xZ2xxQnNrWlprbXM2VWtKbJ5Wlp1ekptZG1hV2V5c3JXbUdGa3lzR2NrNkJnab1pxVng2aVprR2ZIWk0yWG81ekxrMnlYY21tV3lwSEtvbWFJbkp4bWwceCUyQmNTZ2FljMjdUWThaeno4ZWltTIBHbWNlbmJzbVZ4SjJWYWFWHZW9HYW1tNmhlajVobmFwR1ZrbW1jbFdSd2xwdGxsR1pzbHB5WnlXQmdxRzZhWVoRmNKMXJuZyUzRCUzRA==&view=1

Drugs, Biologics, and Devices

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**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


Last Updated: November 2021

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/b65b5ca0c44011e583a295d9366c7ab3/qcrDrSCSCJ


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=bXNiVnpKV2hacDJkcXBPZ3ILQnhrY1prbXM1c2tHalJ5SmFlekpLZhc2VnI5c3JXeDJGa3lybWNscUNDy1oyVmxaxaHJrRIYmMzTG8yN0xtbTJaYTJ1VmlwSEIvcFdjblp4bGNweDVucFdxId6VGJNWNb6OHFqbk1mR29jYWlidFBlekp5bIIldWNvW1NjbjkHYtWtwZWVhYzVqMW1tMG5iaWN1cHVLLeDRLYnQ1VzNuWHVTaG1xS1puaVRAV2xobmladWwyEBsOVNjbTU3TWWyJTJCWmRKbyUzRA==&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/43db5e50d05f11e7910a89ac20768b0f

Clinical Trial Registries

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

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


### Embryos, Stem Cells, and Cloning

#### Key Organizations


#### 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](https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.302907)

### EUROPE – Luxembourg

#### General

- National Ethics Consultative Commission: [http://www.cne.lu](http://www.cne.lu)

#### 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

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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
GUIDANCE NOTES ON GOOD CLINICAL PRACTICE

Devices

Key Organizations
- Malta Competition and Consumer Affairs Authority, Technical Regulations Division: [https://mccaa.org.mt/Section/index?sectionId=1063](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/](https://idpc.org.mt/)

Relevant Standards

EUROPE – Moldova


General

Key Organization

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


LP143 Din 19.07.18, MO309-320/17.08.18 Article 482


Law on personal data protection (2011); The Law on enunciation of certain declarations to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data by the Republic of Moldova: https://datepersonale.md/en/legislation/national-legislation/law/

### Human Biological Materials

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

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

### Embryos, Stem Cells, and Cloning

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

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

### EUROPE – Montenegro

**Drugs, Biologics, and Devices**

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

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

- Various, Rulebooks:
  https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967358763502102&paramPut=Legislation++%3E++Rulebooks&paramRender=2&paramS=95&_adf.ctrl-state=ye0txrsh1_161

- Various, Decrees and Orders:
  https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967402452526204&paramPut=Legislation++%3E++Decrees+and+Orders&paramRender=2&paramS=98&_adf.ctrl-state=ye0txrsh1_195

- Various, Good Practice Guidelines:
  https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967427083926799&paramPut=Legislation++%3E++Good+Practice+guidelines&paramRender=2&paramS=99&_adf.ctrl-state=ye0txrsh1_229

- Forms, Medicines:
  https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967477611251621&paramPut=Legislation++%3E++Forms+%E2%80%93+Medicines&paramRender=2&paramS=62&_adf.ctrl-state=ye0txrsh1_297

- Forms, Devices:
  https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967525698520403&paramPut=Legislation++%3E++Forms++Medical+devices&paramRender=2&paramS=100&_adf.ctrl-state=ye0txrsh1_331

- Various, Instructions:
  https://www.cinmed.me/Portal/faces/dinamickeStrane?_afrLoop=967545352596410&paramPut=Legislation++%3E++Instructions&paramRender=2&paramS=96&_adf.ctrl-state=ye0txrsh1_365

Research Injury

Key Organizations

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

Relevant Standards

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

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

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### Human Biological Materials

**Key Organizations**

**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](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**

**Relevant Standards**

### Embryos, Stem Cells, and Cloning

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### EUROPE – Netherlands

**General**

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

CCMO, Decree of 2014 containing rules for compulsory insurance in medical research involving human subjects and explanatory memorandum:

### Social-Behavioral Research

**Key Organizations**

**Relevant Standards**
- CCMO, Memorandum Behavioural Research:
  https://english.ccmo.nl/investigators/publications/publications/2002/01/01/ccmo-memorandum-behavioural-research

### Privacy/Data Protection

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

**Relevant Standards**

### Human Biological Materials

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

**Relevant Standards**
- Civil Code, Article 467 (1994)
- Human Tissue and Medical Research: Code of Conduct for responsible use (2011):

### Genetic Research

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

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

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

Relevant Standards

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**


Organization of Health Research: https://lovdata.no/dokument/SF/forskrift/2009-07-01-955

Population-Based Health Survey: https://lovdata.no/dokument/SF/forskrift/2018-04-27-645

Right of Children Between 12-16 Years to Consent to Participate in Health Research: https://lovdata.no/dokument/SF/forskrift/2017-06-28-1000


Payment for Research Participants in Medical and Health Research (2009)


Drugs, Biologics, and Devices

Drugs

Key Organizations

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

Relevant Standards


Regulation Relating to Clinical Trials on Medicinal Products for Human Use (2009): http://lovdata.no/dokument/SF/forskrift/2009-10-30-1321?q=forskrift+om+kliniske+utpr%C3%B8vning

**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)

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**Research Injury**

**Key Organizations**

**Relevant Standards**

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

Relevant Standards

Devices

Key Organizations

Relevant Standards
- Regulation of the Minister of Health on Detailed Conditions to be Met for Clinical Evaluation of Medical Devices or Active Implantable Medical Devices (2011): http://prawo.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20110630331

Clinical Trial Registries

Key Organizations

Relevant Standards
- The Central Register of Clinical Trials: https://bkwp.pl/
Research Injury

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

Relevant Standards
- Order of the Minister of Finance Amending the Regulation Concerning the Mandatory Civil Liability Insurance of Researchers and Sponsors (2005): http://isap.sejm.gov.pl/DetailsServlet?id=WDU20051010845

Social-Behavioral Research

Key Organizations

Relevant Standards

Privacy/Data Protection

Key Organizations

Relevant Standards

Human Biological Materials

Key Organizations

Relevant Standards

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

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

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

Research Injury

Relevant Standards

Privacy/Data Protection

Key Organizations

Relevant Standards
- Constitution, Article 35 (1997)

FAQs: Consent (2018): [https://www.cnpd.pt/bin/faqs/faqs.htm#consentimento](https://www.cnpd.pt/bin/faqs/faqs.htm#consentimento)

### 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**

**Relevant Standards**

### Drugs, Biologics, and Devices

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

Relevant Standards

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

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

Relevant Standards
- Law No. 95/2006 Regarding the Reform in Health Field. Title VI. Performing of Sampling and Transplant of Organs, Tissues and Human Origin Cells with Therapeutic Purpose: http://legislatie.just.ro/Public/DetaliiDocument/71139

Genetic Research

Key Organizations

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

Embryos, Stem Cells, and Cloning

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

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

General

Key Organization
- 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**
- Medicines and Medical Devises Agency of Serbia: [https://www.alims.gov.rs/eng/](https://www.alims.gov.rs/eng/)

**Relevant Standards**
- Medicines and Medical Devises Agency of Serbia, Regulations: [https://www.alims.gov.rs/eng/regulations/](https://www.alims.gov.rs/eng/regulations/)

**Drugs, Biologics, and Devices**

**Key Organizations**
- Medicines and Medical Devises Agency of Serbia: [https://www.alims.gov.rs/eng/](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](https://www.alims.gov.rs/eng/files/2012/10/7-Rules-on-clinical-trials.pdf)

**Clinical Trial Registries**

**Key Organizations**
- Medicines and Medical Devises Agency of Serbia: [https://www.alims.gov.rs/eng/](https://www.alims.gov.rs/eng/)

**Relevant Standards**
- Search approved clinical trials: [https://www.alims.gov.rs/eng/medicina-products/search-for-the-approved-clinical-trials/](https://www.alims.gov.rs/eng/medicina-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_usl_ovljenih_anomalija_i_retkih_bolesti.html

Embryos, Stem Cells, and Cloning

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

Embryos, Stem Cells, and Cloning

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

EUROPE – Slovenia

General

Key Organization
- 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
Drugs, Biologics, and Devices

Drugs

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

Relevant Standards
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: [https://www.jazmp.si/en/](https://www.jazmp.si/en/)

Devices

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

Relevant Standards
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: [https://www.jazmp.si/en/](https://www.jazmp.si/en/)

Clinical Trial Registries

Key Organizations
- Agency for Medicinal Products and Medical Devices of the Republic of Slovenia: [https://www.jazmp.si/en/](https://www.jazmp.si/en/)
Research Injury

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

Relevant Standards
- Medical devices Act Official Gazette No. 98/2009: [http://www.pisrs.si/Pis.web(pregledPredpisa?id=ZAKO5503](http://www.pisrs.si/Pis.web(pregledPredpisa?id=ZAKO5503)
- 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](http://pisrs.si/Pis.web(pregledPredpisa?id=URED3728)
- Rules on Clinical Testing of Medicinal Products, Official Gazette, No. 54/2006 and 17/2014: [http://www.pisrs.si/Pis.web(pregledPredpisa?id=PRAV6611](http://www.pisrs.si/Pis.web(pregledPredpisa?id=PRAV6611)
- Rules on Medical Devices, Official Gazette Nos. 37/2010 and 66/2012: [http://www.pisrs.si/Pis.web(pregledPredpisa?id=PRAV9508](http://www.pisrs.si/Pis.web(pregledPredpisa?id=PRAV9508)

Social-Behavioral Research

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

Privacy/Data Protection

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

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

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

- Coordinating Center for Ethical Committees on Clinical Research (Spanish): [http://www.msc.es/profesionales/farmacia/ceic/home.htm](http://www.msc.es/profesionales/farmacia/ceic/home.htm)
- Ministry of Science and Innovation [https://ciencia.sede.gob.es/](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/](https://www.aemps.gob.es/)

**Relevant Standards**


Devices

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

Relevant Standards
- 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
- 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
- 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.catedraderechogenomahumano.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.catedraderechogenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf

Embryos, Stem Cells, and Cloning

Key Organizations
- Spanish Bioethics Committee: http://www.comitedebioetica.es/?lang=en_US
Commission for the Donation and Use of Human Cells and Tissues: [https://www.isciii.es/QueHacemos/Servicios/ComitesEtica/ComisionGarantias/Paginas/FuncionesComposicion.aspx](https://www.isciii.es/QueHacemos/Servicios/ComitesEtica/ComisionGarantias/Paginas/FuncionesComposicion.aspx)

National Biobank Network: [https://redbiobancos.es/](https://redbiobancos.es/)

National Bank of Cell Lines: [https://www.isciii.es/QueHacemos/Servicios/BIOBANCOS/BNLC/Paginas/default.aspx](https://www.isciii.es/QueHacemos/Servicios/BIOBANCOS/BNLC/Paginas/default.aspx)

**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/](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](https://www.codex.uu.se/?languageId=1)*

**General**

**Key Organization**

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

**Relevant Standards**

Drugs, Biologics, and Devices

**Drugs**

**Key Organizations**
- Medical Products Agency: [https://lakemedelsverket.se/english/](https://lakemedelsverket.se/english/)

**Relevant Standards**
- Pharmaceuticals Act No. No. 2015:315: [https://open.karnovgroup.se/halso-och-sjukvard/lakemedelslagen](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](http://www.vr.se/english)

**Relevant Standards**

Privacy/Data Protection

**Key Organizations**
- Swedish Authority for Privacy Protection: [https://www.imy.se/en/](https://www.imy.se/en/)

**Relevant Standards**

**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**
Embryos, Stem Cells, and Cloning

Key Organizations


Relevant Standards


EUROPE – Switzerland

General

Key Organization

- Swiss Association of Research Ethics Committees: [https://swissethics.ch/en/](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

▪ Federal Data Protection and Information Commissioner (FDPIC):

Relevant Standards

▪ Federal Act of 19 June 1992 on Data Protection (FADP), RS 235.1:

▪ Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 2, 3, 8, 16-18, 31-35, 41-45, 47, 49, 58-60, and 63:

▪ Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301, Articles 5 - 8, 10, 15, 21, 24-34, 37-39, 41, and 44-45, and Annex 2:

▪ 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:

### Human Biological Materials

Key Organizations


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

Relevant Standards

▪ Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), RS 810.30, Articles 2, 3, 17, 18, 31, 32 - 35, 41-43, 45, 47, 49, and 63:

▪ Ordinance of 14 February 2007 on Human Genetic Testing, RS 810.122.1:

▪ Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), RS 810.301 Articles 5 - 8, 10, 15, 21, 24-30, 33-34, 37 - 39, 41, 44-45 and Annex 2:

▪ Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, CLinO), RS 810.305, Articles 7, 9, 12, 16 - 18 and Annex 2:

### Genetic Research

Key Organizations


Relevant Standards

▪ Federal Constitution of the Swiss Confederation of 18 April 1999, RS 101, Article 119:

▪ Federal Act of 8 October 2004 on Human Genetic Testing (HGTA), RS 810.12:
### Embryos, Stem Cells, and Cloning

**Key Organizations**

**Relevant Standards**
- Pre-Implantation Genetic Diagnosis II, Opinion No. 14/2007: [https://www.nek-cne.admin.ch/inhalte/Themen/Stellungnahmen/PID_II_d.pdf](https://www.nek-cne.admin.ch/inhalte/Themen/Stellungnahmen/PID_II_d.pdf)

### EUROPE – Ukraine

#### General

**Key Organization**
Relevant Standards

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

Drugs, Biologics, and Devices

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

Relevant Standards

- Ministry of Health Act on Procedure of Clinical Trials and Basic Statute of Ethics Commission 23.09/2009 No. 690: https://zakon.rada.gov.ua/laws/show/z1010-09#n16
- Preclinical studies, various laws: https://www.dec.gov.ua/materials/doklinichni-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

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

Relevant Standards

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

Embryos, Stem Cells, and Cloning

Key Organizations

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

Relevant Standards

- To search all documents in the Ukraine Legislation database visit: https://zakon.rada.gov.ua/laws/main/ay2021
- 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
- Department of Health and Social Care (DHSC):
- 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
- Health and Safety Executive (HSE): http://www.hse.gov.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/


Devices

Key Organizations

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

Relevant Standards

- Clinical Trials for Medical Devices: https://www.gov.uk/government/collections/regulatory-guidance-for-medical-devices
- Notify MHRA About a Clinical Investigation for a Medical Device: https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device

Clinical Trial Registries

Key Organizations

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

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

Research Injury

Key Organizations


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

International Compilation of Human Research Standards
2021 Edition

- 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
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


**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

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

Relevant Standards

LATIN AMERICA AND THE CARIBBEAN – Bermuda

General

Key Organization
- Department of 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/
- 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)
Drugs, Biologics, and Devices

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

Relevant Standards
- National Norms, various: 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

LATIN AMERICA AND THE CARIBBEAN – Brazil

NOTE: For an overview of clinical research regulations in Brazil, see the ClinRegs report: http://clinregs.niaid.nih.gov/single_country.php?c_id=30

General

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

Relevant Standards
- Resolution CNS No. 370/07 on Registration and Accreditation or Renewal of Registration and Accreditation of CEP: http://conselho.saude.gov.br/resolucoes/2007/Reso370.doc
Resolution CNS No. 466/2012 on Guidelines and Rules for Research Involving humans Subjects:

Resolution CNS No. 506/2016 Accreditation of CEP:

Resolution CNS No. 563/2017 on Research Participant's Right in Ultra-rare Diseases:

Resolution CNS No. 580/2018 on Research of Strategic Interest for the Unified Health System (SUS):

Operating Normative 001/2013 Organization and Operation of CEP/CONEP System:

Various: http://plataformabrasil.saude.gov.br/login.jsf

Drugs and Biologics

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

Relevant Standards
- Law No. 9782/99 Defining the National Health Surveillance System:
  http://www.planalto.gov.br/ccivil_03/leis/L9782.htm
- Resolution CNS No. 251/1997: On Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests:
- Resolution CNS No. 301, 16th March 2002: Regarding Placebos:
- Resolution CFM No. 1.885, 2008 – about placebo:
- Resolution ANVISA 09/15 - Regulations for Clinical Trials with Drugs:
- Resolution RDC No. 9, 20 February 2015 Regarding Regulation for Realization of Clinical Trials of Medication in Brazil:
- Resolution RDC No. 506 of 05/26/2021, revoking RDC No. 260 of December 21, 2018 and RDC No. 453 of December 17, 2020:
  http://antigo.anvisa.gov.br/documents/10181/6278627/RDC_506_2021_.pdf/e932e631-4040-4014-9a4a-9813474e44a4


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_18FYGiAB05F_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%2CBA-33-de-02-de-agosto-de-2021?redirect=http%3A%2F%2Fctnbio.mctic.gov.br%2Fresolucoes-normativas%3Fp_id%3D101_INSTANCE_OgW431Rs9dQ6%26p_lifecycle%3D0%26p_state%3Dnormal%26p_mode%3Dview%26p_col_id%3Dcolumn-2%26p_col_count%3D3

### Embryos, Stem Cells, and Cloning

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

#### 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 cannot be included 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)
- Supreme Decree No. 30/2013, modifying Decree No. 114 of 2010 and Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning Official Diary January 14, 2013: [http://www.leychile.cl/Navegar?idNorma=1048008](http://www.leychile.cl/Navegar?idNorma=1048008)

### 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**


### Research Injury

#### 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

### Privacy/Data Protection

#### Key Organizations
- Ministry of Health: [http://www.minsal.cl](http://www.minsal.cl)
- Ministry of the Secretary General of the Government: [http://www.msgg.gob.cl](http://www.msgg.gob.cl)

#### Relevant Standards

### Genetic Research

#### Key Organizations
- Ministry of Health: [http://www.minsal.cl](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

▪ National Institute of Drug and Food Surveillance (INVIMA): http://www.invima.gov.co/

Relevant Standards


▪ 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/9b129f5-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=resolucion+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_de_%C3%A9tica_en_investigaci%C3%B3n_Octubre2015.pdf/1c5049a4-e2c2-6825-1aff-811b09c61e3f


■ 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-c2a3-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

▪ National Institute of Drug and Food Surveillance: http://www.invima.gov.co/

Relevant Standards


Research Injury

Key Organizations

▪ Ministry of Health and Social Protection: 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

Relevant Standards


Human Biological Materials

**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**

Genetic Research

**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**

LATIN AMERICA AND THE CARIBBEAN – Costa Rica

**General**

**Key Organization**
- Ministry of Health: [https://www.ministeriodesalud.go.cr/](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](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/](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://rpecc.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**


**LATIN AMERICA AND THE CARIBBEAN – Ecuador**

**General**

**Key Organization**


**Relevant Standards**

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

**Drugs, Biologics, and Devices**

**Key Organizations**

- National Health Agency for Regulation, Control, and Oversight: [http://www.controlsanitario.gob.ec/ensayos-clinicos](http://www.controlsanitario.gob.ec/ensayos-clinicos)
Relevant Standards

- Approval of Clinical Trials: [https://www.controlsanitario.gob.ec/ensayos-clinicos/](https://www.controlsanitario.gob.ec/ensayos-clinicos/)

Privacy/Data Protection

Key Organizations


Relevant Standards

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

Human Biological Materials

Key Organizations


Relevant Standards

- 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%B3ticas..pdf](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%B3ticas..pdf)

Genetic Research

Key Organizations

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


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


Relevant Standards


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

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

General

Key Organization

- Ministry of Health: https://www.gob.mx/salud
- General Health Council: http://www.csg.gob.mx/
- Federal Commission for Protection Against Health Risks (Cofepris): https://www.gob.mx/cofepris

Relevant Standards

International Compilation of Human Research Standards
2021 Edition

▪ Agreement establishing reforms to the general dispositions on integration and operation of Research Ethics Committees (REC), as well as the health establishments that require a REC, in compliance with criteria set forth by the National Bioethics Commission (2012): https://www.dof.gob.mx/nota_detalle.php?codigo=5607368&fecha=10/12/2020

Drugs, Biologics, and Devices

Relevant Standards

Privacy/Data Protection

Key Organizations
▪ Federal Institute on Access to Public Information: www.inai.org.mx/

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
- Law of Medicines and Pharmacies, No. 292:
- Normative-064, Standard for the registration of medical devices:
  [http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Notativa-064%E2%80%9CNorma-para-el-registro-de-dispositivos-m%C3%A9dicos%E2%80%9D/](http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Notativa-064%E2%80%9CNorma-para-el-registro-de-dispositivos-m%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-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-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 (OGITT): 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

- Decree 189/998, Application of International Agreements for the Regulation of Good Clinical Practices in Pharmaceutical Research:

Drugs, Biologics, and Devices

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

Relevant Standards

- Decree 189/998, Application of International Agreements for the Regulation of Good Clinical Practices in Pharmaceutical Research:

Research Injury

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

Relevant Standards

- Decree 189/998, Application of International Agreements for the Regulation of Good Clinical Practices in Pharmaceutical Research:

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/

**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%D9%88%D8%A7%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%D9%88%D8%82%D8%A7%D8%B1%D9%8A%D8%A9/

MIDDLE EAST/NORTH AFRICA – Iran

**General**

**Key Organization**
- Ministry of Health and Medical Education: https://behdasht.gov.ir/

**Relevant Standards**
- Protection Code for Human Subjects in Medical Research (1999)

**Clinical Trial Registries**

**Key Organization**
- Iranian Registry of Clinical Trials: http://www.irct.ir/
MIDDLE EAST/NORTH AFRICA – Israel

General

Key Organization
▪ Ministry of Health: http://www.health.gov.il/english/

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

Relevant Standards
▪ Public Health Order (1940)
▪ Public Health Regulations (Clinical Studies in Human Subjects) (1980) (as subsequently amended)

Privacy/Data Protection

Key Organizations
▪ The Privacy Protection Authority: https://www.gov.il/en/departments/the_privacy_protection_authority/govil-landing-page

Relevant Standards

Genetic Research

Key Organizations
▪ Ministry of Health: http://www.health.gov.il/english/

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](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%A9.pdf](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%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**


Last Updated: November 2021
Relevant Standards
- Ethical Guidelines for Biomedical Research

MIDDLE EAST/NORTH AFRICA – Qatar

General

Key Organization

Relevant Standards

Human Biological Materials

Key Organizations

Relevant Standards

Genetic Research

Key Organizations
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**

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

### Drugs, Biologics, and Devices

**Key Organization**

**Relevant Standards**

### Human Biological Materials

**Key Organizations**
- 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](http://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

- Ministry of Health (Turkish): http://www.saglik.gov.tr/

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
- Clinical Research Association (CRA): www.klinikarastirmalar.org
- Ministry of Health (MoH): http://www.saglik.gov.tr/

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
- 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/

Relevant Standards
- Personal Data Protection Law: https://www.kvkk.gov.tr/Icerik/6649/Personal-Data-Protection-Law

Human Biological Materials

Key Organizations
- Ministry of Health (Turkish): http://www.saglik.gov.tr/

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
- Ministry of Health (Turkish): http://www.saglik.gov.tr/

Relevant Standards

Embryos, Stem Cells, and Cloning

Key Organizations
- Ministry of Health (Turkish): http://www.saglik.gov.tr/

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

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<td>▪ Health Authority - Abu Dhabi: <a href="http://www.haad.ae/haad/">http://www.haad.ae/haad/</a></td>
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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

Key Organizations

Relevant Standards

Devices

Key Organizations

Relevant Standards
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)
Click on the links to access relevant websites and standards:

### 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](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/

Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP): www.hhs.gov/ohrp/


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

Other relevant standards by U.S. Federal departments and agencies include:


2. Central Intelligence Agency: https://www.cia.gov/index.html:
   - Executive Order 12333, adopting 45 CFR 46 Subparts A, B, C, and D

   - United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects

   - Protection of Pupil Rights Amendment (1974)
   - 34 CFR 98 (1984)
   - 34 CFR 350.4(c) (1991)
   - 34 CFR 356.3(c) (1991)

   - DOE Order 443.1B
   - DOE Order 481.1

   - 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


Privacy/Data Protection

Key Organizations

▪ Various

Relevant Standards


▪ HHS, OCR, Various: [https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html](https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html) and [https://www.hhs.gov/hipaa/for-professionals/faq/research-uses-and-disclosures](https://www.hhs.gov/hipaa/for-professionals/faq/research-uses-and-disclosures)


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

NIH, HIPAA Resources, various: http://privacyruleandresearch.nih.gov/


OCR, HIPAA Privacy Rule Provisions Implementing GINA Requirements at 45 CFR 160.103; 45 CFR 164.502(a)(5)(i); 45 CFR 164.514(g); and 45 CFR 164.520(b)(1)(iii)(C)

Embryos, Stem Cells, and Cloning

Key Organizations

- National Academy of Sciences (NAS): http://www.nasonline.org/
- National Institutes of Health: http://stemcells.nih.gov/

Relevant Standards

- NIH, Various: http://stemcells.nih.gov/
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