

# International Compilation of Human Research Standards 2021 Edition

Compiled By:

**Office for Human Research Protections (OHRP)**

**Office of the Assistant Secretary for Health (OASH)**

**U.S. Department of Health and Human Services (HHS)**



Office for  
Human Research  
Protections

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

## **PURPOSE**

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

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 However, not all countries provided corroboration, so some of the information contain in this document may be outdated or incomplete (please see disclaimer below).

## **ORGANIZATION**

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

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

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

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

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

## **TOPICS NOT COVERED**

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

1. Standards from the state, provincial, or local levels

*International Compilation of Human Research Standards  
2021 Edition*

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

**NEW STANDARDS, UPDATES, AND BROKEN LINKS**

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

**DISCLAIMER**

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

## TABLE OF CONTENTS

<b>INTERNATIONAL ORGANIZATIONS..... 6</b>	Kyrgyzstan..... 46
<b>AFRICA..... 11</b>	Malaysia ..... 48
Regionwide..... 12	Myanmar ..... 52
Algeria..... 12	Nepal ..... 53
Benin ..... 12	New Zealand..... 53
Botswana ..... 12	Pakistan ..... 56
Burkina Faso..... 13	Philippines ..... 57
Cameroon ..... 13	Singapore..... 59
Congo, Democratic Republic of..... 14	South Korea..... 62
Côte-d’Ivoire ..... 14	Sri Lanka ..... 67
Ethiopia ..... 14	Taiwan ..... 67
Gambia ..... 15	Tajikistan ..... 70
Ghana..... 15	Thailand..... 70
Guinea ..... 16	Uzbekistan ..... 72
Kenya..... 16	Vietnam ..... 73
Liberia ..... 17	<b>EUROPE ..... 75</b>
Madagascar..... 17	Regionwide..... 76
Malawi..... 18	Armenia ..... 81
Mali ..... 19	Austria ..... 81
Mozambique..... 20	Belarus..... 84
Nigeria..... 20	Belgium ..... 86
Rwanda..... 21	Bosnia and Herzegovina..... 89
Senegal ..... 21	Bulgaria ..... 93
Sierra Leone ..... 21	Croatia ..... 97
South Africa ..... 22	Cyprus ..... 100
Tanzania ..... 24	Czech Republic..... 101
Uganda..... 25	Denmark ..... 103
Zambia..... 26	Estonia ..... 105
Zimbabwe..... 27	Finland..... 107
<b>ASIA/PACIFIC ..... 29</b>	France ..... 111
Australia ..... 30	Georgia ..... 114
Bangladesh ..... 33	Germany ..... 116
China, People’s Republic of..... 34	Greece..... 120
India..... 38	Hungary ..... 122
Indonesia ..... 41	Iceland ..... 125
Japan ..... 42	Ireland..... 128
Kazakhstan ..... 45	Italy..... 129
	Latvia..... 132

*International Compilation of Human Research Standards  
2021 Edition*

Lithuania.....	134	Guatemala.....	212
Luxembourg .....	138	Haiti .....	213
Malta.....	140	Honduras .....	213
Moldova.....	141	Jamaica .....	214
Montenegro .....	143	Mexico.....	214
Netherlands.....	145	Nicaragua.....	216
North Macedonia, Republic of.....	148	Panama .....	217
Norway .....	151	Paraguay .....	218
Poland.....	155	Peru.....	219
Portugal .....	158	Saint Lucia.....	220
Romania.....	160	Trinidad and Tobago .....	220
Russia .....	163	Uruguay .....	220
San Marino .....	164	Venezuela .....	222
Serbia.....	165		
Slovakia.....	167	<b>MIDDLE EAST/NORTH AFRICA .....</b>	<b>223</b>
Slovenia.....	168	Egypt .....	224
Spain.....	172	Iran.....	224
Sweden .....	175	Israel .....	225
Switzerland.....	178	Jordan .....	226
Ukraine .....	182	Kuwait.....	226
United Kingdom.....	184	Qatar .....	227
		Saudi Arabia.....	228
<b>LATIN AMERICA and the CARIBBEAN.....</b>	<b>191</b>	Sudan.....	229
Regionwide.....	192	Tunisia.....	229
Argentina.....	192	Turkey .....	230
Barbados.....	194	United Arab Emirates.....	233
Bermuda .....	194		
Bolivia .....	194	<b>NORTH AMERICA .....</b>	<b>234</b>
Brazil .....	195	Canada.....	235
Chile .....	201	United States.....	237
Colombia .....	203		
Costa Rica.....	207	<b>ACKNOWLEDGEMENTS .....</b>	<b>245</b>
Cuba.....	208		
Dominica .....	208		
Dominican Republic.....	209		
Ecuador.....	209		
El Salvador .....	211		
Grenada .....	212		
Guyana.....	212		

International Compilation of Human  
Research Standards  
2021 Edition

# International Organizations



## INTERNATIONAL ORGANIZATIONS

### General

**Council for International Organizations of Medical Sciences (CIOMS):** <http://www.cioms.ch/>

- International Ethical Guidelines for <http://www.saveservices.org/wp-content/uploads/Analysis-of-113-Lawsuits-9.16.2019.xlsx> Research Involving Humans (2016):  
<https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/>

**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/6fef854a3517b75ac125641e004a9e68>
- Additional Protocol I Relating to the Protection of Victims of International Armed Conflicts, Article 11 (1977):  
<http://www.icrc.org/ihl.nsf/7c4d08d9b287a42141256739003e636b/f6c8b9fee14a77fdc125641e0052b079>

**Office of the United Nations High Commissioner for Human Rights (OHCHR):**

<https://www.ohchr.org/EN/pages/home.aspx>

- International Covenant on Civil and Political Rights, Article 7 (1976):  
<http://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx>

**TRUST Project:** <http://www.globalcodeofconduct.org>

- Global Code of Conduct for Research in Resource-Poor Settings (2018):  
<http://www.globalcodeofconduct.org/wp-content/uploads/2018/05/Global-Code-of-Conduct-Brochure.pdf>

**UNAIDS:** <http://www.unaids.org/>

- Good Participatory Practice: Guidelines for Biomedical HIV Prevention Trials (2011):  
[http://www.unaids.org/sites/default/files/media\\_asset/JC1853\\_GPP\\_Guidelines\\_2011\\_en\\_0.pdf](http://www.unaids.org/sites/default/files/media_asset/JC1853_GPP_Guidelines_2011_en_0.pdf)
- Ethical Considerations in Biomedical HIV Prevention Trials (2012):  
[http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399\\_ethical\\_considerations\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/jc1399_ethical_considerations_en.pdf)

**United Nations Educational, Scientific, and Cultural Organization, Bioethics Program (UNESCO):** <https://en.unesco.org/>

- Universal Declaration on Bioethics and Human Rights (2005): [http://portal.unesco.org/en/ev.php-URL\\_ID=31058&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html)

**World Health Organization:** <http://www.who.int/en/>

- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011): <https://www.who.int/publications/i/item/9789241502948>
- Ethical Issues in Patient Safety Research: Interpreting Existing Guidance (2013):  
<https://www.who.int/publications/i/item/9789241505475>

*International Compilation of Human Research Standards  
2021 Edition*

- Managing Ethical Issues in Infectious Disease Outbreaks: Guidance Document (2016): <https://www.who.int/publications/i/item/guidance-for-managing-ethical-issues-in-infectious-disease-outbreaks>
- WHO Guidelines on Ethical Issues in Public Health Surveillance (2017): <https://www.who.int/publications/i/item/who-guidelines-on-ethical-issues-in-public-health-surveillance>
- Various: <https://www.who.int/publications/i?healthtopics=487178c1-f124-4085-bf1f-564051f1cd63>

**World Medical Association:** <http://www.wma.net/e/>

- Declaration of Helsinki (2013): <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

**Drugs, Biologics, and Devices**

**Drugs**

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

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

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

- Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation (2005): [http://whqlibdoc.who.int/publications/2005/924159392X\\_eng.pdf](http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf)
- Operational Guidance: Information Needed to Support Clinical Trials of Herbal Products (2005)

**Devices**

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

- IMDRF: Statement Regarding Use of ISO 14155:2011 “Clinical Investigation of Medical Devices for Human Subjects-Good Clinical Practice” (2015): <http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-150326-statement-iso141552011.pdf>
- 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>

**International Standards Organization:** <http://www.iso.org/iso/home.html>

- Clinical Investigation of Medical Devices for Human Subjects -- Good Clinical Practice. Standard Number 14155:2011: [http://www.iso.org/iso/iso\\_catalogue/catalogue\\_ics/catalogue\\_detail\\_ics.htm?csnumber=45557](http://www.iso.org/iso/iso_catalogue/catalogue_ics/catalogue_detail_ics.htm?csnumber=45557)

**Clinical Trial Registries**

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

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

**United States, National Institutes of Health, ClinicalTrials.gov:**

<https://www.clinicaltrials.gov/ct2/home>

**World Health Organization – International Clinical Trials Registry Platform:**

<http://www.who.int/ictrp/en/>



*International Compilation of Human Research Standards  
2021 Edition*

- 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/>

- Declaration of Helsinki, Article 35 (2013): <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

## Research Injury

**Council for International Organizations of Medical Sciences:** <http://www.cioms.ch/>

- International Ethical Guidelines for Health-related Research Involving Humans (2016), Guideline 14: <https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/>

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

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

**World Medical Association:** <https://www.wma.net/>

- Declaration of Helsinki, Paragraph 15 (2013): <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

## Social-Behavioral Research

**UNESCO:** <http://www.unesco.org/>

- Code of Conduct and Ethical Guidelines for Social Science Research: [http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/SHS/pdf/Soc\\_Sci\\_Code.pdf](http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/SHS/pdf/Soc_Sci_Code.pdf)

## Privacy/Data Protection

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

- Declaration of Helsinki, Paragraph 24 (2013): <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
- Declaration of Taipei (2016): <https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/>

## Human Biological Materials

**International Air Transport Association:** <http://www.iata.org/>

- Infectious Substances and Diagnostic Specimens Shipping Guidelines (2005)

**International Society for Biological and Environmental Repositories:** <https://www.isber.org/>

- ISBER Best Practices: Recommendations for Repositories (2019) and Addendums: <https://www.isber.org/page/BPR>

**World Health Organization:** <http://www.who.int/en/>

- Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens (1997): [www.who.int/csr/emc97\\_3.pdf](http://www.who.int/csr/emc97_3.pdf)

*International Compilation of Human Research Standards  
2021 Edition*

- Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells, and Fluids in Research (2003):  
[http://www.who.int/reproductivehealth/topics/ethics/human\\_tissue\\_use.pdf](http://www.who.int/reproductivehealth/topics/ethics/human_tissue_use.pdf)

### **World Medical Association**

- Declaration of Taipei (2016): <https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/>

## **Genetic Research**

### **Human Genome Organization:** <http://www.hugo-international.org/>

- Statement on the Principled Conduct of Genetic Research (1996):  
<http://www.eubios.info/HUGO.htm>
- Statement on DNA Sampling: Control and Access (1998):  
<http://hrlibrary.umn.edu/instreet/dnastatement.html>
- Statement on Gene Therapy Research (2001): [http://www.hugo-international.org/img/gene\\_2001.pdf](http://www.hugo-international.org/img/gene_2001.pdf)
- Statement on Human Genomic Databases (2002): <https://www.cairn.info/revue-journal-international-de-bioethique-2003-3-page-207.htm>

### **UNESCO Bioethics Program:** [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=1372&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html)

- Universal Declaration on the Human Genome and Human Rights Section 16 of III Programme for 1998-1999 (1997): <http://unesdoc.unesco.org/images/0011/001102/110220e.pdf#page=47>
- International Declaration on Human Genetic Data: Section 22 of Major Programme III – Social and Human Sciences (2003): <http://unesdoc.unesco.org/images/0013/001331/133171e.pdf#page=45>

## **Embryos, Stem Cells, and Cloning**

### **International Society for Stem Cell Research:** <http://www.isscr.org/>

- Guidelines for the Conduct of Human Embryonic Stem Cell Research (2006):  
[https://www.isscr.org/docs/default-source/all-isscr-guidelines/hesc-guidelines/isscrhescguidelines2006.pdf?sfvrsn=91f5f996\\_0](https://www.isscr.org/docs/default-source/all-isscr-guidelines/hesc-guidelines/isscrhescguidelines2006.pdf?sfvrsn=91f5f996_0)

International Compilation of Human  
Research Standards  
2021 Edition

# Africa



## AFRICA – Regionwide

### Clinical Trial Registries

**Pan African Clinical Trials Registry:** <http://www.pactr.org/>

- PACTR, Terms and Conditions: <https://pactr.samrc.ac.za/TermsAndConditions.aspx>
- PACTR, FAQs: <https://pactr.samrc.ac.za/FAQ.aspx>

## AFRICA – Algeria

### Drugs, Biologics, and Devices

#### Key Organizations

- Directorate of Pharmacy and Medicine

#### Relevant Standards

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

## AFRICA – Benin

### General

#### Relevant Standards

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

## AFRICA – Botswana

### General

#### Key Organizations

- Ministry of Health and Wellness

#### Relevant Standards

- Anthropological Research Act 45 (1967):  
<http://webcache.googleusercontent.com/search?q=cache:A7aea2ZEMhkJ:static1.1.sqspcdn.com/static/f/723732/25889598/1422112465653/ch59-02%2BANANTHROPOLOGICAL%2BRESEARCH.pdf%3Ftoken%3DTSMJNydKWHdUJ7iPvvm7Qkzk4uU%253D+&cd=1&hl=en&ct=clnk&gl=us>
- Guidelines for Application for Research Permit (2004)
- Guide for a Consent Form (2005)
- Guidelines for the Review of Research Proposals (2005)

### Drugs, Biologics, and Devices

#### Key Organizations

- Ministry of Health and Wellness

*International Compilation of Human Research Standards  
2021 Edition*

### **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**

- Anthropological Research Act 45 (1967):  
<http://webcache.googleusercontent.com/search?q=cache:A7aea2ZEMhkJ:static1.1.sqspcdn.com/static/f/723732/25889598/1422112465653/ch59-02%2BANTHROPOLOGICAL%2BRESEARCH.pdf%3Ftoken%3DTSMJNydkWHdUJ7iPvvm7Qkzk4uU%253D+%&cd=1&hl=en&ct=clnk&gl=us>

## **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](http://www.cambin.org)

### **Relevant Standards**

- Ministerial Order No. 079/A/MSP/DS of MINSANTE (1987):  
[http://elearning.trree.org/pluginfile.php/34735/mod\\_folder/content/0/cm-arrete-079-MSP-CreationComiteEthique-1987.pdf?forcedownload=1](http://elearning.trree.org/pluginfile.php/34735/mod_folder/content/0/cm-arrete-079-MSP-CreationComiteEthique-1987.pdf?forcedownload=1)
- Operational Guidelines for Ethics Committees in Charge of the Evaluation of Biomedical Research

## **AFRICA – Congo, Democratic Republic of**

*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>*

### **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>
- Proposal for Ministerial Order No. 1250 Establishing the National Advisory Committee on Ethics Health (2004): <https://healthresearchweb.org/?action=download&file=DRCPolicy.pdf>
- Guidelines for the Ethical Evaluation of Research Involving Human Subjects in the Democratic Republic of Congo (2011) (French): <https://clinregs.niaid.nih.gov/sites/default/files/documents/DRC/G-EthicalEval.pdf>

## **AFRICA – Côte-d’Ivoire**

### **Drugs, Biologics, and Devices**

#### **Key Organizations**

- National Committee on Ethics and Research

#### **Relevant Standards**

- Decree No. 317 / SP / DSPH of 14 July 1987 on the Regulation of Drugs Before and After Marketing in Ivory Coast: [http://elearning.trree.org/pluginfile.php/34816/mod\\_folder/content/0/20\\_Arrete\\_Regl\\_exp\\_clinique\\_des\\_substances\\_med.pdf?forcedownload=1](http://elearning.trree.org/pluginfile.php/34816/mod_folder/content/0/20_Arrete_Regl_exp_clinique_des_substances_med.pdf?forcedownload=1)

## **AFRICA – Ethiopia**

### **General**

#### **Key Organizations**

- Ethiopian Science and Technology Commission, Health Department

#### **Relevant Standards**

- Proclamation 60/1999, Section 21
- National Health Research Ethics Review Guideline, Fourth Edition (2014): <http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guideline.pdf>

### **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

*International Compilation of Human Research Standards  
2021 Edition*

- Proclamations, various: <http://www.fmhaca.gov.et/doc-category/policies-legislation-and-regulation/proclamations/>
- Regulations, various: <http://www.fmhaca.gov.et/doc-category/policies-legislation-and-regulation/regulations/>
- Policies, various: <http://www.fmhaca.gov.et/doc-category/policies-legislation-and-regulation/policies/>

## Human Biological Materials

### Key Organizations

- Ethiopian Science and Technology Commission, Health Department

### Relevant Standards

- National Health Research Ethics Review Guideline, Fourth Edition, Chapter 9 (2005): <http://www.ccghr.ca/wp-content/uploads/2013/11/national-research-ethics-review-guidline.pdf>

## 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:*

[http://www.fdaghana.gov.gh/index.php?option=com\\_content&view=article&id=71&Itemid=55](http://www.fdaghana.gov.gh/index.php?option=com_content&view=article&id=71&Itemid=55)

### Drugs, Biologics, and Devices

#### Key Organizations

- Food and Drugs Authority: <http://www.fdaghana.gov.gh>

#### Relevant Standards

- Act 851, Public Health Act, 2012: [https://bcp.gov.gh/acc/registry/docs/PUBLIC%20HEALTH%20ACT,%202012%20\(ACT%20851\).pdf](https://bcp.gov.gh/acc/registry/docs/PUBLIC%20HEALTH%20ACT,%202012%20(ACT%20851).pdf)
- Applications for Clinical Trials as Defined Under Section 150-166 (Part 8) of the Public Health Act 2012, Act 851: <http://www.fdaghana.gov.gh/images/stories/pdfs/Clinical%20Trials/REGULATION%20OF%20CLINICAL%20TRIALS%20IN%20GHANA.pdf>
- Clinical Trials, Biological Products, Devices, and More, Guidelines and Forms, various: <http://www.fdaghana.gov.gh/operational-guide.php>
- Clinical Trials, Biological Products, Devices, and More, Operational Guidelines, various: <http://www.fdaghana.gov.gh/application-form.php>

## AFRICA – Guinea

*NOTE: For an overview of the clinical research regulations in Guinea, see the ClinRegs report: [https://clinregs.niaid.nih.gov/single\\_country.php?c\\_id=90](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

- Public Health Code, Articles 237-316 (1997): [http://www.vertic.org/media/National%20Legislation/Guinea/GN\\_Code\\_Sante\\_Publique.pdf](http://www.vertic.org/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf)
- Decree No. D/218/PRG/SGG: On the Establishment, Functions and Organization of the National Ethics Committee for Research in Health (CNERs), Chapters I and II (1998): <https://cners-guinee.org/wp-content/uploads/2020/07/De%CC%81cret-.pdf>
- 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

- Public Health Code, Articles 301-302 (1997): [http://www.vertic.org/media/National%20Legislation/Guinea/GN\\_Code\\_Sante\\_Publique.pdf](http://www.vertic.org/media/National%20Legislation/Guinea/GN_Code_Sante_Publique.pdf)

## AFRICA – Kenya

*NOTE: For an overview of the clinical research regulations in Kenya, see the ClinRegs report: [http://clinregs.niaid.nih.gov/single\\_country.php?c\\_id=111](http://clinregs.niaid.nih.gov/single_country.php?c_id=111)*

### General

#### Key Organizations

- National Council for Science and Technology (NCST): <http://www.nacosti.go.ke/>
- Ministry of Health (MOH): [www.health.go.ke/](http://www.health.go.ke/)

#### Relevant Standards

- Science and Technology Act (2001)
- HIV and AIDS Prevention and Control Act, Chapter 14 (2006)
- MOH, National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): <https://healthresearchweb.org/?action=download&file=Final%20national%20ethical%20guidelines-last%20draft.pdf>

### Drugs, Biologics, and Devices

#### Key Organizations

- Pharmacy and Poisons Board: <http://www.pharmacyboardkenya.org/>



### **Relevant Standards**

- Pharmacy and Poisons Act, Chapter 244 (2009):  
<http://apps.who.int/medicinedocs/documents/s18245en/s18245en.pdf>
- MOH, Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005)
- MOH, Guidelines for Applications to Conduct Clinical Trials in Kenya (2014):  
<http://pharmacyboardkenya.org/downloads/?file=Clinical%20Trial%20Guidelines%202014.pdf>

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

- Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines, page 44 (2005)

## **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**

- Ministry of Health and Social Welfare: <https://moh.gov.lr/>

### **Relevant Standards**

- Institutional Review Board (IRB) Policies and Procedures Handbook (2020):  
[https://clinregs.niaid.nih.gov/sites/default/files/documents/liberia/G-UL-PIRE-IRB\\_2020.pdf](https://clinregs.niaid.nih.gov/sites/default/files/documents/liberia/G-UL-PIRE-IRB_2020.pdf)
- Ethics Committee Guidelines: Procedures for Researchers, Section 1 (2011):  
<http://clinregs.niaid.nih.gov/documents/liberia/G-LIBR-NHSREC.pdf>
- Operational Guidelines of the National Research Ethics Board (2019):  
<https://clinregs.niaid.nih.gov/sites/default/files/documents/liberia/G-NREB-revised.pdf>

## **Drugs, Biologics, and Devices**

### **Key Organizations**

- Liberia Medicines and Health Products Regulatory Authority

### **Relevant Standards**

- Guideline for Application to Conduct Clinical Trials in Liberia (2014):  
<https://clinregs.niaid.nih.gov/documents/liberia/G-LibClinTrial.pdf>

## **AFRICA – Madagascar**

## **Drugs, Biologics, and Devices**

### **Relevant Standards**

- Law No. 2011-002, Article 122 Regarding Clinical Trials:  
<https://www.ilo.org/dyn/natlex/docs/ELECTRONIC/97799/116199/F1071917999/MDG-97799.pdf>

## 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](http://clinregs.niaid.nih.gov/single_country.php?c_id=129)*

### General

#### Key Organizations

- National Commission for Science and Technology (NCST): <http://www.ncst.mw/>
- 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](http://www.malawi.gov.mw)

#### Relevant Standards

- Presidential Decree on 30<sup>th</sup> March 1974
- Malawi Government Gazette, June 11, 1976, General Notice No. 398
- Constitution of Malawi, Article 19(5) (1994): [https://www.constituteproject.org/constitution/Malawi\\_2017.pdf?lang=en](https://www.constituteproject.org/constitution/Malawi_2017.pdf?lang=en)
- NCST, The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011)
- NCST, Policy Requirements, Procedures and Guidelines for the Conduct and Review of Research (2012)
- NCST, National Policy Measures and Requirements for the Improvement of Health Research Co-ordination in Malawi (2012)
- NCST, National Policy Requirements and Guidance for the Provision of Insurance Cover for Research Participants in Clinical Trials in Malawi (2012)
- NHSRC, Operational Guidelines (2001)
- NHSRC, Summary Guidelines for Writing Research Proposals (2001)
- COMREC, General Guidelines on Health Research (2010): [http://comrec.medcol.mw/wp-content/uploads/2014/07/comrec\\_guidelines.pdf](http://comrec.medcol.mw/wp-content/uploads/2014/07/comrec_guidelines.pdf)
- COMREC, Research Policies and Procedures: <https://www.medcol.mw/research-policies-and-procedures/>

### Drugs, Biologics, and Devices

#### Key Organizations

- Pharmacy, Medicines, and Poisons Board of Malawi

#### Relevant Standards

- Pharmacy, Medicines, and Poisons Act, Act 15 of 1988: <https://malawilii.org/mw/legislation/act/1988/15>

## 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): <http://www.ncst.mw/wp-content/uploads/2014/03/NATIONAL-FRAMEWORK-OF-GUIDELINES-IN-SSH.pdf>

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- National Regulatory Requirement and Position on Accessing, Collection, Storage, and Use of Human Biological Specimens for Research (2014): <https://www.ncst.mw/wp-content/uploads/2014/03/National-regulatory-requirement-on-human-samples.pdf>
- Circular on Human Biological Samples and Participants Recompense in Research Involving Human Subjects (2019): [https://clinregs.niaid.nih.gov/sites/default/files/documents/malawi/CIRCULAR.ON\\_.SAMPLES.AND\\_.RECOMPENSE-RECs.pdf](https://clinregs.niaid.nih.gov/sites/default/files/documents/malawi/CIRCULAR.ON_.SAMPLES.AND_.RECOMPENSE-RECs.pdf)

## Genetic Research

### Key Organizations

- National Research Council of Malawi (NRCM): [www.sdn.org.mw/nrcm/](http://www.sdn.org.mw/nrcm/)

### 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>

## Drugs, Biologics, and Devices

### Key Organizations

- Directorate of Pharmacy and Medicine

### Relevant Standards

- Law No. 09-059 of 28 December 2009 Governing Biomedical Research on Humans: <https://clinregs.niaid.nih.gov/documents/LawNo09-059.pdf>
- Fixing the Terms of Application of Law No. 09-059 of December 28, 2009 Governing Biomedical Research on Humans (2017) (French): <https://clinregs.niaid.nih.gov/sites/default/files/documents/mali/DecreeNo2017-0245.pdf>

## **AFRICA – Mozambique**

### **General**

#### **Relevant Standards**

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

## **AFRICA – Nigeria**

### **General**

#### **Key Organizations**

- National Health Research Ethics Committee: <https://nhrec.net/>

#### **Relevant Standards**

- National Health Act (2014): [https://nigeriahealthwatch.com/wp-content/uploads/bsk-pdf-manager/2018/07/01\\_-Official-Gazette-of-the-National-Health-Act-FGN.pdf](https://nigeriahealthwatch.com/wp-content/uploads/bsk-pdf-manager/2018/07/01_-Official-Gazette-of-the-National-Health-Act-FGN.pdf)
- Nigerian Code of Health Research Ethics (2007):  
[http://www.nhrec.net/nhrec/NCHRE\\_Aug%2007.pdf](http://www.nhrec.net/nhrec/NCHRE_Aug%2007.pdf)
- Policy Statement Regarding Enrollment of Children in Research in Nigeria (2016):  
<http://nhrec.net/nhrec/Final%20NHREC%20Policy%20Statement%20on%20Enrollment%20of%20Children%20in%20Research.pdf>
- 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
- Good Clinical Practice Guidelines (2020): [https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/CTD\\_Guidelines/NAFDAC-Good-Clinical-Practices-Guidelines-2020.pdf](https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Guidelines/CTD_Guidelines/NAFDAC-Good-Clinical-Practices-Guidelines-2020.pdf)

## **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/>

### Relevant Standards

- Nigerian Code of Health Research Ethics (2007):  
[http://www.nhrec.net/nhrec/NCHRE\\_Aug%2007.pdf](http://www.nhrec.net/nhrec/NCHRE_Aug%2007.pdf)

## Human Biological Materials

### Key Organizations

- National Health Research Ethics Committee: <http://nhrec.net/>

### Relevant Standards

- Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria (2013):  
[http://nhrec.net/nhrec/NHREC\\_Policy\\_Statement\\_on\\_Biobanks\\_FINAL.pdf](http://nhrec.net/nhrec/NHREC_Policy_Statement_on_Biobanks_FINAL.pdf)

## AFRICA – Rwanda

### General

### Key Organizations

- Ministry of Health: <https://www.moh.gov.rw/>
- National Ethics Committee: <http://www.rnecrwanda.org/>

### Relevant Standards

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

## AFRICA – Senegal

### General

### Key Organizations

- National Committee on Health Research Ethics

### Relevant Standards

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

## AFRICA – Sierra Leone

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

### General

### Key Organizations

- Sierra Leone Ethics and Scientific Review Committee

### Relevant Standards

- Application Guidelines (2017): <https://mohs2017.files.wordpress.com/2017/03/guidelines-and-checklist-for-ethical-clearance-2017.pdf>

## 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>
- Guideline for Good Clinical Practice (GCP) in Sierra Leone, Sections 3.2 and 3.3 (2018): [https://clinregs.niaid.nih.gov/sites/default/files/documents/sierra\\_leone/PBSL-GCP-Guideline-V2.pdf](https://clinregs.niaid.nih.gov/sites/default/files/documents/sierra_leone/PBSL-GCP-Guideline-V2.pdf)
- Guidelines, various: <http://www.pharmacyboard.gov.sl/Resources/Guidelines.aspx>
- Clinical Trials, various: <http://www.pharmacyboard.gov.sl/Resources/ClinicalTrials.aspx>
- Forms, various: <http://www.pharmacyboard.gov.sl/Resources/Forms.aspx>

## AFRICA – South Africa

*NOTE: For an overview of the clinical research regulations in South Africa, see the ClinRegs report: [http://clinregs.niaid.nih.gov/single\\_country.php?c\\_id=199](http://clinregs.niaid.nih.gov/single_country.php?c_id=199)*

## General

### Key Organizations

- Department of Health (DH): <http://www.health.gov.za/>
- 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

- Constitution of South Africa, Section 12 (2) (1996): <https://www.gov.za/documents/constitution/constitution-republic-south-africa-1996-1>
- National Health Act No. 61, Chapter 9 (2003): [http://www.saflii.org/za/legis/consol\\_act/nha2003147.pdf](http://www.saflii.org/za/legis/consol_act/nha2003147.pdf)
- Regulations Relating to Research with Human Participants No. R719 (2014): [https://www.gov.za/sites/default/files/gcis\\_document/201409/38000rg10268gon719.pdf](https://www.gov.za/sites/default/files/gcis_document/201409/38000rg10268gon719.pdf)
- DH, Ethics in Health Research: Principles, Structures, and Processes (2015): <https://www.sun.ac.za/english/research-innovation/Research->

*International Compilation of Human Research Standards  
2021 Edition*

[Development/Documents/Integrity%20and%20Ethics/DoH%202015%20Ethics%20in%20Health%20Research%20-%20Principles,%20Processes%20and%20Structures%202nd%20Ed.pdf](#)

- MRC, Various Guideline Documents: <https://www.samrc.ac.za/research/ethics/guideline-documents>

## **Drugs, Biologics, and Devices**

### **Key Organizations**

- Department of Health (DH): <http://www.health.gov.za/>
- Health Products Regulatory Authority: <https://www.sahpra.org.za/>

### **Relevant Standards**

- Medicines and Related Substances Control Act, 101 of 1965: <https://www.gov.za/documents/drugs-control-act-7-jul-1965-0000>
- General Regulations Made in Terms of the Medicines and Related Substances Act, 1965 (2003)
- South African Good Clinical Practice: Clinical Trial Guidelines (2020)  
[https://www.sahpra.org.za/wp-content/uploads/2021/06/SA-GCP-2020\\_Final.pdf](https://www.sahpra.org.za/wp-content/uploads/2021/06/SA-GCP-2020_Final.pdf)

## **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**

- Department of Health (DH): <http://www.health.gov.za/>

### **Relevant Standards**

- Ethics in Health Research: Principles, Processes, and Structures, Section 3.3.7(i) (2015):  
<https://www.sun.ac.za/english/research-innovation/Research-Development/Documents/Integrity%20and%20Ethics/DoH%202015%20Ethics%20in%20Health%20Research%20-%20Principles,%20Processes%20and%20Structures%202nd%20Ed.pdf>

## **Human Biological Materials**

### **Key Organizations**

- Department of Health (DH): <http://www.health.gov.za/>

### **Relevant Standards**

- National Health Act No. 61, Chapter 8, Sections 53-68 (2003):  
[https://www.hpcsa.co.za/Uploads/Legal/legislation/NATIONAL\\_HEALTH\\_ACT%C2%A061\\_OF\\_2003.pdf](https://www.hpcsa.co.za/Uploads/Legal/legislation/NATIONAL_HEALTH_ACT%C2%A061_OF_2003.pdf)
- Regulations Relating to the Use of Human Biological Material, 2 March 2012:  
[https://www.gov.za/sites/default/files/gcis\\_document/201409/35099rg9699gon177.pdf](https://www.gov.za/sites/default/files/gcis_document/201409/35099rg9699gon177.pdf)

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

- Regulations Regarding General Control of Human Bodies, Tissues, Blood Products and Gametes, 2 March 2012
- Regulations Relating to Blood and Blood Products, 2 March 2012:  
[https://www.gov.za/sites/default/files/gcis\\_document/201409/35099rg9699gon180.pdf](https://www.gov.za/sites/default/files/gcis_document/201409/35099rg9699gon180.pdf)
- Regulations Relating to Artificial Insemination of Persons (2016):  
[https://www.gov.za/sites/default/files/gcis\\_document/201609/40312gon1165.pdf](https://www.gov.za/sites/default/files/gcis_document/201609/40312gon1165.pdf)

### **Genetic Research**

#### **Key Organizations**

- Medical Research Council of South Africa (MRC): <https://www.samrc.ac.za/>

#### **Relevant Standards**

- Guidelines on Ethics for Medical Research, Reproductive Biology and Genetic Research (2002):  
<http://www.kznhealth.gov.za/research/ethics2.pdf>

### **Embryos, Stem Cells, and Cloning**

#### **Key Organizations**

- Medical Research Council of South Africa (MRC): <https://www.samrc.ac.za/>

#### **Relevant Standards**

- National Health Act No. 61, Chapter 8, Section 57 (2003):  
[https://www.hpcs.co.za/Uploads/Legal/legislation/NATIONAL\\_HEALTH\\_ACT%C2%A061\\_OF\\_2003.pdf](https://www.hpcs.co.za/Uploads/Legal/legislation/NATIONAL_HEALTH_ACT%C2%A061_OF_2003.pdf)
- Regulations relating to Stem Cell Banks, 2 March 2012:  
[https://www.gov.za/sites/default/files/gcis\\_document/201409/35099rg9699gon183.pdf](https://www.gov.za/sites/default/files/gcis_document/201409/35099rg9699gon183.pdf)
- Guidelines on Ethics in Reproductive Biology and Genetic Research (2002):  
<http://www.kznhealth.gov.za/research/ethics2.pdf>

### **AFRICA – Tanzania**

*NOTE: For an overview of the clinical research regulations in Tanzania, see the ClinRegs report:  
[http://clinregs.niaid.nih.gov/single\\_country.php?c\\_id=212](http://clinregs.niaid.nih.gov/single_country.php?c_id=212)*

### **General**

#### **Key Organizations**

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

#### **Relevant Standards**

- National Institute for Medical Research, Act of Parliament No. 23, of 1979:  
<https://www.nimr.or.tz/wp-content/uploads/2020/08/NIMR-Act.pdf>



*International Compilation of Human Research Standards  
2021 Edition*

- Tanzania Commission for Science and Technology, Act No. 7 of 1986: <https://www.costech.or.tz/storage/uploads/mSre0zVqCMimUgIsnKrOrRIqHPgNxwwFIrpnkjX0.pdf>
- NIMR, Research Policies, Guidelines, and Regulations: [https://www.nimr.or.tz/wp-content/uploads/2018/11/NIMR\\_RESEARCH\\_POLICY\\_REGULATIONS\\_2015.pdf](https://www.nimr.or.tz/wp-content/uploads/2018/11/NIMR_RESEARCH_POLICY_REGULATIONS_2015.pdf)
- Guidelines on Ethics for Health Research in Tanzania (2009): <https://clinregs.niaid.nih.gov/documents/tanzania/G-EthicsHR.pdf>
- COSTECH, Various, including Guidelines on Research Permits and Clearance (2006): Various: <https://www.costech.or.tz/documents-and-publications>

## Drugs, Biologics, and Devices

### *Drugs*

#### **Key Organizations**

- Tanzania Medicines and Medical Devices Authority: <https://www.tmda.go.tz/>

#### **Relevant Standards**

- Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66, 67, and 69 (2003): [https://www.tmda.go.tz/uploads/publications/en1545477980-GN%20-%20THE%20TANZANIA%20FOOD,%20DRUGS%20AND%20COSMETICS%20\(CLINICAL%20TRIALS%20CONTROL\)%20REGULATIONS,%202013.pdf](https://www.tmda.go.tz/uploads/publications/en1545477980-GN%20-%20THE%20TANZANIA%20FOOD,%20DRUGS%20AND%20COSMETICS%20(CLINICAL%20TRIALS%20CONTROL)%20REGULATIONS,%202013.pdf)

### *Devices*

#### **Key Organizations**

- Tanzania Medicines and Medical Devices 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](http://clinregs.niaid.nih.gov/single_country.php?c_id=223)*

## General

#### **Key Organizations**

- Uganda National Council for Science and Technology (UNCST): <http://www.uncst.go.ug/>

*International Compilation of Human Research Standards  
2021 Edition*

### **Relevant Standards**

- Uganda National Council for Science and Technology Act of 1990 (CAP 209): <https://old.ulii.org/ug/legislation/consolidated-act/209>
- National Guidelines for Research Involving Humans as Research Participants (2014): <https://iuea.ac.ug/sitepad-data/uploads//2021/03/Human-Subjects-Protection-Guidelines-July-2014.pdf>
- Research Registration and Clearance Policy and Guidelines (2016): <https://clinregs.niaid.nih.gov/sites/default/files/documents/uganda/G-UNCSTreg.pdf>
- National Guidelines for the Conduct of Research During the COVID-19 Pandemic: <https://uncst.go.ug/main/wp-content/uploads/download-manager-files/National%20Guidelines.pdf>

## **Drugs, Biologics, and Devices**

### **Key Organizations**

- National Drug Authority: <http://www.nda.or.ug/>

### **Relevant Standards**

- Human Medicine Guidelines, including Guidelines for the Conduct of Drug Related Clinical Trials (2019): <https://www.nda.or.ug/human-medicine-guidelines/>
- National Drug Policy and Authority Act Regulations: <https://www.nda.or.ug/ndpa-act-regulations/>
- Human Medicine Guidelines: <https://www.nda.or.ug/human-medicine-guidelines/>
- Clinical Trial Application Forms: <https://www.nda.or.ug/application-forms/>

## **AFRICA – Zambia**

### **General**

### **Key Organizations**

- Ministry of Health: <https://www.moh.gov.zm/>

### **Relevant Standards**

- National Health Research Act (2013): <http://www.parliament.gov.zm/sites/default/files/documents/acts/Health%20%20Research%20%20Act%202013.pdf>

## **Drugs, Biologics, and Devices**

### **Key Organizations**

- Zambia Medicines Regulatory Authority: <http://www.zamra.co.zm/>

### **Relevant Standards**

- Medicines and Allied Substances Act, Part VI: Regulation of Clinical Trials, 2013: <https://www.zamra.co.zm/wp-content/uploads/2021/01/MASA-No-3-2013.pdf>
- 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

- National Health Research Act, Part VI (2013):  
<http://www.parliament.gov.zm/sites/default/files/documents/acts/Health%20%20Research%20%20Act%202013.pdf>

## AFRICA – Zimbabwe

### General

#### Key Organizations

- Medical Research Council of Zimbabwe: <http://www.mrcz.org.zw>

#### Relevant Standards

- Medical Research Government Notice Act (1974)
- 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
- Pharmacovigilance and Clinical Trials, Various Guidelines:  
<https://www.mcaz.co.zw/index.php/downloads/category/15-guidelines>

### Devices

#### Key Organizations

- Medicines Control Authority of Zimbabwe: <https://www.mcaz.co.zw/>

#### Relevant Standards

- Medicines and Allied Substances Control Act, Chapter 15:03 (1997):  
<https://www.mcaz.co.zw/index.php/downloads/category/8-acts>
- 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:  
[https://www.constituteproject.org/constitution/Zimbabwe\\_2013.pdf](https://www.constituteproject.org/constitution/Zimbabwe_2013.pdf)
- Access to Information and Protection of Privacy Act, Chapter 10:27:  
<http://www.veritaszim.net/node/240#:~:text=An%20Act%20to%20provide%20members,or%20disclosure%20of%20personal%20information>

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

- Research Act (2001): <http://faolex.fao.org/docs/pdf/zim93551.pdf>
- Various: <http://www.rcz.ac.zw/research-registration/>

## **Genetic Research**

### **Key Organizations**

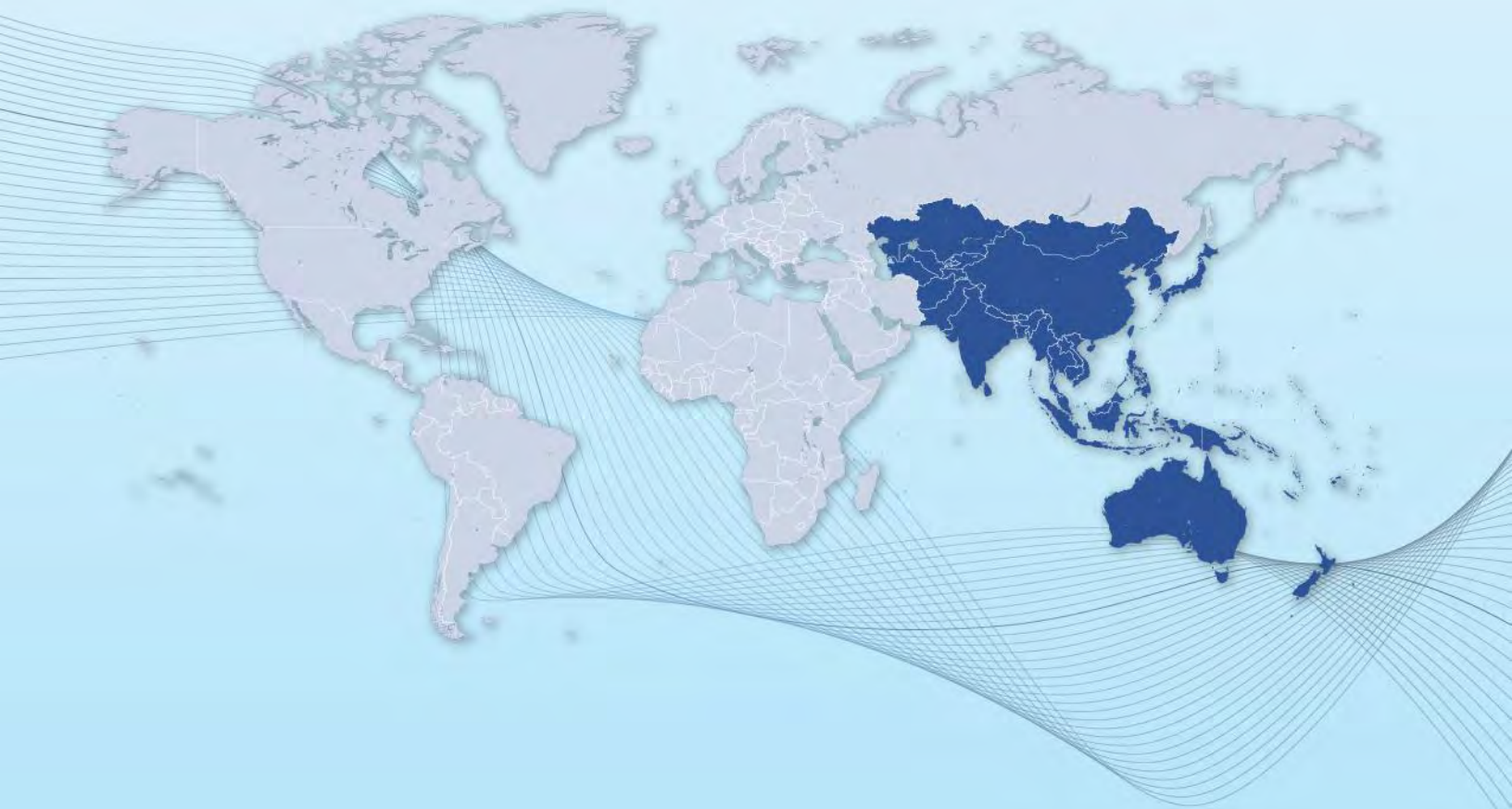
- National Biotechnology Authority of Zimbabwe: <http://www.nba.ac.zw/>

### **Relevant Standards**

- National Biotechnology Authority Act, Chapter 14:31 (2006):  
[https://www.nba.ac.zw/books/national\\_biotechnolgy\\_act.pdf](https://www.nba.ac.zw/books/national_biotechnolgy_act.pdf)

International Compilation of Human  
Research Standards  
2021 Edition

# Asia/Pacific



## 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

- National Health and Medical Research Council Act 1992 (2014): <http://www.comlaw.gov.au/Details/C2014C00364>
- National Health and Medical Research Regulation 2016: <https://www.legislation.gov.au/Details/F2016L00682>
- NHMRC, Ethical guidelines for research with Aboriginal and Torres Strait Islander Peoples (2018): <https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-and-torres-strait-islander-peoples>
- NHMRC, Australian Code for the Responsible Conduct of Research (2018): <https://nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>
- NHMRC, National Statement on Ethical Conduct in Human Research, 2007 (2018): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>
- Australian States and Territories, National Mutual Acceptance of Scientific and Ethical Review of Multi-Centre Human Research: <https://www.australianclinicaltrials.gov.au/ethical-review-process-each-australian-state-and-territory>
- AIATSIS, Guidelines for Ethical Research in Australian Indigenous Studies (2012): <http://www.aiatsis.gov.au/research/ethics/GERAIS.html>

### Drugs, Biologics, and Devices

#### Drugs

##### Key Organizations

- Therapeutic Goods Administration (TGA): <http://www.tga.gov.au>

##### Relevant Standards

- Therapeutic Goods Act 1989 (2016): <https://www.legislation.gov.au/Details/C2016C00269>
- Therapeutic Goods Regulations 1990 (2016): <https://www.legislation.gov.au/Details/F2016C00801>
- Australian Clinical Trial Handbook (2018): <https://www.tga.gov.au/publication/australian-clinical-trial-handbook>

#### Devices

##### Key Organizations

- Therapeutic Goods Administration: <http://www.tga.gov.au/industry/devices.htm>

### **Relevant Standards**

- Therapeutic Goods Act 1989 (2016): <https://www.legislation.gov.au/Details/C2016C00269>
- Therapeutic Goods (Medical Devices) Regulations 2002 (2016): <https://www.legislation.gov.au/Details/F2016C00801>
- Australian Regulatory Guidelines for Medical Devices (ARGMD) (2011): <http://www.tga.gov.au/industry/devices-argmd.htm>

## **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**

- National Statement on Ethical Conduct in Human Research, 3.1.7 (2018): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>
- FAQs: <http://www.anzctr.org.au/Faq.aspx>

## **Research Injury**

### **Key Organizations**

- Therapeutic Goods Administration (TGA): <http://www.tga.gov.au/>
- Medicines Australia: <https://medicinesaustralia.com.au>
- National Health and Medical Research Council (NHMRC): <http://www.nhmrc.gov.au>

### **Relevant Standards**

- TGA, Guidance on Good Clinical Practice (CPMP/ICH-135/95). (2018): <https://www.tga.gov.au/publication/note-guidance-good-clinical-practice>
- Medicines Australia, Industry Standard Compensation Guidelines (2012): <https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/Clinical-Trials-Compensation-Guidelines-1.pdf>
- NHMRC, National Statement on Ethical Conduct in Human Research. Paragraphs 5.1.38 and 5.1.39 (2018): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>

## **Social-Behavioral Research**

### **Key Organizations**

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

### **Relevant Standards**

- National Statement on Ethical Conduct in Human Research, Chapter 3.1 (2018): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>

## Privacy/Data Protection

### Key Organizations

- Office of the Australian Information Commissioner: <http://www.oaic.gov.au/>

### Relevant Standards

- Privacy Act 1988 (2016): <https://www.legislation.gov.au/Details/C2016C00838>
- Australian Privacy Principles Guidelines (Combined, 2019): [https://www.oaic.gov.au/\\_data/assets/pdf\\_file/0009/1125/app-guidelines-july-2019.pdf](https://www.oaic.gov.au/_data/assets/pdf_file/0009/1125/app-guidelines-july-2019.pdf)
- Guidelines under Section 95 of the Privacy Act 1988 (2014): <https://nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988>
- Guidelines Approved under Section 95A of the Privacy Act 1988 (2014): <https://nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988>
- Guidelines Approved under Section 95A of the Privacy Act 1988 (2014): <https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988#block-views-block-file-attachments-content-block-1>
- Privacy Regulation 2013 (2016): <https://www.legislation.gov.au/Details/F2016C00599>
- Guidelines Approved under Section 95AA of the Privacy Act 1988 (2014): <https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95aa-privacy-act-1988-cth>
- Privacy in Australian States and Territories: <https://www.oaic.gov.au/privacy/privacy-in-your-state>

## Human Biological Materials

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

### Key Organizations

- National Health and Medical Research Council (NHMRC): <http://www.nhmrc.gov.au/>
- Therapeutic Goods Administration (TGA): <http://www.tga.gov.au/>

### Relevant Standards

- NHMRC, National Statement on Ethical Conduct in Human Research, Chapter 3.2 (2018): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>
- TGA, Australian Regulatory Guidelines for Biologicals (2017): <http://www.tga.gov.au/industry/biologicals-argb.htm>

## Genetic Research

### Key Organizations

- National Health and Medical Research Council (NHMRC): <http://www.nhmrc.gov.au/>
- Office of the Gene Technology Regulator: <http://www.ogtr.gov.au/>

### Relevant Standards

- Gene Technology Act 2000 (2016): <https://www.legislation.gov.au/Details/C2016C00792>
- Gene Technology Regulations 2001 (2016): <https://www.legislation.gov.au/Details/F2016C00615>



*International Compilation of Human Research Standards  
2021 Edition*

- NHMRC, National Statement on Ethical Conduct in Human Research, Chapter 3.3 (2018): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

- Prohibition of Human Cloning for Reproduction Act 2002 (2008): <http://www.comlaw.gov.au/Details/C2008C00694>
- Research Involving Human Embryos Act 2002 (2014): <http://www.comlaw.gov.au/Details/C2014C00605>
- Research Involving Human Embryos Regulations (2017): <https://www.legislation.gov.au/Details/F2017L01213>
- NHMRC, National Statement on Ethical Conduct in Human Research, Chapter 3.2 (2018): <https://nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research>
- NHMRC, Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2017): <https://nhmrc.gov.au/about-us/publications/ethical-guidelines-use-assisted-reproductive-technology>

## ASIA/PACIFIC – Bangladesh

### General

#### Key Organizations

- Bangladesh Medical Research Council, National Research Ethics Committee: <http://www.bmrcbd.org>

#### Relevant Standards

- Ethical Guidelines for Conducting Research Studies Involving Human Subjects: [https://www.bmrcbd.org/application\\_form/EthicalGuideline](https://www.bmrcbd.org/application_form/EthicalGuideline)
- Standard Operating Procedures (SOPs): [https://www.bmrcbd.org/application\\_form/SOPs](https://www.bmrcbd.org/application_form/SOPs)

## Drugs, Biologics, and Devices

#### Key Organizations

- Bangladesh Directorate of Drug Administration: <http://www.dgda.gov.bd/>

#### Relevant Standards

- The Drugs Act (1964)
- Drugs (Control) Ordinance 1982, Ordinance No. VIII: <http://bdlaws.minlaw.gov.bd/act-623.html>
- Good Clinical Practice (GCP) Guidelines: <http://www.dgda.gov.bd/index.php/2013-03-31-05-16-29/registered-medical-device-list-4/129-good-clinical-practice-gcp-guidelines/file>

## Human Biological Materials

### Key Organizations

- Bangladesh Medical Research Council, National Research Ethics Committee:  
<http://www.bmrcbd.org>

### Relevant Standards

- Guidelines for Transfer of Human Biological Materials Abroad for Research Purposes (2004)

## 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>*

## General

### Key Organizations

- National Health Commission of the People’s Republic of China (NHC): <http://en.nhc.gov.cn/>
- State Administration for Market Regulation: <http://www.samr.gov.cn/>
- National Medical Products Administration: <http://www.nmpa.gov.cn>

### Relevant Standards

- Law on Practicing Doctors (June 26, 1998), Articles 26 and 37: [http://www.gov.cn/banshi/2005-08/01/content\\_18970.htm](http://www.gov.cn/banshi/2005-08/01/content_18970.htm)
- People’s Republic of China Human Genetic Resources Management Regulations (2019):  
[http://www.gov.cn/zhengce/content/2019-06/10/content\\_5398829.htm](http://www.gov.cn/zhengce/content/2019-06/10/content_5398829.htm)
- NHFPC, Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2016):  
[http://www.gov.cn/gongbao/content/2017/content\\_5227817.htm](http://www.gov.cn/gongbao/content/2017/content_5227817.htm)
- Management Guidelines for Conducting Clinical Research at Medical/Health Institutions (Mandarin) (2014): <http://www.nhc.gov.cn/yzygj/s3593g/201410/9bd03858c3aa41ed8aed17467645fb68.shtml>

## Drugs, Biologics, and Devices

### Drugs

#### Key Organizations

- National Medical Products Administration: <http://www.nmpa.gov.cn>

#### Relevant Standards

- Drug Administration Law of the People's Republic of China (2019):  
<http://www.npc.gov.cn/npc/c30834/201908/26a6b28dd83546d79d17f90c62e59461.shtml>
- Vaccine Management Law of the People’s Republic of China (2019):  
<http://www.npc.gov.cn/npc/c30834/201907/11447c85e05840b9b12c62b5b645fe9d.shtml>
- Regulations for Implementation of the Drug Administration Law of the People's Republic of China (2016): <http://www.nmpa.gov.cn/WS04/CL2076/300567.html>
- Chinese Good Clinical Practice (2003): <http://www.nmpa.gov.cn/WS04/CL2077/300595.html>

*International Compilation of Human Research Standards  
2021 Edition*

- Measures for the Administration of Drug Registration (2007): <http://www.nmpa.gov.cn/WS04/CL2174/300629.html>
- Interim Measures for the Confirmation of Clinical Trial Sites/Institutions (2004): <http://www.nmpa.gov.cn/WS04/CL2079/337621.html>
- Provisions for Adverse Drug Reaction Reporting and Monitoring (2011): [http://english.nmpa.gov.cn/2019-12/14/c\\_432227.htm](http://english.nmpa.gov.cn/2019-12/14/c_432227.htm)
- Administrative Measures for the Signing and Issuing of Biological Product (2017): <http://www.nmpa.gov.cn/WS04/CL2077/300708.html>
- Guideline for HIV Vaccine Research Technology (2003)
- Guideline for Vaccine Research Technology (2004)
- Guidelines on Ethical Review of Drug Clinical Trials (2010): [http://www.gov.cn/gzdt/2010-11/08/content\\_1740976.htm](http://www.gov.cn/gzdt/2010-11/08/content_1740976.htm)
- Interim Guidelines on International Multi-Regional Drug Clinical Trials (2015)
- Interim Guidelines for Reporting and Supervision of Adverse Drug Reactions (2015): <http://www.nmpa.gov.cn/WS04/CL2196/324118.html>

## **Devices**

### **Key Organizations**

- National Medical Products Administration: <http://www.nmpa.gov.cn>

### **Relevant Standards**

- Good Clinical Practice on Medical Device Clinical Trials (2016): <http://www.nmpa.gov.cn/WS04/CL2077/300685.html>
- Regulations on the Supervision and Administration of Medical Devices (revised 2017): <http://www.nmpa.gov.cn/WS04/CL2076/331389.html>
- Measures for the Registration and Administration of In Vitro Diagnostic Reagents (2014): <http://www.nmpa.gov.cn/WS04/CL2077/300661.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>
- Administrative Measures for Recall of Medical Devices (2017): <http://www.nmpa.gov.cn/WS04/CL2186/300689.html>
- Guiding Principles of the Clinical Trail Technology on In Vitro Diagnostic (IVD) Reagents (2014): <http://www.nmpa.gov.cn/WS04/CL2138/299988.html>
- Management Measures for the Monitoring and Re-evaluation of Adverse Events on Medical Devices (2019): <http://www.nmpa.gov.cn/WS04/CL2077/330071.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

- FAQs: <http://www.chictr.org.cn/questionen.aspx>

## Privacy/Data Protection

### *Mainland*

#### Key Organizations

- Ministry of Industry and Information Technology of People's Republic of China
- Office of the Central Cyberspace Affairs Commission: <http://www.cac.gov.cn/>
- National Information Security Standardization Technical Committee: <https://www.tc260.org.cn/>

#### Relevant Standards

- People's Republic of China Cyber Security Law (2016): [http://www.cac.gov.cn/2016-11/07/c\\_1119867116.htm](http://www.cac.gov.cn/2016-11/07/c_1119867116.htm)
- People's Republic of China Electronic Commerce Law, Articles 23-25 and 32 (2018): [http://www.cac.gov.cn/2018-09/01/c\\_1123362506.htm](http://www.cac.gov.cn/2018-09/01/c_1123362506.htm)
- Information Security Technology-Personal Information Security Specification (2017, GB/T 35273-2017): <https://www.tc260.org.cn/front/postDetail.html?id=20180124211617>

### *Hong Kong*

#### Key Organizations

- Privacy Commissioner for Personal Data, Hong Kong: <http://www.pcpd.org.hk>
- eHealth Electronic Health Record Sharing System: <https://www.ehealth.gov.hk/en/home/index.html>

#### Relevant Standards

- Personal Data (Privacy) Ordinance (2018): <https://www.elegislation.gov.hk/hk/cap486!en-zh-Hant-HK.pdf?FROMCAPINDEX=Y>
- Code of Practice on the Identity Card Number and Other Personal Identifiers (2016): [https://www.pcpd.org.hk/english/data\\_privacy\\_law/code\\_of\\_practices/files/picode\\_en.pdf](https://www.pcpd.org.hk/english/data_privacy_law/code_of_practices/files/picode_en.pdf)
- Code of Practice on Human Resource Management (2016): [https://www.pcpd.org.hk/english/data\\_privacy\\_law/code\\_of\\_practices/files/PCPD\\_HR\\_Booklet\\_En\\_g\\_AW07\\_Web.pdf](https://www.pcpd.org.hk/english/data_privacy_law/code_of_practices/files/PCPD_HR_Booklet_En_g_AW07_Web.pdf)

## Research Injury

### Key Organizations

- National Health Commission of the People's Republic of China (NHC): <http://en.nhc.gov.cn/>
- National Medical Products Administration: <http://www.nmpa.gov.cn>

## **Relevant Standards**

- Tort Liability law of the People's Republic of China, Chapter 7 (2009): [http://www.gov.cn/flfg/2009-12/26/content\\_1497435.htm](http://www.gov.cn/flfg/2009-12/26/content_1497435.htm)
- Chinese Good Clinical Practice, Article 43 (2003): <http://www.nmpa.gov.cn/WS04/CL2077/300595.html>
- Administrative Measures for Recall of Medical Devices, Article 36 (2017): <http://www.nmpa.gov.cn/WS04/CL2186/300689.html>
- Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2016), Articles 18.5, 20.8, 36.6, and 37: [http://www.gov.cn/gongbao/content/2017/content\\_5227817.htm](http://www.gov.cn/gongbao/content/2017/content_5227817.htm)
- Good Clinical Practice on Medical Device Clinical Trials (2016), Articles 10, 22, 33, and 48: <http://www.nmpa.gov.cn/WS04/CL2077/300685.html>
- 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**

- National Health Commission of the People's Republic of China (NHC): <http://en.nhc.gov.cn/>
- Ministry of Science and Technology of the People's Republic of China (MOST): <http://www.most.cn/eng/>

### **Relevant Standards**

- People's Republic of China Human Genetic Resources Management Regulations (2019): [http://www.gov.cn/zhengce/content/2019-06/10/content\\_5398829.htm](http://www.gov.cn/zhengce/content/2019-06/10/content_5398829.htm)
- Service Guidelines for the Collection, Selling, Export. and Admission Application of Human Genetic Resources (2015): [http://www.most.gov.cn/tztg/201507/t20150703\\_120547.htm](http://www.most.gov.cn/tztg/201507/t20150703_120547.htm)
- Service Guideline for the Approval of Administrative Licensing Items for Exporting Human Genetic Resources Outside of China: <https://fuwu.most.gov.cn/r/cms/zwpt/web/assets/pdf/4.rlyczycjpsfwzn.pdf>

## **Embryos, Stem Cells, and Cloning**

### *Mainland*

### **Key Organizations**

- National Health Commission of the People's Republic of China (NHC): <http://en.nhc.gov.cn/>
- 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)
- Interim Measures for the Administrative Measures of Stem Cell Clinical Research (2015): <http://www.nmpa.gov.cn/WS04/CL2077/300673.html>

*International Compilation of Human Research Standards  
2021 Edition*

- Ethical Guidelines for Research on Human Embryo Stem Cells (2003): [http://www.most.gov.cn/fggw/zfwj/zfwj2003/200512/t20051214\\_54948.htm](http://www.most.gov.cn/fggw/zfwj/zfwj2003/200512/t20051214_54948.htm)
- Interim Guidelines for the Quality Control of Stem Cell Preparations and Preclinical Research (2015): <http://www.nmpa.gov.cn/WS04/CL2196/324124.html>

## **Hong Kong**

### **Key Organizations**

- Legislative Council of the Hong Kong Special Administrative Region of the People's Republic of China: <http://www.legco.gov.hk/index.html>

### **Relevant Standards**

- Human Reproductive Technology (Amendment) Ordinance 2016: <https://www.legco.gov.hk/yr15-16/english/ord/ord020-2016-e.pdf>

## **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](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**

- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (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)
- National Ethical Guidelines for Biomedical Research Involving Children (2017): [https://ethics.ncdirindia.org//asset/pdf/National\\_Ethical\\_Guidelines\\_for\\_BioMedical\\_Research\\_Involving\\_Children.pdf](https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf)
- National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During Covid-19 Pandemic: [https://ethics.ncdirindia.org//asset/pdf/EC\\_Guidance\\_COVID19.pdf](https://ethics.ncdirindia.org//asset/pdf/EC_Guidance_COVID19.pdf)

## **Drugs, Biologics, and Devices**

### **Drugs**

#### **Key Organizations**

- Central Drugs Standard Control Organization (CDSCO), Office of Drugs Controller General of India (DCGI): <https://cdsco.gov.in/opencms/opencms/en/>
- Indian Council of Medical Research (ICMR): <http://www.icmr.nic.in/>

#### **Relevant Standards**

- CDSCO, Drugs and Cosmetics Act (1940 amended up to 31<sup>st</sup> December, 2016): [https://cdsco.gov.in/opencms/export/sites/CDSCO\\_WEB/Pdf-documents/acts\\_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf) (pages 584)

*International Compilation of Human Research Standards  
2021 Edition*

- CDSCO, New Drugs and Clinical Trials Rules (2019):  
[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=NDI2MQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDI2MQ==) (English from page 147)
- CDSCO, Good Clinical Practice Guidelines for Clinical Research in India (2001):  
<https://rgcb.res.in/documents/Good-Clinical-Practice-Guideline.pdf>
- ICMR, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 7 (2017):  
[https://ethics.ncdirindia.org//asset/pdf/National\\_Ethical\\_Guidelines\\_for\\_BioMedical\\_Research\\_Involving\\_Children.pdf](https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf)

## **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==](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):  
[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)

## **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):  
[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=NDI2MQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDI2MQ==) (English from page 147)
- ICMR, National Ethical Guidelines For Biomedical and Health Research Involving Human Participants, Section 2.6 (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)

## Social-Behavioral Research

### Key Organizations

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

### Relevant Standards

- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 9 (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)

## Privacy/Data Protection

### Key Organizations

- Indian Council of Medical Research (ICMR): <http://www.icmr.nic.in/>
- National AIDS Control Organization (NACO): <http://naco.gov.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)
- NACO, Data Protection Guidelines of the National AIDS Control Programme:  
<http://www.naco.gov.in/sites/default/files/Data%20Protection%20Guideline%20of%20National%20AIDS%20Control%20Programme.pdf>

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- Govt. of India Office Memorandum (O.M. No.19015/53/1997 - IH Pt.) 19<sup>th</sup> November, 1997 on Exchange of Human Biological Material for Biomedical Research Purposes
- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 11 (2017):  
[https://main.icmr.nic.in/sites/default/files/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017](https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017)

## Genetic Research

### Key Organizations

- Department of Biotechnology (DBT): <https://dbtindia.gov.in/>
- Indian Council of Medical Research (ICMR): <http://www.icmr.nic.in/>

### Relevant Standards

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



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

- DBT, Regulations and Guidelines for Recombinant DNA Research and Biocontainment (2017): [https://ibkp.dbtindia.gov.in/DBT\\_Content\\_Test/CMS/Guidelines/20181115134719867\\_Regulations-Guidelines-for-Reocminant-DNA-Research-and-Biocontainment-2017.pdf](https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115134719867_Regulations-Guidelines-for-Reocminant-DNA-Research-and-Biocontainment-2017.pdf)
- DBT, Ethical Policies on the Human Genome, Genetic Research, and Services (2002)
- ICMR, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, Section 10 (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)

### **Embryos, Stem Cells, and Cloning**

#### **Key Organizations**

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

#### **Relevant Standards**

- ICMR and DBT Combined, National Guidelines for Stem Cell Research (2017): <https://dbtindia.gov.in/regulations-guidelines/guidelines/national-guidelines-stem-cell-research-%E2%80%93-2017>
- DBT, Biosafety Programme, Guidelines, Rules, and Regulations: <https://dbtindia.gov.in/regulations-guidelines/regulations/biosafety-programme>
- CDSCO, Stem cell and Cell based Products: <https://cdsco.gov.in/opencms/opencms/en/biologicals/Stem-cells-and-Cell-based-Products/>

### **ASIA/PACIFIC – Indonesia**

#### **General**

#### **Key Organizations**

- Ministry of Health, National Institute of Health Research and Development: <https://www.kemkes.go.id/index.php?lg=LN02>

#### **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
- National Guidelines on Ethics in Health Research (2003)

### **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

- Ministry of Education, Culture, Sports, Science, and Technology (MEXT): <http://www.mext.go.jp/english/>
- Ministry of Health, Labor, and Welfare (MHLW): <http://www.mhlw.go.jp/english/index.html>

#### Relevant Standards

- Ethical Guidelines for Medical and Biological Research Involving Human Subjects (2021): [https://www.lifescience.mext.go.jp/bioethics/seimeikagaku\\_igaku.html](https://www.lifescience.mext.go.jp/bioethics/seimeikagaku_igaku.html)
- Clinical Trials Act (2009): <https://elaws.e-gov.go.jp/document?lawid=429AC0000000016>

## Drugs, Biologics, and Devices

### Drugs

#### Key Organizations

- Ministry of Health, Labor, and Welfare (MHLW): <http://www.mhlw.go.jp/english/index.html>
- Pharmaceuticals and Medical Devices Agency: <http://www.pmda.go.jp/english/index.html>

#### Relevant Standards

- Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (2016): <https://elaws.e-gov.go.jp/document?lawid=335AC0000000145>
- Clinical Trials Act (2017): <https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000213334.pdf>
- Ministerial Ordinance on Good Clinical Practice for Drugs (2020): [https://elaws.e-gov.go.jp/document?lawid=409M50000100028\\_20200901\\_502M60000100155](https://elaws.e-gov.go.jp/document?lawid=409M50000100028_20200901_502M60000100155)

### Devices

#### Key Organizations

- Ministry of Health, Labor, and Welfare (MHLW): <http://www.mhlw.go.jp/english/index.html>
- Pharmaceuticals and Medical Devices Agency: <http://www.pmda.go.jp/english/index.html>

#### Relevant Standards

- Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (2016): <https://elaws.e-gov.go.jp/document?lawid=335AC0000000145>
- Clinical Trials Act (2017): <https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000213334.pdf>
- 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

- Ministry of Health, Labor, and Welfare (MHLW): <http://www.mhlw.go.jp/english/index.html>
- National Institute of Public Health: [https://www.niph.go.jp/index\\_en.html](https://www.niph.go.jp/index_en.html)
- Japan Registry of Clinical Trials: <https://jrct.niph.go.jp/>

### Relevant Standards

- Clinical Trials Act (2017): <https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000213334.pdf>
- NIPH Clinical Trials Search: <https://rctportal.niph.go.jp/en/>

## Research Injury

### Key Organizations

- Ministry of Health, Labor, and Welfare (MHLW): <http://www.mhlw.go.jp/english/index.html>

### Relevant Standards

- Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act (2016): <https://elaws.e-gov.go.jp/document?lawid=335AC0000000145>
- Clinical Trials Act (2017): <https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000213334.pdf>
- Ministerial Ordinance on Good Clinical Practice for Drugs (2020), Article 14, 23: [https://elaws.e-gov.go.jp/document?lawid=409M50000100028\\_20200901\\_502M60000100155](https://elaws.e-gov.go.jp/document?lawid=409M50000100028_20200901_502M60000100155)
- 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>

## Privacy/Data Protection

### Key Organizations

- Personal Information Protection Commission: <http://www.ppc.go.jp/en/>
- Office of Healthcare Policy of the Cabinet Secretariat: <http://www.kantei.go.jp/jp/singi/kenkouiryou/en/>

### Relevant Standards

- Act on the Protection of Personal Information (2020): <https://elaws.e-gov.go.jp/document?lawid=415AC0000000057>
- Act on the Protection of Personal Information, Various Laws and Policies: <https://www.ppc.go.jp/en/legal/>
- Act Regarding Anonymized Medical Data to Contribute to R&D in the Medical Field (2017): [http://www.kantei.go.jp/jp/singi/kenkouiryou/jisedai\\_kiban/pdf/170310\\_shiryu3.pdf](http://www.kantei.go.jp/jp/singi/kenkouiryou/jisedai_kiban/pdf/170310_shiryu3.pdf)
- Amendment to the Cabinet Order to Enforce the Act on the Protection of Personal Information (2016): [https://www.ppc.go.jp/files/pdf/Cabinet\\_Order.pdf](https://www.ppc.go.jp/files/pdf/Cabinet_Order.pdf)
- Enforcement Rules for the Act on the Protection of Personal Information (2016): [https://www.ppc.go.jp/files/pdf/PPC\\_rules.pdf](https://www.ppc.go.jp/files/pdf/PPC_rules.pdf)

*International Compilation of Human Research Standards  
2021 Edition*

- Regulation for Enforcement of the Clinical Trials Act, Article 20 (2018):  
<https://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000195391.pdf>

## Human Biological Materials

### Key Organizations

- Ministry of Health, Labor, and Welfare (MHLW): <http://www.mhlw.go.jp/english/index.html>

### Relevant Standards

- On Research and Development Utilizing Human Tissues Removed for Surgery and Other Procedures (1998): [https://www.mhlw.go.jp/www1/shingi/s9812/s1216-2\\_10.html](https://www.mhlw.go.jp/www1/shingi/s9812/s1216-2_10.html)

## Genetic Research

### Key Organizations

- Council for Science, Technology, and Innovation (CSTI):  
<https://www8.cao.go.jp/cstp/english/index.html>
- Ministry of Education, Culture, Sports, Science, and Technology (MEXT):  
<http://www.mext.go.jp/english/>
- Ministry of Health, Labor, and Welfare (MHLW): <http://www.mhlw.go.jp/english/index.html>
- Ministry of Economy, Trade, and Industry (METI): <http://www.meti.go.jp/english/>

### Relevant Standards

- Ethical Guidelines for Medical and Biological Research Involving Human Subjects (2021):  
[https://www.lifescience.mext.go.jp/bioethics/seimeikagaku\\_igaku.html](https://www.lifescience.mext.go.jp/bioethics/seimeikagaku_igaku.html)
- Fundamental Principles of Research on the Human Genome (2000)
- Ethics Guidelines for Human Genome/Gene Analysis Research (2017)
- Guidelines for Clinical Research in Gene Therapy and Others (2019): [https://www.neurology-jp.org/news/pdf/news\\_20190307\\_02\\_02.pdf](https://www.neurology-jp.org/news/pdf/news_20190307_02_02.pdf)
- 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

- Council for Science, Technology, and Innovation (CSTI):  
<https://www8.cao.go.jp/cstp/english/index.html>
- Ministry of Education, Culture, Sports, Science, and Technology (MEXT):  
<http://www.mext.go.jp/english/>
- Ministry of Health, Labor, and Welfare (MHLW): <http://www.mhlw.go.jp/english/index.html>

### Relevant Standards

- Act on Regulation of Human Cloning Techniques (2014), English version (2000):  
<http://www.cas.go.jp/jp/seisaku/hourei/data/htc.pdf>

*International Compilation of Human Research Standards  
2021 Edition*

- Ordinance for Enforcement of Act on Regulation of Human Cloning Techniques (2021): [https://www.lifescience.mext.go.jp/files/pdf/n2276\\_09.pdf](https://www.lifescience.mext.go.jp/files/pdf/n2276_09.pdf)
- Act on Safety of Regenerative Medicine (2013): <http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/0000030847.pdf>
- Ordinance for Enforcement of Act on Safety of Regenerative Medicine (2019): [https://www.lifescience.mext.go.jp/files/pdf/n2163\\_01.pdf](https://www.lifescience.mext.go.jp/files/pdf/n2163_01.pdf)
- Rules for Enforcement of Act on Safety of Regenerative Medicine (2018): <https://www.mhlw.go.jp/content/000452630.pdf>
- Guidelines on the Distribution of Human Embryonic Stem Cells (2019): <https://www.lifescience.mext.go.jp/files/pdf/hESCdistributionguideline2019.pdf>
- Guidelines on the Utilization of Human Embryonic Stem Cells (2019): <https://www.lifescience.mext.go.jp/files/pdf/hESCutilizationguideline2019.pdf>
- Guidelines on Research on Producing Germ Cells from Human Induced Pluripotent Stem Cells or Human Tissue Stem Cells (2015): [http://www.lifescience.mext.go.jp/files/pdf/n1492\\_01r2.pdf](http://www.lifescience.mext.go.jp/files/pdf/n1492_01r2.pdf)
- English version (2010): [http://www.lifescience.mext.go.jp/files/pdf/n1567\\_02r2.pdf](http://www.lifescience.mext.go.jp/files/pdf/n1567_02r2.pdf)
- Fundamental Philosophy on Handling of Human Embryo (2004)
- Guidelines on the Handling of a Specified Embryo (2021): [https://www.lifescience.mext.go.jp/files/pdf/n2276\\_11.pdf](https://www.lifescience.mext.go.jp/files/pdf/n2276_11.pdf)
- Ethical Guidelines for Research on Assisted Reproductive Technology to Develop Human Fertilized Embryos(2021): [https://www.lifescience.mext.go.jp/files/pdf/n2281\\_01.pdf](https://www.lifescience.mext.go.jp/files/pdf/n2281_01.pdf)
- Guidelines for Research Using Gene-altering Technologies on Human Fertilized Embryos (2021): [https://www.lifescience.mext.go.jp/files/pdf/n2282\\_01.pdf](https://www.lifescience.mext.go.jp/files/pdf/n2282_01.pdf)

## 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:*

[http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical\\_review\\_cis\\_book\\_kubar\\_english.pdf](http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf)

### General

#### Key Organizations

- Ministry of Healthcare and Social Development, Central Commission on Research Ethics: <https://www.gov.kz/memleket/entities/dsm?lang=en>

#### Relevant Standards

- Guidelines on Ethics in Health Research. (2007)
- Local Ethics Committees: Policy, Rules and Procedures (2014)
- Guidelines on Ethics in Biomedical Research (2015)

## Drugs, Biologics, and Devices

### Key Organizations

- Ministry of Healthcare and Social Development, Committee for Medical and Pharmaceutical Control: <https://www.gov.kz/memleket/entities/kmfk?lang=en>

### Relevant Standards

- Code of the Republic of Kazakhstan "On People's Health and the Health Care System" (18.09.2009 No.193-IV), Articles 74 and 180 (2015): [http://online.zakon.kz/Document/?doc\\_id=30479065#pos=1;-8](http://online.zakon.kz/Document/?doc_id=30479065#pos=1;-8)
- 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
- Guidelines on Clinical Trials in Kazakhstan (2003)

## Privacy/Data Protection

### Key Organizations

- Ministry of Healthcare and Social Development: <http://www.mzsr.gov.kz/en>

### Relevant Standards

- Code of the Republic of Kazakhstan "On People's Health and the Health Care System" (18.09.2009 No.193-IV), Article 28 (2015): [http://online.zakon.kz/Document/?doc\\_id=30479065#pos=1;-8](http://online.zakon.kz/Document/?doc_id=30479065#pos=1;-8)

## ASIA/PACIFIC – Kyrgyzstan

### General

### Key Organizations

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

### Relevant Standards

- Constitution of Kyrgyz Republic, Chapter II, Article 22 (2010): [http://www.gov.kg/?page\\_id=263&lang=ru](http://www.gov.kg/?page_id=263&lang=ru)
- 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>
- Ministry of Health, National Bioethics Committee
- Pharmaceutical Union of Kyrgyzstan, Ethics Committee

### Relevant Standards

- Law on the Circulation of Medicinal Products of the Kyrgyz Republic, as amended by the Law of the Kyrgyz Republic of May 3, 2018 N 44, Chapter VII, Articles 24-25: <http://cbd.minjust.gov.kg/act/view/ru-ru/111672>
- DDMD, National Standard KMC 1195:2010: Medical Devices: Rules for Clinical Trials (2010): <http://www.pharm.kg/ru/legislation/>
- DDMD, Technical Regulations on the Safety of Medical Products for Medical Application, Approved by the Governmental Order # 74 from February 1, 2012: <http://www.pharm.kg/ru/legislation/>

## Research Injury

### Key Organizations

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

### Relevant Standards

- Law on the Circulation of Medicinal Products of the Kyrgyz Republic, as amended by the Law of the Kyrgyz Republic of May 3, 2018 N 44, Chapter VII, Articles 24-25: <http://cbd.minjust.gov.kg/act/view/ru-ru/111672>
- DDMD, National Standard KMC 1195:2010: Medical Devices, Rules for Clinical Trials, Paragraphs 3, 4, and 6 (2010): <http://www.pharm.kg/ru/legislation/>

## Human Biological Materials

### Key Organizations

- Ministry of Health, Department of Drug and Medical Devices Provision: <http://www.pharm.kg>
- Ministry of Health, National Bioethics Committee

### Relevant Standards

- Law on Health Protection of the Kyrgyz Republic (09.01.2005 No. 6): Article 39: <http://www.pharm.kg/ru/legislation>
- Technical Regulations on the Safety of Medical Products for Medical Application, Approved by the Governmental Order #74 from February 1, 2012: <http://www.pharm.kg/ru/legislation/>

## Social-Behavioral Research

### Key Organizations

- Ministry of Justice of the Kyrgyz Republic: <http://minjust.gov.kg/ru/>

### Relevant Standards

- Law On the Protection of Traditional Knowledge, as amended by the Law of the Kyrgyz Republic of July 18, 2014 No. 144): <http://cbd.minjust.gov.kg/act/view/ru-ru/202149/20?cl=ru-ru>

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- Law on Health Protection of the Kyrgyz Republic (09.01.2005 No. 6): Article 91: <http://www.pharm.kg/ru/legislation>
- DDMD, National Standard KMC 1195:2010: Medical Devices, Rules for Clinical Trials, Paragraphs 3, 4, and 6 (2010): <http://www.pharm.kg/ru/legislation/>
- DDMD, Technical Regulations on the Safety of Medical Products for Medical Application, Approved by the Governmental Order #74 from February 1, 2012: <http://www.pharm.kg/ru/legislation/>

## ASIA/PACIFIC – Malaysia

### General

### Key Organizations

- Ministry of Health Malaysia, National Institutes of Health, Medical Review and Ethics Committee (MREC): <https://www.nih.gov.my/mrec/>
- Malaysian Industry-Government Group For High Technology (MIGHT): <https://www.might.org.my/>
- Academy of Sciences Malaysia (ASM): <https://www.akademisains.gov.my/>

### Relevant Standards

- Malaysian Guidelines of Good Clinical Practice (2020): <https://www.npra.gov.my/easyarticles/images/users/1059/NPRA-GUIDELINES-FOR-GCP-INPECTION-IN-MSIA-ED2.1.pdf>
- ASM, The Malaysian Code of Responsible Conduct in Research (2020): <https://www.akademisains.gov.my/asm-publication/the-malaysian-code-of-responsible-conduct-in-research-2nd-edition/>
- Clinical Trials and Biomedical Research (2007) (<https://mmc.gov.my/wp-content/uploads/2019/11/Clinical-TrialsBiomedical-Research.pdf>)



*International Compilation of Human Research Standards  
2021 Edition*

- Malaysian Guideline for Application of Clinical Trial Import License and Clinical Trial Exemption, 7th Edition (2021):  
<https://www.npra.gov.my/easyarticles/images/users/1069/CTIL%20Guidelines%20Ed%207%20&%20Form%20Version%202001/Malaysian-Guideline-for-Application-of-CTIL-and-CTX-7.1-Edition-16.09.2pdf>

## Drugs, Biologics, and Devices

### Key Organizations

- Ministry of Health Malaysia, National Pharmaceutical Regulatory Agency (NPR):  
<https://npra.gov.my/index.php/en/>
- National Committee for Clinical Research (NCCR): <http://www.nccr.gov.my/>
- Ministry of Health, National Institutes of Health (NIH): <http://www.nih.gov.my/>
- Medical Device Authority (MDA), Ministry of Health Malaysia: <https://portal.mda.gov.my/>
- National Pharmaceutical Regulatory Agency (NPR), Ministry of Health Malaysia: <https://npra.gov.my/index.php/en/>
- Clinical Research Malaysia (CRM), Ministry of Health: <https://clinicalresearch.my/>
- Society of Clinical Research Professionals Malaysia (SCRPM): <https://scrpm.ucoz.com/>

### Relevant Standards

- Malaysian Guidelines of Good Clinical Practice (2020):  
<https://www.npra.gov.my/easyarticles/images/users/1059/NPRA-GUIDELINES-FOR-GCP-INPECTION-IN-MSIA-ED2.1.pdf>
- Malaysian Guideline for Phase I Unit Inspection and Accreditation Program (2018):  
[https://www.npra.gov.my/images/Guidelines\\_Central/Guidelines\\_on\\_Clinical\\_Trial/MALAYSIAN\\_GUIDELINEFORPHASEIUNITINSPECTION.pdf](https://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Clinical_Trial/MALAYSIAN_GUIDELINEFORPHASEIUNITINSPECTION.pdf)
- Malaysian Phase I Clinical Trial Guidelines: <https://clinicalresearch.my/wp-content/uploads/2020/11/Malaysian-Phase-I-Clinical-Trial-Guidelines.pdf>
- NIH, Guidelines for Conducting Research in Ministry of Health Institutions and Facilities (2015):  
<https://www.pharmacy.gov.my/v2/sites/default/files/document-upload/nih-guidelines-conducting-research-moh-institutions-facilities-revision-01-2015.pdf>
- A Guide To Conducting Clinical Trials in Malaysia (2016): <https://clinicalresearch.my/wp-content/uploads/2020/11/A-Guide-to-Conduct-Clinical-Trials-in-Malaysia.pdf>
- Medical Device Act 2012: <https://portal.mda.gov.my/documents/regulation/685-medical-device-act-2012-eng/file.html>
- Medical Device Authority Act 2012: <https://portal.mda.gov.my/documents/regulation/685-medical-device-act-2012-eng/file.html>
- Medical Device Regulations 2012: <https://portal.mda.gov.my/documents/regulation/688-medical-device-regulations-2012/file.html>
- Medical Device (Exemption) Order 2016 <https://portal.mda.gov.my/documents/medical-device-exemption-order-2016.html>

*International Compilation of Human Research Standards  
2021 Edition*

- Medical Device Guidance Document Notification of Exemption from Registration of Medical Devices For The Purpose Of Clinical Research Or Performance Evaluation (Medical Device Guidance) (2017): <https://portal.mda.gov.my/documents/guidance-documents/807-16-notification-for-clinical-research-or-performance-evaluation/file.html>

## Clinical Trial Registries

### Key Organizations

- National Medical Research Register (NMRR): <https://nmrr.gov.my/>

### Relevant Standards

- NMRR, User Manual: <https://nmrr.gov.my/documents?type=user-manual>
- NMRR, Guidelines, various: <https://nmrr.gov.my/documents?type=guidelines>

## Research Injury

### Key Organizations

- Ministry of Health Malaysia, National Pharmaceutical Regulatory Agency (NPRA): <https://npra.gov.my/index.php/en/>
- Attorney General's Chambers of Malaysia (AGC)
- Department of Occupational Safety and Health (DOSH), Ministry of Human Resources: <https://www.dosh.gov.my/index.php/about-us/dosh-profile>
- National Committee for Clinical Research (CRC): <http://www.nccr.gov.my/>

### Relevant Standards

- Occupational Safety and Health Act 1994: Section 32: <https://www.dosh.gov.my/index.php/legislation/acts-legislation/23-02-occupational-safety-and-health-act-1994-act-514/file>
- Malaysian Guidelines of Good Clinical Practice (2020): <https://www.npra.gov.my/easyarticles/images/users/1059/NPRA-GUIDELINES-FOR-GCP-INPECTION-IN-MSIA-ED2.1.pdf>

## Social-Behavioral Research

### Key Organizations

- Malaysian Industry-Government Group For High Technology (MIGHT): <https://www.might.org.my/>
- Ministry of Health Malaysia, Institute for Health Behavioural Research (IPTK): <https://iptk.moh.gov.my/>

### Relevant Standards

- The Malaysian Code of Responsible Conduct in Research (2020): <https://www.akademisains.gov.my/asm-publication/the-malaysian-code-of-responsible-conduct-in-research-2nd-edition/>

## Privacy/Data Protection

### Key Organizations

- Department of Personal Data Protection: <https://www.pdp.gov.my/jpdpv2/?lang=en>

### Relevant Standards

- Act 709: Personal Data Protection Act (2010): Section 38, 39 and 40 (<https://www.pdp.gov.my/jpdpv2/laws-of-malaysia-pdpa/personal-data-protection-act-2010/?lang=en>)

## Human Biological Materials

### Key Organizations

- National Committee for Clinical Research (NCCR): <http://www.nccr.gov.my/>
- Laws of Malaysia. Attorney General's Chambers of Malaysia (AGC)

### Relevant Standards

- Act 130, Human Tissues Act (1974): Section 2 Removal of parts of bodies for therapeutic purpose: <http://www.agc.gov.my/agcportal/uploads/files/Publications/LOM/EN/Act%20130.pdf>
- Act 699, DNA Identification Act 2009. Malaysian Government Gazette of 3 September 2009: [http://www.agc.gov.my/agcportal/uploads/files/Publications/LOM/EN/Act%20699%209\\_7\\_2015.pdf](http://www.agc.gov.my/agcportal/uploads/files/Publications/LOM/EN/Act%20699%209_7_2015.pdf)
- Act 795 Access to Biological Resources and Benefit Sharing Act (2017): <https://www.mybis.gov.my/pb/3567>
- Malaysian Guideline on the Use of Human Biological Sample for Research (2015) [https://www.crc.gov.my/wp-content/uploads/2016/07/Guideline\\_on\\_Human\\_Tissue\\_in\\_Clinical\\_Research.pdf](https://www.crc.gov.my/wp-content/uploads/2016/07/Guideline_on_Human_Tissue_in_Clinical_Research.pdf)

## Genetic Research

### Key Organizations

- Malaysian Medical Council: <http://mmc.gov.my/>
- Laws of Malaysia. Attorney General's Chambers of Malaysia (AGC)
- Medical Development Division, Ministry of Health (MOH): <https://www.moh.gov.my/index.php/pages/view/270?mid=248>
- Ministry of Energy and Natural Resources: <https://www.mybis.gov.my/pb/4497>

### Relevant Standards

- Act 678. Biosafety Act 2007: <http://bch.cbd.int/database/attachment/?id=17640>
- Biosafety (Approval and Notification) Regulations 2010: <http://bch.cbd.int/database/attachment/?id=17640>
- MMC, Medical Genetics and Genetic Services. MMC Guidelines 010/2006: [http://www.npra.gov.my/images/Guidelines\\_Central/Guidelines\\_on\\_Regulatory/CGTP\\_guidelines.doc](http://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Regulatory/CGTP_guidelines.doc)
- Various Guidelines for Institutional Biosafety Committees: <https://umresearch.um.edu.my/ibbc-policy-amp-guidelines>

*International Compilation of Human Research Standards  
2021 Edition*

- Guidelines on Ethical Issues in the provision of Medical Genetics Services in Malaysia (2019) [https://www.moh.gov.my/moh/resources/Penerbitan/Garis%20Panduan/Garis%20panduan%20Umu%20\(Awam\)/Guidelines\\_On\\_Ethical\\_Issues\\_In\\_The\\_Provision\\_Of\\_Medical\\_Genetics\\_Services\\_In\\_Malaysia\\_\(1\).pdf](https://www.moh.gov.my/moh/resources/Penerbitan/Garis%20Panduan/Garis%20panduan%20Umu%20(Awam)/Guidelines_On_Ethical_Issues_In_The_Provision_Of_Medical_Genetics_Services_In_Malaysia_(1).pdf)
- User's Guide to the Access to Biological Resources and Benefit Sharing Act 2017 (Act 795): <https://www.mybis.gov.my/pb/4497>

## Embryos, Stem Cells, and Cloning

### Key Organizations

- Ministry of Health, National Pharmaceutical Control Bureau (NPCB): <https://npra.gov.my/index.php/en/>
- Medical Development Division, Ministry of Health (MOH): <https://www.moh.gov.my/index.php/pages/view/270?mid=248>
- Ministry of Health, National Stem Cell Research and Ethics Subcommittee (NSCERT)

### Relevant Standards

- Checklist for Research on Stem Cell and Cell-Based Therapies (2015): <https://nih.gov.my/mrec/wp-content/uploads/2014/11/Stem-Cell-checklist.pdf>
- Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) in Malaysia (2016): [https://www.npra.gov.my/images/00NPRA/biologic/guidelines/CGTP\\_guidelinesbio.pdf](https://www.npra.gov.my/images/00NPRA/biologic/guidelines/CGTP_guidelinesbio.pdf)
- Medical Development Division, Guidelines for Stem Cell Research and Gene Therapy (2009): <http://www.moh.gov.my/moh/resources/auto%20download%20images/586f38d1c77ed.pdf>
- National Organ, Tissue and Cell Transplantation Policy: <http://www.mst.org.my/articles/MALAYSIA%20TRANSPLANT%20POLICY.pdf>
- National Standards for Cord Blood Banking and Transplantation: <http://www.moh.gov.my/moh/resources/auto%20download%20images/589d78e8689af.pdf>
- National Standards For Stem Cell Transplantation: Collection, Processing, Storage and Infusion of Haemopoietic Stem Cells and Therapeutic Cells (2nd Edition) (2018): [https://www.moh.gov.my/index.php/database\\_stores/store\\_view\\_page/70/70](https://www.moh.gov.my/index.php/database_stores/store_view_page/70/70)
- National Guidelines For Haemopoietic Stem Cell Therapy (2009): [https://www.moh.gov.my/index.php/database\\_stores/store\\_view\\_page/70/47](https://www.moh.gov.my/index.php/database_stores/store_view_page/70/47)

## ASIA/PACIFIC – Myanmar

### General

#### Key Organizations

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

#### Relevant Standards

- DMR, Guideline for Submission to Ethics Review Committee (2016)

## Drugs, Biologics, and Devices

### Key Organizations

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

### Relevant Standards

- National Drug Law (1992)

## Human Biological Materials

### Relevant Standards

- Blood and Blood Products Law (2003) (Burmese): [http://www.moh.gov.mm/file/Law/Blood%20and%20Blood%20Product%20Law%20\(2003\).pdf](http://www.moh.gov.mm/file/Law/Blood%20and%20Blood%20Product%20Law%20(2003).pdf)
- Body Organ Donation Law (2004)

## ASIA/PACIFIC – Nepal

### General

### Key Organizations

- Nepal Health Research Council, Ethical Review Board: <http://nhrc.gov.np/ethics/ethical-review-board/>

### Relevant Standards

- Nepal Health Research Council, Acts, various: <http://nhrc.gov.np/publication-category/act/>
- Nepal Health Research Council, Guidelines, various: <http://nhrc.gov.np/publication-category/guidelines/>
- Nepal Health Research Council, Policies, various: <http://nhrc.gov.np/publication-category/policy/>

## Drugs, Biologics, and Devices

### Key Organizations

- Nepal Health Research Council: <http://nhrc.gov.np/>

### Relevant Standards

- Nepal Health Research Council, Acts, various: <http://nhrc.gov.np/publication-category/act/>
- Nepal Health Research Council, Guidelines, various: <http://nhrc.gov.np/publication-category/guidelines/>
- Nepal Health Research Council, Policies, various: <http://nhrc.gov.np/publication-category/policy/>

## 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/>
- National Ethics Advisory Committee (NEAC): <http://www.neac.health.govt.nz/>

*International Compilation of Human Research Standards  
2021 Edition*

- 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/>
- Ministry of Business, Innovation and Employment: <http://www.mbie.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
- HDC, The Code of Health and Disability Services Consumers' Rights (the Code of Rights) (2004): <https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/>
- HRC, The Role of Ethics (scroll down to Specific Considerations), various: <http://www.hrc.govt.nz/ethics-and-regulatory/applying-ethical-approval>
- NEAC, National Ethical Standards, various: <https://neac.health.govt.nz/national-ethical-standards/>
- NEAC, Publications and Resources, various: <https://neac.health.govt.nz/publications-and-resources/neac-publications/>
- MOH, Standard Operating Procedures for Health and Disability Ethics Committees (2012): <http://www.ethics.health.govt.nz/operating-procedures>

## **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**

- Accident Compensation Act 2001, Section 32 (2010)
- Medicines Act 1981(2012)
- Medsafe, Medicines Regulations 1984: <http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM95668.html>
- Medsafe, Good Clinical Research Practice and Obtaining Approval for Clinical Trials (2013): <http://www.medsafe.govt.nz/medicines/clinical-trials.asp>
- 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**

- Medicines (Database of Medical Devices) Regulations (2003): <http://www.legislation.govt.nz/regulation/public/2003/0325/latest/DLM224223.html>
- Standard Operating Procedures for Health and Disability Ethics Committees (2012): <http://www.ethics.health.govt.nz/operating-procedures>
- 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**

- FAQs: <http://www.anzctr.org.au/Faq.aspx>

## **Privacy/Data Protection**

### **Key Organizations**

- Privacy Commissioner: <http://www.privacy.org.nz/>

### **Relevant Standards**

- Official Information Act 1982 (2012)
- Public Records Act (2005)
- Privacy Act 1993 (2012)
- Health Information Privacy Code 1994: <http://www.privacy.org.nz/assets/Files/Codes-of-Practice-materials/Health-Information-Privacy-Code-1994-including-Amendment.pdf>

## **Human Biological Materials**

### **Key Organizations**

- Ministry of Health (MOH): <http://www.moh.govt.nz/>
- 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/>
- Office of the Health and Disability Commissioner (HDC): <http://www.hdc.org.nz>
- Ministry of Business, Innovation and Employment: <http://www.mbie.govt.nz/>

### **Relevant Standards**

- Health Act 1956 (2012)

*International Compilation of Human Research Standards  
2021 Edition*

- Human Tissue Act 2008
- MOH, Guidelines for the Use of Human Tissue for Future Unspecified Research Purposes (2007): <http://www.health.govt.nz/publication/guidelines-use-human-tissue-future-unspecified-research-purposes>

## Genetic Research

### Key Organizations

- Environmental Protection Authority: <http://www.epa.govt.nz/>
- Health Research Council (HRC), Gene Technology Advisory Committee: <http://www.hrc.govt.nz/about-us/committees/gene-technology-advisory-committee-gtac>

### Relevant Standards

- Hazardous Substances and New Organisms Act 1996 (2012)

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

- Human Assisted Reproductive Technology Act 2004 (2009)
- Human Assisted Reproductive Technology (HART) Order (2005): <http://www.legislation.govt.nz/regulation/public/2005/0181/latest/DLM335192.html>
- ACART, Publications and Resources, various: <https://acart.health.govt.nz/publications-and-resources/publications/>

## ASIA/PACIFIC – Pakistan

### General

#### Key Organizations

- National Bioethics Committee: <http://nbcPakistan.org.pk/>

#### Relevant Standards

- Various: <http://nbcPakistan.org.pk/guidelines.html>

## Drugs, Biologics, and Devices

#### Key Organizations

- National Bioethics Committee: <http://nbcPakistan.org.pk/>

#### Relevant Standards

- Guidelines For Healthcare Professionals Interaction with Pharmaceutical Trade and Industry (PPI Guidelines): [http://nbcPakistan.org.pk/?page\\_id=61](http://nbcPakistan.org.pk/?page_id=61)



## Human Biological Materials

### Key Organizations

- National Bioethics Committee: <http://nbcPakistan.org.pk/>

### Relevant Standards

- Ethical Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials (HBM): <http://nbcPakistan.org.pk/assets/hbm-nbc-guidelines-final-18june-2016.pdf>

## Embryos, Stem Cells, and Cloning

### Key Organizations

- National Bioethics Committee: <http://nbcPakistan.org.pk/>

### Relevant Standards

- Protocol/Guidelines for Stem Cell Research/Regulation in Pakistan: [http://nbcPakistan.org.pk/?page\\_id=61](http://nbcPakistan.org.pk/?page_id=61)

## ASIA/PACIFIC – Philippines

### General

### Key Organizations

- Philippine Health Research Ethics Board (PHREB): [www.ethics.healthresearch.ph](http://www.ethics.healthresearch.ph)
- Department of Science and Technology (DOST): <http://www.dost.gov.ph/>
- Department of Health (DOH): <http://www.doh.gov.ph/>
- Commission of Higher Education (CHED): <https://ched.gov.ph/>
- National Commission on Indigenous Peoples (NCIP): <https://ncip.gov.ph/>

### Relevant Standards

- Republic Act No. 10532: An Act Institutionalizing the Philippine National Health Research System (2013): <https://www.officialgazette.gov.ph/2013/05/07/republic-act-no-10532/>
- PNHRs Act Implementing Rules and Regulations: <https://www.healthresearch.ph/index.php/about-pnhrs/downloads/category/162-irr>
- Memorandum: Registration and Accreditation of all Ethics Review Committees in the Philippines (2015): <https://www.healthresearch.ph/index.php/about-pnhrs/downloads/category/163-ra>
- PHREB National Ethical Guidelines for Health and Health-Related Research, Page 70 (2017): <https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg>
- PHREB, Orders and Memoranda, various: <https://ethics.healthresearch.ph/index.php/orders-and-memorandums>

## Drugs, Biologics, and Devices

### Drugs

### Key Organizations

- Food and Drug Administration (FDA): <http://www.fda.gov.ph/>

### **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
- PHREB, Orders and Memoranda, various: <https://ethics.healthresearch.ph/index.php/orders-and-memorandums>
- PHREB, National Ethical Guidelines for Health and Health-Related Research, Page 70 (2017): <https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg>

### **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-neg>

### **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](http://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-neg>

### **Social-Behavioral Research**

#### **Key Organizations**

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

### **Relevant Standards**

- National Ethical Guidelines for Health and Health-Related Research, Pages 108-118. (2017): <https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg>

## **Privacy/Data Protection**

### **Relevant Standards**

- Republic Act No. 10173: Data Privacy Act of 2012: <http://www.officialgazette.gov.ph/2012/08/15/republic-act-no-10173/>
- Data Privacy Act Implementing Rules and Regulations (2016): <https://privacy.gov.ph/implementing-rules-and-regulations-of-republic-act-no-10173-known-as-the-data-privacy-act-of-2012/>

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

- National Ethical Guidelines for Health and Health-Related Research, Pages 91, 157 and 163 (2017): <http://www.ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=96:2017-national-ethical-guidelines-for-health-and-health-related-research>

## **ASIA/PACIFIC – Singapore**

### **General**

#### **Key Organizations**

- Ministry of Health (MOH): <http://www.moh.gov.sg>
- Bioethics Advisory Committee (BAC): <https://www.bioethics-singapore.gov.sg>

#### **Relevant Standards**

- Human Biomedical Research Act 2015: <https://sso.agc.gov.sg/Act/HBRA2015>
- Human Biomedical Research Regulations 2017: <https://sso.agc.gov.sg/SL/HBRA2015-S621-2017>
- Resources on Human Biomedical Research Act: <https://www.moh.gov.sg/policies-and-legislation/human-biomedical-research-act>
- Ethics Guidelines for Human Biomedical Research (2015): <https://www.bioethics-singapore.gov.sg/publications/reports/ethics-guidelines-for-human-biomedical-research>

## **Drugs, Biologics, and Devices**

### **Drugs**

#### **Key Organizations**

- Health Sciences Authority of Singapore (HSA): <https://www.hsa.gov.sg/>
- Ministry of Health (MOH): <http://www.moh.gov.sg/>
- National Environment Agency (NEA), Centre For Radiation Protection And Nuclear Science: <https://www.nea.gov.sg/anti-pollution-radiation-protection/radiation-protection>

*International Compilation of Human Research Standards  
2021 Edition*

### **Relevant Standards**

- Health Products Act 2007: <https://sso.agc.gov.sg/Act/HPA2007>
- Medicines Act 1975: <https://sso.agc.gov.sg/Act/MA1975>
- Health Products (Clinical Trials) Regulations 2016: <https://sso.agc.gov.sg/SL/HPA2007-S331-2016>
- Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016: <https://sso.agc.gov.sg/SL/HPA2007-S332-2016>
- Medicines (Clinical Trials) Regulations 2016: <https://sso.agc.gov.sg/SL/MA1975-S335-2016>
- Medicines (Medicinal Products as Clinical Research Materials) Regulations 2016: <https://sso.agc.gov.sg/SL/MA1975-S336-2016>
- Singapore Guidance on Good Clinical Practice Compliance Inspection Framework (2021): [https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa\\_gn-ioctb-11\\_gcp\\_inspection\\_1mar2021.pdf](https://www.hsa.gov.sg/docs/default-source/hprg-io-ctb/hsa_gn-ioctb-11_gcp_inspection_1mar2021.pdf)
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH E6(R2) Good Clinical Practice Guideline, 2016: [https://database.ich.org/sites/default/files/E6\\_R2\\_Addendum.pdf](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf)
- Health Products (Medical Device) Regulations 2010: <http://sso.agc.gov.sg/SL/HPA2007-S436-2010>
- Directive on the Use of Cell, Tissue and Gene Therapy Products Manufactured In-House by Healthcare Institutions (2020): <https://www.moh.gov.sg/licensing-and-regulation/regulations-guidelines-and-circulars/details/directive-on-the-use-of-cell-tissue-and-gene-therapy-products-manufactured-in-house-by-healthcare-institutions>
- Radiation Protection Act 2007: <https://sso.agc.gov.sg/Act/RPA2007>
- Radiation Protection (Non-Ionising Radiation) Regulations 1991: <https://sso.agc.gov.sg/SL/262-RG1>

### **Research Injury**

#### **Key Organizations**

- Ministry of Health (MOH): <http://www.moh.gov.sg/>
- Health Sciences Authority: <http://www.hsa.gov.sg>

#### **Relevant Standards**

- Human Biomedical Research Act 2015: <https://sso.agc.gov.sg/Act/HBRA2015>
- Health Products Act (Cap 122D): <https://sso.agc.gov.sg/Act/HPA2007>
- Human Biomedical Research Regulations 2017: <https://sso.agc.gov.sg/SL/HBRA2015-S621-2017>
- Health Products (Clinical Trials) Regulations 2016: <https://sso.agc.gov.sg/SL/HPA2007-S331-2016>
- Medicines (Clinical Trials) Regulations (2016): <https://sso.agc.gov.sg/SL/MA1975-S335-2016>
- Singapore Guideline for Good Clinical Practice (2016): [http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6/E6\\_R2\\_Step\\_4\\_2016\\_1109.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step_4_2016_1109.pdf)

### **Privacy/Data Protection**

#### **Key Organizations**

- Ministry of Health (MOH): <http://www.moh.gov.sg/>

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

- Personal Data Protection Commission (PDPC): <https://www.pdpc.gov.sg>
- Bioethics Advisory Committee (BAC): <https://www.bioethics-singapore.gov.sg>

### **Relevant Standards**

- Personal Data Protection Act 2012: <https://sso.agc.gov.sg/Act/PDPA2012>
- Healthcare Sector Specific Guidelines Promulgated by PDPC: <https://www.pdpc.gov.sg/-/media/Files/PDPC/PDF-Files/Sector-Specific-Advisory/advisoryguidelinesforthehealthcaresector28mar2017.pdf?la=en>
- Personal Information in Biomedical Research (2007): <https://www.bioethics-singapore.gov.sg/files/publications/reports/personal-informations-in-biomedical-research-full-report.pdf>

## **Human Biological Materials**

### **Key Organizations**

- Ministry of Health (MOH): <http://www.moh.gov.sg/>
- Bioethics Advisory Committee (BAC): <https://www.bioethics-singapore.gov.sg>

### **Relevant Standards**

- Medical (Therapy, Education, and Research) Act 1972: <https://sso.agc.gov.sg/Act/MTERA1972>
- Human Biomedical Research (Tissue Banking) Regulations 2019: <https://sso.agc.gov.sg/SL-Supp/S702-2019/>
- Guidance on Prohibition against Commercial Trading of Human Tissue (2017): <https://www.moh.gov.sg/docs/librariesprovider5/legislation/guidance-on-prohibition-against-commercial-trading-of-human-tissue-under-hbra---february-2017.pdf>
- Guide on the Requirement of Appropriate Consent for the Conduct of HBR and Handling of Human Tissue (2019): [https://www.moh.gov.sg/docs/librariesprovider5/legislation/guidance-on-appropriate-consent\\_17-may-2019.pdf](https://www.moh.gov.sg/docs/librariesprovider5/legislation/guidance-on-appropriate-consent_17-may-2019.pdf)
- Bioethics Advisory Committee, Human Tissue Research (2002): <https://www.bioethics-singapore.gov.sg/files/publications/reports/human-tissue-research-full-report.pdf>

## **Genetic Research**

### **Key Organizations**

- Bioethics Advisory Committee (BAC): <https://www.bioethics-singapore.gov.sg>

### **Relevant Standards**

- Genetic Testing and Genetic Research (2005): <https://www.bioethics-singapore.gov.sg/files/publications/reports/genetic-testing-and-genetic-research-full-report.pdf>

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

- Ministry of Health (MOH): <http://www.moh.gov.sg/>
- Bioethics Advisory Committee (BAC): <https://www.bioethics-singapore.gov.sg>

## Relevant Standards

- Human Cloning and Other Prohibited Practices Act 2004: <https://sso.agc.gov.sg/Act/HCOPPA2004>
- Human Biomedical Research (Restricted Research) Regulations 2017: <https://sso.agc.gov.sg/SL/HBRA2015-S622-2017>
- Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning (2002): <https://www.bioethics-singapore.gov.sg/files/publications/reports/ethical-legal-and-social-issues-in-human-stem-cell-research-reproduction-full-report.pdf>
- Donation of Human Eggs for Research (2008): <https://www.bioethics-singapore.gov.sg/files/publications/reports/donation-of-human-eggs-for-research-full-report.pdf>
- Human-Animal Combinations in Stem-Cell Research (2010): <https://www.bioethics-singapore.gov.sg/files/publications/reports/human-animal-combinations-in-stem-cell-research-full-report.pdf>

## ASIA/PACIFIC – South Korea

### General

#### Key Organizations

- Ministry of Health and Welfare (MOHW): <http://www.mohw.go.kr/eng/index.jsp>

#### Relevant Standards

- Bioethics and Safety Act No. 16372 (2019.04.23): [https://elaw.klri.re.kr/kor\\_service/lawView.do?lang=ENG&hseq=52559](https://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=52559)
- Enforcement Decree of Bioethics and Safety Act No. 30141 (2019.10.22): [https://elaw.klri.re.kr/eng\\_service/lawView.do?hseq=52561&lang=ENG](https://elaw.klri.re.kr/eng_service/lawView.do?hseq=52561&lang=ENG)
- Enforcement Rule of Bioethics and Safety Act No. 733 (2020.12.31): <https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙>

## Drugs, Biologics, and Devices

#### Key Organizations

- Ministry of Food and Drug Safety (MFDS): <http://www.mfds.go.kr/eng/index.do>

#### 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>
- Medical Device Act No. 16402 (2019.04.23): [https://elaw.klri.re.kr/kor\\_service/lawView.do?lang=ENG&hseq=50798](https://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=50798)
- Act on In Vitro Diagnostic Medical Devices Act No. 16433 (2019.05.01): [https://www.mfds.go.kr/eng/brd/m\\_40/view.do?seq=72621&srchFr=&srchTo=&srchWord=&srchTp=&itm\\_seq\\_1=0&itm\\_seq\\_2=0&multi\\_itm\\_seq=0&company\\_cd=&company\\_nm=&page=1](https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=72621&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=1)
- Enforcement Decree of the Medical Device Act No. 1580 (2019.12.23): <https://www.law.go.kr/LSW/eng/engLsSc.do?query=medical+device+act&menuId=2&section=lawNm&y=20&x=23#liBgcolor8>

*International Compilation of Human Research Standards  
2021 Edition*

- Regulations for Clinical Trial Personnel Education and Certification for the Educational Institution Notice No.2019-3 (2019.01.17):  
[https://www.law.go.kr/행정규칙/의약품임상시험종사자교육및교육실시기관지정에관한규정/\(2019-3,20190117\)](https://www.law.go.kr/행정규칙/의약품임상시험종사자교육및교육실시기관지정에관한규정/(2019-3,20190117))
- Regulation on Approval for Investigational New Drug Application of Drugs, Notice No. 2021-12 (2021.02.25): [https://www.law.go.kr/행정규칙/의약품임상시험계획승인에관한규정/\(2021-12,20210225\)](https://www.law.go.kr/행정규칙/의약품임상시험계획승인에관한규정/(2021-12,20210225))
- Regulation on Approval for Investigational Device Exemption Application No. 2019-33 (2019.04.30): [https://www.law.go.kr/행정규칙/의료기기임상시험계획승인에관한규정/\(2019-33,20190430\)](https://www.law.go.kr/행정규칙/의료기기임상시험계획승인에관한규정/(2019-33,20190430))
- Regulation for Medical Device Approvals, Notifications and Reviews No. 2021-35 (2021.04.22): [https://www.law.go.kr/행정규칙/의료기기허가·신고·심사등에관한규정/\(2021-35,20210422\)](https://www.law.go.kr/행정규칙/의료기기허가·신고·심사등에관한규정/(2021-35,20210422))
- Regulation on Medical Device Re-examination No. 2020-29 (2020.05.01):  
[https://www.law.go.kr/행정규칙/의료기기재심사에관한규정/\(2020-29,20200501\)](https://www.law.go.kr/행정규칙/의료기기재심사에관한규정/(2020-29,20200501))
- Guidelines on Human Research Protection Program 0053-01 (2014.3) 2017.5.31 고시:  
<https://nedrug.mfds.go.kr/bbs/38/65>
- Bioethics and Safety Act No. 16372 (2019.04.23):  
<https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=208465&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000>
- Enforcement Decree of Pharmaceutical Affairs Act No. 30141 (2019.10.22):  
<https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=210861&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000>
- Enforcement Rule of Bioethics and Safety Act No. 733 (2020.12.31):  
<https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙>

## Clinical Trial Registries

### Key Organizations

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

### Relevant Standards

- Regulation on Safety of Medicinal Products, No.1576 (2019.12.06):  
[https://www.mfds.go.kr/eng/brd/m\\_18/view.do?seq=71487&srchFr=&srchTo=&srchWord=&srchTp=&itm\\_seq\\_1=0&itm\\_seq\\_2=0&multi\\_itm\\_seq=0&company\\_cd=&company\\_nm=&page=2](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)

## Research Injury

### Key Organizations

- Ministry of Food and Drug Safety (MFDS): <http://www.mfds.go.kr/eng/index.do>

## Relevant Standards

- Pharmaceutical Affairs Act No.16250 (2019.01.15):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?hseq=49635&lang=ENG](https://elaw.klri.re.kr/kor_service/lawView.do?hseq=49635&lang=ENG)
- 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](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.):  
[https://elaw.klri.re.kr/eng\\_mobile/viewer.do?hseq=54331&type=part&key=36](https://elaw.klri.re.kr/eng_mobile/viewer.do?hseq=54331&type=part&key=36) [Amended 2021.06.24]
- 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](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](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 Health and Welfare: <http://www.mohw.go.kr/eng/index.jsp>
- Ministry of the Interior and Safety: <https://www.mois.go.kr/frt/a01/frtMain.do>

### Relevant Standards

- Bioethics and Safety Act No.16372(2019.04.):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?lang=ENG&hseq=52559](https://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=52559)
- Enforcement Decree of the Bioethics and Safety Act No. 30141(2019.10.):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?hseq=52561&lang=ENG](https://elaw.klri.re.kr/kor_service/lawView.do?hseq=52561&lang=ENG)
- Enforcement Rule of Bioethics and Safety Act No. 733 (2020.12.31):  
<https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙>
- Personal Information Protection Act No.16930 (2020.02.):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?hseq=53044&lang=ENG](https://elaw.klri.re.kr/kor_service/lawView.do?hseq=53044&lang=ENG)
- Enforcement Decree of the Personal Information Protection Act No.30892 (2020.08.):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?hseq=54521&lang=ENG](https://elaw.klri.re.kr/kor_service/lawView.do?hseq=54521&lang=ENG)

## Privacy/Data Protection

### Key Organizations

- Ministry of the Interior and Safety (MOIS): <http://www.mois.go.kr/eng/a01/engMain.do>
- Ministry of Health and Welfare (MOHW): <http://www.mohw.go.kr/eng/index.jsp>
- Personal Information Protection Commission (PIPC): <https://www.pipc.go.kr/eng/index.do>

### Relevant Standards

- Personal Information Protection Act No. 16930 (2020.02.04):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?hseq=53044&lang=ENG](https://elaw.klri.re.kr/kor_service/lawView.do?hseq=53044&lang=ENG)



*International Compilation of Human Research Standards  
2021 Edition*

- Enforcement Decrees to Personal Information Protection Act No. 30892 (2020.02.04): [https://elaw.klri.re.kr/kor\\_service/lawView.do?hseq=54521&lang=ENG](https://elaw.klri.re.kr/kor_service/lawView.do?hseq=54521&lang=ENG)
- Bioethics and Safety Act No. 16372 (2019.04.23): [https://elaw.klri.re.kr/kor\\_service/lawView.do?lang=ENG&hseq=52559](https://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=52559)
- Act on Dissection and Preservation of Corpses No. 17472 (2021.04.08): <https://www.law.go.kr/법령/시체해부및보존등에관한법률>
- Guidelines for the Use of Health and Medical data (2021.01): [http://www.mohw.go.kr/react/al/sal0101vw.jsp?PAR\\_MENU\\_ID=04&MENU\\_ID=040101&CONT\\_SEQ=363309&page=1](http://www.mohw.go.kr/react/al/sal0101vw.jsp?PAR_MENU_ID=04&MENU_ID=040101&CONT_SEQ=363309&page=1)
- Standard Personal Information Protection Guidelines (2020.08.11): <https://www.law.go.kr/admRulSc.do?menuId=5&subMenuId=41&tabMenuId=183&query=%ED%91%9C%EC%A4%80%EA%B0%9C%EC%9D%B8%EC%A0%95%EB%B3%B4%EB%B3%B4%ED%98%B8%EC%A7%80%EC%B9%A8#liBgcolor0>
- Criteria for ensuring the Safety of Personal Information (2020.08.11): <https://www.law.go.kr/admRulSc.do?menuId=5&subMenuId=41&tabMenuId=183&query=%ED%91%9C%EC%A4%80%20%EA%B0%9C%EC%9D%B8%EC%A0%95%EB%B3%B4%20%EB%B3%B4%ED%98%B8%EC%A7%80%EC%B9%A8#liBgcolor7>
- Guidelines for the Pseudonymisation of Personal Information (2020.09): <https://www.pipc.go.kr/np/cop/bbs/selectBoardArticle.do?bbsId=BS217&mCode=D010030000&nttId=6840>

## Human Biological Materials

### Key Organizations

- Ministry of Health and Welfare (MOHW): <http://www.mohw.go.kr/eng/index.jsp>
- Ministry of Food and Drug Safety (MFDS): <http://www.mfds.go.kr/eng/index.do>

### Relevant Standards

- Bioethics and Safety Act No. 16372 (23Apr2019): <https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=208465&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000> (amended in 2020.09.12)
- Enforcement Rule of Bioethics and Safety Act No. 733 (2020.12.31): <https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙>
- Enforcement Decree of Pharmaceutical Affairs Act No. 30141 (22Oct2019): <https://www.law.go.kr/LSW/lsInfoP.do?lsiSeq=210861&chrClsCd=010203&urlMode=engLsInfoR&viewCls=engLsInfoR#0000>
- Guidelines on Biological material management in clinical trial (2018.08): [https://www.mfds.go.kr/brd/m\\_218/view.do?seq=33339&srchFr=&srchTo=&srchWord=&srchTp=&itm\\_seq\\_1=0&itm\\_seq\\_2=0&multi\\_itm\\_seq=0&company\\_cd=&company\\_nm=&page=7](https://www.mfds.go.kr/brd/m_218/view.do?seq=33339&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=7)

## Genetic Research

### Key Organizations

- Ministry of Health and Welfare (MOHW): <http://www.mohw.go.kr/eng/index.jsp>

*International Compilation of Human Research Standards  
2021 Edition*

- Ministry of Food and Drug Safety (MFDS): <http://www.mfds.go.kr/eng/index.do>

### **Relevant Standards**

- Bioethics and Safety Act No.16372(2019.04.):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?lang=ENG&hseq=52559](https://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=52559)
- Enforcement Decree of the Bioethics and Safety Act No. 30141(2019.10.):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?hseq=52561&lang=ENG](https://elaw.klri.re.kr/kor_service/lawView.do?hseq=52561&lang=ENG)
- Enforcement Rule of Bioethics and Safety Act No. 733 (2020.12.31):  
<https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙>

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

- Ministry of Health and Welfare (MOHW):  
<http://www.mohw.go.kr/eng/index.jsp>
- Ministry of Food and Drug Safety (MFDS): <http://www.mfds.go.kr/eng/index.do>

### **Relevant Standards**

- Bioethics and Safety Act No.16372(2019.04.):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?lang=ENG&hseq=52559](https://elaw.klri.re.kr/kor_service/lawView.do?lang=ENG&hseq=52559)
- Enforcement Decree of the Bioethics and Safety Act No. 30141(2019.10.):  
[https://elaw.klri.re.kr/kor\\_service/lawView.do?hseq=52561&lang=ENG](https://elaw.klri.re.kr/kor_service/lawView.do?hseq=52561&lang=ENG)
- Enforcement Rule of Bioethics and Safety Act No. 733 (2020.12.31):  
<https://www.law.go.kr/법령/생명윤리및안전에관한법률시행규칙>
- Enforcement Rule of the Safety and Support of Advanced Regenerative Medicine No. 746 (2020.08.28): <https://www.law.go.kr/법령/첨단재생의료안전및지원에관한규칙>
- Advanced Regenerative Medicine and Advanced Biopharmaceuticals Safety and Support Act No. 17472 (2020.8.11.):  
<https://www.law.go.kr/법령/첨단재생의료및첨단바이오의약품안전및지원에관한법률>
- Enforcement Decree of Advanced Regenerative Medicine and Advanced Biopharmaceuticals Safety and Support Act No. 30979 (2020.08.28):  
<https://www.law.go.kr/법령/첨단재생의료및첨단바이오의약품안전및지원에관한법률시행령>
- Enforcement Rule of Advanced Biopharmaceuticals Safety and Support No. 1641 (2020.09.07):  
<https://www.law.go.kr/법령/첨단바이오의약품안전및지원에관한규칙>
- Guideline on Quality Assessment for Gene-Editing Based Advanced Therapy Medicinal Products (2018.12): [https://www.mfds.go.kr/eng/brd/m\\_27/view.do?seq=71877](https://www.mfds.go.kr/eng/brd/m_27/view.do?seq=71877)

## ASIA/PACIFIC – Sri Lanka

### Drugs, Biologics, and Devices

#### Key Organizations

- Cosmetics, Devices, and Drugs Regulatory Authority, Subcommittee on Clinical Trials: [http://www.cdda.gov.lk/index.php?option=com\\_content&view=article&id=78&Itemid=115&lang=en](http://www.cdda.gov.lk/index.php?option=com_content&view=article&id=78&Itemid=115&lang=en)

#### Relevant Standards

- Legislation, various: [http://nmra.gov.lk/index.php?option=com\\_content&view=article&id=263&Itemid=190&lang=en](http://nmra.gov.lk/index.php?option=com_content&view=article&id=263&Itemid=190&lang=en)
- Guidelines, various: [http://nmra.gov.lk/index.php?option=com\\_content&view=article&id=441:general-guideline-topics&catid=42&Itemid=331&lang=en#medicines-regulatory-division](http://nmra.gov.lk/index.php?option=com_content&view=article&id=441:general-guideline-topics&catid=42&Itemid=331&lang=en#medicines-regulatory-division)

### Clinical Trial Registries

#### Key Organizations

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

#### Relevant Standards

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

## ASIA/PACIFIC – Taiwan

### General

#### Key Organizations

- Ministry of Health and Welfare (MOHW): <https://www.mohw.gov.tw/mp-2.html>

#### Relevant Standards

- Human Subjects Research Act (2019) (Chinese): <https://law.moj.gov.tw/LawClass/LawAll.aspx?pcode=L0020176>
- Medical Care Act (2018): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020021>
- Regulations on Human Trials (2016): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020162>
- Enforcement Rules of the Medical Care Act (2017) (Chinese): <http://law.moj.gov.tw/LawClass/LawContent.aspx?PCODE=L0020023>
- Regulations for the Organization and Operation of Human Research Ethics Review Boards (2018): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020179>
- Exempt Review Categories for Human Research (2012): [https://gazette.nat.gov.tw/egFront/e\\_detail.do?metaid=54295](https://gazette.nat.gov.tw/egFront/e_detail.do?metaid=54295)
- Informed Consent Exemptions for Human Research (2012): [https://gazette.nat.gov.tw/egFront/e\\_detail.do?metaid=54273](https://gazette.nat.gov.tw/egFront/e_detail.do?metaid=54273)
- Expedited Review Categories for Human Research (2012): [https://gazette.nat.gov.tw/egFront/e\\_detail.do?metaid=54277](https://gazette.nat.gov.tw/egFront/e_detail.do?metaid=54277)

*International Compilation of Human Research Standards  
2021 Edition*

- Regulations Governing the Organization and Operation of the Human Research Ethics Review Board (2018): <http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?PCODE=L0020179>

## Drugs, Biologics, and Devices

### Key Organizations

- Ministry of Health and Welfare (MOHW): <https://www.mohw.gov.tw/mp-2.html>
- Taiwan Food and Drug Administration (FDA): <https://www.fda.gov.tw/ENG/>

### Relevant Standards

- Medical Care Act (2018): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020021>
- Pharmaceutical Affairs Act (2018): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030001>
- Regulations on Human Trials (2016): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020162>
- Pharmaceutical Affairs Act Enforcement Rules (2016): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030002>
- Regulations for Drug Safety Monitoring (2013): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030050>
- Regulations for Good Clinical Practice (2014): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030056>
- Regulations for Governing the Management of Medical Devices (2014)
- Regulation on Bioavailability and Bioequivalence Studies (2015): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030065>

## Research Injury

### Key Organizations

- Ministry of Health and Welfare (MOHW): <https://www.mohw.gov.tw/mp-2.html>
- Food and Drug Administration (FDA), MOHW: <https://www.fda.gov.tw/ENG/>

### Relevant Standards

- Medical Care Act (2018): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020021>
- FDA, Regulation for Good Clinical Practice (2014): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030056>

## Social-Behavioral Research

### Key Organizations

- Ministry of Health and Welfare: <https://www.mohw.gov.tw/mp-2.html>

### Relevant Standards

- Exempt Review Categories for Human Research (2012): [https://gazette.nat.gov.tw/egFront/e\\_detail.do?metaid=54295](https://gazette.nat.gov.tw/egFront/e_detail.do?metaid=54295)

## Privacy/Data Protection

### Key Organizations

- Ministry of Justice: <https://www.moj.gov.tw/2832/>

### Relevant Standards

- Personal Information Protection Act (2015):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=I0050021>
- Enforcement Rules of the Personal Data Protection Act (2016):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=I0050022>

## Human Biological Materials

### Key Organizations

- Ministry of Health and Welfare: <https://www.mohw.gov.tw/mp-2.html>

### Relevant Standards

- Human Biobank Management Act (2012):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020164>
- Medical Care Act (2018): <https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020021>
- Regulations on Human Trials (2009):  
<http://law.moj.gov.tw/Eng/LawClass/LawContent.aspx?pcode=L0020162>
- Administrative Regulations on the Establishment of Human Biobanks (2011):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020173>
- Good Tissue Practice (2002) (Chinese):  
<http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1153&chk=342a5c73-c206-4756-ade9-9c63265c859d&mid=46&name=fdContent>
- Guidelines for the Collection and Use of Human Specimens for Research (2006) (Chinese):  
<http://www.fda.gov.tw/TC/includes/GetFile.ashx?id=1598&chk=6056f7dd-eb0a-48bf-ae7e-8a2a5875e6e0&mid=46&name=fdContent>

## Genetic Research

### Key Organizations

- Ministry of Health and Welfare (MOHW): <https://www.mohw.gov.tw/mp-2.html>
- 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

- Human Biobank Management Act (2012):  
<http://law.moj.gov.tw/Eng//LawClass/LawContent.aspx?pcode=L0020164>
- Regulations on Commercial Benefit Feedback of Human Biobanks (2010) (Chinese):  
<https://law.moj.gov.tw/LawClass/LawAll.aspx?pcode=L0020170>
- Administrative Regulations on the Establishment of Human Biobanks (2011):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0020173>

*International Compilation of Human Research Standards  
2021 Edition*

- Guidance for Information Safety of Human Biobank (2010) (Chinese):  
[http://regulation.cde.org.tw/doc\\_data\\_display?sid=1929&doctype2](http://regulation.cde.org.tw/doc_data_display?sid=1929&doctype2)

## Embryos, Stem Cells, and Cloning

### Key Organizations

- Ministry of Health and Welfare (MOHW): <https://www.mohw.gov.tw/mp-2.html>

### Relevant Standards

- Artificial Reproduction Act (2018):  
<https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0070024>

## ASIA/PACIFIC – Tajikistan

*NOTE: For an overview of human subject protections in Tajikistan, see “Ethical Review of Biomedical Research in the CIS Countries,” Chapter 3, Section 9:*

[http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical\\_review\\_cis\\_book\\_kubar\\_english.pdf](http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf)

## 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](https://clinregs.niaid.nih.gov/single_country.php?c_id=213)

## General

### Key Organizations

- National Research Council of Thailand (NCRT): <http://en.nrct.go.th/en/home.aspx>
- Medical Council of Thailand (MCT): [http://www.tmc.or.th/en\\_home.php](http://www.tmc.or.th/en_home.php)
- Forum for Ethical Review Committees in Thailand (FERCIT): <http://www.fercit.org/>

### Relevant Standards

- Medical Professions Act (2009), Articles 47-50: [http://www.fercit.org/SIDCER-FERCAP/Handout\\_10/4.%20Accreditation-update\\_surveyor\\_aj.Sopit.pdf](http://www.fercit.org/SIDCER-FERCAP/Handout_10/4.%20Accreditation-update_surveyor_aj.Sopit.pdf)
- NCRT, Regulation on the Permission of Foreign Researchers (1982):  
[https://foreignresearcher.nrct.go.th/index.php?lang=th&mod=forms&op=regulations\\_en](https://foreignresearcher.nrct.go.th/index.php?lang=th&mod=forms&op=regulations_en)
- NCRT, Guidance for Foreign researcher Conducting Research in Thailand, various:  
[https://foreignresearcher.nrct.go.th/index.php?lang=en&mod=forms&op=guidelines\\_en](https://foreignresearcher.nrct.go.th/index.php?lang=en&mod=forms&op=guidelines_en)
- MCT, Rule of the Medical Council on the Observance of Medical Ethics (1983):  
[http://thailaws.com/law/t\\_laws/tlaw0510.pdf](http://thailaws.com/law/t_laws/tlaw0510.pdf)

*International Compilation of Human Research Standards  
2021 Edition*

- MCT, National Guideline for Ethical Research on Human Subjects (2002)
- FERCIT, Ethical Guidelines for Research on Human Subject in Thailand (2007):  
[http://www.fercit.org/file/Guideline\\_English\\_version.pdf](http://www.fercit.org/file/Guideline_English_version.pdf)

## 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/>

#### **Relevant Standards**

- Consumer Protection Act (2007)
- FDA, Rules, Procedures and Conditions for Accepting Ethics Committee for Research Involving Human Subjects (2018)
- MCT, Acts and Rules, various: [https://tmc.or.th/En/act\\_rules\\_en.php](https://tmc.or.th/En/act_rules_en.php)
- MCT, Thailand Good Clinical Practice Guidelines (2002)

### *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/>

#### **Relevant Standards**

- FAQs:  
<http://www.clinicaltrials.in.th/index.php?meun=home&smenu=4&task=home&task1=openpage&task2=view&topid=4>

## Privacy/Data Protection

#### **Key Organizations**

- Office of the Information Commission: <http://www.oic.go.th/web2017/en/main.html#>

#### **Relevant Standards**

- Official Information Act, B.E. 2540 (1997):  
[http://www.oic.go.th/web2017/en/ACTOfficial\\_Information.htm](http://www.oic.go.th/web2017/en/ACTOfficial_Information.htm)

*International Compilation of Human Research Standards  
2021 Edition*

- Ministerial Regulations, various:  
[http://www.oic.go.th/web2017/en/bookshell\\_law.htm?title=Ministerial%20Regulations&cid=142](http://www.oic.go.th/web2017/en/bookshell_law.htm?title=Ministerial%20Regulations&cid=142)

## ASIA/PACIFIC – Uzbekistan

### General

#### Key Organizations

- Government of the Republic of Uzbekistan: <http://www.gov.uz>
- Ministry of Health: <https://ssv.uz/en>

#### Relevant Standards

- Constitution of Republic of Uzbekistan, Articles 24, 26, 40, 44 (1992)
- Law on Protection of Citizens' Health (1997)

### 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 Protection of Citizens' Health (1997)
- 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)
- State standard of the Republic of Uzbekistan. Good Clinical Practice (GCP) (2018): [https://uzpharm-control.uz/uploads/documents/GCP\\_2765-2018.pdf](https://uzpharm-control.uz/uploads/documents/GCP_2765-2018.pdf).
- Model rules of ethical conduct of the Agency for the Development of the Pharmaceutical Industry under the Ministry of Health of the Republic of Uzbekistan (Order No. 90 of July 26, 2018):  
<https://uzpharm-control.uz/en/documents/category/9>

### 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)



- National Standard of Uzbekistan: Good Clinical Practice (2013)

## ASIA/PACIFIC – Vietnam

**NOTE:** For an overview of the clinical research regulations in Vietnam, see the ClinRegs report: [https://clinregs.niaid.nih.gov/single\\_country.php?c\\_id=233](https://clinregs.niaid.nih.gov/single_country.php?c_id=233)

### General

#### Key Organizations

- Ministry of Health (MOH): [https://www.moh.gov.vn/en\\_US/web/ministry-of-health](https://www.moh.gov.vn/en_US/web/ministry-of-health)

#### Relevant Standards

- Decision No. 111/QD-BYT – On Promulgation of Regulation on Organization and Operation of Council of Ethics in Biomedical Research at Grass-Roots Level, Chapter I (Articles 3 and 4), Chapter II, and Chapter III (2013): <http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo111-QD-BYT.pdf>
- Decision No. 460/QD-BYT – On the Promulgation of Regulations on Organization and Operation of Ethical Evaluation Committee in Biomedical Research of the Ministry of Health, Period 2012-2017, Chapters I-III (2012): <http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo460-QD-BYT.pdf>
- Circular No. 45/2017/TT-BYT – Regulation on the Establishment, Functions, Tasks, and Powers of the Ethics Committee in Biomedical Research (2017) (Vietnamese): <https://thuvienphapluat.vn/van-ban/The-thao-Y-te/Thong-tu-45-2017-TT-BYT-nhiem-vu-quyen-han-Hoi-dong-dao-duc-nghien-cuu-y-sinh-hoc-354849.aspx>
- Decision No. 1122/QD-BYT – On the Establishment of the Ethics Committee in Biomedical Research of the Ministry of Health, Period 2018-2023: [http://crc.pasteurhcm.gov.vn/upload/files/1122\\_2018.pdf](http://crc.pasteurhcm.gov.vn/upload/files/1122_2018.pdf)

### Drugs, Biologics, and Devices

#### Key Organizations

- Ministry of Health: [https://www.moh.gov.vn/en\\_US/web/ministry-of-health](https://www.moh.gov.vn/en_US/web/ministry-of-health)

#### Relevant Standards

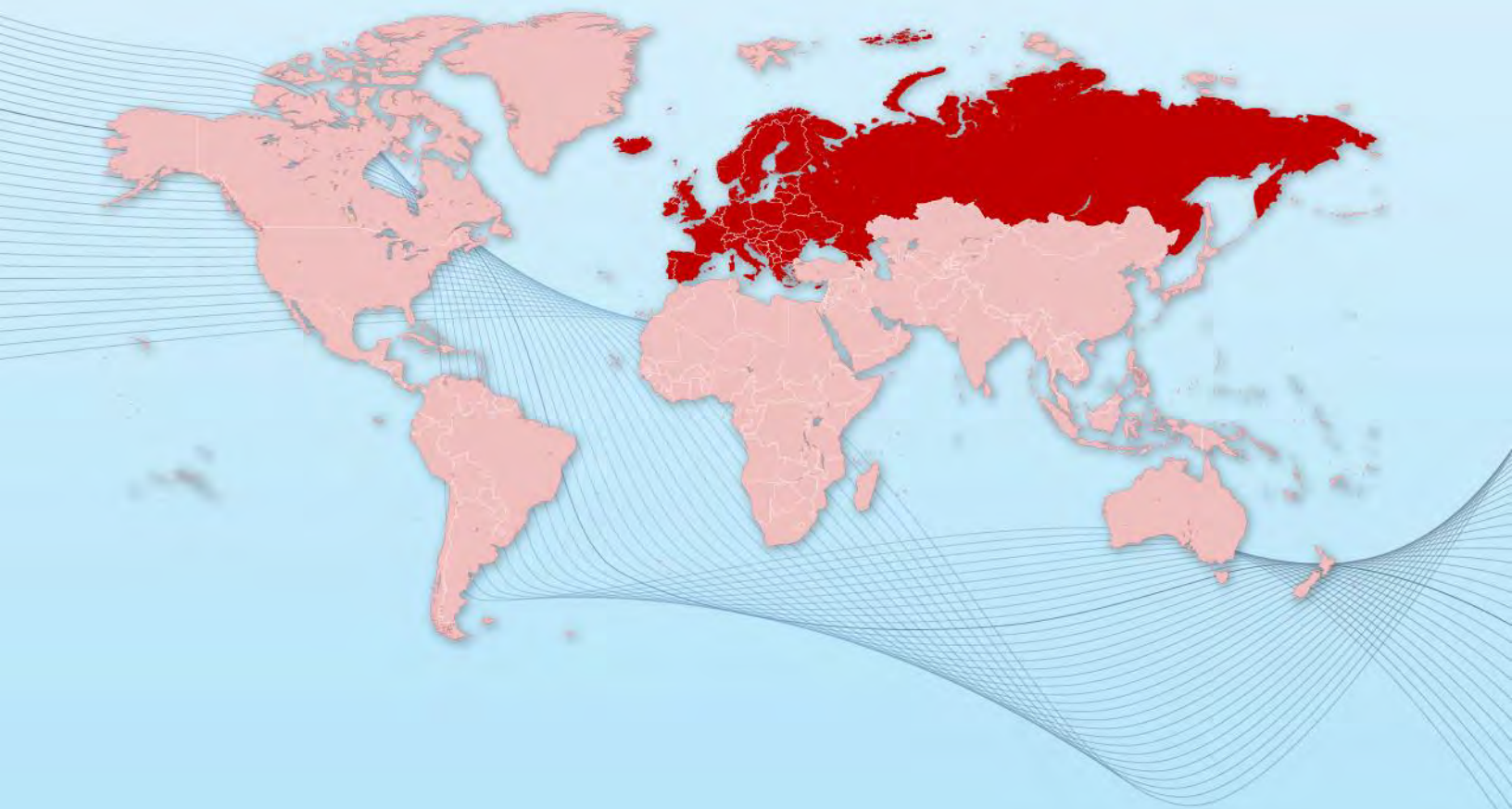
- Law on Pharmacy (No. 34/2005/QH11), Chapter II (Section III, Article 20), Chapter VIII (Articles 54 and 59) (2005): [http://www.vertic.org/media/National%20Legislation/Vietnam/VN\\_Law\\_on\\_Pharmacy.pdf](http://www.vertic.org/media/National%20Legislation/Vietnam/VN_Law_on_Pharmacy.pdf)
- Decision No. 799/QD-BYT on the Issuance of Guideline on Good Clinical Practice, Chapter III, Articles 1 and 2 (2008): <http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo799-QD-BYT.pdf>
- Decision No. 799/QD-BYT of the Minister of Health on the Promulgation of the Guidelines on Good Clinical Practice of Clinical Trials (2008): <http://clinregs.niaid.nih.gov/documents/vietnam/DecisionNo799-QD-BYT.pdf>
- Circular – Guidelines for Clinical Trials on Drugs (C-ClinDrugTrial), Articles 2, 4, 5, 9, 17, 18, 31, and 39 (2012): <http://clinregs.niaid.nih.gov/documents/vietnam/C-ClinDrugTrial.pdf>

*International Compilation of Human Research Standards  
2021 Edition*

- Guidelines for Clinical Trials of Drugs, Chapter III, Articles 10, 16, and 17 (2012):  
<https://clinregs.niaid.nih.gov/documents/vietnam/C-ClinDrugTrial.pdf>
- Circular No. 29/2018/TT-BYT – Regulations for Clinical Trials on Drugs (Vietnamese):  
<https://thuvienphapluat.vn/van-ban/The-thao-Y-te/Circular-29-2018-TT-BYT-clinical-trial-of-drugs-401541.aspx>

International Compilation of Human  
Research Standards  
2021 Edition

# Europe



## EUROPE – Regionwide

### General

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

<https://ec.europa.eu/research/ege/index.cfm>

**European Commission, Directorate-General for Research and Innovation:**

[https://ec.europa.eu/info/research-and-innovation\\_en](https://ec.europa.eu/info/research-and-innovation_en)

- European Commission, Research and Innovation, Law and Regulations: [https://ec.europa.eu/info/research-and-innovation/law-and-regulations\\_en](https://ec.europa.eu/info/research-and-innovation/law-and-regulations_en)
- Ethical Aspects of Clinical Research in Developing Countries (2003): [http://ec.europa.eu/bepa/european-group-ethics/docs/avis17\\_en.pdf](http://ec.europa.eu/bepa/european-group-ethics/docs/avis17_en.pdf)
- Horizon 2020: How to Complete your Ethics Self –Assessment (2015): [http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-msca-if-2015/1645175-h2020\\_-\\_guidance\\_ethics\\_self\\_assess\\_en.pdf](http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-msca-if-2015/1645175-h2020_-_guidance_ethics_self_assess_en.pdf)

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

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

### Drugs, Biologics, and Devices

#### Drugs

**European Commission, DG SANTE: Directorate-General for Health and Food Safety:**

[http://ec.europa.eu/health/index\\_en.htm](http://ec.europa.eu/health/index_en.htm)

- Directive 2001/20/EC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use: [https://ec.europa.eu/health/human-use/clinical-trials/directive\\_en](https://ec.europa.eu/health/human-use/clinical-trials/directive_en)
- Directive 2005/28/EC Laying Down Principles and Detailed Guidelines for Good Clinical Practice as Regards Investigational Medicinal Products for Human Use, as Well as the Requirements for Authorization of the Manufacturing or Importation of Such Products: <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32005L0028&qid=1634151900874&from=EN>
- Regulation No. 536/2014 of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, Repealing Directive 2001/20/EC: [http://ec.europa.eu/health/files/eudralex/vol-1/reg\\_2014\\_536/reg\\_2014\\_536\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf)
- Commission Implementing Regulation (EU) 2017/556 of 24 March 2017 on the Detailed Arrangements for the Good Clinical Practice Inspection Procedures Pursuant to Regulation (EU) No. 536/2014 of the European Parliament and Council: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0556&from=EN>

*International Compilation of Human Research Standards  
2021 Edition*

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

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

- Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (1997):  
[https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/3cc1aen\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/3cc1aen_en.pdf)
- Reflection Paper on Ethical and GCP Aspects of Clinical Trials of Medicinal Products for Human Use Conducted Outside of the EU/EEA and Submitted in Marketing Authorization Applications to the EU Regulatory Authorities (2012):  
[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2012/04/WC500125437.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2012/04/WC500125437.pdf)
- Guideline for Good Clinical Practice E6(R2) (2016):  
[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500002874.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf)

**Devices**

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

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

**Clinical Trial Registries**

**EU Clinical Trials Register:** <https://www.clinicaltrialsregister.eu/>

- FAQs: [https://www.clinicaltrialsregister.eu/doc/EU\\_CTR\\_FAQ.pdf](https://www.clinicaltrialsregister.eu/doc/EU_CTR_FAQ.pdf)

**Research Injury**

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

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

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

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (1997):

*International Compilation of Human Research Standards  
2021 Edition*

<http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG>

- Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, Article 13, CETS No. 195 (2005):  
<http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG>
- Council of Europe Committee on Bioethics Guide for research ethics committee members:  
<https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=0900001680307e6c>

**Privacy/Data Protection**

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

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation):  
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>
- Guidelines on consent under Regulation 2016/679, WP259 rev.01:  
[http://ec.europa.eu/newsroom/article29/item-detail.cfm?item\\_id=623051](http://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051)
- Transfers of Personal Data to Third Countries: Applying Articles 25 and 26 of the EU Data Protection Directive (1998): [http://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/1998/wp12\\_en.pdf](http://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/1998/wp12_en.pdf)
- Working Document on Adequacy Referential (2018):  
<https://ec.europa.eu/newsroom/article29/items/614108>
- Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (2019):  
[https://edpb.europa.eu/our-work-tools/our-documents/opinion-art-70/opinion-32019-concerning-questions-and-answers\\_en](https://edpb.europa.eu/our-work-tools/our-documents/opinion-art-70/opinion-32019-concerning-questions-and-answers_en)

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

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

**Council of Europe, Data Protection and Cybercrime Division:**

[http://www.coe.int/t/dghl/standardsetting/dataprotection/default\\_EN.asp](http://www.coe.int/t/dghl/standardsetting/dataprotection/default_EN.asp)

- Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (1981): <http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=108&CL=ENG>

*International Compilation of Human Research Standards  
2021 Edition*

- Protocol amending the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (2018): <https://rm.coe.int/16808ac918>
- Recommendation No. R (97) 5 on the Protection of Medical Data (1997): <https://wcd.coe.int/ViewDoc.jsp?id=571075&Site=CM&BackColorInternet=C3C3C3&BackColorIntranet=EDB021&BackColorLogged=F5D383>
- Recommendation CM/Rec(2019)2 of the Committee of Ministers to member States on the protection of health-related data (2019): <https://edoc.coe.int/en/international-law/7969-protection-of-health-related-data-recommendation-cmrec20192.html>
- Article 29 Working Party Documentation: [http://ec.europa.eu/justice/data-protection/article-29/index\\_en.htm](http://ec.europa.eu/justice/data-protection/article-29/index_en.htm)

### **Human Biological Materials**

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

<http://ec.europa.eu/research/ege/index.cfm>

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

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

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

### **Genetic Research**

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

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

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

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 12-14, ETS No. 164 (1997): <http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CM=7&DF=9/15/2008&CL=ENG>
- Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research, CETS No. 195 (2005): <http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=195&CM=1&DF=10/24/2007&CL=ENG>

*International Compilation of Human Research Standards  
2021 Edition*

- Recommendation No. R (92) on Genetic Testing and Screening for Health Care Purposes (1992): <http://wcd.coe.int/ViewDoc.jsp?id=612007&Site=CM&BackColorInternet=9999CC&BackColorIntranet=FFBB55&BackColorLogged=FFAC75>
- Recommendation Rec (2006)4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin (2016): [https://search.coe.int/cm/Pages/result\\_details.aspx?ObjectId=090000168064e8ff](https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=090000168064e8ff)
- Recommendation Rec(2016)8 of the Committee of Ministers to Member States on the Processing of Personal Health-Related Data for Insurance Purposes, Including Data Resulting from Genetic Tests (2016): [https://search.coe.int/cm/Pages/result\\_details.aspx?ObjectId=09000016806b2c5f](https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016806b2c5f)

**Embryos, Stem Cells, and Cloning**

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

<http://ec.europa.eu/research/ege/index.cfm>

- Statements by the Commission Re: Article 6 (2006): [http://www.uv.es/operuv/docs\\_7pm/FP7ECStatementsComm\\_Ethical.pdf](http://www.uv.es/operuv/docs_7pm/FP7ECStatementsComm_Ethical.pdf)
- Statement of the Commission Related to Research Activities Involving Human Embryonic Stem Cells (2013): <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF>
- Commission Staff Working Paper Report on Human Embryonic Stem Cell Research (2003): [https://ec.europa.eu/research/press/2003/pdf/sec2003-441report\\_en.pdf](https://ec.europa.eu/research/press/2003/pdf/sec2003-441report_en.pdf)
- Opinion No. 22 - The Ethics Review of hESC FP7 Research Projects (2007): [http://bookshop.europa.eu/ga/recommendations-on-the-ethical-review-of-hesc-fp7-research-projects-pbKAAJ07022/downloads/KA-AJ-07-022-EN-C/KAAJ07022ENC\\_002.pdf;pgid=y8dIS7GUWMdSR0EAIMEUUsWb0000dz-kvfzb;sid=lexx3tq0IOFxyokBvtfvebiRj93DZfXP54=?FileName=KAAJ07022ENC\\_002.pdf&SKU=KAAJ07022ENC\\_PDF&CatalogueNumber=KA-AJ-07-022-EN-C](http://bookshop.europa.eu/ga/recommendations-on-the-ethical-review-of-hesc-fp7-research-projects-pbKAAJ07022/downloads/KA-AJ-07-022-EN-C/KAAJ07022ENC_002.pdf;pgid=y8dIS7GUWMdSR0EAIMEUUsWb0000dz-kvfzb;sid=lexx3tq0IOFxyokBvtfvebiRj93DZfXP54=?FileName=KAAJ07022ENC_002.pdf&SKU=KAAJ07022ENC_PDF&CatalogueNumber=KA-AJ-07-022-EN-C)

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

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



## EUROPE – Armenia

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

[http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical\\_review\\_cis\\_book\\_kubar\\_english.pdf](http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf)

### Drugs, Biologics, and Devices

#### Key Organizations

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

#### Relevant Standards

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

## EUROPE – Austria

### General

#### Key Organization

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

#### Relevant Standards

- University Act (2011): [http://www.ris.bka.gv.at/Dokumente/Erv/ERV\\_2002\\_1\\_120/ERV\\_2002\\_1\\_120.pdf](http://www.ris.bka.gv.at/Dokumente/Erv/ERV_2002_1_120/ERV_2002_1_120.pdf)
- Hospitals Act (2014): <http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010285&ShowPrintPreview=True>
- Regulation on Leading Ethics Committees (2004): <http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20003352&ShowPrintPreview=True>
- Bioethics Commission, various publications: <https://www.bundestkanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html>

## Drugs, Biologics, and Devices

### **Drugs**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Devices**

#### **Key Organizations**

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

#### **Relevant Standards**

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

## Research Injury

#### **Key Organizations**

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

#### **Relevant Standards**

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

## Privacy/Data Protection

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

#### **Key Organizations**

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

## **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

- Law on Safety of Blood (2009):  
<http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=1001145&ShowPrintPreview=True>
- Law on Quality and Safety of Human Tissue and Cells (2013):  
<http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005698&ShowPrintPreview=True>
- Regulation on Tissue Banks (2014):  
<http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20005848&ShowPrintPreview=True>
- Bioethics Commission, various publications:  
<https://www.bundestkanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html>

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

## Relevant Standards

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

## EUROPE – Belarus

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

[http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical\\_review\\_cis\\_book\\_kubar\\_english.pdf](http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf)

## General

### Key Organization

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

### Relevant Standards

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

## Drugs, Biologics, and Devices

### Drugs

#### Key Organizations

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

#### Relevant Standards

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

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

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

### **Devices**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Clinical Trial Registries**

#### **Key Organizations**

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

### **Research Injury**

#### **Key Organizations**

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

### **Social-Behavioral Research**

#### **Key Organizations**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – Belgium**

*NOTE: For an overview of human subject standards in Belgium, see The Ethics Committees:*  
[https://www.famhp.be/en/human\\_use/medicines/medicines/research\\_development/ethic\\_committee](https://www.famhp.be/en/human_use/medicines/medicines/research_development/ethic_committee)

## **General**

### **Key Organization**

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

### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

[http://www.ejustice.just.fgov.be/cgi\\_loi/change\\_lg.pl?language=fr&la=F&cn=2014040446&table\\_name=loi](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2014040446&table_name=loi)

- Royal Decree Dated 30 June 2004 Determining the Measures for Carrying Out the Law Dated 7 May 2004 Relating to Experiments on Humans, Modified by the Royal Decree Dated 18 May 2006:  
[http://www.ejustice.just.fgov.be/cgi\\_loi/change\\_lg.pl?language=fr&la=F&cn=2004063030&table\\_name=loi](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2004063030&table_name=loi)
- FAMHP, Various Circulars:  
[https://www.famhp.be/en/human\\_use/medicines/medicines/research\\_development/ethic\\_committee](https://www.famhp.be/en/human_use/medicines/medicines/research_development/ethic_committee)
- BACB, various: <https://www.health.belgium.be/en/list-opinions>

## Drugs, Biologics, and Devices

### Key Organizations

- Federal Agency for Medicines and Health Products (FAMHP), Drugs:  
[https://www.famhp.be/en/human\\_use/medicines/medicines/research\\_development/clinical\\_trials](https://www.famhp.be/en/human_use/medicines/medicines/research_development/clinical_trials)
- Federal Agency for Medicines and Health Products (FAMHP), Devices:  
[https://www.famhp.be/en/human\\_use/health\\_products/medical\\_devices\\_accessories](https://www.famhp.be/en/human_use/health_products/medical_devices_accessories)
- Belgian Advisory Committee on Bioethics (BACB):  
<https://www.health.belgium.be/en/belgian-advisory-committee-bioethics>
- Clinical Trial College: <https://consultativebodies.health.belgium.be/en/advisory-and-consultative-bodies/ct-college-clinical-trial-college>

### Relevant Standards

- Law Relating to Experimentation on Humans (2004):  
[http://www.ejustice.just.fgov.be/cgi\\_loi/change\\_lg.pl?language=fr&la=F&cn=2004050732&table\\_name=loi](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2004050732&table_name=loi)
- Royal Decrees to Experimentation on Humans:  
[https://www.famhp.be/en/human\\_use/medicines/medicines/research\\_development/ethic\\_committee](https://www.famhp.be/en/human_use/medicines/medicines/research_development/ethic_committee)
- Royal Decrees on Clinical Trials: <https://consultativebodies.health.belgium.be/en/advisory-and-consultative-bodies/ct-college-clinical-trial-college>
- BACB, Opinion No. 58: Financing Expensive Medication:  
[https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth\\_theme\\_file/opinion\\_58\\_web.pdf](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/opinion_58_web.pdf)

## Research Injury

### Key Organizations

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

### Relevant Standards

- Law Relating to Experimentation on Humans, Chapter XVII (Responsibility and Insurance) Article 29 (2004):  
[https://www.famhp.be/en/human\\_use/medicines/medicines/research\\_development/ethic\\_committee](https://www.famhp.be/en/human_use/medicines/medicines/research_development/ethic_committee)

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

- Law Relating to the Use of Human Biological Materials (19 December 2008): [https://www.afmps.be/fr/humain/produits\\_de\\_sante/materiel\\_corporel\\_humain/banques\\_de\\_materiel\\_corporel\\_humain/legislation/apres\\_le\\_01\\_12\\_2009](https://www.afmps.be/fr/humain/produits_de_sante/materiel_corporel_humain/banques_de_materiel_corporel_humain/legislation/apres_le_01_12_2009)
- Royal Decrees to the Use of Human Biological Materials: [https://www.afmps.be/fr/humain/produits\\_de\\_sante/materiel\\_corporel\\_humain/banques\\_de\\_materiel\\_corporel\\_humain/legislation/apres\\_le\\_01\\_12\\_2009](https://www.afmps.be/fr/humain/produits_de_sante/materiel_corporel_humain/banques_de_materiel_corporel_humain/legislation/apres_le_01_12_2009)
- BACB, various: <http://www.health.belgium.be/en/belgian-advisory-committee-bioethics>
- CSS, various: [https://www.health.belgium.be/en/superior-health-council?f%5B0%5D=field\\_shc\\_doc%3A1145](https://www.health.belgium.be/en/superior-health-council?f%5B0%5D=field_shc_doc%3A1145)

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

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



*International Compilation of Human Research Standards  
2021 Edition*

- Law on Medically Assisted Reproduction and the Destination of Supernumerary Embryos and Gametes (2007): [https://www.afmps.be/fr/humain/produits\\_de\\_sante/materiel\\_corporel\\_humain/banques\\_de\\_materiel\\_corporel\\_humain/legislation/apres\\_le\\_01\\_12\\_2009](https://www.afmps.be/fr/humain/produits_de_sante/materiel_corporel_humain/banques_de_materiel_corporel_humain/legislation/apres_le_01_12_2009)
- Royal Decree Fixing the Criteria for the Program Applicable to the Care Programs ‘Reproductive Medicine’ (15 February 1999): <https://organesdeconcertation.sante.belgique.be/fr/organe-d'avis-et-de-concertation/commission-federale-embryons>
- BACB, various: <http://www.health.belgium.be/en/belgian-advisory-committee-bioethics>

## **EUROPE – Bosnia and Herzegovina**

### **General**

#### ***Federation of Bosnia and Herzegovina***

##### **Key Organization**

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

##### **Relevant Standards**

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

#### ***Republic of Srpska***

##### **Key Organization**

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

### **Drugs, Biologics, and Devices**

#### ***Federation of Bosnia and Herzegovina***

##### **Key Organizations**

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

##### **Relevant Standards**

- Law on Drugs No. 58/08: [http://www.almbih.gov.ba/\\_doc/regulative/medicinal\\_products\\_and\\_medical\\_devices\\_act.pdf](http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf)

*International Compilation of Human Research Standards  
2021 Edition*

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

### ***Republic of Srpska***

#### **Key Organizations**

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

#### **Relevant Standards**

- Law on Drugs No. 58/08:  
[http://www.almbih.gov.ba/\\_doc/regulative/medicinal\\_products\\_and\\_medical\\_devices\\_act.pdf](http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf)
- Law on Changes and Amendments of Law on Drugs No. 34/08
- Regulation about Clinical testing of IMP and Medical Devices (2010):  
[http://www.almbih.gov.ba/\\_doc/regulative/pravilnik\\_klinicka\\_bos.pdf](http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf)
- Regulation about Medical Devices (2010):  
[http://www.almbih.gov.ba/\\_doc/regulative/pravilnik\\_ms\\_bos.pdf](http://www.almbih.gov.ba/_doc/regulative/pravilnik_ms_bos.pdf)
- Standards of GCP in Conducting CTs (2012):  
[http://www.almbih.gov.ba/\\_doc/regulative/Smjernice\\_dobre\\_klinicke\\_prakse-bo.pdf](http://www.almbih.gov.ba/_doc/regulative/Smjernice_dobre_klinicke_prakse-bo.pdf)
- Instructions on Manner of Reporting on Safety in the Framework of Clinical Trials (2016):  
[http://www.almbih.gov.ba/\\_doc/upustva-vodici/uputstvo\\_o\\_nacinu\\_izvjestavanja\\_o\\_sigurnosti.pdf](http://www.almbih.gov.ba/_doc/upustva-vodici/uputstvo_o_nacinu_izvjestavanja_o_sigurnosti.pdf)

### **Clinical Trial Registries**

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **Research Injury**

### *Federation of Bosnia and Herzegovina*

#### **Key Organizations**

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

#### **Relevant Standards**

- Medicinal Products and Medicinal Devices Act, Articles 52 and 116 (2008): [http://www.almbih.gov.ba/\\_doc/regulative/medicinal\\_products\\_and\\_medical\\_devices\\_act.pdf](http://www.almbih.gov.ba/_doc/regulative/medicinal_products_and_medical_devices_act.pdf)
- Law on Health Insurance of the Federation of Bosnia and Herzegovina, Official Gazette No. 46/10
- Regulation about Clinical Testing of IMP and Medical Devices, 4/10: [http://www.almbih.gov.ba/\\_doc/regulative/pravilnik\\_klinicka\\_bos.pdf](http://www.almbih.gov.ba/_doc/regulative/pravilnik_klinicka_bos.pdf)
- Legislation at the state level: <http://www.almbih.gov.ba/en/documents/regulations/>

### *Republic of Srpska*

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **Social-Behavioral Research**

### *Federation of Bosnia and Herzegovina*

#### **Key Organizations**

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

### *Republic of Srpska*

#### **Key Organizations**

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

## **Privacy/Data Protection**

#### **Key Organizations**

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

## **Relevant Standards**

- Law on the Protection of Personal Data in Bosnia and Herzegovina (2005): [https://www.legislationline.org/download/id/5523/file/BiH\\_law\\_protection\\_secret\\_data\\_2005\\_amendments\\_2011\\_en.pdf](https://www.legislationline.org/download/id/5523/file/BiH_law_protection_secret_data_2005_amendments_2011_en.pdf)
- Law on Amendments to the Law on the Protection of Personal Data in Bosnia and Herzegovina, Official Gazette of Bosnia and Herzegovina No. 76/11 (2011): [https://www.legislationline.org/download/id/5523/file/BiH\\_law\\_protection\\_secret\\_data\\_2005\\_amendments\\_2011\\_en.pdf](https://www.legislationline.org/download/id/5523/file/BiH_law_protection_secret_data_2005_amendments_2011_en.pdf)
- Regulation on the Manner of Keeping the Records of Personal Data Filing Systems and the Pertinent Records Form (2009)

## **Human Biological Materials**

### *Federation of Bosnia and Herzegovina*

#### **Key Organizations**

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

#### **Relevant Standards**

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

### *Republic of Srpska*

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **Genetic Research**

### *Federation of Bosnia and Herzegovina*

#### **Key Organizations**

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

#### **Relevant Standards**

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

### *Republic of Srpska*

#### **Key Organizations**

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

#### **Relevant Standards**

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

## Embryos, Stem Cells, and Cloning

### Federation of Bosnia and Herzegovina

#### Key Organizations

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

#### Relevant Standards

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

### Republic of Srpska

#### Key Organizations

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

#### Relevant Standards

- Law on Transplantation of Organs (2010): <http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20transplantaciji%20ljudskih%20organa.pdf>
- Law on Transplantation of Human Tissues and Cells (2010): <http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/Zakon%20o%20transplantaciji%20ljudskih%20tkiva%20i%20celija.pdf>
- Rulebook about Testing Procedure for Donor of Transplant Organs in Terms of Diseases Which can be Transmitted by Transplantation (2010): [http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/%d0%9f%d1%80%d0%b0%d0%b2%d0%b8%d0%bb%d0%bd%d0%b8%d0%ba\\_%d0%be\\_%d0%ba%d1%80%d0%b8%d1%82%d0%b5%d1%80%d0%b8%d1%98%d1%83%d0%bc%d0%b8%d0%bc%d0%b0\\_%d0%b7%d0%b0\\_%d1%82%d0%b5%d1%81%d1%82%d0%b8%d1%80%d0%b0%d1%9a%d0%b5\\_%d0%b4%d0%b0%d0%b2%d0%b0%d0%bb%d0%b0%d1%86%d0%b0\\_%d1%99%d1%83%d0%b4%d1%81%d0%ba%d0%b8%d1%85\\_%d0%be%d1%80%d0%b3%d0%b0%d0%bd%d0%b0\\_64\\_10.pdf](http://www.vladars.net/sr-SP-Cyrl/Vlada/Ministarstva/MZSZ/Documents/%d0%9f%d1%80%d0%b0%d0%b2%d0%b8%d0%bb%d0%bd%d0%b8%d0%ba_%d0%be_%d0%ba%d1%80%d0%b8%d1%82%d0%b5%d1%80%d0%b8%d1%98%d1%83%d0%bc%d0%b8%d0%bc%d0%b0_%d0%b7%d0%b0_%d1%82%d0%b5%d1%81%d1%82%d0%b8%d1%80%d0%b0%d1%9a%d0%b5_%d0%b4%d0%b0%d0%b2%d0%b0%d0%bb%d0%b0%d1%86%d0%b0_%d1%99%d1%83%d0%b4%d1%81%d0%ba%d0%b8%d1%85_%d0%be%d1%80%d0%b3%d0%b0%d0%bd%d0%b0_64_10.pdf)
- Health Protection Laws and Regulations: <https://www.fmoh.gov.ba/index.php/zakoni-i-strategije/lista-zakonskih-i-podzakonskih-akata>

## EUROPE – Bulgaria

### General

#### Key Organization

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

#### Relevant Standards

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

*International Compilation of Human Research Standards  
2021 Edition*

- Oviedo Convention on Human Rights and Biomedicine (2003): <https://www.coe.int/en/web/bioethics/oviedo-convention>
- Law Ratifying the Additional Protocol on Biomedical Research (2006): [https://www.mh.government.bg/media/filer\\_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifikatsirane-protokol-konventsiya-zashtita-pravata-na\\_choveka\\_29-08-2006.pdf](https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifikatsirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf)
- Medicinal Products in Human Medicine Act (2017): [http://www.bda.bg/images/stories/documents/regulations/zakoni/ZLPHM\\_28122017.pdf](http://www.bda.bg/images/stories/documents/regulations/zakoni/ZLPHM_28122017.pdf)
- Healthcare Act, Articles 197-206 (2018): [http://www.mh.government.bg/media/filer\\_public/2018/02/27/zakon-za-zdraveto.pdf](http://www.mh.government.bg/media/filer_public/2018/02/27/zakon-za-zdraveto.pdf)
- List of Laws: <https://www.mh.government.bg/bg/normativni-aktove/zakoni/>

## Drugs, Biologics, and Devices

### *Drugs*

#### **Key Organizations**

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

#### **Relevant Standards**

- Medicinal Products in Human Medicine Act, Chapter 4 (2018): <https://www.lex.bg/laws/ldoc/2135549536>
- Regulation No. 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice (2012): [http://www.bda.bg/images/stories/documents/regulations/naredbi/20180320\\_Naredda\\_31.pdf](http://www.bda.bg/images/stories/documents/regulations/naredbi/20180320_Naredda_31.pdf)
- Medical Devices Act: [https://www.bda.bg/images/stories/documents/legal\\_acts/20210208\\_ZMI\\_english.pdf](https://www.bda.bg/images/stories/documents/legal_acts/20210208_ZMI_english.pdf)
- Ordinance No. 10 (2008): [https://www.bda.bg/images/stories/documents/legal\\_acts/Ordinance\\_Clinical\\_investigations\\_MD\\_EN.pdf](https://www.bda.bg/images/stories/documents/legal_acts/Ordinance_Clinical_investigations_MD_EN.pdf)

### *Devices*

#### **Key Organizations**

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

#### **Relevant Standards**

- Medical Devices Act (2016): [http://www.bda.bg/images/stories/documents/legal\\_acts/ZMI\\_en\\_20160308.pdf](http://www.bda.bg/images/stories/documents/legal_acts/ZMI_en_20160308.pdf)
- Ordinance No. 10 (2008): [http://www.bda.bg/images/stories/documents/legal\\_acts/Ordinance\\_Clinical\\_investigations\\_MD\\_EN.pdf](http://www.bda.bg/images/stories/documents/legal_acts/Ordinance_Clinical_investigations_MD_EN.pdf)
- Various: <http://www.bda.bg/en/114-information-for-companies-section/medical-devices-category>
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>

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

- Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536&qid=1633444926711>

### **Clinical Trial Registries**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Research Injury**

#### **Key Organizations**

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

#### **Relevant Standards**

- Medicinal Products in Human Medicine Act, Chapter 4, Articles 91 and 92 (2016):  
[http://www.bda.bg/images/stories/documents/legal\\_acts/ZLPHM\\_en.pdf](http://www.bda.bg/images/stories/documents/legal_acts/ZLPHM_en.pdf)
- Regulation 31 from 12 August 2007 for Determining the Principles of Good Clinical Practice, Section 5.8 (2012) (Bulgarian):  
[http://www.bda.bg/images/stories/documents/regulations/naredbi/20180320\\_Naredda\\_31.pdf](http://www.bda.bg/images/stories/documents/regulations/naredbi/20180320_Naredda_31.pdf)
- Others:  
[https://www.mh.government.bg/media/filer\\_public/2021/03/08/zakon\\_za\\_lekarstvenite\\_produkti\\_v\\_humannata\\_medicina.pdf](https://www.mh.government.bg/media/filer_public/2021/03/08/zakon_za_lekarstvenite_produkti_v_humannata_medicina.pdf)  
<https://www.bda.bg/images/stories/documents/regulations/naredbi/20210415/%D0%9D%D0%90%D0%A0%D0%95%D0%94%D0%91%D0%90%20%E2%84%96%2031%20%D0%9E%D0%A2%2012%20%D0%90%D0%92%D0%93%D0%A3%D0%A1%D0%A2%202007%20%D0%93.pdf>

### **Privacy/Data Protection**

#### **Key Organizations**

- Bulgarian Commission for Personal Data Protection:  
<https://www.cpdp.bg/en/index.php?p=rubric&aid=2>
- Ombudsman: [www.ombudsman.bg](http://www.ombudsman.bg)

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

- General (2018): <https://www.cdpd.bg/index.php?p=element&aid=1163>
- Research (2018): <https://www.cdpd.bg/en/index.php?p=element&aid=1162>
- Consent (2018): <https://www.cdpd.bg/en/index.php?p=element&aid=1162>
- Personal Data Protection Act [https://www.cdpd.bg/userfiles/file/ZZLD/ZZLD\\_26\\_11\\_2019\\_En.pdf](https://www.cdpd.bg/userfiles/file/ZZLD/ZZLD_26_11_2019_En.pdf)
- Regulation (EU) 2016/679 <https://eur-lex.europa.eu/eli/reg/2016/679/oj>

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006): [https://www.mh.government.bg/media/filer\\_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifiksirane-protokol-konventsiya-zashtita-pravata-na\\_choveka\\_29-08-2006.pdf](https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifiksirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf)
- Act on Transplantation of Organs, Tissues and Cells <https://iamn.bg/en/legislation/>
- Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006): [https://www.mh.government.bg/media/filer\\_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifiksirane-protokol-konventsiya-zashtita-pravata-na\\_choveka\\_29-08-2006.pdf](https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifiksirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf)
- Regulation No. 13 of 4 April 2007 for the Terms and Conditions of Informing Bulgarian Citizens on the Activities regarding the Transplantation of Organs, Tissues and Cells: [http://www2.bgtransplant.bg/sites/default/files/docs/naredbi/Naredba\\_no13\\_ot\\_04\\_april\\_2007\\_g.rtf](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](https://www.mh.government.bg/media/filer_public/2021/03/08/zakon_za_zdraveto.pdf)

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

- Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006): [https://www.mh.government.bg/media/filer\\_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifiksirane-protokol-konventsiya-zashtita-pravata-na\\_choveka\\_29-08-2006.pdf](https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifiksirane-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf)



*International Compilation of Human Research Standards  
2021 Edition*

- Act on Transplantation of Organs, Tissues and Cells: <https://iamn.bg/en/legislation/>
- Law Ratifying the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (2006): [https://www.mh.government.bg/media/filer\\_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifikatsiya-protokol-konventsiya-zashtita-pravata-na\\_choveka\\_29-08-2006.pdf](https://www.mh.government.bg/media/filer_public/c6/12/c612c85a-519f-4a22-b390-5fad298ce80b/zakon-ratifikatsiya-protokol-konventsiya-zashtita-pravata-na_choveka_29-08-2006.pdf)

## **EUROPE – Croatia**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

### **Drugs, Biologics, and Devices**

#### **Drugs**

##### **Key Organizations**

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

##### **Relevant Standards**

- Medicinal Product Act (2013): [http://narodne-novine.nn.hr/clanci/sluzbeni/2013\\_06\\_76\\_1522.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html)
- Rule Book on Amendments to Medicinal Product Act (2014): [http://narodne-novine.nn.hr/clanci/sluzbeni/2014\\_07\\_90\\_1809.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html)
- Ordinance on Clinical Trials and Good Clinical Practice (2015): [http://narodne-novine.nn.hr/clanci/sluzbeni/2015\\_03\\_25\\_534.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html)
- Ordinance on Amendments to the Ordinance on Clinical Trials and Good Clinical Practice (2015): [https://narodne-novine.nn.hr/clanci/sluzbeni/2014\\_07\\_90\\_1809.html](https://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html)

#### **Devices**

##### **Key Organizations**

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

### **Relevant Standards**

- Medical Devices Act (2013): [http://narodne-novine.nn.hr/clanci/sluzbeni/2013\\_06\\_76\\_1521.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1521.html)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (effective 31 January 2022): <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536&qid=1633444926711>

## **Clinical Trial Registries**

### **Key Organizations**

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

### **Relevant Standards**

- Various: [https://zdravlje.gov.hr/?id=1349&pregled=1&datum=Wed%20Mar%202013%202019%2014:46:45%20GMT+0100%20\(Central%20European%20Standard%20Time\)](https://zdravlje.gov.hr/?id=1349&pregled=1&datum=Wed%20Mar%202013%202019%2014:46:45%20GMT+0100%20(Central%20European%20Standard%20Time))
- HALMED Front Page for Industry Representatives: <https://www.halmed.hr/Predstavnici-industrije/>

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

- Law on Mandatory Health Insurance (2013): [http://www.hzzo.hr/wp-content/uploads/2013/10/ZOZO\\_PROCISCENI\\_TEKSTv2.pdf?6d8ad4](http://www.hzzo.hr/wp-content/uploads/2013/10/ZOZO_PROCISCENI_TEKSTv2.pdf?6d8ad4)
- Medicinal Product Act (2013): [http://narodne-novine.nn.hr/clanci/sluzbeni/2013\\_06\\_76\\_1522.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2013_06_76_1522.html)
- Rule Book on Amendments to Medicinal Product Act (2014): [http://narodne-novine.nn.hr/clanci/sluzbeni/2014\\_07\\_90\\_1809.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2014_07_90_1809.html)
- Ordinance on Clinical Trials and Good Clinical Practice, Articles 11 and 16, Act 5.8., 6.8., and 8.2.5 (2015): [http://narodne-novine.nn.hr/clanci/sluzbeni/2015\\_03\\_25\\_534.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2015_03_25_534.html)
- Various: <https://zdravlje.gov.hr/arhiva-80/zakonodavstvo/zakoni-i-pravilnici/pravilnici/pravilnici-zakon-o-lijekovima/1061>

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

- EU General Data Protection Regulation (2016): <https://eur-lex.europa.eu/eli/reg/2016/679/oj>
- Implementation Act of the General Data Protection Act (NN 42/18) (2018): [https://narodne-novine.nn.hr/clanci/sluzbeni/2018\\_05\\_42\\_805.html](https://narodne-novine.nn.hr/clanci/sluzbeni/2018_05_42_805.html)
- General (2018): <http://azop.hr/info-servis/detaljnije/smjernice>

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

- Law about Blood and Blood Products (2006): [http://narodne-novine.nn.hr/clanci/sluzbeni/2006\\_07\\_79\\_1916.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2006_07_79_1916.html)
- Rule Book on Amendments to Law about Blood and Blood Products (2011): [http://narodne-novine.nn.hr/clanci/sluzbeni/2011\\_11\\_124\\_2476.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2011_11_124_2476.html)
- Law on the Implementation of Human Tissues and Cells (2012): [http://narodne-novine.nn.hr/clanci/sluzbeni/2012\\_12\\_144\\_3070.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3070.html)
- Law on Transplantation of Human Organs for the Purpose of Treatment (2012): [http://narodne-novine.nn.hr/clanci/sluzbeni/2012\\_12\\_144\\_3071.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3071.html)
- Ordinance on the Conditions of Space, Professional Workers, Medical-Technical Equipment and Quality Assurance for Collection, Retrieval, Testing, Processing, Preservation, Storage, and Allocation of Human Tissues and Cells (2013): <http://www.propisi.hr/print.php?id=9354>
- Various: <https://zdravlje.gov.hr/arhiva-80/zakonodavstvo/zakoni-i-pravilnici/701>

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

- Law on the Implementation of Human Tissues and Cells (2012): [http://narodne-novine.nn.hr/clanci/sluzbeni/2012\\_12\\_144\\_3070.html](http://narodne-novine.nn.hr/clanci/sluzbeni/2012_12_144_3070.html)
- Ordinance on the Conditions of Space, Professional Workers, Medical-Technical Equipment and Quality Assurance for Collection, Retrieval, Testing, Processing, Preservation, Storage and Allocation of Human Tissues and Cells (2013): <http://www.propisi.hr/print.php?id=9354>
- Various Ordinances - Law on the taking and transplantation of parts of the human body for the purpose of treatment: <https://zdravlje.gov.hr/arhiva-80/zakonodavstvo/zakoni-i-pravilnici/pravilnici/pravilnici-zakon-o-uzimanju-i-presadjivanju-dijelova-ljudskog-tijela-u-svrhu-lijecenja/1057>

## **EUROPE – Cyprus**

### **General**

#### **Relevant Standards**

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

### **Drugs, Biologics, and Devices**

#### **Key Organizations**

- Ministry of Health, Pharmaceutical Services: [https://www.moh.gov.cy/moh/moh.nsf/page15\\_en/page15\\_en?OpenDocument](https://www.moh.gov.cy/moh/moh.nsf/page15_en/page15_en?OpenDocument)
- Ministry of Health, National Bioethics Committee: [http://www.bioethics.gov.cy/moh/cnbc/cnbc.nsf/index\\_en/index\\_en?OpenDocument](http://www.bioethics.gov.cy/moh/cnbc/cnbc.nsf/index_en/index_en?OpenDocument)

#### **Relevant Standards**

- Law for Good Clinical Practice (2004)

### **Research Injury**

#### **Key Organizations**

- Ministry of Health, Pharmaceutical Services: [http://www.moh.gov.cy/moh/moh.nsf/index\\_en/index\\_en?OpenDocument](http://www.moh.gov.cy/moh/moh.nsf/index_en/index_en?OpenDocument)

#### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Relevant Standards**

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

## **EUROPE – Czech Republic**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

## **Drugs, Biologics, and Devices**

### **Drugs**

#### **Key Organizations**

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

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

- Regulation (EU) No. 536/2014 on clinical trials on medicinal products for human use: [https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg\\_2014\\_536/reg\\_2014\\_536\\_en.pdf](https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf)
- Decree No. 226/2008 on Good Clinical Practices and on Detailed Conditions for Evaluation of Pharmaceutical Products: [https://www.sukl.eu/uploads/Legislativa/226\\_2008\\_clinical\\_trials.pdf](https://www.sukl.eu/uploads/Legislativa/226_2008_clinical_trials.pdf)
- Various: <http://www.sukl.cz/medicinal-products-clinical-trials-guidelines-1>

## **Devices**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Clinical Trial Registries**

### **Key Organizations**

- EU Clinical Trials Register

### **Relevant Standards**

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

## **Research Injury**

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – Denmark**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

## **Drugs, Biologics, and Devices**

### **Key Organizations**

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

### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## Clinical Trial Registries

### Key Organizations

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

### Relevant Standards

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

## Research Injury

### Key Organizations

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

### Relevant Standards

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

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

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

## Human Biological Materials

### Key Organizations

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



## **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – Estonia**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

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

- Code of Ethics of Estonian Scientists: [https://www.akadeemia.ee/wp-content/uploads/2020/06/code\\_ethics2002-3.pdf](https://www.akadeemia.ee/wp-content/uploads/2020/06/code_ethics2002-3.pdf)

### **Drugs, Biologics, and Devices**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Research Injury**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Privacy/Data Protection**

#### **Key Organizations**

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

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## Genetic Research

### Relevant Standards

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

## Embryos, Stem Cells, and Cloning

### Relevant Standards

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

## EUROPE – Finland

### General

#### Key Organization

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

#### Relevant Standards

- Decree of the National Research Ethics Council of Finland No. 1347/1991
- Decree on Medical Research Nos. 986/1999, 313/2004, and 65/2016
- Decrees on the National Committee on Medical Research Ethics No. 820/2010 and 788/2018
- Operating Procedures of the National Committee on Medical Research Ethics (2019)
- Decree on Fees, No. 1287/2018
- Report on Children in Medical Research (2003): [https://tukija.fi/documents/1481661/1546647/2003\\_children.pdf/54924377-820e-4a26-be33-47fcaa64f5f0/2003\\_children.pdf?t=1438856851000](https://tukija.fi/documents/1481661/1546647/2003_children.pdf/54924377-820e-4a26-be33-47fcaa64f5f0/2003_children.pdf?t=1438856851000)
- Various Guidelines: <http://tukija.fi/en/publications1>
- Act on Data Protection (1050/2018): <https://www.finlex.fi/fi/laki/kaannokset/2018/en20181050.pdf>
- Criminal Code of Finland (39/1889, numerous amendments; the link includes amendments up until 766/2015): [https://www.finlex.fi/fi/laki/kaannokset/1889/en18890039\\_20150766.pdf](https://www.finlex.fi/fi/laki/kaannokset/1889/en18890039_20150766.pdf)

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

- Act on the Secondary Use of Health and Social Data (552/2019): <https://www.finlex.fi/fi/laki/alkup/2019/20190552#Lidp445824016> (<https://stm.fi/documents/1271139/1365571/The+Act+on+the+Secondary+Use+of+Health+and+Social+Data/a2bca08c-d067-3e54-45d1-18096de0ed76/The+Act+on+the+Secondary+Use+of+Health+and+Social+Data.pdf>; unofficial translation)
- Medical Research Act No. 488/1999 (Amended 295/2004, 794/2010, 143/2015 and one related to a Government Proposal to the Parliament HE 18/2020vp in relation to the application of EU Clinical Trials Regulation 536/2014) upcoming): <http://www.finlex.fi/en/laki/kaannokset/1999/en19990488>
- Government Decree on the National Institute for Health and Welfare (668/2008), latest amendment 1122/2015, <https://www.finlex.fi/en/laki/kaannokset/2008/en20080675>
- Responsible Conduct of Research and Procedures for Handling Allegations of Misconduct in Finland (2012): [https://tenk.fi/sites/tenk.fi/files/HTK\\_ohje\\_2012.pdf](https://tenk.fi/sites/tenk.fi/files/HTK_ohje_2012.pdf)
- The Ethical Principles of Research with Human Participants and Ethical Review in the Human Sciences in Finland (2019): [https://tenk.fi/sites/default/files/2021-01/Ethical\\_review\\_in\\_human\\_sciences\\_2020.pdf](https://tenk.fi/sites/default/files/2021-01/Ethical_review_in_human_sciences_2020.pdf)
- Agreeing on Authorship. Recommendation for Research Publications: [https://tenk.fi/sites/tenk.fi/files/TENK\\_suositus\\_tekijyys.pdf](https://tenk.fi/sites/tenk.fi/files/TENK_suositus_tekijyys.pdf)

### **Drugs, Biologics, and Devices**

#### **Drugs**

##### **Key Organizations**

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

##### **Relevant Standards**

- Medicines Act (395/1987): <http://www.finlex.fi/fi/laki/smur/1987/19870395>
- Medical Research Act No. 488/1999 (Amended 295/2004, 794/2010, and 143/2015): <http://www.finlex.fi/en/laki/kaannokset/1999/en19990488>
- Decree of the National Research Ethics Council of Finland No. 1347/1991: <https://www.finlex.fi/fi/laki/alkup/1991/19911347>
- Decree on Medical Research, Nos. 986/1999, 313/2004 and 65/2016: <https://finlex.fi/fi/laki/alkup/1999/19990986>, <https://finlex.fi/fi/laki/alkup/2016/20160065>
- Decrees on the National Committee on Medical Research Ethics No. 820/2010 and 788/2018: <https://finlex.fi/fi/laki/alkup/2010/20100820>, <https://www.finlex.fi/fi/laki/alkup/2018/20180788>
- Operating Procedures of the National Committee on Medical Research Ethics (2021): [https://tukija.fi/documents/1481661/0/TUKIJAn+toimintaohje\\_07062021\\_EN.pdf/5a2a86df-6a18-d68b-56d8-8dbba3ce5ba2/TUKIJAn+toimintaohje\\_07062021\\_EN.pdf?t=1623235604734](https://tukija.fi/documents/1481661/0/TUKIJAn+toimintaohje_07062021_EN.pdf/5a2a86df-6a18-d68b-56d8-8dbba3ce5ba2/TUKIJAn+toimintaohje_07062021_EN.pdf?t=1623235604734)

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

- Decree on Fees, No. 1171/2020:  
[https://tukija.fi/documents/1481661/0/Maksuasetus+20201171+\(3\).pdf/e7e9dc90-f06f-47b3-98ee-e3beb7253d87/Maksuasetus+20201171+\(3\).pdf?t=1610024226291](https://tukija.fi/documents/1481661/0/Maksuasetus+20201171+(3).pdf/e7e9dc90-f06f-47b3-98ee-e3beb7253d87/Maksuasetus+20201171+(3).pdf?t=1610024226291)
- Decree on Clinical Trials on Medicinal Products No. 841/2010
- Other Decrees related to Medicines Act: <http://www.finlex.fi/fi/laki/smur/1987/19870395#nojalla>
- Administrative Regulation on Clinical Trials on Medicinal Products in Human Subjects No. 2/2012
- Templates for Clinical Trial Information Leaflet and Consent Form (2018):  
<https://tukija.fi/lomakkeet-ja-asiakirjamallit>
- Templates for Clinical Trial Information Leaflet and Consent Form (2018):  
<http://tukija.fi/en/publications1>
- Administrative Regulation on Clinical Investigations (2010):  
[http://www.finlex.fi/data/normit/39644-maarays\\_3\\_2010\\_kliininen\\_laitetutkimus.pdf](http://www.finlex.fi/data/normit/39644-maarays_3_2010_kliininen_laitetutkimus.pdf)
- Finnish Medicines Agency Administrative Regulation on Clinical Trials on Medicinal Products (8/2019): <https://www.fimea.fi/documents/542809/9377176/Regulation+8-2019+Clinical+Trials+-+EN.pdf/8f64f47e-a072-f385-833b-7989111ae81a?t=1575897566370>
- Various Guidelines: <http://tukija.fi/en/publications1>
- Report on Children in Medical Research (2003):  
[https://tukija.fi/documents/1481661/1546647/2003\\_children.pdf/54924377-820e-4a26-be33-47fcaa64f5f0/2003\\_children.pdf?t=1438856851000](https://tukija.fi/documents/1481661/1546647/2003_children.pdf/54924377-820e-4a26-be33-47fcaa64f5f0/2003_children.pdf?t=1438856851000)

### **Devices**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Clinical Trial Registries**

#### **Key Organizations**

- Finnish Medicines Agency Fimea: [https://www.fimea.fi/web/en/supervision/clinical\\_drug\\_trials](https://www.fimea.fi/web/en/supervision/clinical_drug_trials)

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Social-Behavioral Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – France**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

- 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](http://www.ccne-ethique.fr/en/type_publication/avis)

## **Drugs, Biologics, and Devices**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Social-Behavioral Research**

### **Key Organizations**

- National Consultative Ethics Committee

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

- Act No. 78-17 of 6 January 1978 on Information Technology, Data Files, and Civil Liberties (2018): <https://www.cnil.fr/fr/la-loi-informatique-et-libertes>
- Law No. 2016-1321 of 7 October 2016 for a Numeric Republic: <https://www.legifrance.gouv.fr/affichLoiPubliee.do?idDocument=JORFDOLE000031589829&type=general&legislature=14>
- EU General Data Protection Regulation (2016): <https://eur-lex.europa.eu/eli/reg/2016/679/oj>
- Data Protection Act (2018): [https://www.legifrance.gouv.fr/affichLoiPreparation.do;jsessionid=AD5660270AD9F70B94275AC823321680.tplgfr22s\\_3?idDocument=JORFDOLE000036195293&type=contenu&id=2&typeLoi=pr oj&legislature=15](https://www.legifrance.gouv.fr/affichLoiPreparation.do;jsessionid=AD5660270AD9F70B94275AC823321680.tplgfr22s_3?idDocument=JORFDOLE000036195293&type=contenu&id=2&typeLoi=pr oj&legislature=15)



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

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

### **Human Biological Materials**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Genetic Research**

#### **Key Organizations**

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

#### **Relevant Standards**

- Civil Code Articles 16-10 to 16-13: [http://www.legifrance.gouv.fr/affichCode.do;jsessionid=D2DE023194483D3384DE19DE8959BDDA.tpdjo17v\\_3?idSectionTA=LEGISCTA000006136513&cidTexte=LEGITEXT000006070721&dateTexte=20131006](http://www.legifrance.gouv.fr/affichCode.do;jsessionid=D2DE023194483D3384DE19DE8959BDDA.tpdjo17v_3?idSectionTA=LEGISCTA000006136513&cidTexte=LEGITEXT000006070721&dateTexte=20131006)

*International Compilation of Human Research Standards  
2021 Edition*

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

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

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

## EUROPE – Georgia

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

[http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical\\_review\\_cis\\_book\\_kubar\\_english.pdf](http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf)

## General

### Key Organization

- Bioethics and Health Law Studies Society

### Relevant Standards

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

## **Drugs, Biologics, and Devices**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Clinical Trial Registries**

### **Key Organizations**

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

### **Relevant Standards**

- No public registry

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Social-Behavioral Research**

### **Key Organizations**

- Social and Psychological Agency

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

- Bioethics and Health Law Studies Society

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – Germany**

### **General**

### **Key Organization**

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

### **Relevant Standards**

- BÄK, (Model) Professional Code for Physicians in Germany, Article 15 (2018): [https://www.bundesaerztekammer.de/fileadmin/user\\_upload/downloads/pdf-Ordner/MBO/MBO-AE\\_EN\\_2018.pdf](https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/MBO/MBO-AE_EN_2018.pdf)

## **Drugs, Biologics, and Devices**

### ***Drugs***

#### **Key Organizations**

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

#### **Relevant Standards**

- 2021 German version: Medicinal Products Act, Division 6 (2021): [http://www.gesetze-im-internet.de/amg\\_1976/](http://www.gesetze-im-internet.de/amg_1976/)
- 2020 English version: Medicinal Products Act, Division 6 (2020): [https://www.gesetze-im-internet.de/englisch\\_amg/englisch\\_amg.html#p1005](https://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p1005)
- Promulgation on the Principles of the Conduct of Clinical Trials of Drugs According to the Rules (1987)
- Second Promulgation on the Clinical Trial of Drugs in Human (1997)
- Regulation on the Application of Good Clinical Practice in the Conduct of Clinical Trials of Medicinal Products for Human Use (2012): <http://www.gesetze-im-internet.de/gcp-v/>

### ***Devices***

#### **Key Organizations**

- Federal Institute for Drugs and Medical Devices (BfArM): [http://www.bfarm.de/EN/Home/home\\_node.html](http://www.bfarm.de/EN/Home/home_node.html)
- Paul-Ehrlich-Institut (PEI): <http://www.pei.de/EN/home/node.html#4>
- Federal Ministry of Health (BMG): <https://www.bundesgesundheitsministerium.de/en/ministry/the-federal-ministry-of-health.html>

#### **Relevant Standards**

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

## **Clinical Trial Registries**

#### **Key Organizations**

- German Clinical Trials Register (DRKS): [https://www.drks.de/drks\\_web/setLocale\\_EN.do](https://www.drks.de/drks_web/setLocale_EN.do)

#### **Relevant Standards**

- FAQs: [https://www.drks.de/drks\\_web/navigate.do?navigationId=faq&messageEN=FAQ](https://www.drks.de/drks_web/navigate.do?navigationId=faq&messageEN=FAQ)

## Research Injury

### Relevant Standards

- Medicinal Products Act, Section 40(3) (2020): [https://www.gesetze-im-internet.de/englisch\\_amg/englisch\\_amg.html#p1005](https://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p1005)
- Medical Device Law Implementation Act, Section 26 (2021): [https://www.gesetze-im-internet.de/mpdg/\\_26.html](https://www.gesetze-im-internet.de/mpdg/_26.html)

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- EU General Data Protection Regulation (2016): <https://eur-lex.europa.eu/eli/reg/2016/679/oj>
- Federal Data Protection Act (BDSG) (2019): [https://www.gesetze-im-internet.de/englisch\\_bdsG/index.html](https://www.gesetze-im-internet.de/englisch_bdsG/index.html)
- Data Protection Laws in German States: <http://www.datenschutz-bayern.de/infoquel/ds-inst/deutschland.html>
- DSK, Short Paper No. 4: Data Transmission to Third Countries: [https://www.datenschutzkonferenz-online.de/media/kp/dsk\\_kpnr\\_4.pdf](https://www.datenschutzkonferenz-online.de/media/kp/dsk_kpnr_4.pdf)

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- German Ethics Council, Act of Quality and Security of Human Tissue and Cells (2019): <https://www.buzer.de/s1.htm?g=GewebeGesetz&f=1>
- German Ethics Council, Transfusion Law (2020): <http://www.gesetze-im-internet.de/tfg/>
- German Ethics Council, Transplantation Law (2021): <http://www.gesetze-im-internet.de/tpg/>
- German Ethics Council, Opinion on Human Biobanks for Research (2010): [https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/DER\\_StnBiob\\_Engl\\_Online\\_mitKennwort.pdf](https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/DER_StnBiob_Engl_Online_mitKennwort.pdf)
- ZEKO, Opinion on the (Re)Use of Human Body Material for Medical Research Purposes (2003): [http://www.zentrale-ethikkommission.de/fileadmin/user\\_upload/downloads/pdf-Ordner/Zeko/Koerpermat-1.pdf](http://www.zentrale-ethikkommission.de/fileadmin/user_upload/downloads/pdf-Ordner/Zeko/Koerpermat-1.pdf)
- ZEKO, First Addendum: The (Re)Use of Human Body Material of Deceased Persons for Medical Research Purposes (2003): <http://www.zentrale->

*International Compilation of Human Research Standards  
2021 Edition*

[ethikkommission.de/fileadmin/user\\_upload/downloads/pdf-Ordner/Zeko/Erste\\_Ergaenzung\\_Koerpermaterialien.pdf](http://ethikkommission.de/fileadmin/user_upload/downloads/pdf-Ordner/Zeko/Erste_Ergaenzung_Koerpermaterialien.pdf)

- DGCH, Guidelines on Good Professional Practice (GPP) for the Procurement of Human Tissue and Cells for Drug Production:  
[http://www.dgch.de/fileadmin/media/pdf/servicemeldungen/069\\_Gewebe\\_gesetz\\_GFP-Leitfaden\\_der\\_DGCH\\_fuer\\_die\\_Gewinnung\\_menschlicher\\_Gewebe.pdf](http://www.dgch.de/fileadmin/media/pdf/servicemeldungen/069_Gewebe_gesetz_GFP-Leitfaden_der_DGCH_fuer_die_Gewinnung_menschlicher_Gewebe.pdf)

## Genetic Research

### Key Organizations

- German Society of Human Genetics (GfH): <https://gfhev.de/en/home.html>
- German Research Foundation (DFG), Permanent Senate Commission on Genetic Research: [http://www.dfg.de/en/dfg\\_profile/statutory\\_bodies/senate/genetic\\_research/index.html](http://www.dfg.de/en/dfg_profile/statutory_bodies/senate/genetic_research/index.html)

### Relevant Standards

- Embryo Protection Act (2011): <http://www.gesetze-im-internet.de/eschg/>
- Genetic Engineering Act (2021): <http://www.gesetze-im-internet.de/gentg/>
- German Research Foundation, Statements and Publications: [http://www.dfg.de/en/dfg\\_profile/statutory\\_bodies/senate/genetic\\_research/publications/index.html](http://www.dfg.de/en/dfg_profile/statutory_bodies/senate/genetic_research/publications/index.html)

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

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

*International Compilation of Human Research Standards  
2021 Edition*

- German Ethics Council, Should the Stem Cell Law be Amended? (2007): [https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/Archiv/Stn\\_Stammzellgesetz.pdf](https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/Archiv/Stn_Stammzellgesetz.pdf)
- German Ethics Council, Human-Animal Mixtures in Research (2011): <https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/opinion-human-animal-mixtures-in-research.pdf>
- German Ethics Council, Stem Cell Research - New Challenges for the Ban on Cloning and Treatment of Artificially Created Germ Cells? (2014): <https://www.ethikrat.org/fileadmin/Publikationen/Ad-hoc-Empfehlungen/englisch/recommendation-stem-cell-research.pdf>
- German Ethics Council, Germline Intervention in the Human Embryo (2017): <https://www.ethikrat.org/fileadmin/Publikationen/Ad-hoc-Empfehlungen/englisch/recommendation-germline-intervention-in-the-human-embryo.pdf>
- German Ethics Council, Intervening in the Human Germline (2019): <https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/opinion-intervening-in-the-human-germline-summary.pdf>
- ZEKO, Opinion on Stem Cell Research (2002): [http://www.zentrale-ethikkommission.de/fileadmin/user\\_upload/downloads/pdf-Ordner/Zeko/Stammzell.pdf](http://www.zentrale-ethikkommission.de/fileadmin/user_upload/downloads/pdf-Ordner/Zeko/Stammzell.pdf)
- DFG, Opinion on Stem Cell Research (2006): [https://www.dfg.de/download/pdf/dfg\\_im\\_profil/reden\\_stellungnahmen/2006/stammzellforschung\\_d\\_utschland\\_lang\\_0610.pdf](https://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2006/stammzellforschung_d_utschland_lang_0610.pdf)

## **EUROPE – Greece**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

- Research Ethics for Biological Sciences (2008): <http://www.bioethics.gr/index.php/en/gnomes/86-research-ethics-in-biological-sciences>
- A Guide for Research Ethics Committees for Biological Research (2008): [http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS\\_REPORTS/guide.pdf](http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/guide.pdf)
- Conflict of Interest in Biomedical Research (2014): [http://www.bioethics.gr/images/pdf/EKDOSEIS/OPINIONS\\_AND\\_REPORTS\\_2008-2013\\_EN.pdf](http://www.bioethics.gr/images/pdf/EKDOSEIS/OPINIONS_AND_REPORTS_2008-2013_EN.pdf)
- Incidental Findings in Research and Clinical Practice (2015): <http://www.bioethics.gr/index.php/en/gnomes/983-incidentalfindings-in-research-and-clinical-practice>

### **Drugs, Biologics, and Devices**

#### **Key Organizations**

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



## **Relevant Standards**

- Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998)
- Act 3418/2005 Code on Medical Ethics
- Ministerial Decision ΔΥΤ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC
- Ministerial Decision ΔΥΤ 3 α/79602/2007: Harmonization of the Greek Legislation with EU Legislation, according to the Directive 2005/28/EC
- NBC, Recommendation on Clinical Trials:  
[http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS\\_REPORTS/recom\\_clinical\\_trials\\_en.pdf](http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/recom_clinical_trials_en.pdf)
- NBC, Control of Non-Invasive Clinical Trials for Drugs (2013):  
<http://www.bioethics.gr/index.php/en/gnomes/532-control-of-non-invasive-clinical-trials-for-drugs>

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

- Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998)
- Act 3418/2005 Code on Medical Ethics
- Ministerial Decision ΔΥΤ3 89292/2003: Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2001/20/EC
- Ministerial Decision ΔΥΤ 3 α/79602/2007 Harmonization of the Greek Legislation with EU Legislation, According to the Directive 2005/28/EC

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

## **Relevant Standards**

- Greek Constitution 1975/1986/2001, Article 5.5
- Act 2619/98: Ratification of the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1998)
- Act 2472/1997 on the Protection of Individuals with Regard to the Processing of Personal Data (As Amended by Laws 2819/2000 and 2915/2000)
- Act 3418/2005 Code on Medical Ethics
- Recommendation on Banks of Biological Material of Human Origin (Biobanks) in Biomedical Research:  
[http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS\\_REPORTS/biobanks\\_recom\\_eng.pdf](http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/biobanks_recom_eng.pdf)
- Recommendation on the Collection and Use of Genetic Data:  
[http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS\\_REPORTS/recom\\_genetic\\_data\\_eng.pdf](http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/recom_genetic_data_eng.pdf)
- Opinion on Prenatal and Pre-Implantation Diagnosis and Embryo Treatment:  
[http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS\\_REPORTS/1\\_pd\\_pgd\\_opin\\_eng2.pdf](http://www.bioethics.gr/images/pdf/ENGLISH/OPINIONS_REPORTS/1_pd_pgd_opin_eng2.pdf)
- Opinion on Direct-To-Consumer Genetic Testing (2012):  
<http://www.bioethics.gr/index.php/en/gnomes/91-direct-to-consumer-dtc-genetic-testing>
- Opinion on Incidental Findings in Research and Clinical Practice (2015):  
[http://www.bioethics.gr/images/pdf/GNOMES/OPINION\\_Incidental\\_Findings\\_FINAL\\_.pdf](http://www.bioethics.gr/images/pdf/GNOMES/OPINION_Incidental_Findings_FINAL_.pdf)
- Opinion on Advances in Human Genome Editing (2016):  
[http://www.bioethics.gr/images/pdf/GNOMES/OPINION\\_gene%20editing\\_Final\\_EN.pdf](http://www.bioethics.gr/images/pdf/GNOMES/OPINION_gene%20editing_Final_EN.pdf)

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – Hungary**

### **General**

#### **Key Organization**

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

## Relevant Standards

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

## Drugs, Biologics, and Devices

### Drugs

#### Key Organizations

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

#### Relevant Standards

##### Clinical Trials:

- Act XCV of 2005 on Medicinal Products for Human Use, Section 3:  
<https://net.jogtar.hu/jogszabaly?docid=A0500095.TV&searchUrl=/gyorskereso%3Fextraparams%3D%7B%2522Year%2522%3A%25222005%2522%2C%2522SerialNumber%2522%3A%252295%2522%2C%2522ID%2522%3A%2522FullTextSearch%2522%7D>
- Decree 35/2005 (VIII. 26) of the Minister of Health on the Clinical Trial and Application of Correct Clinical Practices of Investigational Medicinal Products Intended for Use in Humans:  
[http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=A0500035.EUM&celpara=#xcelparam](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=A0500035.EUM&celpara=#xcelparam)
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (it will come in application on 31 January 2022):  
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0537>

*International Compilation of Human Research Standards  
2021 Edition*

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

**Devices**

**Key Organizations**

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

**Relevant Standards**

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

Clinical Trials:

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

Non-Interventional Trials:

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

**Research Injury**

**Key Organizations**

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

**Relevant Standards**

- Register of clinical trials: [https://ogyei.gov.hu/klinikai\\_vizsgalatok\\_nyilvantartasa](https://ogyei.gov.hu/klinikai_vizsgalatok_nyilvantartasa)

**Privacy/Data Protection**

**Key Organizations**

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

### Relevant Standards

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

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

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

## Genetic Research

### Key Organizations

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

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

- Act LXXX of 2006 on the Promulgation of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Transplantation of Organs and Tissues of Human Origin:  
[http://net.jogtar.hu/jr/gen/hjegy\\_doc.cgi?docid=A0600080.TV&celpara=#xcelparam](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](http://net.jogtar.hu/jr/gen/hjegy_doc.cgi?docid=99800018.EUM&celpara=#xcelparam)

## EUROPE – Iceland

### General

#### Key Organization

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

## **Relevant Standards**

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

## **Drugs, Biologics, and Devices**

### **Drugs**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Devices**

#### **Key Organizations**

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

#### **Relevant Standards**

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

*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-ad946f3decaa>
- Regulation on In Vitro Diagnostic Medical Devices No. 936/2011:  
<http://stjornartidindi.is/Advert.aspx?ID=f20b3e4e-ab25-44d3-8e32-e5f42a7b02f0>

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

- Biobanks Act No. 110/2000 (2015): [https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar\\_sidur/Biobanks-Act-as-amended-2015.pdf](https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Biobanks-Act-as-amended-2015.pdf)
- Regulations on the Keeping and Utilization of Biological Samples in Biobanks No. 1146/2010:  
<https://www.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**

- Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (2004)
- Act on Artificial Fertilisation and Use of Human Gametes and Embryos for Stem-Cell Research, No. 55/1996 (2010): [https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar\\_sidur/Act\\_No\\_55\\_1996\\_on\\_Artificial\\_Fertilisation\\_etc\\_as\\_amended.pdf](https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Act_No_55_1996_on_Artificial_Fertilisation_etc_as_amended.pdf)
- Regulation on Artificial Fertilization No. 144/2009: <https://www.reglugerd.is/reglugerdir/eftir-raduneytum/heilbrigdis/nr/10797>

## **EUROPE – Ireland**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

- Operational Procedures for Research Ethics Committees: Guidance 2004: [http://health.gov.ie/wp-content/uploads/2014/07/Operational\\_Procedures1.pdf](http://health.gov.ie/wp-content/uploads/2014/07/Operational_Procedures1.pdf)
- Health Service Executive National Consent Policy, Part 3: [http://www.hse.ie/eng/about/Who/qualityandpatientsafety/National\\_Consent\\_Policy/](http://www.hse.ie/eng/about/Who/qualityandpatientsafety/National_Consent_Policy/)

## **Drugs, Biologics, and Devices**

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **Research Injury**

#### **Key Organizations**

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

#### **Relevant Standards**

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



## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

- Human Biological Material: Recommendations for Collection, Use, and Storage in Research (2005): [http://health.gov.ie/wp-content/uploads/2014/07/Human\\_Biological\\_Material1.pdf](http://health.gov.ie/wp-content/uploads/2014/07/Human_Biological_Material1.pdf)

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – Italy**

### **General**

#### **Key Organization**

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

### **Relevant Standards**

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

## **Drugs, Biologics, and Devices**

### ***Drugs***

#### **Key Organizations**

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

#### **Relevant Standards**

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

### ***Devices***

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **Research Injury**

### **Key Organizations**

- Ministry of Labour and Social Policy: [www.lavoro.gov.it](http://www.lavoro.gov.it)

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Relevant Standards**

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

## **EUROPE – Latvia**

### **General**

#### **Key Organization**

- Central Medical Ethics Committee

#### **Relevant Standards**

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

### **Drugs, Biologics, and Devices**

#### **Drugs**

##### **Key Organizations**

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

##### **Relevant Standards**

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

#### **Devices**

##### **Key Organizations**

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

##### **Relevant Standards**

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

### **Research Injury**

#### **Key Organizations**

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

## **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

- Central Medical Ethics Committee

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – Lithuania**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

- V-28, Decree on the Detailed Requirements for the Content of a Person's Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent (2018): <https://www.e-tar.lt/portal/lt/legalAct/0f2f1b70b9db11e5a6588fb85a3cc84b/asr>
- V-1483, Decree on the List of Interventional Methods of Biomedical Research Causing a Slightly Detrimental and Temporary Impact on the Subject's Health (2018): <https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/828d53e095ef11e4b92e9028929aad91/asr>
- V-235/A1-83, Decree on the Procedure for a Minor's Participation in Biomedical Research (2018): <https://www.e-tar.lt/portal/lt/legalAct/104c2540d3e711e583a295d9366c7ab3>
- V-28, Decree on the Procedure to Conduct Biomedical Research on Medical Documents, No. V-28 (2011): <https://www.e-tar.lt/portal/lt/legalAct/TAR.480CDD584ADB>
- V-7, Decree on the Sample Form of the Biomedical Research Protocol, Summary of the Protocol and the CV of Investigator (2017): <https://www.e-tar.lt/portal/lt/legalAct/352d55b0c44111e583a295d9366c7ab3/asr>
- V-24, Decree on the Procedure for Submission of the Documents to the Lithuanian Bioethics Committee to Issue Favorable Opinion to Conduct a Clinical Trial on Medicinal Products or Approval to Conduct Biomedical Research by the Sponsor of the Clinical Trial on Medicinal Product or Other Type of Biomedical Research (2016): <https://www.e-tar.lt/portal/lt/legalAct/3790a050be7e11e5a6588fb85a3cc84b>
- V-4, Decree on the Request to Issue Approval to Conduct Biomedical Research, the Application Form and the Biomedical Research Ethical Assessment Form (2016): <https://www.e-tar.lt/portal/lt/legalAct/27a3460090f011e4bb408baba2bddd3/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=bnNIV3pKeWhhWjJlcW1xZ2xxQnNrWlprbXM2VWtKbJ5Wlp1ekptZG1hV2V5c3JXbUdGa3IzR2NrNkNab1pxVng2aVprR2ZIWk0yWG81ekxrMnlYY21tV3lwSEtVbWFjbp4bWNwcUyQmNZT2FIMjdUWThacno4ZW1iTiBHbWNlbnJzbVZ4SjJWYWFHYZW9HYW1tNmhvajVobmFwR1ZrbW1jbFdSd2xwdGxsR1pzbHB5WnlXQmdxRzZhWVozRmNKMXJuZyUzRCUzRA==&view=1](http://bioetika.sam.lt/get_file.php?file=bnNIV3pKeWhhWjJlcW1xZ2xxQnNrWlprbXM2VWtKbJ5Wlp1ekptZG1hV2V5c3JXbUdGa3IzR2NrNkNab1pxVng2aVprR2ZIWk0yWG81ekxrMnlYY21tV3lwSEtVbWFjbp4bWNwcUyQmNZT2FIMjdUWThacno4ZW1iTiBHbWNlbnJzbVZ4SjJWYWFHYZW9HYW1tNmhvajVobmFwR1ZrbW1jbFdSd2xwdGxsR1pzbHB5WnlXQmdxRzZhWVozRmNKMXJuZyUzRCUzRA==&view=1)

## Drugs, Biologics, and Devices

### *Drugs*

#### **Key Organizations**

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

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

- Corrections of GCP Terminology in Lithuanian (2006): <https://www.e-tar.lt/portal/lt/legalAct/TAR.1C6613E02B96>
- Decree No. V-6 on the Sample Form of the Request to Issue Favorable Opinion to Conduct Clinical Trial on Medicinal Product Form and the Ethical Assessment Form (2016): <https://www.e-tar.lt/portal/lt/legalAct/b65b5ca0c44011e583a295d9366c7ab3/qcrDrSCSCJ>
- Decree No. 435 on the Procedure for Issuing a Favorable Opinion to Conduct Clinical Trials on Medicinal Product, Approval for Clinical Trials on Medicinal Product, and Conducting and Controlling Clinical Trials (2017): <https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.277308/QPLLKpOUKw>
- Guidelines to Advertise Clinical Trials, Adopted by the Group of Experts on Biomedical Research of the LBEC (2018):  
[http://bioetika.sam.lt/get\\_file.php?file=bXNIVnpKV2hacDJkcXBPZ3ILQnhrY1prbXM1c2tHalJ5SmFlekplZHC2Vnl5c3JXeDJGa3IybWNscUNYb1oyVmxxaHJR1RIYmMzTG8yN0xtbTJaYTJ1VmlwSElvcFdjblp4bGNweDVucFdxb1d6VGJNWNb6OHFqbk1mR29jYWlidFBIEkpb5blldWNvWlNjbktHYWtwZWVhYzVqMW1tMG5IaWN1cHVLeDRLYnQ1VzNuWHVTaG1xS1puaVRaV2xobmladWwyeVBsOVNjbTU3TWwyJTJCWmRKbyUzRA==&view=1](http://bioetika.sam.lt/get_file.php?file=bXNIVnpKV2hacDJkcXBPZ3ILQnhrY1prbXM1c2tHalJ5SmFlekplZHC2Vnl5c3JXeDJGa3IybWNscUNYb1oyVmxxaHJR1RIYmMzTG8yN0xtbTJaYTJ1VmlwSElvcFdjblp4bGNweDVucFdxb1d6VGJNWNb6OHFqbk1mR29jYWlidFBIEkpb5blldWNvWlNjbktHYWtwZWVhYzVqMW1tMG5IaWN1cHVLeDRLYnQ1VzNuWHVTaG1xS1puaVRaV2xobmladWwyeVBsOVNjbTU3TWwyJTJCWmRKbyUzRA==&view=1)

## **Devices**

### **Key Organizations**

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

### **Relevant Standards**

- Decree No. V-2 on the Procedure to Issue Approvals to Conduct Biomedical Research (2017): <https://www.e-tar.lt/portal/lt/legalAct/TAR.47B235393D3A/zpczrvbOOR>
- Law on Ethics of Biomedical Research (2016): <https://www.e-tar.lt/portal/lt/legalAct/TAR.234B15954C2F/dReKXfNqQ>
- Changes of Law on Ethics of Biomedical Research (2017): <https://www.e-tar.lt/portal/lt/legalAct/43db5e50d05f11e7910a89ac20768b0f>
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials on Medicinal Products for Human Use (Effective 31 January 2022): <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0537>

## **Clinical Trial Registries**

### **Key Organizations**

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

### **Relevant Standards**

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



*International Compilation of Human Research Standards  
2021 Edition*

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

### **Research Injury**

#### **Key Organizations**

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

### **Social-Behavioral Research**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Privacy/Data Protection**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Human Biological Materials**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Genetic Research**

#### **Key Organizations**

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

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

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

## EUROPE – Luxembourg

### General

#### Key Organization

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

#### Relevant Standards

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

## **Drugs, Biologics, and Devices**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Clinical Trial Registries**

### **Key Organizations**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation): <https://eur-lex.europa.eu/eli/reg/2016/679/oj>

*International Compilation of Human Research Standards  
2021 Edition*

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – Malta**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

## **Drugs, Biologics, and Devices**

### *Drugs*

#### **Key Organizations**

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

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## **Devices**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – Moldova**

*NOTE: For an overview of human subject protections in Moldova, see “Ethical Review of Biomedical Research in the CIS Countries,” Chapter 3, Section 7:*

[http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical\\_review\\_cis\\_book\\_kubar\\_english.pdf](http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf)

## **General**

### **Key Organization**

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

### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## **Drugs, Biologics, and Devices**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

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

- Law No. 982 Dated 11.05.2000 on Access to Information: <http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=311759>
- Law No.133 Dated 08.07.2011 on the Protection of Personal Data: <http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=340495>
- EU General Data Protection Regulation (2016): <https://eur-lex.europa.eu/eli/reg/2016/679/oj>
- LP143 Din 19.07.18, MO309-320/17.08.18 Article 482
- Decision of Government No. 1123 Dated 14.12.2010 on the Approval of the Requirements for the Assurance of Personal Data Security at their Processing within the Information Systems of Personal Data: [http://old.datepersonale.md/file/hotariri/cerinte\\_securitate%20eng\\_101228.pdf](http://old.datepersonale.md/file/hotariri/cerinte_securitate%20eng_101228.pdf)
- Law on personal data protection (2011); The Law on enunciation of certain declarations to the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data by the Republic of Moldova: <https://datepersonale.md/en/legislation/national-legislation/law/>

### **Human Biological Materials**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Embryos, Stem Cells, and Cloning**

#### **Key Organizations**

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

#### **Relevant Standards**

- REGULATION No. 902 of 09.02.2000 on the manner of issuing licenses for conducting research in the field of genetics and microbiology in the Republic of Moldova: [http://www.vertic.org/media/National%20Legislation/Moldova/MD\\_Regulation\\_902\\_Genetics\\_Microbiology.pdf](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](https://www.cinmed.me/Portal/faces/glavna.jspx?_adf.ctrl-state=ye0txrsh1_4)

## **Relevant Standards**

- Various, Legislations:  
[https://www.cinmed.me/Portal/faces/dinamickeStrane?\\_afLoop=967271693989170&paramPut=Legislation+++%3E++Laws&paramRender=2&paramS=94&\\_adf.ctrl-state=ye0txrsh1\\_122](https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=967271693989170&paramPut=Legislation+++%3E++Laws&paramRender=2&paramS=94&_adf.ctrl-state=ye0txrsh1_122)
- Various, Rulebooks:  
[https://www.cinmed.me/Portal/faces/dinamickeStrane?\\_afLoop=967358763502102&paramPut=Legislation+++%3E++Rulebooks&paramRender=2&paramS=95&\\_adf.ctrl-state=ye0txrsh1\\_161](https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=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?\\_afLoop=967402452526204&paramPut=Legislation+++%3E++Decrees+and+Orders&paramRender=2&paramS=98&\\_adf.ctrl-state=ye0txrsh1\\_195](https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=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?\\_afLoop=967427083926799&paramPut=Legislation+++%3E++Good+Practice+guidelines&paramRender=2&paramS=99&\\_adf.ctrl-state=ye0txrsh1\\_229](https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=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?\\_afLoop=967477611251621&paramPut=Legislation+++%3E++Forms+%E2%80%93+Medicines&paramRender=2&paramS=62&\\_adf.ctrl-state=ye0txrsh1\\_297](https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=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?\\_afLoop=967525698520403&paramPut=Legislation+++%3E++Forms+-+Medical+devices&paramRender=2&paramS=100&\\_adf.ctrl-state=ye0txrsh1\\_331](https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=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?\\_afLoop=967545352596410&paramPut=Legislation+++%3E++Instructions&paramRender=2&paramS=96&\\_adf.ctrl-state=ye0txrsh1\\_365](https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=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](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?\\_afLoop=967271693989170&paramPut=Legislation+++%3E++Laws&paramRender=2&paramS=94&\\_adf.ctrl-state=ye0txrsh1\\_122](https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=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?\\_afLoop=967271693989170&paramPut=Legislation+++%3E++Laws&paramRender=2&paramS=94&\\_adf.ctrl-state=ye0txrsh1\\_122](https://www.cinmed.me/Portal/faces/dinamickeStrane?_afLoop=967271693989170&paramPut=Legislation+++%3E++Laws&paramRender=2&paramS=94&_adf.ctrl-state=ye0txrsh1_122)



## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

- Rulebook on the Collection, Storage, and Use of Stem Cells (2012): <http://www.mzdravlja.gov.me/ResourceManager/FileDownload.aspx?rid=222783&rType=2&file=Pravilnik%20o%20postupku%20prikupljanja,%20%C4%86Duvanja%20i%20upotrebe%20matice%20%C4%86Dnih%20%C4%86elija%2056-2012.pdf>

## **EUROPE – Netherlands**

### **General**

#### **Key Organization**

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

### **Relevant Standards**

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

## **Drugs, Biologics, and Devices**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Clinical Trial Registries**

### **Key Organizations**

- Netherlands Trial Register: <http://www.trialregister.nl/trialreg/index.asp>
- CCMO Register: [https://www.toetsingonline.nl/to/ccmo\\_search.nsf/Searchform?OpenForm](https://www.toetsingonline.nl/to/ccmo_search.nsf/Searchform?OpenForm)

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## **Social-Behavioral Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

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

## EUROPE – North Macedonia, Republic of

## Drugs, Biologics, and Devices

### *Drugs*

#### Key Organizations

- Ministry of Health of Republic of Macedonia: [www.zdravstvo.gov.mk](http://www.zdravstvo.gov.mk)
- Drug and Devices Register: <https://lekovi.zdravstvo.gov.mk/>
- Drug Agency: <http://malmed.gov.mk/>

#### Relevant Standards

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

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

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

### **Devices**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Research Injury**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Social-Behavioral Research**

#### **Key Organizations**

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

## **Privacy/Data Protection**

### **Key Organizations**

- Directorate for Personal Data Protection: [www.dzlp.mk](http://www.dzlp.mk)

### **Relevant Standards**

- Law on Ratification on Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2005)
- Law on Ratification on Additional Protocol to the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (2008)
- Law on Personal Data Protection, Consolidated (2016): [https://www.dzlp.mk/sites/default/files/Law\\_on\\_Personal\\_Data\\_Protection\\_Cleared\\_version\\_0.pdf](https://www.dzlp.mk/sites/default/files/Law_on_Personal_Data_Protection_Cleared_version_0.pdf) ; and amendments (2021): [https://www.dzlp.mk/sites/default/files/u4/lpdp\\_2020.pdf](https://www.dzlp.mk/sites/default/files/u4/lpdp_2020.pdf)
- Regulations on Protection of Personal Data: <https://dzlp.mk/sites/default/files/77121008d1284263a9e519ae9b24f80c.pdf>
- Directorate for Personal Data Protection, Rule book for the Manner of Performing Inspection Supervision: <https://www.dzlp.mk/sites/default/files/u4/RULEBOOK%20FOR%20THE%20MANNER%20OF%20PERFORMING%20INSPECTION%20SUPERVISION.pdf>
- Rulebook on transfer of personal data: <https://dzlp.mk/sites/default/files/052e8e10cf2e4bd48e7827e7bc85fb62.pdf>

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

- Regulation on Criteria Relating to Space, Personnel and Equipment for Collection, Transplantation and Exchange of Organs and Tissues, the Necessary Space, Equipment and Staff Required to be Provided by the Health Institution for the Collection, Transfer, Exchange and Storage of Organs and Tissues from Human Body for Treatment Purposes (2012): [http://zdravstvo.gov.mk/wp-content/uploads/2012/12/za\\_pobliskite\\_kriteriumi\\_vo\\_odnos\\_na\\_prostorot\\_kadarot\\_i\\_opremata\\_za\\_zemawe\\_presaduvawe\\_i\\_razmenvawe\\_na\\_organite\\_i\\_tkivata\\_za\\_potrebniot\\_pr.pdf](http://zdravstvo.gov.mk/wp-content/uploads/2012/12/za_pobliskite_kriteriumi_vo_odnos_na_prostorot_kadarot_i_opremata_za_zemawe_presaduvawe_i_razmenvawe_na_organite_i_tkivata_za_potrebniot_pr.pdf)

## Genetic Research

### Key Organizations

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

### Relevant Standards

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

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

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

## EUROPE – Norway

### General

#### Key Organization

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

#### Relevant Standards

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## Drugs, Biologics, and Devices

### *Drugs*

#### **Key Organizations**

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

#### **Relevant Standards**

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



## **Devices**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Social-Behavioral Research**

### **Key Organizations**

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

### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

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

## EUROPE – Poland

### General

#### Key Organization

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

#### Relevant Standards

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

## Drugs, Biologics, and Devices

### *Drugs*

#### **Key Organizations**

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

#### **Relevant Standards**

- Pharmaceutical Law (2017):  
<http://prawo.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20190000499>
- Decree of the Minister of Health on Clinical Trials on Minors (2004):  
<http://prawo.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20041041108>
- Act on Medical Devices:  
<http://isap.sejm.gov.pl/isap.nsf/download.xsp/WDU20190000175/U/D20190175Lj.pdf>
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (Effective 31 January 2022): <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536>

### *Devices*

#### **Key Organizations**

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

#### **Relevant Standards**

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

## Clinical Trial Registries

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Social-Behavioral Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – Portugal**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

## **Drugs, Biologics, and Devices**

### **Drugs**

#### **Key Organizations**

- National Institute of Pharmacy and Medicines:  
<http://www.infarmed.pt/portal/page/portal/INFARMED/ENGLISH>
- Ethics Commission for Clinical Research (CEIC):  
[http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS\\_USO\\_HUMANO/CEIC](http://www.infarmed.pt/portal/page/portal/INFARMED/MEDICAMENTOS_USO_HUMANO/CEIC)

#### **Relevant Standards**

- Approval of the Applicable Legal Standards for the Conduct of Clinical Trials of Medicines for Human Use, Law No. 46/2004
- Approval of the Composition, Operations, and Financing of the Ethics Commission for Clinical Research, Decree No. 57/2005:  
[http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO\\_FARMAC\\_EUTICA\\_COMPILADA/TITULO\\_III/TITULO\\_III\\_CAPITULO\\_I/portaria\\_57-2005.pdf](http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMAC_EUTICA_COMPILADA/TITULO_III/TITULO_III_CAPITULO_I/portaria_57-2005.pdf)
- Decree-Law No. 102/2007 of April 2

### **Devices**

#### **Key Organizations**

- National Institute of Pharmacy and Medicines:  
[http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS\\_MEDICOS](http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS)

#### **Relevant Standards**

- Various:  
[http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO\\_FARMAC\\_EUTICA\\_COMPILADA/TITULO\\_V/TITULO\\_V\\_CAPITULO\\_II](http://www.infarmed.pt/portal/page/portal/INFARMED/LEGISLACAO/LEGISLACAO_FARMAC_EUTICA_COMPILADA/TITULO_V/TITULO_V_CAPITULO_II)
- Various:  
[http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS\\_MEDICOS/NOTAS\\_INFORMATIVAS](http://www.infarmed.pt/portal/page/portal/INFARMED/DISPOSITIVOS_MEDICOS/NOTAS_INFORMATIVAS)

## **Research Injury**

#### **Relevant Standards**

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

## **Privacy/Data Protection**

#### **Key Organizations**

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

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

### **Genetic Research**

#### **Key Organizations**

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

#### **Relevant Standards**

- Law 12/2005

### **Embryos, Stem Cells, and Cloning**

#### **Key Organizations**

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

#### **Relevant Standards**

- Oviedo Convention on Human Rights and Biomedicine, Additional Protocol on Prohibition of Human Cloning (2001): <https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treaty-num=168>
- Portuguese Law on Assisted Reproductive Technologies, Articles 7 and 9 (2006)
- Opinion 15/CNECV/95 on Embryo Research (1995)
- Opinion 47/CNECV/2005 on Stem Cell Research (2005): <http://www.cnecv.gov.pt/NR/rdonlyres/F13B34FD-F9F7-4C9D-96DC-419999D9B693/0/47CNECV2005.pdf>
- Opinion 48/CNECV/2006 on Human Cloning (2006): [http://www.cnecv.gov.pt/NR/rdonlyres/770EA390-9326-4FF9-B28D-D70A7E9AD961/0/p048\\_en.pdf](http://www.cnecv.gov.pt/NR/rdonlyres/770EA390-9326-4FF9-B28D-D70A7E9AD961/0/p048_en.pdf)

## **EUROPE – Romania**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

### **Drugs, Biologics, and Devices**

#### **Key Organizations**

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



*International Compilation of Human Research Standards  
2021 Edition*

- 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 904/25 July 2006 on Approval of Rules Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use -- Transposition of 2001/20/EC Directive, and various legislation for CTs
- Various legislation for clinical trials: <https://www.anm.ro/medicamente-de-uz-uman/studii-clinice/legislatie-specifica-pentru-studii-clinice/>
- Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use (it will come in application on 31 January 2022): <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0537>

## **Clinical Trial Registries**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Social-Behavioral Research**

### **Key Organizations**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Relevant Standards**

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

## EUROPE – Russia

*NOTE: For an overview of human subject protections in Russia, see [http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical\\_review\\_cis\\_book\\_kubar\\_english.pdf](http://www.unesco.org/new/fileadmin/MULTIMEDIA/FIELD/Moscow/pdf/ethical_review_cis_book_kubar_english.pdf)*

### General

#### Key Organization

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

#### Relevant Standards

- Constitution of the Russian Federation, Article 21 (1993): <http://www.constitution.ru/en/10003000-03.htm>
- Federal Law #FZ 323 “On Foundations of Protection of Citizen’s Health in the Russian Federation” (2011): [http://acto-russia.org/en/index.php?option=com\\_content&task=view&id=105](http://acto-russia.org/en/index.php?option=com_content&task=view&id=105)
- Federal Law #FZ55 “On Introduction of Changes in FZ “On Foundations of Protection of Citizens’ Health in the Russian Federation” with Regard to Questions of Organization of Medical Aid Administered in the Course of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation” (2015): [http://www.consultant.ru/document/cons\\_doc\\_LAW\\_176159](http://www.consultant.ru/document/cons_doc_LAW_176159)
- Ministry of Health Order 433n (July 10, 2015) “On Adoption of the Regulations on Organization of Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment and Rehabilitation (Including Order of Patients’ Assignment for Administering Such Medical Help), Standard Form of Protocol for Clinical Approbation of the Methods of Prevention, Diagnostics, Treatment, and Rehabilitation”: <http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=183847>
- Ministry of Health Order 435h “On Ethics Committee of the Ministry of Health of the Russian Federation” (July 10, 2015): <http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=LAW;n=183677>

### Drugs, Biologics, and Devices

#### Key Organizations

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

#### Relevant Standards

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

*International Compilation of Human Research Standards  
2021 Edition*

- Ministry of Health Order of April 1, 2016 No. 200H "On Approval of the Rules of Good Clinical Practice": [http://acto-russia.org/files/prikaz\\_200n.docx](http://acto-russia.org/files/prikaz_200n.docx)
- GOST, Good Clinical Practice. GOST-R 52379-2005 (September 27, 2005): [http://acto-russia.org/index.php?option=com\\_content&task=view&id=17](http://acto-russia.org/index.php?option=com_content&task=view&id=17)

## **Research Injury**

### **Relevant Standards**

- Federal Law No. 61FZ “On Circulation of Medicines” (2011), Art. 38-44: [http://acto-russia.org/files/zakon\\_ob\\_obr\\_ls\\_en.docx](http://acto-russia.org/files/zakon_ob_obr_ls_en.docx)

## **Privacy/Data Protection**

### **Relevant Standards**

- Federal Law of the Russian Federation on Information, Information Technologies, and Protection of Information (2006): [http://www.consultant.ru/document/cons\\_doc\\_LAW\\_165971/](http://www.consultant.ru/document/cons_doc_LAW_165971/)
- Federal Law of the Russian Federation No. 152-FZ on Personal Data (2006): <http://base.garant.ru/12148567/>

## **Genetic Research**

### **Key Organizations**

- Interdepartmental Commission on Genetic-Engineering Activity

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Relevant Standards**

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

## **EUROPE – San Marino**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

## **Research Injury**

### **Relevant Standards**

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

## **EUROPE – Serbia**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

## **Drugs, Biologics, and Devices**

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **Clinical Trial Registries**

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Social-Behavioral Research**

### **Key Organizations**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

- Law on the Prevention and Diagnosis of Genetically Conditioned Diseases, Genetically Caused Anomalies and Rare Diseases, Official Gazette 8/2015:  
[https://www.paragraf.rs/propisi/zakon\\_o\\_preveniriji\\_i\\_dijagnostici\\_genetickih\\_bolesti\\_geneticki\\_uslavljenih\\_anomalija\\_i\\_retkih\\_bolesti.html](https://www.paragraf.rs/propisi/zakon_o_preveniriji_i_dijagnostici_genetickih_bolesti_geneticki_uslavljenih_anomalija_i_retkih_bolesti.html)

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

### **Relevant Standards**

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

## **EUROPE – Slovakia**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

### **Drugs, Biologics, and Devices**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Research Injury**

#### **Relevant Standards**

- Law 277/1994 on Health Care, Section 44

### **Privacy/Data Protection**

#### **Key Organizations**

- Office for Personal Data Protection: <https://dataprotection.gov.sk/uouu/en>

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

- Act no. 18/2018 On Personal Data Protection and Amending and Supplementing Certain Acts (2018):  
[https://dataprotection.gov.sk/uouu/sites/default/files/2019\\_10\\_03\\_act\\_18\\_2018\\_on\\_personal\\_data\\_protection\\_and\\_amending\\_and\\_supplementing\\_certain\\_acts.pdf#overlay-context=sk/content/182018#overlay-context=sk/content/182018%22](https://dataprotection.gov.sk/uouu/sites/default/files/2019_10_03_act_18_2018_on_personal_data_protection_and_amending_and_supplementing_certain_acts.pdf#overlay-context=sk/content/182018#overlay-context=sk/content/182018%22)

## **Human Biological Materials**

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Relevant Standards**

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

## **EUROPE – Slovenia**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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



*International Compilation of Human Research Standards  
2021 Edition*

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

## **Drugs, Biologics, and Devices**

### ***Drugs***

#### **Key Organizations**

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

#### **Relevant Standards**

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

### ***Devices***

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **Clinical Trial Registries**

#### **Key Organizations**

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

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Social-Behavioral Research**

### **Key Organizations**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

## Relevant Standards

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

## EUROPE – Spain

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

### General

#### Key Organization

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

#### Relevant Standards

- Oviedo Convention on Human Rights and Biomedicine (1999): [http://www.coe.int/t/dg3/healthbioethic/texts\\_and\\_documents/ETS164Spanish.pdf](http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/ETS164Spanish.pdf)
- Law 14/2007 on Biomedical Research: <http://www.catedraderchoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf>

### Drugs, Biologics, and Devices

#### Drugs

##### Key Organizations

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

##### Relevant Standards

- Order SCO/362/2008 that Modifies Order SCO/256/2007: [http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rc1\\_2008\\_410.pdf](http://www.aemps.gob.es/legislacion/espana/investigacionClinica/docs/rc1_2008_410.pdf)
- Order SAS/3470/2009 on Drugs Post Authorization Research: [http://www.aemps.gob.es/legislacion/espana/medicamentosUsoHumano/docs/farmacovigilancia/rc1\\_2009\\_2577.pdf](http://www.aemps.gob.es/legislacion/espana/medicamentosUsoHumano/docs/farmacovigilancia/rc1_2009_2577.pdf)
- Royal Decree 1015/2009: Drug Availability for Special Purposes: <http://www.boe.es/boe/dias/2009/07/20/pdfs/BOE-A-2009-12002.pdf>

*International Compilation of Human Research Standards  
2021 Edition*

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

## **Devices**

### **Key Organizations**

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

### **Relevant Standards**

- Royal Decree 1591/2009, Regulating Sanitary Devices: [http://www.ont.es/infesp/Legislacin/RD\\_1591\\_2009.pdf](http://www.ont.es/infesp/Legislacin/RD_1591_2009.pdf)
- Various: <https://www.aemps.gob.es/productos-sanitarios/prodsanitarios/>

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

[https://www.boe.es/biblioteca\\_juridica/codigos/codigo.php?id=055\\_Proteccion\\_de\\_Datos\\_de\\_Caracter\\_Personal&modo=1](https://www.boe.es/biblioteca_juridica/codigos/codigo.php?id=055_Proteccion_de_Datos_de_Caracter_Personal&modo=1)

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

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- Law 14/2007 of July 3 on Biomedical Research, Title I, Article 11; Title III, Article 37; Title V: <http://www.catedraderechoygenomahumano.es/images/novedades/SpanishLawonBiomedicalResearchEnglish.pdf>
- Royal Decree 65/2006 of Requirements for the Import and Export of Biological Samples: <http://www.boe.es/boe/dias/2006/02/07/pdfs/A04626-04636.pdf>
- Royal Decree 1723/2012 Regarding Activities of Collection, Clinical Use and Territorial Coordination of Human Organs for Transplants and Establishing Their Quality and Safety Requirements: [http://noticias.juridicas.com/base\\_datos/Admin/rd1716-2011.html](http://noticias.juridicas.com/base_datos/Admin/rd1716-2011.html)
- Royal Decree 1716/2011 on Biobanks: [http://www.comitedebioetica.es/normativa/docs/RD%201716\\_2011\\_de%20autorizacion%20y%20funcionamiento%20de%20los%20biobancos.pdf](http://www.comitedebioetica.es/normativa/docs/RD%201716_2011_de%20autorizacion%20y%20funcionamiento%20de%20los%20biobancos.pdf)
- Royal Decree 9/2014 on Quality and Security Rules Regarding Donating, Gathering, Evaluation, Processing, Storage, Preservation, and Distribution of Human Cells and Tissues and Rules Regarding Coordination and Functioning of their Use in Human Beings: <http://www.boe.es/buscar/doc.php?id=BOE-A-2014-7065>

## Genetic Research

### Key Organizations

- Spanish Bioethics Committee: [http://www.comitedebioetica.es/?lang=en\\_US](http://www.comitedebioetica.es/?lang=en_US)

### Relevant Standards

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

## Embryos, Stem Cells, and Cloning

### Key Organizations

- Spanish Bioethics Committee: [http://www.comitedebioetica.es/?lang=en\\_US](http://www.comitedebioetica.es/?lang=en_US)

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

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

### **Relevant Standards**

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

## **EUROPE – Sweden**

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

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

## **Drugs, Biologics, and Devices**

### **Drugs**

#### **Key Organizations**

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

#### **Relevant Standards**

- Pharmaceuticals Act No. No. 2015:315: <https://open.karnovgroup.se/halso-och-sjukvard/lakemedelslagen>
- MPA Regulations on Clinical Trials in Humans -- LVFS 2011:19: [http://www.lakemedelsverket.se/upload/lvfs/LVFS\\_2011\\_19.pdf](http://www.lakemedelsverket.se/upload/lvfs/LVFS_2011_19.pdf)

### **Devices**

#### **Key Organizations**

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

#### **Relevant Standards**

- Swedish Medical Devices Act (SFS 1993:584): <http://www.notisum.se/rnp/sls/lag/19930584.htm>
- Medical Devices Ordinance (SFS1993:876): [http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-1993876-om-medicintekniska\\_sfs-1993-876](http://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-1993876-om-medicintekniska_sfs-1993-876)
- Swedish Implementation of Directive 93/42/EEC -- LVFS 2003:11: [https://lakemedelsverket.se/upload/lvfs/LVFS\\_2003-11.pdf](https://lakemedelsverket.se/upload/lvfs/LVFS_2003-11.pdf)
- HSLF-FS 2021:52 The National Board of Health and Welfare's regulations on the use of medical devices in health care: <https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/foreskrifter-och-allmanna-rad/2021-6-7503.pdf>

## **Social-Behavioral Research**

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **Privacy/Data Protection**

#### **Key Organizations**

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

#### **Relevant Standards**

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



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

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

### **Human Biological Materials**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Genetic Research**

#### **Key Organizations**

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

#### **Relevant Standards**

- Act on Genetic Integrity (2006:351): <http://www.notisum.se/rnp/sls/lag/20060351.htm>
- Drug Administration Regulations and Guidelines (LVFS 2004:10) on the Intentional Release of Clinical Trials of Medicinal Products Containing or Consisting of Genetically Modified Organisms: [http://www.lakemedelsverket.se/upload/lvfs/LVFS\\_2004-10.pdf](http://www.lakemedelsverket.se/upload/lvfs/LVFS_2004-10.pdf)

*International Compilation of Human Research Standards  
2021 Edition*

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – Switzerland**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## Drugs, Biologics, and Devices

### *Drugs*

#### **Key Organizations**

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

#### **Relevant Standards**

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

### *Devices*

#### **Key Organizations**

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

#### **Relevant Standards**

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

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

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

### **Clinical Trial Registries**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Research Injury**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Privacy/Data Protection**

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

## **Key Organizations**

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

## **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## Embryos, Stem Cells, and Cloning

### Key Organizations

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

### Relevant Standards

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

## EUROPE – Ukraine

### General

#### Key Organization

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

### **Relevant Standards**

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

## **Drugs, Biologics, and Devices**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Privacy/Data Protection**

### **Key Organizations**

- State Service of Ukraine on Personal Data Protection
- Ukrainian Parliament Commissioner for Human Rights: [www.ombudsman.gov.ua](http://www.ombudsman.gov.ua)

*International Compilation of Human Research Standards  
2021 Edition*

### **Relevant Standards**

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

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

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

### **Relevant Standards**

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

## **EUROPE – United Kingdom**

*NOTE: For an overview of clinical research regulations in the United Kingdom, see the ClinRegs report: [http://clinregs.niaid.nih.gov/single\\_country.php?c\\_id=226](http://clinregs.niaid.nih.gov/single_country.php?c_id=226)*

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



## General

### *England*

#### **Key Organization**

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

#### **Relevant Standards**

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

### *Scotland*

#### **Key Organizations**

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

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

## ***Wales***

### **Key Organizations**

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

### **Relevant Standards**

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

## ***Northern Ireland***

### **Key Organizations**

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

### **Relevant Standards**

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

## **Drugs, Biologics, and Devices**

## ***Drugs***

### **Key Organizations**

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

### **Relevant Standards**

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

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

- Amendment Regulations (SI 2006/1928): <http://www.legislation.gov.uk/uksi/2006/1928/contents/made>
- Amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 and Adults with Incapacity (Scotland) Act 2000 to Facilitate Clinical Research in Emergency Settings (SI 2006/2984): [http://www.legislation.gov.uk/uksi/2006/2984/pdfs/uksi\\_20062984\\_en.pdf](http://www.legislation.gov.uk/uksi/2006/2984/pdfs/uksi_20062984_en.pdf)
- SI 2008 No.941 The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment Regulations 2008: <http://www.legislation.gov.uk/uksi/2008/941/contents/made>
- Genetically Modified Organisms (Deliberate Release) Regulations 2002: <http://www.legislation.gov.uk/uksi/2002/2443/contents/made>
- Genetically Modified Organisms (Contained Use) Regulations 2014 (England, Scotland and Wales): <http://www.legislation.gov.uk/uksi/2014/1663/part/1/made>
- Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015: <http://www.legislation.gov.uk/nisr/2015/339/contents/made>
- ABPI, Guidelines for Phase I Clinical Trials (2018): <https://www.abpi.org.uk/publications/guidelines-for-phase-i-clinical-trials-2018-edition/>
- National Institute for Health Research, Clinical Trials Toolkit: <http://www.ct-toolkit.ac.uk/>
- HRA, Clinical Trials of Investigational Medicinal Products (CTIMPs) – Resource page: <http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/clinical-trials-of-investigational-medicinal-products/>

### **Devices**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Clinical Trial Registries**

#### **Key Organizations**

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

### **Relevant Standards**

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

## **Research Injury**

### **Key Organizations**

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

### **Relevant Standards**

- MHRA, Medicines for Human Use (Clinical Trials) Regulations, Statutory Instrument No. 1031, Regulation 15(5)(i)(j)(k) and Schedule 3 Part 1, Paragraphs 1(g) and 3(c) (2004): <http://www.legislation.gov.uk/ukxi/2004/1031/contents/made>
- DH, NHS Indemnity Arrangements for Clinical Negligence Claims in the NHS: <https://resolution.nhs.uk/wp-content/uploads/2018/10/NHS-Indemnity.pdf>
- ABPI, Insurance and Compensation in the Event of Injury in Phase I Clinical Trials (2012): <https://www.abpi.org.uk/media/1647/phase-i-clinical-trials-insurance-guidance.pdf>
- ABPI, Clinical Trial Compensation Guidelines (2014): [https://www.abpi.org.uk/media/1607/compensation\\_guidelines\\_2014.pdf](https://www.abpi.org.uk/media/1607/compensation_guidelines_2014.pdf)
- ABHI, Clinical Investigations Compensation Guidelines (2014): [http://www.abhi.org.uk/multimedia/groups/clinical-investigations/ci\\_compensationguidelines.doc](http://www.abhi.org.uk/multimedia/groups/clinical-investigations/ci_compensationguidelines.doc)

## **Social-Behavioral Research**

### **Key Organizations**

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

### **Relevant Standards**

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

## **Privacy/Data Protection**

### ***United Kingdom***

#### **Key Organization**

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

*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**

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

### **England and Wales**

#### **Key Organizations**

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

#### **Relevant Standards**

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

## **Human Biological Materials**

### **United Kingdom**

#### **Key Organization**

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

#### **Relevant Standards**

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

*International Compilation of Human Research Standards  
2021 Edition*

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

### **Scotland**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Genetic Research**

#### **Key Organizations**

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

### **Embryos, Stem Cells, and Cloning**

#### **Key Organizations**

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

#### **Relevant Standards**

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

International Compilation of Human  
Research Standards  
2021 Edition

Latin America and the Caribbean



## 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/>

- PAHO, Working Group on Good Clinical Practices, various documents: [https://www3.paho.org/hq/index.php?option=com\\_content&view=article&id=1588:2009-grupo-trabajo-buenas-practicas-clinicas&Itemid=41776&limitstart=1&lang=en](https://www3.paho.org/hq/index.php?option=com_content&view=article&id=1588:2009-grupo-trabajo-buenas-practicas-clinicas&Itemid=41776&limitstart=1&lang=en)
- PAHO, A Model Regulatory Program for Medical Devices: An International Guide (2001): <https://iris.paho.org/handle/10665.2/51975>

## 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

- Civil and Commercial Code, Articles 26, 58, and 59 (2015): <http://servicios.infoleg.gob.ar/infolegInternet/anexos/235000-239999/235975/norma.htm>
- Ministerial Resolution 1480/2011 Approving the Guidelines for Human Health Research and Creating the National Registry of Health Research: <http://servicios.infoleg.gob.ar/infolegInternet/anexos/185000-189999/187206/norma.htm>
- Resolution 1480/2011: Approving the Guidelines for Human Health Research and Creating the National Registry of Health Research: <http://servicios.infoleg.gob.ar/infolegInternet/anexos/185000-189999/187206/norma.htm>

### Drugs, Biologics, and Devices

#### Drugs

#### Key Organizations

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

#### Relevant Standards

- Provision ANMAT 6677/10: Regulatory Guideline for Good Clinical Practices in Clinical
- Pharmacological Studies (2010): [http://www.anmat.gov.ar/Comunicados/Dispo\\_6677-10\\_en.pdf](http://www.anmat.gov.ar/Comunicados/Dispo_6677-10_en.pdf)



*International Compilation of Human Research Standards  
2021 Edition*

- Provision ANMAT 12.792/2016: Request for Import of Medication /Treatment and Materials – Procedure (2016): [http://www.anmat.gov.ar/boletin\\_anmat/Noviembre\\_2016/Dispo\\_12792-16.pdf](http://www.anmat.gov.ar/boletin_anmat/Noviembre_2016/Dispo_12792-16.pdf)
- Provision ANMAT 828/2017: Authorization of Expanded Access Programs: [http://www.anmat.gov.ar/boletin\\_anmat/enero\\_2017/Dispo\\_0828-17.pdf](http://www.anmat.gov.ar/boletin_anmat/enero_2017/Dispo_0828-17.pdf)
- Provision ANMAT 4008/2017: Substitution of Article 2° of Provision ANMAT NO. 6677/10: [http://www.anmat.gov.ar/boletin\\_anmat/Abril\\_2017/Dispo\\_4008-17.pdf](http://www.anmat.gov.ar/boletin_anmat/Abril_2017/Dispo_4008-17.pdf)
- Provision ANMAT 4009/2017: Health Care Institutions: Requirements and Conditions of Authorization for Conducting Phase I and/or Bioequivalence Clinical Pharmacology Studies: [http://www.anmat.gov.ar/boletin\\_anmat/Abril\\_2017/Dispo\\_4009-17.pdf](http://www.anmat.gov.ar/boletin_anmat/Abril_2017/Dispo_4009-17.pdf)
- Provision 10017-E/2017 ANMAT: Promoting Cooperation Between ANMAT and Jurisdictional Health Authorities for the Evaluation and Oversight of Clinical Research Sites and Investigators: <http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?id=279820>

## **Devices**

### **Key Organizations**

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

### **Relevant Standards**

- Provision ANMAT No. 969/97 on the Regulation of Good Clinical Practice with Medical Devices (1997): [http://www.anmat.gov.ar/webanmat/Legislacion/Medicamentos/Disp\\_969-97\\_actualizada.pdf](http://www.anmat.gov.ar/webanmat/Legislacion/Medicamentos/Disp_969-97_actualizada.pdf)

## **Clinical Trial Registries**

### **Key Organizations**

- National Registry of Health Research: <https://www.argentina.gob.ar/salud/registroinvestigaciones>

### **Relevant Standards**

- Resolution 1480/2011 Approving a Guide for Human Subjects Research: <http://servicios.infoleg.gob.ar/infolegInternet/anexos/185000-189999/187206/norma.htm>
- 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**

- Personal Data Protection Act No. 25.326 (2000): <http://www.protecciondedatos.com.ar/law25326.htm>
- Decree 1558/2001. Regulation of the Personal Data Protection Act: <http://servicios.infoleg.gob.ar/infolegInternet/anexos/70000-74999/70368/norma.htm>

## **Human Biological Materials**

### **Key Organizations**

- Ministry of Health: <https://www.argentina.gob.ar/salud>

### **Relevant Standards**

- Resolution 1789/2006: Authorization for Import and Export of Biological Material for Diagnosis, Research and Surveillance Purposes: <http://servicios.infoleg.gob.ar/infolegInternet/anexos/120000-124999/122199/norma.htm>
- Resolution 1480/2011: Approving the Guidelines for Human Health Research and Creating the National Registry of Health Research, Section A3: <http://servicios.infoleg.gob.ar/infolegInternet/anexos/185000-189999/187206/norma.htm>

## **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**

- Research Ethics Policy and Guidelines: [https://www.cavehill.uwi.edu/researchethics/docs/uwi\\_policy\\_research\\_ethics\\_oct.aspx](https://www.cavehill.uwi.edu/researchethics/docs/uwi_policy_research_ethics_oct.aspx)

## **LATIN AMERICA AND THE CARIBBEAN – Bermuda**

### **General**

#### **Key Organization**

- Department of Health: <https://www.gov.bm/department/health>

#### **Relevant Standards**

- Research Governance Framework (2008): <https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.592.8671&rep=rep1&type=pdf>

## **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
- New Political Constitution of the State, Article 44 (2009): [https://www.constituteproject.org/constitution/Bolivia\\_2009.pdf](https://www.constituteproject.org/constitution/Bolivia_2009.pdf)
- Regulations on Public Health Research, Chapter V (1978)

*International Compilation of Human Research Standards  
2021 Edition*

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

## Drugs, Biologics, and Devices

### Key Organization

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

### Relevant Standards

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

## LATIN AMERICA AND THE CARIBBEAN – Brazil

*NOTE: For an overview of clinical research regulations in Brazil, see the ClinRegs report:  
[http://clinregs.niaid.nih.gov/single\\_country.php?c\\_id=30](http://clinregs.niaid.nih.gov/single_country.php?c_id=30)*

## General

### Key Organization

- National Health Council (CNS): <http://www.conselho.saude.gov.br/>
- National Commission on Research Ethics (CONEP): <http://conselho.saude.gov.br/comissoes-cns/conep>

### Relevant Standards

- Resolution CNS No. 240/97 - Defining "Participating User" According to IRB: [https://bvsmis.saude.gov.br/bvs/saudelegis/cns/1997/res0240\\_05\\_06\\_1997.html](https://bvsmis.saude.gov.br/bvs/saudelegis/cns/1997/res0240_05_06_1997.html)
- Resolution CNS No. 292/99 on Research with Foreign Cooperation: [https://bvsmis.saude.gov.br/bvs/saudelegis/cns/1999/res0292\\_08\\_07\\_1999.html](https://bvsmis.saude.gov.br/bvs/saudelegis/cns/1999/res0292_08_07_1999.html)
- Resolution CNS No. 304/2000: Rules on Research Involving Human Beings – Area of Indigenous Peoples: [http://conselho.saude.gov.br/resolucoes/2000/Res304\\_en.pdf](http://conselho.saude.gov.br/resolucoes/2000/Res304_en.pdf)
- Internal CONEP Regulation (2001): <http://conselho.saude.gov.br/comissao/conep/regimento.doc>
- Resolution CNS No. 346/2005 on Multicenter Research: [http://conselho.saude.gov.br/resolucoes/2005/Res346\\_en.pdf](http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf)
- 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. 446/2011 on Composition of the National Commission on Research Ethics: [http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Resolucao\\_n\\_446\\_-\\_2011\\_-\\_Sobre\\_composicao\\_da\\_CONEP.pdf](http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Resolucao_n_446_-_2011_-_Sobre_composicao_da_CONEP.pdf)

*International Compilation of Human Research Standards  
2021 Edition*

- Resolution CNS No. 466/2012 on Guidelines and Rules for Research Involving humans Subjects: [http://conselho.saude.gov.br/resolucoes/2012/466\\_english.pdf](http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf)
- Resolution CNS No. 506/2016 Accreditation of CEP: [http://conselho.saude.gov.br/resolucoes/2016/Reso\\_506.pdf](http://conselho.saude.gov.br/resolucoes/2016/Reso_506.pdf)
- Resolution CNS No. 563/2017 on Research Participant's Right in Ultra-rare Diseases: [http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Resolucao\\_n\\_563\\_-\\_2017\\_-\\_Regulamenta\\_direito\\_participante\\_de\\_pesquisa\\_com\\_doencas\\_ultrarraras.pdf](http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Resolucao_n_563_-_2017_-_Regulamenta_direito_participante_de_pesquisa_com_doencas_ultrarraras.pdf)
- Resolution CNS No. 580/2018 on Research of Strategic Interest for the Unified Health System (SUS): <http://conselho.saude.gov.br/resolucoes/2018/Reso580.pdf>
- Operating Normative 001/2013 Organization and Operation of CEP/CONEP System: [http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Norma\\_Operacional\\_n\\_001-2013\\_Procedimento\\_Submisso\\_de\\_Projeto.pdf](http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Norma_Operacional_n_001-2013_Procedimento_Submisso_de_Projeto.pdf)
- Various: <http://plataformabrasil.saude.gov.br/login.jsf>

## Drugs, Biologics, and Devices

### *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>
- Federal Council of Medicine (CFM): <http://portal.cfm.org.br/>
- National Commission on Research Ethics (CONEP): <http://conselho.saude.gov.br/comissoes-cns/conep>

#### **Relevant Standards**

- Law No. 9782/99 Defining the National Health Surveillance System: [http://www.planalto.gov.br/ccivil\\_03/leis/L9782.htm](http://www.planalto.gov.br/ccivil_03/leis/L9782.htm)
- Resolution CNS No. 251/1997: On Complimentary Rules for Research with New Pharmaceutical Products, Medicines, Vaccines, and Diagnostic Tests: [http://conselho.saude.gov.br/resolucoes/1997/Res251\\_en.pdf](http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf)
- Resolution CNS No. 301, 16th March 2002: Regarding Placebos: [http://conselho.saude.gov.br/resolucoes/2000/Res301\\_en.pdf](http://conselho.saude.gov.br/resolucoes/2000/Res301_en.pdf)
- Resolution CFM No. 1.885, 2008 – about placebo: [http://www.portalmedico.org.br/resolucoes/cfm/2008/1885\\_2008.htm](http://www.portalmedico.org.br/resolucoes/cfm/2008/1885_2008.htm)
- Resolution ANVISA 09/15 - Regulations for Clinical Trials with Drugs: <https://clinregs.niaid.nih.gov/documents/brazil/ResolutionNo9-English.pdf>
- Resolution RDC No. 9, 20 February 2015 Regarding Regulation for Realization of Clinical Trials of Medication in Brazil: <https://clinregs.niaid.nih.gov/documents/brazil/ResolutionNo9-English.pdf>
- 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/e932e631-4054-4014-9ac9-9813474e44a4](http://antigo.anvisa.gov.br/documents/10181/6278627/RDC_506_2021_.pdf/e932e631-4054-4014-9ac9-9813474e44a4)

*International Compilation of Human Research Standards  
2021 Edition*

- Manual for Submission of “Drug Clinical Development Dossier” (DDCM) (2017): <http://portal.anvisa.gov.br/documents/33836/2492465/Manual+para+Submiss%C3%A3o+de+Dossi%C3%AA+de+Desenvolvimento+Cl%C3%ADnico+de+Medicamento+%28DDCM%29+e+Dossi%C3%AA+Espec%C3%ADfico+de+Ensaio+Cl%C3%ADnico+-+3%C2%AA+edi%C3%A7%C3%A3o/29e9c5b1-2942-4bb9-a4dd-4fcc6fccda3>
- Manual for Submission of Modifications, Amendments, Suspensions and Cancellations, 5th edition (2021): <https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/medicamentos/pesquisa-clinica/manuais-e-guias/manual-para-submissao-de-modificacoes-emendas-suspensoes-e-cancelamentos-4a-edicao.pdf>
- Manual Relating to Quality Requirements for Products under Investigation Used in Clinical Trials – Biological Products (2019): <https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/medicamentos/pesquisa-clinica/manuais-e-guias/manual-de-submissao-dos-requisitos-de-qualidade-referente-aos-produtos-sob-investigacao-utilizados-em-ensaios-clinicos-2013-produtos-biologicos-3a-edicao.pdf/view>

## **Devices**

### **Key Organizations**

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

### **Relevant Standards**

- Regulations: Resolution of the Collegiate Board - RDC No. 548 of 08/30/2021 - Regulations for Clinical Trials with Medical Devices. Revokes RDC No. 10 of February 20, 2015: [http://antigo.anvisa.gov.br/documents/10181/6319629/RDC\\_548\\_2021\\_.pdf/d78b3f19-3f88-4216-b857-c9984d7c301c](http://antigo.anvisa.gov.br/documents/10181/6319629/RDC_548_2021_.pdf/d78b3f19-3f88-4216-b857-c9984d7c301c)
- Manual for Submission of Modifications, Amendments, Suspensions, and Cancellations on DDCD (2015): <http://portal.anvisa.gov.br/documents/33912/2785629/Manual+Para+Submiss%C3%A3o+de+Modific%C3%A7%C3%B5es%2C+Emendas%2C+Suspens%C3%B5es+e+Cancelamentos/431fa7ef-24e6-4b14-80b9-ce68bccc24d8>

## **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/>
- National Commission on Research Ethics (CONEP): <http://conselho.saude.gov.br/comissoes-cns/conep>

## **Relevant Standards**

- Law No. 6360/76: [http://www.planalto.gov.br/ccivil\\_03/leis/16360.htm](http://www.planalto.gov.br/ccivil_03/leis/16360.htm)
- Standards Survey of New Drugs, Medicines, Vaccines, and Diagnostic Tests Involving Human Beings - Resolution CNS No. 251/97: [http://conselho.saude.gov.br/resolucoes/1997/Res251\\_en.pdf](http://conselho.saude.gov.br/resolucoes/1997/Res251_en.pdf)
- Resolution CNS No. 346/2005 on Multicenter Research: [http://conselho.saude.gov.br/resolucoes/2005/Res346\\_en.pdf](http://conselho.saude.gov.br/resolucoes/2005/Res346_en.pdf)
- Resolution MS/CNS No. 466/2012 - Guidelines and Rules for Research Involving Human Subjects: [http://conselho.saude.gov.br/resolucoes/2012/466\\_english.pdf](http://conselho.saude.gov.br/resolucoes/2012/466_english.pdf)
- Orientation of Adverse Event Reporting in Clinical Trials (008/2011): [http://conselho.saude.gov.br/images/comissoes/conep/documentos/CARTAS/Carta\\_Circular\\_008.pdf](http://conselho.saude.gov.br/images/comissoes/conep/documentos/CARTAS/Carta_Circular_008.pdf)
- Manual of Adverse Event Notification and Safety Monitoring in Clinical Trials Involving Drugs (2016): <https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/medicamentos/pesquisa-clinica/manuais-e-guias/manual-para-notificacao-de-eventos-adversos-e-monitoramento-de-seguranca-em-ensaios-clinicos-1a-edicao.pdf/view>
- 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\\_I8FYG1AB05F\\_db/view](https://drive.google.com/file/d/12zhLX2RB3o7gkCzjD_I8FYG1AB05F_db/view)

## **Social-Behavioral Research**

### **Key Organizations**

- National Commission on Research Ethics (CONEP): <http://conselho.saude.gov.br/comissoes-cns/conep>

### **Relevant Standards**

- Resolution No. 510 of April 7, 2016: <http://conselho.saude.gov.br/resolucoes/2016/Reso510.pdf>

## **Privacy/Data Protection**

### **Key Organizations**

- National Health Council (CNS): <http://www.conselho.saude.gov.br/>
- National Commission on Research Ethics (CONEP): <http://conselho.saude.gov.br/comissoes-cns/conep>
- Federal Council of Medicine (CFM): <http://portal.cfm.org.br>

### **Relevant Standards**

- Law No. 13.709, of August 14, 2018 - General Data Protection Law: [http://www.planalto.gov.br/ccivil\\_03/\\_Ato2015-2018/2018/Lei/L13709.htm](http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2018/Lei/L13709.htm)
- 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](http://www.planalto.gov.br/ccivil_03/_Ato2019-2022/2019/Lei/L13853.htm#art1)
- Circular Letter No. 039/2011 - Use of Medical Record Data for Research Purposes: <http://conselho.saude.gov.br/images/comissoes/conep/documentos/CARTAS/CartaCircular039.pdf>
- Resolution CFM No. 1.821, 23 November 2007: [http://www.portalmedico.org.br/resolucoes/cfm/2007/1821\\_2007.htm](http://www.portalmedico.org.br/resolucoes/cfm/2007/1821_2007.htm)

## **Human Biological Materials**

### **Key Organizations**

- National Health Council (CNS): <http://www.conselho.saude.gov.br/>
- National Commission on Research Ethics (CONEP): <http://conselho.saude.gov.br/comissoes-cns/conep>
- Ministry of Health (MS) – National Institute of Cancer (INCA): <https://www.inca.gov.br/en>
- Brazilian Health Surveillance Agency: <http://portal.anvisa.gov.br/english>

### **Relevant Standards**

- Ordinance No. 2.201/11: Establishing the National Guidelines for Biobanks of Human Biological Material for Research Purposes (2011): <https://www.inca.gov.br/sites/ufu.sti.inca.local/files//media/document//portaria-ms-gm-2201-11.pdf>
- Resolution CNS No. 441 of 12 May 2011: Storage of Human Biological Material or Use of Material Stored in Previous Research: [http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Resolucao\\_441\\_2011\\_Armazenamento\\_de\\_Material\\_Biologico.pdf](http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Resolucao_441_2011_Armazenamento_de_Material_Biologico.pdf)
- Decree CNS No. 2201 of 14 Sep 2001 - The National Bio-Repository and Biobank Guideline: [http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Portaria\\_MS\\_n%C2%BA\\_2.201\\_de\\_2011.pdf](http://conselho.saude.gov.br/images/comissoes/conep/documentos/NORMAS-RESOLUCOES/Portaria_MS_n%C2%BA_2.201_de_2011.pdf)
- Circular Letter No. 014/2014 - Regularization of biobanks: <http://conselho.saude.gov.br/images/comissoes/conep/documentos/CARTAS/CartaCircular014.pdf>
- 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>
- Regulations RDC No. 506 of 05/26/2021 - provides rules for conducting clinical trials with advanced investigational therapy products in Brazil, and other measures. Revokes 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/e932e631-4054-4014-9ac9-9813474e44a4](http://antigo.anvisa.gov.br/documents/10181/6278627/RDC_506_2021_.pdf/e932e631-4054-4014-9ac9-9813474e44a4)

## **Genetic Research**

### **Key Organizations**

- National Commission on Research Ethics (CONEP): <http://conselho.saude.gov.br/comissoes-cns/conep>
- National Biosafety Technical Commission (CTNBio): <http://ctnbio.metic.gov.br/inicio>
- National Health Council (CNS): <http://www.conselho.saude.gov.br/>

### **Relevant Standards**

- Biosafety [Law 11.105/05](http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/lei/111105.htm) (2005): [http://www.planalto.gov.br/ccivil\\_03/\\_ato2004-2006/2005/lei/111105.htm](http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/lei/111105.htm)
- Decree No. 5,591, of November 22, 2005: [http://www.planalto.gov.br/ccivil\\_03/\\_ato2004-2006/2005/Decreto/D5591.htm](http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/Decreto/D5591.htm)

*International Compilation of Human Research Standards  
2021 Edition*

- Law 13.123/2015 (2015), Brazilian Legislation on Biodiversity Access (Genetic Heritage): [http://www.planalto.gov.br/ccivil\\_03/\\_Ato2015-2018/2015/Lei/L13123.htm](http://www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Lei/L13123.htm)
- Law Decree No. 8.772/2016 (2016), Regulating Law No. 13.123/2015: [http://www.planalto.gov.br/ccivil\\_03/\\_ato2015-2018/2016/decreto/D8772.htm](http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2016/decreto/D8772.htm)
- Instruction CTNBio No. 8 of 9 July 1997: [http://ctnbio.mctic.gov.br/publicacao-d.o.u?p\\_auth=XziTzIW3&p\\_p\\_id=visualizarpublicacaodou\\_WAR\\_manterdouportlet&p\\_p\\_lifecycle=1&p\\_p\\_state=normal&p\\_p\\_mode=view&p\\_p\\_col\\_id=column-2&p\\_p\\_col\\_count=1&visualizarpublicacaodou\\_WAR\\_manterdouportlet\\_publicacaoId=173&visualizarpublicacaodou\\_WAR\\_manterdouportlet\\_javax.portlet.action=visualizarPublicacao](http://ctnbio.mctic.gov.br/publicacao-d.o.u?p_auth=XziTzIW3&p_p_id=visualizarpublicacaodou_WAR_manterdouportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=1&visualizarpublicacaodou_WAR_manterdouportlet_publicacaoId=173&visualizarpublicacaodou_WAR_manterdouportlet_javax.portlet.action=visualizarPublicacao)
- Instruction CTNBio No. 9 of 10 October 1997: [http://ctnbio.mctic.gov.br/publicacao-d.o.u?p\\_auth=XziTzIW3&p\\_p\\_id=visualizarpublicacaodou\\_WAR\\_manterdouportlet&p\\_p\\_lifecycle=1&p\\_p\\_state=normal&p\\_p\\_mode=view&p\\_p\\_col\\_id=column-2&p\\_p\\_col\\_count=1&visualizarpublicacaodou\\_WAR\\_manterdouportlet\\_publicacaoId=174&visualizarpublicacaodou\\_WAR\\_manterdouportlet\\_javax.portlet.action=visualizarPublicacao](http://ctnbio.mctic.gov.br/publicacao-d.o.u?p_auth=XziTzIW3&p_p_id=visualizarpublicacaodou_WAR_manterdouportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-2&p_p_col_count=1&visualizarpublicacaodou_WAR_manterdouportlet_publicacaoId=174&visualizarpublicacaodou_WAR_manterdouportlet_javax.portlet.action=visualizarPublicacao)
- Resolution CNS No. 340/2004: On Research on Human Genetics (2004): [http://conselho.saude.gov.br/resolucoes/2004/Res340\\_en.pdf](http://conselho.saude.gov.br/resolucoes/2004/Res340_en.pdf)
- Guidance to Researchers and Ethics Committees about the Item V.1.a of CNS Resolution 340 2004: <http://conselho.saude.gov.br/images/comissoes/conep/documentos/CARTAS/CartaCircular041-15.pdf>
- Statement on Pharmacogenetic Studies in Brazil No. 011/2012/CONEP, 12 January 2012: [http://www.fcm.unicamp.br/fcm/sites/default/files/11\\_-\\_Comunicado\\_sobre\\_estudos\\_farmacogeneticos\\_no\\_Brasil.pdf](http://www.fcm.unicamp.br/fcm/sites/default/files/11_-_Comunicado_sobre_estudos_farmacogeneticos_no_Brasil.pdf)
- Normative Resolution No. 33, of August 2, 2021: [http://ctnbio.mctic.gov.br/resolucoes-normativas/-/asset\\_publisher/OgW431Rs9dQ6/content/resolucao-normativa-n%C2%BA-33-de-02-de-agosto-de-2021?redirect=http%3A%2F%2Fctnbio.mctic.gov.br%2Fresolucoes-normativas%3Fp\\_p\\_id%3D101\\_INSTANCE\\_OgW431Rs9dQ6%26p\\_p\\_lifecycle%3D0%26p\\_p\\_state%3Dnormal%26p\\_p\\_mode%3Dview%26p\\_p\\_col\\_id%3Dcolumn-2%26p\\_p\\_col\\_count%3D3](http://ctnbio.mctic.gov.br/resolucoes-normativas/-/asset_publisher/OgW431Rs9dQ6/content/resolucao-normativa-n%C2%BA-33-de-02-de-agosto-de-2021?redirect=http%3A%2F%2Fctnbio.mctic.gov.br%2Fresolucoes-normativas%3Fp_p_id%3D101_INSTANCE_OgW431Rs9dQ6%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-2%26p_p_col_count%3D3)

## Embryos, Stem Cells, and Cloning

### Key Organizations

- National Biosafety Technical Commission: <http://ctnbio.mctic.gov.br/inicio>
- National Commission on Research Ethics (CONEP): <http://conselho.saude.gov.br/comissoes-cns/conep>
- National Health Council (CNS): <http://www.conselho.saude.gov.br/>

### Relevant Standards

- Biosafety [Law 11.105/05](#) (2005): [http://www.planalto.gov.br/ccivil\\_03/\\_ato2004-2006/2005/lei/111105.htm](http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/lei/111105.htm)
- Decree No. 5,591, of November 22, 2005: [http://www.planalto.gov.br/ccivil\\_03/\\_ato2004-2006/2005/Decreto/D5591.htm](http://www.planalto.gov.br/ccivil_03/_ato2004-2006/2005/Decreto/D5591.htm)
- Resolution RDC No. 9, 14 March 2011: [http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2011/prt0009\\_14\\_03\\_2011.html](http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2011/prt0009_14_03_2011.html)



*International Compilation of Human Research Standards  
2021 Edition*

- Resolution RDC No. 29, 12 May 2008:  
[http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2008/rdc0029\\_12\\_05\\_2008.html](http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2008/rdc0029_12_05_2008.html)
- Resolution RDC No.260, 21 December 2018: Regulation for Conducting Clinical Trials with Investigational Advanced Therapy Product in Brazil, and Makes Other Arrangements:  
[http://portal.anvisa.gov.br/documents/10181/2718376/RDC\\_260\\_2018\\_.pdf/dd889184-bd4a-40ea-ae1c-b93155b20ea1](http://portal.anvisa.gov.br/documents/10181/2718376/RDC_260_2018_.pdf/dd889184-bd4a-40ea-ae1c-b93155b20ea1)
- Resolution of the Collegiate Board - RDC No. 508 of 05/26/2021 - provides Good Practices in Human Cells for Therapeutic Use and Clinical Research, and other provisions:  
[http://antigo.anvisa.gov.br/documents/10181/6278627/%282%29RDC\\_508\\_2021\\_COMP.pdf/f7887768-24dc-4c61-acc4-464ef7a04f7d](http://antigo.anvisa.gov.br/documents/10181/6278627/%282%29RDC_508_2021_COMP.pdf/f7887768-24dc-4c61-acc4-464ef7a04f7d)

## LATIN AMERICA AND THE CARIBBEAN – Chile

### General

#### Key Organization

- Ministry of Health: <http://www.minsal.cl>
- Institute of Public Health: <http://www.ispch.cl>

#### Relevant Standards

- Law No. 20.120 Regarding Scientific Research in Human Beings, their Genome, and the Prohibition of Human Cloning (2006): <http://www.leychile.cl/Navegar?idNorma=253478>
- Law No. 20.584. Regulating the Rights and Duties Incumbent upon Persons in Connection with Actions Linked to their Health Care (2012): <http://www.leychile.cl/Navegar?idNorma=1039348>
- Law No. 21.331, modifying law 20.584 and establishing that children or adolescents can refuse to participate in research. Also, adults who are physically or mentally unable to express their consent or preferences cannot be included in research: <https://www.bcn.cl/leychile/navegar?idNorma=1159383>
- Law No. 20.724 Modifying the Health Code in the Area of the Regulation of Pharmacies and Medications (2014): <http://www.leychile.cl/Navegar?idNorma=1058373>
- Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: <http://www.leychile.cl/Navegar?idNorma=1032919>
- 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&>

### Drugs, Biologics, and Devices

#### Key Organizations

- Ministry of Health: <http://www.minsal.cl>
- Institute of Public Health: <http://www.ispch.cl>

#### Relevant Standards

- Law No. 20.724 Modifying the Health Code in the Area of the Regulation of Pharmacies and Medications (2014): <http://www.leychile.cl/Navegar?idNorma=1058373>

*International Compilation of Human Research Standards  
2021 Edition*

- Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: <http://www.leychile.cl/Navegar?idNorma=1032919>
- Supreme Decree No. 3 of 2010. Regulation of the National Control System of Pharmaceutical Products for Human Use. Official Diary of June 25, 2011: [http://www.ispch.cl/ley20285/t\\_activa/marco\\_normativo/7c/ds\\_minsal\\_3\\_2010.pdf](http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/ds_minsal_3_2010.pdf)
- Exempt Resolution 2263, July 30th 2015 Modifying Resolution N° 403 Ex. February 5, 2015 that Approves the Guidelines for Use Control of Pharmaceuticals Products in Scientific Research: <http://www.leychile.cl/Navegar?idNorma=1080011>

## Research Injury

### Key Organizations

- Ministry of Health: <http://www.minsal.cl>
- Institute of Public Health: <http://www.ispch.cl>

### Relevant Standards

- Law No. 20.120 Regarding Scientific Research in Human Beings, their Genome, and the Prohibition of Human Cloning (2006): <http://www.leychile.cl/Navegar?idNorma=253478>
- Supreme Decree No. 3 of 2010. Regulation of the National Control System of Pharmaceutical Products for Human Use. Official Diary of Jun 25, 2011: [http://www.ispch.cl/ley20285/t\\_activa/marco\\_normativo/7c/ds\\_minsal\\_3\\_2010.pdf](http://www.ispch.cl/ley20285/t_activa/marco_normativo/7c/ds_minsal_3_2010.pdf)
- General Technical Rule No. 140 Regarding the National System of Pharmacovigilance of Pharmaceutical Products for Human Use. June 20, 2012: <http://web.minsal.cl/portal/url/item/c4a31ad6db50e085e040010165017a39.pdf>
- Resolution No. 441, Notification of Adverse events in Clinical Research in Chile, February 13, 2012: [http://www.ispch.cl/sites/default/files/res\\_441.pdf](http://www.ispch.cl/sites/default/files/res_441.pdf)

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- Law for the Protection of Private Life No. 19.628 (1999): <http://www.bcn.cl/leyes/141599>
- Law No. 20584. Regulating the Rights and Duties Incumbent upon Persons in Connection with Actions Linked to their Health Care (2012): <http://www.leychile.cl/Navegar?idNorma=1039348>
- Supreme Decree No. 41 of 2012: Regulation Regarding Clinical Records of December 15, 2012: <http://www.leychile.cl/Navegar?idNorma=1046753>

## Genetic Research

### Key Organizations

- Ministry of Health: <http://www.minsal.cl>

## Relevant Standards

- Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2006): <http://www.leychile.cl/Navegar?idNorma=253478>
- Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: <http://www.leychile.cl/Navegar?idNorma=1032919>

## Embryos, Stem Cells, and Cloning

### Key Organizations

- Ministry of Health: <http://www.minsal.cl>

### Relevant Standards

- Law No. 20.120: Scientific Research Involving Human Beings, Their Genome, and Prohibition of Human Cloning (2006): <http://www.leychile.cl/Navegar?idNorma=253478>
- Supreme Decree No. 114 of 2010: Regulation on Law No. 20.120 Regarding Scientific Research in Human Beings, the Genome, and the Prohibition of Human Cloning. Official Diary of November 19, 2011: <http://www.leychile.cl/Navegar?idNorma=1032919>

## LATIN AMERICA AND THE CARIBBEAN – Colombia

### General

#### Key Organization

- Ministry of Health and Social Protection: <https://www.minsalud.gov.co/Paginas/default.aspx>
- National Institute of Drug and Food Surveillance (INVIMA): <https://www.invima.gov.co/>
- Administrative Department of Science, Technology, and Innovation (COLCIENCIAS): <http://www.colciencias.gov.co/>

#### Relevant Standards

- Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 8430 (1993): <https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF>
- Guide for Research Ethics Committees. Code ASS-RSA-GU040 Version: 00 (2015): <https://www.invima.gov.co/documents/20143/453029/ASS-RSA-GU040.pdf/96ea752d-2639-3024-4287-4527589fb26b?version=1.0&t=1550508307814>
- Guide for Assessing and Monitoring of Research Protocols. Code ASS-RSA-GU039 Version: 05 (2020): <https://www.invima.gov.co/documents/20143/1252100/ASS-RSA-GU039.pdf>
- Guide for the Presentation of Amendments, New Centers, New Researchers, and Informed Consent of Research Protocols. Code ASS-RSA-GU031 Version: 03 (2020): <https://www.invima.gov.co/documents/20143/1252100/ASS-RSA-GU031.pdf/f63b30b1-e410-c78c-ba3a-441b7fe29bfb?version=1.0&t=1586984573923>
- Policy on Ethical Research, Bioethics, and Scientific Integrity (2018): [http://www.colciencias.gov.co/sites/default/files/ckeditor\\_files/PDF%20Pol%C3%ADtica.pdf](http://www.colciencias.gov.co/sites/default/files/ckeditor_files/PDF%20Pol%C3%ADtica.pdf)

## Drugs, Biologics, and Devices

### **Drugs**

#### **Key Organizations**

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

#### **Relevant Standards**

- Resolution No. 2378 of 2008, Adapting Good Clinical Practices for Institutions that Conduct Research with Medicines in Human Beings:  
[https://normograma.invima.gov.co/docs/resolucion\\_minproteccion\\_2378\\_2008.htm?q=resolucion+2378](https://normograma.invima.gov.co/docs/resolucion_minproteccion_2378_2008.htm?q=resolucion+2378)
- Resolution No. 2011020764 of June 10th, 2011: Regulation Related to the Content and Frequency of Adverse Event Reports in Clinical Investigation in Humans:  
[https://normograma.invima.gov.co/docs/resolucion\\_invima\\_20764\\_2011.htm?q=resolucion+2011020764](https://normograma.invima.gov.co/docs/resolucion_invima_20764_2011.htm?q=resolucion+2011020764)
- Resolution 1403 of 2007 - Which determines the Pharmaceutical Service Management Model, adopts the Essential Conditions and Procedures Manual and establishes other provisions:  
<https://www.invima.gov.co/documents/20143/453029/Resoluci%C3%B3n+1403+de+2007.pdf/6b2e1ce1-bb34-e17f-03ef-34e35c126949>
- Decree 780 of 2016 - By which the Sole Regulatory Decree of the Health and Social Protection Sector is issued. Chapter 10 Drugstores and pharmaceutical service:  
<https://www.invima.gov.co/documents/20143/453029/Decreto+0780+de+2016.pdf/1a19484b-e3f1-f7f8-8b66-aacc81849a7a>
- Resolution 839 of 2017 - By which Resolution 1995 of 1999 is amended:  
<https://www.invima.gov.co/documents/20143/453029/Resoluci%C3%B3n+839+de+2017.pdf/9b129af5-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](https://normograma.invima.gov.co/docs/resolucion_minsaludps_3100_2019.htm?q=resolucion+3100)
- ABC Good Clinical Practice (2009):  
[https://www.invima.gov.co/documents/20143/790879/ABCBPCultima\\_version.pdf](https://www.invima.gov.co/documents/20143/790879/ABCBPCultima_version.pdf)
- Circular No. 600-5776-14: Processes of Good Clinical Practice (2014):  
[https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas\\_practicas/normatividad/CIRCULAR\\_600-5776-14-2.pdf](https://www.invima.gov.co/images/pdf/tecnovigilancia/buenas_practicas/normatividad/CIRCULAR_600-5776-14-2.pdf)
- 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%89tica\\_en\\_investigaci%C3%B3n\\_Octubre2015.pdf/1c5049a4-e2c2-6825-1aff-811b09c61e3f](https://www.invima.gov.co/documents/20143/453029/Circular_600-9915-15_Comit%C3%A9s_de_%C3%89tica_en_investigaci%C3%B3n_Octubre2015.pdf/1c5049a4-e2c2-6825-1aff-811b09c61e3f)
- Circular\_600-0511-16\_Changes of headquarters of research centers\_January2016:  
[https://www.invima.gov.co/documents/20143/1525233/Circular\\_600-0511-16\\_Cambios\\_de\\_sede\\_de\\_los\\_centros\\_de\\_investigacion\\_Enero2016.pdf](https://www.invima.gov.co/documents/20143/1525233/Circular_600-0511-16_Cambios_de_sede_de_los_centros_de_investigacion_Enero2016.pdf)

*International Compilation of Human Research Standards  
2021 Edition*

- Guidelines for Research Ethics Committees. Code: ASS-RSA-GU040 Version: 00 of 1/04/2015: <https://www.invima.gov.co/documents/20143/453029/ASS-RSA-GU040.pdf/96ea752d-2639-3024-4287-4527589fb26b>
- Guide for the Submission of Research Protocols, Code ASS-RSA-GU030 Version 5 date 03/03/2020: <https://www.invima.gov.co/documents/20143/1665510/ASS-RSA-GU030.pdf>
- Guide for the Evaluation and Monitoring of Research Protocols. Code: ASS-RSAGU039 Version 5, date: 18/02/2020: <https://www.invima.gov.co/documents/20143/1252100/ASS-RSA-GU039.pdf>
- Guidelines for the Submission of Amendments, New Centers, New Investigators and Informed Consents for Research Protocols. Code: ASS-RSA-GU031 Version 3, date: 30/03/2020: <https://www.invima.gov.co/documents/20143/1252100/ASS-RSA-GU031.pdf>
- Guide of Medications and Supplies for Clinical Research, Version 1 (2018): <https://www.invima.gov.co/images/stories/formatotramite/ASS-RSA-GU045.pdf>
- Guidance for the submission of investigational drug stability studies. Code: ASS-RSA-GU055, version 2 of 2018: <https://www.invima.gov.co/documents/20143/453029/ASS-RSA-GU055.pdf/44b5b1ec-b5ab-b761-fd17-3399a09e401a?t=1540909864133>
- External Circular No. 600-1414-16: Notification of Deviations (2016): <https://www.invima.gov.co/documents/20143/453029/Circular+600-1414-16+Notificaci%C3%B3n+de+desviaciones.pdf/e03d7820-8839-061e-b7aa-480e3de4a79c>
- External Circular No. 600-2006-16: National Reporting Serious Adverse Events (2016): [https://www.invima.gov.co/documents/20143/453029/Circular\\_600-2006-16\\_Alcance-Circular-600-1081-16\\_Abril2016.pdf/35631718-ab4f-2eb1-121a-3883170669b8?t=1560972349199](https://www.invima.gov.co/documents/20143/453029/Circular_600-2006-16_Alcance-Circular-600-1081-16_Abril2016.pdf/35631718-ab4f-2eb1-121a-3883170669b8?t=1560972349199)
- 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](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>
- Circular 1000-043-20 - Safety Monitoring and Adverse Event Reporting Systems: [https://www.invima.gov.co/documents/20143/1020331/CIRCULAR\\_1000-043-20\\_SISTEMA\\_MONITOREO\\_DE\\_SEGURIDAD.pdf](https://www.invima.gov.co/documents/20143/1020331/CIRCULAR_1000-043-20_SISTEMA_MONITOREO_DE_SEGURIDAD.pdf)
- 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+investigaci%C3%B3n+del%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**

- Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapters I and III (1993):  
<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF>

### **Clinical Trial Registries**

#### **Key Organizations**

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

#### **Relevant Standards**

- Publication of clinical studies with drugs in humans developed in Colombia 2014-2021. Consolidated clinical studies from 2014 - 2021:  
<https://www.invima.gov.co/documents/20143/1251430/Consolidado+estudios+clnicos+2014-2021+SEP2021.xlsx>
- Publication of clinical studies with drugs in humans closed as of February 2021. Clinical research protocols closed in Colombia: <https://www.invima.gov.co/documents/20143/900585/BD-Estudios-cerrados-publicacion-FEB2021.xlsx>
- Publication of clinical studies with drugs in humans for covid developed in Colombia. Authorized clinical studies for COVID-19: <https://www.invima.gov.co/estudios-clnicos-autorizados-para-covid-19>

### **Research Injury**

#### **Key Organizations**

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

#### **Relevant Standards**

- Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Art. 13 (1993):  
<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF>

### **Privacy/Data Protection**

#### **Key Organizations**

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

#### **Relevant Standards**

- Constitution of Colombia, Article 15 (2003):  
<http://www.corteconstitucional.gov.co/Inicio/Constitucion%20politica%20de%20Colombia%20-%2002015.pdf>
- Law 1581 of 2012: General Regimen of Protection of Personal Data:  
<https://www.funcionpublica.gov.co/eva/gestornormativo/norma.php?i=49981>

*International Compilation of Human Research Standards  
2021 Edition*

- Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter I, Article 8 (1993):  
<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF>

## **Human Biological Materials**

### **Key Organizations**

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

### **Relevant Standards**

- Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title II, Chapter VI (1993):  
<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF>
- Requirements for the Use of Unclaimed Cadavers for Research Purposes, Resolution No. 002640, Article 21 (2005):  
[https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/Resolución\\_2640\\_de\\_2005.pdf](https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/Resolución_2640_de_2005.pdf)

## **Genetic Research**

### **Key Organizations**

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

### **Relevant Standards**

- Scientific, Technical, and Administrative Regulations for Health Research, Resolution No. 008430, Title III, Chapter II (1993):  
<https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/RESOLUCION-8430-DE-1993.PDF>

## **LATIN AMERICA AND THE CARIBBEAN – Costa Rica**

### **General**

#### **Key Organization**

- Ministry of Health: <https://www.ministeriodesalud.go.cr/>

#### **Relevant Standards**

- Reform Regulation to the Biomedical Research Regulatory Law:  
[http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm\\_texto\\_completo.aspx?param1=NR\\_TC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC](http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NR_TC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC)

## **Drugs, Biologics, and Devices**

### **Key Organizations**

- National Health Research Council: <https://www.ministeriodesalud.go.cr/conis/>

## **Relevant Standards**

- Regulatory Law of Biomedical Research No. 9234 (2014):  
[http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm\\_texto\\_completo.aspx?param1=NR TC&nValor1=1&nValor2=77070&nValor3=96424&strTipM=TC](http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NR 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:  
[http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm\\_texto\\_completo.aspx?param1=NRTC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC](http://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?param1=NRTC&nValor1=1&nValor2=81213&nValor3=103450&strTipM=TC)
- Reforms to the Regulatory Decree No. 39533-S (2016) Regulatory Law of Biomedical Research No. 9234:  
[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)
- 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.cecmecd.cu/>

#### **Relevant Standards**

- Various: <http://www.cecmecd.cu/ensayos-clinicos/autorizos>

### **Clinical Trial Registries**

#### **Key Organizations**

- Public Cuban Registry of Clinical Trials: <https://rpcec.sld.cu/>

## **LATIN AMERICA AND THE CARIBBEAN – Dominica**

### **General**

#### **Key Organization**

- Ministry of Health: <http://www.dominica.gov.dm/cms/index.php?q=node/21>



## Relevant Standards

- Guidelines for the Conduct of Research on Human Subjects (2005)

## LATIN AMERICA AND THE CARIBBEAN – Dominican Republic

### General

#### Key Organization

- National Council on Health Bioethics (CONABIOS): <http://conabios.gob.do/>

#### Relevant Standards

- National Health Law 42-01, Chapter VI:  
<http://www.ilo.org/dyn/natlex/docs/ELECTRONIC/98207/116781/F-1794279886/DOM98207.pdf>
- CONABIOS, Legal Basis, various: <http://conabios.gob.do/base-legal-del-conabios/>

## LATIN AMERICA AND THE CARIBBEAN – Ecuador

### General

#### Key Organization

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

#### Relevant Standards

- Constitution of the Republic:  
[http://www.asambleanacional.gob.ec/sites/default/files/documents/old/constitucion\\_de\\_bolsillo.pdf](http://www.asambleanacional.gob.ec/sites/default/files/documents/old/constitucion_de_bolsillo.pdf)
- Organic Health Law of 22 December 2006, Articles 207-208 (2018)
- Code on Childhood and Adolescence. Law 100 Official Register 737 of January 3, 2003 (2019)
- Regulation on Research, Ministerial Agreement No. 0066, Public Registry No. 292 (March 11, 2008): <https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/01/A.M.-66-REGLAMENTO-DE-PROYECTOS-EN-INVESTIGACION-DE-SALUD.pdf>
- Regulation for the Approval of Ethics Committees (2014): <https://www.salud.gob.ec/aprobacion-de-comites-de-etica/>
- Regulation on Health Research Ethics Committees (2014): <https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2016/12/A-4889-Reglamento-para-la-aprobaci%C3%B3n-y-seguimiento-de-CEISH-y-CEAS-L.pdf>
- National Policy on Scientific Research. Ministerial Agreement 209, Public Registry No. 87 of August 23, 2005
- Approval of Ethics Committees: <https://www.salud.gob.ec/aprobacion-de-comites-de-etica/>
- Approval of Health Research: <https://www.salud.gob.ec/autorizacion-de-investigaciones-en-salud/>

## Drugs, Biologics, and Devices

#### Key Organizations

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

## Relevant Standards

- Regulation for the Approval, Development, Oversight, and Control of Clinical Trials (2017): <http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/08/Normativa-Ensayos-Cli%CC%81nicos-Registro-Oficial.pdf>
- Regulation for the Approval of Ethics Committees (2014): <http://instituciones.msp.gob.ec/images/Documentos/CNBS/1%20normativa/Registro%20Oficial%20Comites%20de%20Etica%20julio%202014.pdf>
- Regulation on Research, Ministerial Agreement No. 0066, Public Registry No. 292 (March 11, 2008): <https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/01/A.M.-66-REGLAMENTO-DE-PROYECTOS-EN-INVESTIGACION-DE-SALUD.pdf>
- Approval of Clinical Trials: <https://www.controlsanitario.gob.ec/ensayos-clinicos/>

## Privacy/Data Protection

### Key Organizations

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

### Relevant Standards

- Constitution of the Republic of Ecuador 2008 (Article: 92): [http://www.asambleanacional.gob.ec/sites/default/files/documents/old/c\\_onstitucion\\_de\\_bolsillo.pdf](http://www.asambleanacional.gob.ec/sites/default/files/documents/old/c_onstitucion_de_bolsillo.pdf)
- Ministerial Agreement No. 005216, Public Registry No. 427, Confidential Information in National Health System (January 29, 2015)

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- Organic Health Law of December 22, 2006, Articles 81-86 (2018)
- Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells (2017)
- Executive Order 1205, July 13, 2012: Regulation for the Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells
- Import and Export of Human Biological Samples for research. Ministerial Agreement No. 0088, Public Registry No. 34, (July 12, 2017): [http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/08/Acuerdo-Ministerial-0088-2017\\_Autorizaci%C3%B3n-de-importaci%C3%B3n-y-exportaci%C3%B3n-de-muestras-biol%C3%B3gicas.pdf](http://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/08/Acuerdo-Ministerial-0088-2017_Autorizaci%C3%B3n-de-importaci%C3%B3n-y-exportaci%C3%B3n-de-muestras-biol%C3%B3gicas.pdf)
- Authorization of Import and Export of Human Biological Samples for Research and Health: <https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/10/IE-B.3.3.2-EC-01-Instructivo-Externo-Autorizaci%C3%B3n-Muestras-Biol%C3%B3gicas..pdf>

## Genetic Research

### Key Organizations

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

### **Relevant Standards**

- Organic Health Law, December 22, 2006, Articles 209-210 (2011)

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

- Ministry of Public Health: <http://www.salud.gob.ec/>
- National Institute of Donation and Transplantation of Organs, Tissues, and Cells: <http://www.donaciontrasplante.gob.ec/indot/>

### **Relevant Standards**

- Organic Health Law of 22 December 2006, Article 214 (2018)
- Regulation for the Organic Law on the Donation and Transplantation of Organs, Tissues, and Cells. Executive Order 1205, July 13, 2012

## **LATIN AMERICA AND THE CARIBBEAN – El Salvador**

### **General**

#### **Key Organization**

- National Health Research Ethics Committee: <http://www.cneis.org.sv/>

#### **Relevant Standards**

- Law on Duties and Rights of Patients and Healthcare Providers, Articles 9 and 16 (2016): [https://www.asamblea.gob.sv/sites/default/files/documents/decretos/171117\\_073651293\\_archivo\\_documento\\_legislativo.pdf](https://www.asamblea.gob.sv/sites/default/files/documents/decretos/171117_073651293_archivo_documento_legislativo.pdf)
- Law on the Comprehensive Protection of Childhood and Adolescence, Article 19 (2009): <https://www.asamblea.gob.sv/sites/default/files/documents/decretos/F312B814-45C5-48EB-A71D-0DFC612FF135.pdf>
- Law on the Integrated National System of Health, Article 28 (2019): <https://www.diariooficial.gob.sv/diarios/do-2019/05-mayo/17-05-2019.pdf>
- Regulation on the Law on Duties and Rights of Patients and Healthcare Providers, Article 12 (2018): <http://cssp.gob.sv/wp-content/uploads/2016/05/Reglamento-de-la-ley-de-Deberes-y-Derechos-de-los-Pacientes-y-prestadores-de-Servicios-de-Salud.pdf>
- Standard Operating Procedures for the Ethical Evaluation of Health Research (2015): <http://cssp.gob.sv/wp-content/uploads/2016/06/MANUAL-CNEIS-2017-03-15.pdf>
- Manual on the Functioning of the National Health Research Ethics Committee (2017): [http://cssp.gob.sv/wp-content/uploads/2016/06/manual\\_funcionamiento\\_comite\\_nacional\\_etica\\_investigacion\\_en\\_salud.pdf](http://cssp.gob.sv/wp-content/uploads/2016/06/manual_funcionamiento_comite_nacional_etica_investigacion_en_salud.pdf)

## **Drugs, Biologics, and Devices**

### **Key Organizations**

- National Directorate of Medications: <http://www.medicamentos.gob.sv/index.php/es/>

### **Relevant Standards**

- Medication Law, Articles 29 and 66 (2012):  
[https://www.asamblea.gob.sv/sites/default/files/documents/decretos/171117\\_073104135\\_archivo\\_documento\\_legislativo.pdf](https://www.asamblea.gob.sv/sites/default/files/documents/decretos/171117_073104135_archivo_documento_legislativo.pdf)
- User's Guide for the Application of Clinical Investigation Protocols:  
<http://www.medicamentos.gob.sv/index.php/es/servicios-m/descargables/ensayos-clinicos>

## **LATIN AMERICA AND THE CARIBBEAN – Grenada**

### **General**

#### **Key Organization**

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

#### **Relevant Standards**

- U.S. 45 CFR 46: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

## **LATIN AMERICA AND THE CARIBBEAN – Guyana**

### **General**

#### **Key Organization**

- Ministry of Health: <https://www.health.gov.gy/>

#### **Relevant Standards**

- Medical Research Involving Human Subjects Regulations (2007):  
[https://parliament.gov.gy/documents/regulations/17828-reg\\_9\\_of\\_2008.pdf](https://parliament.gov.gy/documents/regulations/17828-reg_9_of_2008.pdf)

## **LATIN AMERICA AND THE CARIBBEAN – Guatemala**

### **General**

#### **Key Organization**

- Ministry of Public Health and Social Assistance: <http://www.mspas.gob.gt/>

#### **Relevant Standards**

- Ministerial Accords and Amendments, various:  
<https://medicamentos.mspas.gob.gt/index.php/legislacion-vigente/acuerdos>
- Internal Regulations of the National Committee on Health Ethics (2018):  
<http://www.mspas.gob.gt/images/files/acuerdosministeriales/2018/AcuerdoMinisterial1392018NormativaCNES.pdf>

## **Drugs, Biologics, and Devices**

#### **Key Organizations**

- Ministry of Public Health and Social Assistance, Department of Regulation and Control of Pharmaceutical Products: <https://medicamentos.mspas.gob.gt/>

### **Relevant Standards**

- Governmental Agreement 712-99, Articles 91-94 (1999): [http://asisehace.gt/media/ag\\_712\\_99.pdf](http://asisehace.gt/media/ag_712_99.pdf)
- Rules for the Regulation of Human Clinical Trials, Ministerial Accord 82-2019: <https://medicamentos.mspas.gob.gt/phocadownload/Acuerdo%20Ministerial%2082-2019.pdf>
- 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**

- Ministry of Public Health and Population: <http://mspp.gouv.ht/newsite/>

#### **Relevant Standards**

- Internal Regulations (2010)

## **LATIN AMERICA AND THE CARIBBEAN – Honduras**

### **General**

#### **Key Organization**

- Secretariat of Health: <http://www.salud.gob.hn/>

#### **Relevant Standards**

- Code, Decree No. 65-91, Articles 175 and 176 (1996): <https://www.acnur.org/fileadmin/Documentos/BDL/2016/10636.pdf>
- 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**

- Regulation for the Health Control of Products, Services, and Health Establishments (2015): <https://honduras.eregulations.org/media/Acuerdo-06-2005-REGLAMENTO-PARA-EL-CONTROL-SANITARIO.pdf>

### **Human Biological Materials**

#### **Relevant Standards**

- Law of Donation and Transplantation of Anatomical Organs in Human Beings (2014): [http://www.tsc.gob.hn/leyes/Ley\\_donacion\\_transp\\_organos\\_2014.pdf](http://www.tsc.gob.hn/leyes/Ley_donacion_transp_organos_2014.pdf) n. 329-2013

## Embryos, Stem Cells, and Cloning

### Relevant Standards

- Penal Code Decree No. 130-2017 (2019): <https://criterio.hn/wp-content/uploads/2019/05/C%C3%B3digo-Penal-1.pdf>

## LATIN AMERICA AND THE CARIBBEAN – Jamaica

### General

#### Key Organization

- Ministry of Health, Ethics and Medico-Legal Affairs Panel: <http://moh.gov.jm/>

#### Relevant Standards

- Ministry of Health Guidelines for the Conduct of Research on Human Subjects (2010): <http://moh.gov.jm/guidelines/guidelines-for-the-conduct-of-research-on-human-subjects/>

## Drugs, Biologics, and Devices

#### Key Organizations

- Ministry of Health, Standards and Regulation Division: <http://moh.gov.jm/divisions-agencies/divisions/standards-and-regulation-division/>

#### Relevant Standards

- Food and Drugs Act (1975): <http://www.moj.gov.jm/sites/default/files/laws/Food%20and%20Drugs%20Act%20LN%2065%20of%2075.pdf>
- Food and Drugs Regulations (1975): <http://www.moj.gov.jm/sites/default/files/laws/Food%20and%20Drugs%20Act%20LN%2065%20of%2075.pdf>

## 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/>
- National Bioethics Commission (Conbioética): <https://www.gob.mx/salud/conbioetica>
- Federal Commission for Protection Against Health Risks (Cofepris): <https://www.gob.mx/cofepris>

#### Relevant Standards

- General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2018): General Health Law, Title V, Chapter 1, Articles 96-103: Health Research (2021): [http://www.diputados.gob.mx/LeyesBiblio/pdf\\_mov/Ley\\_General\\_de\\_Salud.pdf](http://www.diputados.gob.mx/LeyesBiblio/pdf_mov/Ley_General_de_Salud.pdf)

*International Compilation of Human Research Standards  
2021 Edition*

- Rule NOM-012-SSA3-2012 Establishing Criteria for the Conduct of Health Research Projects (2013): [http://dof.gob.mx/nota\\_detalle.php?codigo=5284148&fecha=04/01/2013](http://dof.gob.mx/nota_detalle.php?codigo=5284148&fecha=04/01/2013)
- Regulation on the General Health Law in the Matter of Health Research (2014): [http://www.diputados.gob.mx/LeyesBiblio/regley/Reg\\_LGS\\_MIS.pdf](http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf)
- National Guidelines on the Composition and Functioning of Research Ethics Committees (2018): [https://www.gob.mx/cms/uploads/attachment/file/460756/7\\_Guia\\_CEI\\_2018\\_6a.pdf](https://www.gob.mx/cms/uploads/attachment/file/460756/7_Guia_CEI_2018_6a.pdf)
- 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](https://www.dof.gob.mx/nota_detalle.php?codigo=5607368&fecha=10/12/2020)
- Agreement establishing reforms to the general dispositions on integration and operation of Research Ethics Committees (REC): [https://www.dof.gob.mx/nota\\_detalle.php?codigo=5607368&fecha=10/12/2020](https://www.dof.gob.mx/nota_detalle.php?codigo=5607368&fecha=10/12/2020)

## Drugs, Biologics, and Devices

### Relevant Standards

- General Health Law, Title V, Chapter I, Articles 96-103: Health Research (2014): General Health Law, Title V, Chapter I, Articles 96-103: Health Research (2014): [http://www.diputados.gob.mx/LeyesBiblio/pdf\\_mov/Ley\\_General\\_de\\_Salud.pdf](http://www.diputados.gob.mx/LeyesBiblio/pdf_mov/Ley_General_de_Salud.pdf)
- Regulation on the General Health Law in the Matter of Health Research (2014): Regulations to the General Health Law on Health Research (2014): [http://www.diputados.gob.mx/LeyesBiblio/regley/Reg\\_LGS\\_MIS.pdf](http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MIS.pdf)
- Official standard NOM-220, SSA1-2002, establishment and operation of pharmacovigilance: <http://www.salud.gob.mx/unidades/cdi/nom/220ssa102.html>
- Guidelines of Good Clinical Practice in Health Research (2012): [https://www.imss.gob.mx/sites/all/statics/profesionalesSalud/investigacionSalud/normativaNac/6\\_Lineamientos\\_BPC.pdf](https://www.imss.gob.mx/sites/all/statics/profesionalesSalud/investigacionSalud/normativaNac/6_Lineamientos_BPC.pdf)
- Guidelines for the Submission of Human Research Protocols – Observational Studies (2016): [https://www.gob.mx/cms/uploads/attachment/file/149032/Gu\\_a\\_de\\_Sometimiento\\_COFEPRIS-04-010-A.pdf](https://www.gob.mx/cms/uploads/attachment/file/149032/Gu_a_de_Sometimiento_COFEPRIS-04-010-A.pdf)
- Guidelines for the Submission of Human Research Protocol Amendments – Requirements for Applicant Information Changes (2016): [https://www.gob.mx/cms/uploads/attachment/file/149028/Gu\\_a\\_de\\_Sometimiento\\_COFEPRIS-09-012\\_MODIFICACION.pdf](https://www.gob.mx/cms/uploads/attachment/file/149028/Gu_a_de_Sometimiento_COFEPRIS-09-012_MODIFICACION.pdf)

## Privacy/Data Protection

### Key Organizations

- Federal Institute on Access to Public Information: [www.inai.org.mx/](http://www.inai.org.mx/)

### Relevant Standards

- Federal Law for the Protection of Personal Data in Possession of Private Individuals (2017): <http://www.diputados.gob.mx/LeyesBiblio/pdf/LGPDPSO.pdf>

*International Compilation of Human Research Standards  
2021 Edition*

- Federal Law on Transparency and Access to Public Information (2021):  
[http://www.diputados.gob.mx/LeyesBiblio/pdf/LFTAIP\\_200521.pdf](http://www.diputados.gob.mx/LeyesBiblio/pdf/LFTAIP_200521.pdf)

## Human Biological Materials

### Key Organizations

- Secretariat of Health: <https://www.gob.mx/salud>

### Relevant Standards

- General Health Law, Title XIV, Articles 313-342 (2021):  
[http://www.diputados.gob.mx/LeyesBiblio/pdf\\_mov/Ley\\_General\\_de\\_Salud.pdf](http://www.diputados.gob.mx/LeyesBiblio/pdf_mov/Ley_General_de_Salud.pdf)
- Regulations to 1. General Health Law, Title XIV, Articles 313-342 (2018):  
[http://dof.gob.mx/nota\\_detalle.php?codigo=4652777&fecha=07/02/1984](http://dof.gob.mx/nota_detalle.php?codigo=4652777&fecha=07/02/1984)
- Regulation of the General Law of Health on Transplantation (2014):  
[http://www.diputados.gob.mx/LeyesBiblio/regley/Reg\\_LGS\\_MT.pdf](http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LGS_MT.pdf)

## Genetic Research

### Key Organizations

- National Institute of Genomic Medicine: <http://www.inmegen.gob.mx/>

### Relevant Standards

- Biosafety Law on Genetically Modified Organisms (2020):  
[http://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM\\_061120.pdf](http://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM_061120.pdf)
- Regulations to the Biosafety Law on Genetically Modified Organisms (2009):  
[http://www.diputados.gob.mx/LeyesBiblio/regley/Reg\\_LBOGM.pdf](http://www.diputados.gob.mx/LeyesBiblio/regley/Reg_LBOGM.pdf)
- 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](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

- General Healthcare Law, No. 423 Republica de Nicaragua:  
[http://www.vertic.org/media/National%20Legislation/Nicaragua/NI\\_Ley\\_423\\_General\\_de\\_Salud\\_2002.pdf](http://www.vertic.org/media/National%20Legislation/Nicaragua/NI_Ley_423_General_de_Salud_2002.pdf);  
[http://legislacion.asamblea.gob.ni/Normaweb.nsf/\(\\$All\)/FF82EA58EC7C712E062570A1005810E1?OpenDocument](http://legislacion.asamblea.gob.ni/Normaweb.nsf/($All)/FF82EA58EC7C712E062570A1005810E1?OpenDocument)



## Drugs, Biologics, and Devices

### Key Organization

- Ministry of Health, Directorate of Sanitary Regulations: <http://www.minsa.gob.ni>

### Relevant Standards

- Law of Medicines and Pharmacies, No. 292: [http://legislacion.asamblea.gob.ni/Normaweb.nsf/\(\\$All\)/10B9BC0F73CCA7FD062570A10057793D?OpenDocument](http://legislacion.asamblea.gob.ni/Normaweb.nsf/($All)/10B9BC0F73CCA7FD062570A10057793D?OpenDocument)
- Normative-064, Standard for the registration of medical devices: <http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Dispositivos-M%C3%A9dicos/Normativa-064%E2%80%9CNorma-para-el-registro-de-dispositivos-m%C3%A9dicos%E2%80%9D/>

## Clinical Trial Registries

### Key Organization

- Ministry of Health, Directorate of Sanitary Regulations: <http://www.minsa.gob.ni>

### Relevant Standards

- Clinical Trial Standards: <http://www.minsa.gob.ni/index.php/repository/Descargas-MINSA/Direcci%C3%B3n-General-de-Regulaci%C3%B3n-Sanitaria/Direcci%C3%B3n-de-Farmacia/Ensayos-Cli%C3%ADnicos/Norma-de-Ensayos-Clinicos/>

## LATIN AMERICA AND THE CARIBBEAN – Panama

### General

### Key Organization

- Ministry of Health (MINSAs): <http://www.minsa.gob.pa/>
- National Committee of Research Bioethics: <https://cnbi.senacyt.gob.pa>

### Relevant Standards

- Law No. 84 on Research with Human Beings (2019): <https://cnbi.senacyt.gob.pa/wp-content/uploads/2019/07/Ley-NO.84-del-14-de-mayo-de-2019-Ley-de-investigaci3n.pdf>
- MINSAs, Executive Decree N°1, January 21, 2013: <https://cnbi.senacyt.gob.pa/wp-content/uploads/2019/07/Decreto-Ejecutivo-NO.1-del-21-de-Enero-de-2013.pdf>
- MINSAs, Executive Decree NO.1843 on the National Research Ethics Committee of Panama (2014): [http://gacetas.procuraduria-admon.gob.pa/27681-A\\_2014.pdf](http://gacetas.procuraduria-admon.gob.pa/27681-A_2014.pdf)
- MINSAs, Executive Decree NO. 6 on the National Research Ethics Committee of Panama (2015): [https://www.gacetaoficial.gob.pa/pdfTemp/27716/GacetaNo\\_27716\\_20150206.pdf](https://www.gacetaoficial.gob.pa/pdfTemp/27716/GacetaNo_27716_20150206.pdf)

## Drugs, Biologics, and Devices

### Relevant Standards

- Law 1 of 2001, Official Gazette 24,218: <http://www.perezcarrera.com/leyes/ley-registro-sanitario-panama.pdf>

## **Privacy/Data Protection**

### **Relevant Standards**

- Law No. 68, November 20, 2003: <https://cnbi.senacyt.gob.pa/wp-content/uploads/2019/07/Ley-68-del-20-de-noviembre-de-2003.pdf>
- 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)
- Executive Directive No. 1458 of 6 November 2012: [https://www.gacetaoficial.gob.pa/pdfTemp/27160\\_A/39630.pdf](https://www.gacetaoficial.gob.pa/pdfTemp/27160_A/39630.pdf)

## **Human Biological Materials**

### **Relevant Standards**

- Law 3 of 2010, Official Gazette 26,468-B on Transplant of Organs and Tissues: [https://www.gacetaoficial.gob.pa/pdfTemp/26468\\_B/GacetaNo\\_26468b\\_20100210.pdf](https://www.gacetaoficial.gob.pa/pdfTemp/26468_B/GacetaNo_26468b_20100210.pdf)
- Executive Directive No. 179 of 8 June 2018: [https://www.gacetaoficial.gob.pa/pdfTemp/28546\\_A/68013.pdf](https://www.gacetaoficial.gob.pa/pdfTemp/28546_A/68013.pdf)
- Executive Decree N°179, June 8, 2018: <https://cnbi.senacyt.gob.pa/wp-content/uploads/2019/07/Decreto-Ejecutivo-NO.-179-del-8-de-junio-de-2018.pdf>

## **Embryos, Stem Cells, and Cloning**

### **Relevant Standards**

- Law No. 3, 15 January 2004: <https://docs.panama.justia.com/federales/leyes/3-de-2004-jan-19-2004.pdf>

## **LATIN AMERICA AND THE CARIBBEAN – Paraguay**

### **General**

#### **Key Organization**

- National Institute of Health, Research Ethics Committee: <http://www.ins.gov.py/>

#### **Relevant Standards**

- Statute and Operating Procedures (2017) (Spanish): <https://www.mspbs.gov.py/dependencias/cnbioetica/adjunto/a03ba4-CEIINS.VersionFinal.pdf>

## **Drugs, Biologics, and Devices**

#### **Key Organization**

- Ministry of Public Health and Social Welfare: <https://www.mspbs.gov.py/index.php>

#### **Relevant Standards**

- Law 1119/97 Regarding Health Products and Other Products, Article 30: <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](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

- General Health Law No. 26842, Article 28 (1997): <https://www.gob.pe/institucion/minsa/normas-legales/256661-26842>
- Resolución Ministerial No. 233-2020: <https://www.gob.pe/institucion/minsa/normas-legales/541139-233-2020-minsa>

### 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 (MINSAs): [www.digemid.minsa.gob.pe](http://www.digemid.minsa.gob.pe)

#### Relevant Standards

- Supreme Decree No. 021-2017-SA. Regulation of Clinical Trials (2017): <https://www.gob.pe/institucion/minsa/normas-legales/189280-021-2017-sa>
- Errata - Supreme Decree No. 021-2017-SA – Clinical Trials Regulation (2017): <https://busquedas.elperuano.pe/normaslegales/-fe-de-errata-ds-n-021-2017-sa-1542992-1/>
- Ministerial Resolution No. 655-2019/MINSA (2019): <https://www.gob.pe/institucion/minsa/normas-legales/286523-655-2019-minsa>
- Procedures Manual for Clinical Trials (2017)

### Clinical Trial Registries

#### Key Organization

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

#### Relevant Standards

- Supreme Decree No. 021-2017-SA. Regulation of Clinical Trials, Articles 102-103 (2017): <https://www.gob.pe/institucion/minsa/normas-legales/189280-021-2017-sa>
- 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**

- Regulation on Clinical Trials in Peru: Articles 27-29:  
[https://cdn.www.gob.pe/uploads/document/file/189787/189280\\_DS\\_021-2017-SA.pdf](https://cdn.www.gob.pe/uploads/document/file/189787/189280_DS_021-2017-SA.pdf)  
[20180823-24725-cfjcm1.pdf](https://cdn.www.gob.pe/uploads/document/file/189787/189280_DS_021-2017-SA.pdf)

## **Privacy/Data Protection**

### **Key Organizations**

- National Directorate of Drugs and Medical Devices: [www.digemid.minsa.gob.pe](http://www.digemid.minsa.gob.pe)

### **Relevant Standards**

- Law 29733 for the Protection of Personal Information (2011):  
<https://cdn.www.gob.pe/uploads/document/file/19041/Decreto-Legislativo-1353-2017.pdf>
- Law for Electronic Medical Charts (2013): <http://elperuanolegal.blogspot.com/2013/05/ley-30024-ley-que-crea-el-registro.html>
- Supreme Decree No. 003-2013-JUS, Regulation of Law No. 29733 for the protection of personal information (2013): [https://cdn.www.gob.pe/uploads/document/file/1913756/DS-3-2013-JUS.REGLAMENTO.LPDP\\_.pdf](https://cdn.www.gob.pe/uploads/document/file/1913756/DS-3-2013-JUS.REGLAMENTO.LPDP_.pdf)
- Supreme Decree No. 009-2017-SA, Regulation of Law No. 30024 for Electronic Medical Charts (2017): <https://busquedas.elperuano.pe/normaslegales/aprueban-el-reglamento-de-la-ley-n-30024-ley-que-crea-el-r-decreto-supremo-n-009-2017-sa-1500555-3/>

## **LATIN AMERICA AND THE CARIBBEAN – Saint Lucia**

### **Drugs, Biologics, and Devices**

### **Relevant Standards**

- Clinical Trials Act (2016):  
[http://slugovprintery.com/template/files/document\\_for\\_sale/laws/3742/Act%2010%20of%202016.pdf](http://slugovprintery.com/template/files/document_for_sale/laws/3742/Act%2010%20of%202016.pdf)

## **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:  
[http://www.mercosur.int/msweb/Normas/normas\\_web/Resoluciones/PT/GMC\\_RES\\_1996-129\\_PT\\_RT%20Verifica%20BPPesquisaClinica.PDF](http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF)
- Decree 379/008, Approving the Bioethics Commission Project Related to Research with Human Beings: <http://www.impo.com.uy/bases/decretos-originales/379-2008>

## **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:  
[http://www.mercosur.int/msweb/Normas/normas\\_web/Resoluciones/PT/GMC\\_RES\\_1996-129\\_PT\\_RT%20Verifica%20BPPesquisaClinica.PDF](http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF)

## **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:  
[http://www.mercosur.int/msweb/Normas/normas\\_web/Resoluciones/PT/GMC\\_RES\\_1996-129\\_PT\\_RT%20Verifica%20BPPesquisaClinica.PDF](http://www.mercosur.int/msweb/Normas/normas_web/Resoluciones/PT/GMC_RES_1996-129_PT_RT%20Verifica%20BPPesquisaClinica.PDF)
- Decree 379/008, Approving the Bioethics Commission Project Related to Research with Human Beings: <http://www.impo.com.uy/bases/decretos-originales/379-2008>

## **Privacy/Data Protection**

### **Key Organizations**

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

### **Relevant Standards**

- Law 18.331, Law for the Protection of Personal Data: <https://www.impo.com.uy/bases/leyes/18331-2008>
- Decree 379/008, Approving the Bioethics Commission Project Related to Research with Human Beings: <http://www.impo.com.uy/bases/decretos-originales/379-2008>

## **Human Biological Materials**

### **Key Organizations**

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

*International Compilation of Human Research Standards  
2021 Edition*

- National Institute on Donation and Transplantation: [www.indt.edu.uy](http://www.indt.edu.uy)

**Relevant Standards**

- Decree 160/006, Regulatory Framework Regarding the Transplantation of Human Cells and Tissues: [http://www.indt.edu.uy/documentos/documentacion\\_legal/decreto\\_160-006.pdf](http://www.indt.edu.uy/documentos/documentacion_legal/decreto_160-006.pdf)

**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/>

**Relevant Standards**

- Constitution, Article 46 (3): <http://www.venezuelaemb.or.kr/english/ConstitutionoftheBolivarianingles.pdf>
- Resolution No. 48 (1998)
- FONACIT, Code on Bioethics and Biosecurity (2002)
- IVIC, Legal Norms, various: <https://www.ivic.gob.ve/institucion-2/normativa-legal-26>

**Drugs, Biologics, and Devices**

**Key Organization**

- National Institute of Hygiene “Rafael Rangel”: <http://www.inhrr.gob.ve/>

**Relevant Standards**

- Medicines Act, Title III, Chapter II

**Genetic Research**

**Key Organizations**

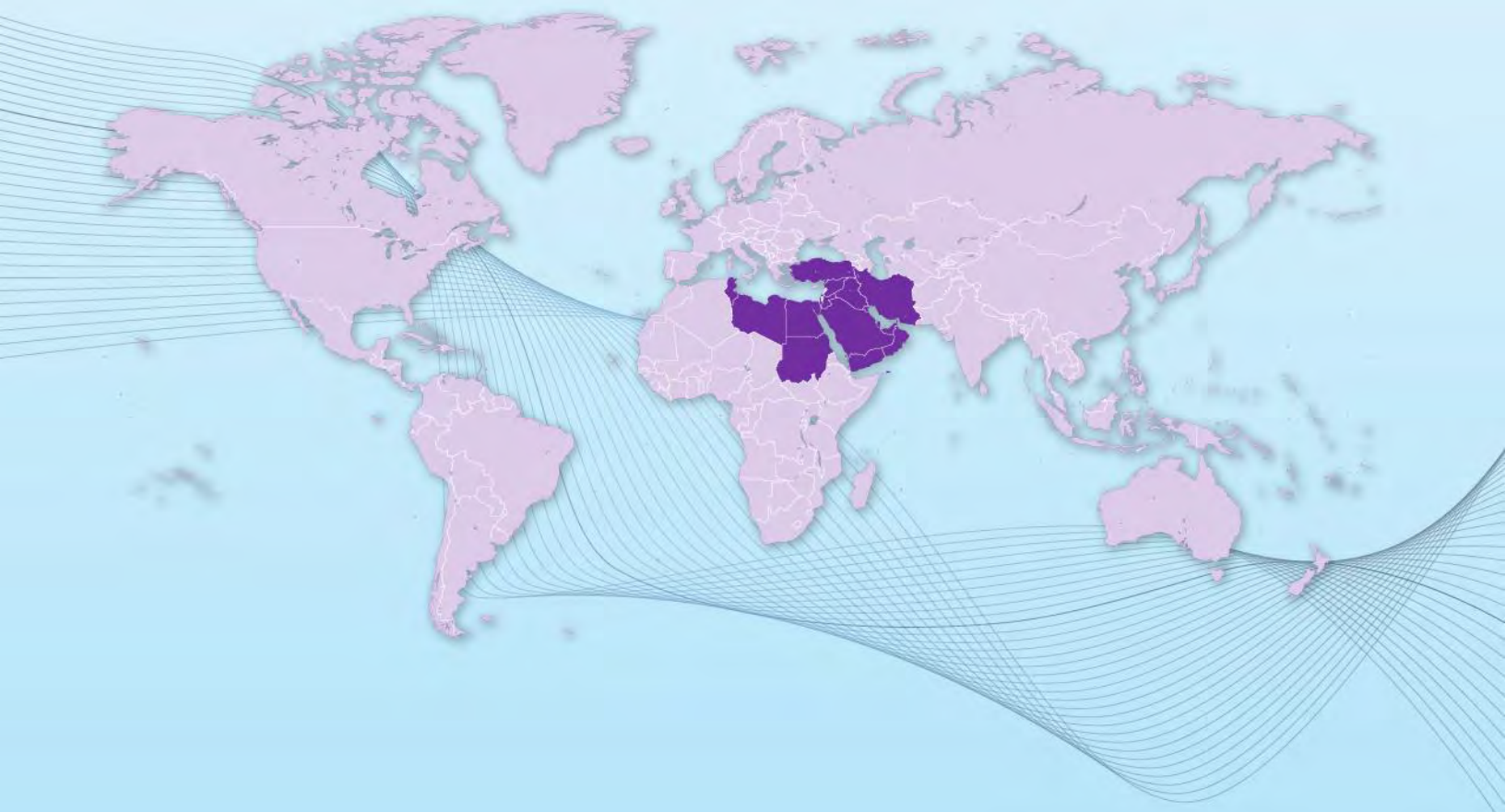
- Venezuelan Institute of Scientific Research (IVIC): <https://www.ivic.gob.ve/>

**Relevant Standards**

- Contract for Accessing Genetic Resources (2003)
- Revised Outline of the International Declaration of Human Genetic Data (2003)

International Compilation of Human  
Research Standards  
2021 Edition

# Middle East/North Africa



## MIDDLE EAST/NORTH AFRICA – Egypt

### General

#### Key Organization

- Medical Professionals Union

#### Relevant Standards

- Constitution of the Arab Republic of Egypt, Article 43: <http://www.sis.gov.eg/Newvr/Dustor-en001.pdf>
- 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

- Law No. 214 of 2020, Regulating Clinical Research: <https://www.edaegypt.gov.eg/media/cyyn0r4r/2020-214.pdf>
- Ministerial Resolution No. 436 of 2006, Concerning the Egyptian Code for Evaluating Clinical Trials of Biological Preparations, Serums and Vaccines: <https://www.edaegypt.gov.eg/media/wjcjhndl/436-2006.pdf>
- Ministerial Resolutions, various: <https://www.edaegypt.gov.eg/ar/%D8%A7%D9%84%D9%82%D9%88%D8%A7%D9%86%D9%8A%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%B1%D8%A7%D8%AA-%D8%A7%D9%84%D9%88%D8%B2%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/>



## Relevant Standards

- Trial Registration: <https://www.irct.ir/page/help>

## 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)
- Guidelines for Clinical Trials in Human Subjects (2006): <https://rnd.sheba.co.il/62382.pdf>
- Various procedures,  
<https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/ClinicalTrials/Pages/CTH.aspx>

### Privacy/Data Protection

#### Key Organizations

- The Privacy Protection Authority:  
[https://www.gov.il/en/departments/the\\_privacy\\_protection\\_authority/govil-landing-page](https://www.gov.il/en/departments/the_privacy_protection_authority/govil-landing-page)

#### Relevant Standards

- Legislations, various: <https://www.gov.il/en/Departments/legalInfo/legislation>
- Guidelines, various: [https://www.gov.il/en/Departments/General/guidelines\\_ppa](https://www.gov.il/en/Departments/General/guidelines_ppa)

### Genetic Research

#### Key Organizations

- Ministry of Health: <http://www.health.gov.il/english/>

#### Relevant Standards

- Genetic Information Law (2000):  
<https://www.jewishvirtuallibrary.org/jsourc/Health/GeneticInformationLaw.pdf>
- 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

- Ministry of Health: <http://www.moh.gov.jo/en/Pages/default.aspx>
- Jordan Food and Drug Administration: <http://www.jfda.jo/Default.aspx>

#### Relevant Standards

- Law of Clinical Studies, Law No. 2 (2011):  
[http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/50\\_211.pdf](http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/50_211.pdf)
- Drug and Pharmacy Law No. 12 (2013):  
<http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugDirectorate/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D8%AF%D9%88%D8%A7%D8%A1%20%D9%88%D8%A7%D9%84%D8%B5%D9%8A%D8%AF%D9%84%D8%A9.pdf>
- Narcotic and Psychotropic Law No. 23 (2016):  
<http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/DrugsAndPsychotropicSubstances/%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D9%85%D8%AE%D8%AF%D8%B1%D8%A7%D8%AA%20%D9%88%D8%A7%D9%84%D9%85%D8%A4%D8%AB%D8%B1%D8%A7%D8%AA%20%D8%A7%D9%84%D8%B9%D9%82%D9%84%D9%8A%D8%A9.pdf>

## Research Injury

### Relevant Standards

- Regulations for Insurance on Research-Related Injury (2013):  
[http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/22\\_252.pdf](http://www.jfda.jo/EchoBusV3.0/SystemAssets/PDF/AR/LawsAndRegulation/Drug/PharmaceuticalStudies/22_252.pdf)

## Embryos, Stem Cells, and Cloning

### Relevant Standards

- Stem Cell By-law No. 10 (2014)

## MIDDLE EAST/NORTH AFRICA – Kuwait

### General

#### Key Organization

- Ministry of Health, Kuwait Institute for Medical Specialization: <http://www.kims.org.kw/>

## Relevant Standards

- Ethical Guidelines for Biomedical Research

## MIDDLE EAST/NORTH AFRICA – Qatar

### General

#### Key Organization

- Ministry of Public Health, Health Research Governance Department:  
<https://www.moph.gov.qa/english/derpartments/policyaffairs/healthresearchgovernance/Pages/default.aspx>

#### Relevant Standards

- Human Research Policies & Regulations, various:  
<https://research.moph.gov.qa/en/Pages/HumanResearch.aspx?csrt=16566705229134832818>
- IRB Registration and Assurance:  
<https://research.moph.gov.qa/en/Pages/IRB.aspx?csrt=16566705229134832818>
- Guidelines on Reviewing and Reporting Adverse Events:  
[https://researchportal.moph.gov.qa/\\_layouts/15/ResearchPortal/RDLogin.aspx?ReturnUrl=%2f\\_layouts%2f15%2fAuthenticate.aspx%3fSource%3d%252F&Source=%2F](https://researchportal.moph.gov.qa/_layouts/15/ResearchPortal/RDLogin.aspx?ReturnUrl=%2f_layouts%2f15%2fAuthenticate.aspx%3fSource%3d%252F&Source=%2F)
- Clinical trials, various:  
<https://research.moph.gov.qa/en/Pages/ClinicalTrials.aspx?csrt=16566705229134832818>

### Human Biological Materials

#### Key Organizations

- Ministry of Public Health, Health Research Governance Department:  
<https://www.moph.gov.qa/english/derpartments/policyaffairs/healthresearchgovernance/Pages/default.aspx>

#### Relevant Standards

- Guidance for the Use of Stored Data and Biological Specimens in Human Research:  
<https://research.moph.gov.qa//DepartmentalDocuments/Guidance%20for%20the%20Use%20of%20Stored%20Data%20and%20Biological%20Specimens%20in%20Human%20Research.pdf?csrt=16566705229134832818>
- Human Research Policies & Regulations, various:  
<https://research.moph.gov.qa/en/Pages/HumanResearch.aspx?csrt=16566705229134832818>

### Genetic Research

#### Key Organizations

- Ministry of Public Health, Health Research Governance Department:  
<https://www.moph.gov.qa/english/derpartments/policyaffairs/healthresearchgovernance/Pages/default.aspx>

### **Relevant Standards**

- Guidance for the Design, Ethical Review, and Conduct of Genomic Research in Qatar:  
<https://research.moph.gov.qa/DepartmentalDocuments/Guidance%20for%20the%20Design,%20Ethical%20Review,%20and%20Conduct%20of%20Genomic%20Research%20in%20Qatar.pdf?csrt=16566705229134832818>
- Guidelines for Gene Transfer Research in Humans:  
<https://research.moph.gov.qa/DepartmentalDocuments/Guidelines%20for%20Gene%20Transfer%20Research%20in%20Humans.pdf?csrt=16566705229134832818>
- Human Research Policies & Regulations, various:  
<https://research.moph.gov.qa/en/Pages/HumanResearch.aspx?csrt=16566705229134832818>

## **Embryos, Stem Cells, and Cloning**

### **Key Organizations**

- Ministry of Public Health, Health Research Governance Department:  
<https://www.moph.gov.qa/english/derpartments/policyaffairs/healthresearchgovernance/Pages/default.aspx>

### **Relevant Standards**

- Human Research Policies & Regulations, various:  
<https://research.moph.gov.qa/en/Pages/HumanResearch.aspx?csrt=16566705229134832818>

## **MIDDLE EAST/NORTH AFRICA – Saudi Arabia**

### **General**

#### **Key Organization**

- National Committee of BioEthics: <http://bioethics.kacst.edu.sa/?lang=en-US>

#### **Relevant Standards**

- Law of Ethics of Research on Living Creatures (2016)
- Implementing Regulations of the Law of Ethics of Research on Living Creatures (2016):  
[http://prod.kau.edu.sa/Med/ali/files/Publications/Guide/National\\_Committe\\_of\\_BioEthics-Regulations\\_of\\_the\\_Law\\_of\\_Ethics\\_of\\_Research\\_on\\_Living\\_Creatures.pdf](http://prod.kau.edu.sa/Med/ali/files/Publications/Guide/National_Committe_of_BioEthics-Regulations_of_the_Law_of_Ethics_of_Research_on_Living_Creatures.pdf)

### **Social-Behavioral Research**

#### **Key Organization**

- National Committee of BioEthics: <http://bioethics.kacst.edu.sa/?lang=en-US>

#### **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):  
[http://prod.kau.edu.sa/Med/ali/files/Publications/Guide/National\\_Committe\\_of\\_BioEthics-Regulations\\_of\\_the\\_Law\\_of\\_Ethics\\_of\\_Research\\_on\\_Living\\_Creatures.pdf](http://prod.kau.edu.sa/Med/ali/files/Publications/Guide/National_Committe_of_BioEthics-Regulations_of_the_Law_of_Ethics_of_Research_on_Living_Creatures.pdf)

## **MIDDLE EAST/NORTH AFRICA – Sudan**

### **General**

#### **Key Organization**

- Federal Ministry of Health: <http://www.fmoh.gov.sd/>

#### **Relevant Standards**

- National Guidelines for Ethical Conduct of Research Involving Human Subjects (2008): <http://sites.google.com/site/healthresearchlibrary/national-guidelines>
- Accreditation Guidelines for Research Ethics Committees in Sudan (2017): <http://snrec.sd/wp-content/uploads/2017/05/Accreditation-guidelines.pdf>
- Operation Guidelines, Functions, and Procedures (2016)
- NHREC protocol application form: <http://snrec.sd/wp-content/uploads/2017/05/NHREC-PROTOCOL-APPLICATION-FORM.pdf>

### **Drugs, Biologics, and Devices**

#### **Key Organization**

- National Medicines and Poisons Board: <http://www.nmpb.gov.sd/en/>

#### **Relevant Standards**

- Act on Pharmaceuticals and Poisons (2009) (Arabic): <http://www.nmpb.gov.sd/index.php/2015-08-05-11-05-04/regulations/113-laws2009>

### **Human Biological Materials**

#### **Key Organizations**

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

#### **Relevant Standards**

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

### **Genetic Research**

#### **Key Organizations**

- University of Khartoum, Institute of Endemic Diseases: <http://iend.uofk.edu/index.php?lang=en>

#### **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)
- Oviedo Convention on Human Rights and Biomedicine (2004): <https://www.coe.int/en/web/bioethics/oviedo-convention>
- Update on the Law of the Support of Research and Development Activities (2016): <http://www.resmigazete.gov.tr/eskiler/2016/02/2016022-1.pdf>
- Regulation on Medical Deontology, Article 11 (1960)
- Bylaw on Patient Rights No. 23420 (1998)
- Guideline on novel Clinical Trials with COVID-19 vaccine Candidates: <https://www.titck.gov.tr/duyuru/covid-19-asi-gelistirme-calismasi-yuruten-arastirma-gruplarinin-dikkatine-16032021142718>

## **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](http://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 Clinical Trials with Drugs and Biological Products (2015): An Update of 2014 Clinical Trials Regulation: <http://www.klinikarastirmalar.org/Detail/1992/ilac-ve-biyolojik-urunlerin-klinik-arastirmalari-hakkinda-yonetmelikte-degisiklik-yapilmasina-dair-yonetmelik-2015>
- Regulation on Efficacy, Safety, and Clinical Trials of Cosmetic Products (2015)
- Update on the Regulation of the Management and Inspection of the Support of Research and Development Activities (2016): <http://www.resmigazete.gov.tr/eskiler/2016/08/20160810-7.htm>

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

- Bylaw on Clinical Research of Traditional and Complementary Medicine (2019): <http://www.klinikarastirmalar.org/Detail/2631/geleneksel-ve-tamamlayici-tip-uygulamalarinin-klinik-arastirmalari-hakkinda-yonetmelik-2019>
- Guideline on Phase 1 Clinical Research Centers (2019): <https://titck.gov.tr/storage/Archive/2019/legislation/ad316d19-8b9e-420c-86db-3946c56add1d.pdf>
- GCP Guideline (2015): [http://www.farmakovijilansdernegi.org/files/2015.09.13\\_Regulation\\_on\\_clinical\\_trials\\_of\\_medicinal\\_and\\_biological\\_products.PDF](http://www.farmakovijilansdernegi.org/files/2015.09.13_Regulation_on_clinical_trials_of_medicinal_and_biological_products.PDF)
- Guideline on the Audit of Pharmacovigilance: <https://titck.gov.tr/storage/Archive/2019/legislation/05ef1188-6756-4165-b0d5-bb0a28bbebb3.pdf>
- Bylaw on Medical Devices aimed for Invitro Diagnostics: <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>

#### **Relevant Standards**

- Regulation on Research on Medical Devices (2014): <https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=20028&MevzuatTur=7&MevzuatTertip=5>

### **Research Injury**

#### **Key Organizations**

- Turkish Medicines and Medical Devices Agency (TMMDA): <https://www.titck.gov.tr/mevzuat>

#### **Relevant Standards**

- Convention on Human Rights and Biomedicine (Convention of Oviedo), Article 24, ETS No. 164 (2004): <https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatyNum=164>
- Guidance on Insuring Volunteers in a Clinical Trial (2011): <https://titck.gov.tr/storage/Archive/2019/legislation/972bae83-9d23-45ae-b3a3-85b53bd853e1.pdf>
- Various other guidance: <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>
- Istanbul University Consumer Behavior and Behavioral Economics Application and Research Center: <https://www.istanbul.edu.tr/tr/>

#### **Relevant Standards**

- Istanbul University Consumer Behavior and Behavioral Economics Application and Research Center Regulations: <https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=18305&MevzuatTur=8&MevzuatTertip=5>

## 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)
- Convention on Human Rights and Biomedicine (Convention of Oviedo), Articles 21-22 (1999): <https://www.coe.int/en/web/bioethics/oviedo-convention>
- Good Clinical Practice Guidelines for Advanced Therapy Medicinal Products (2011)
- Blood and Blood Products Regulation: <https://www.mevzuat.gov.tr/anasayfa/MevzuatFihristDetayIframe?MevzuatTur=7&MevzuatNo=12632&MevzuatTertip=5>
- Law on Removal, Storage and Transplantation of Organs and Tissues: <https://www.saglik.gov.tr/TR,10372/tarihi29051979--sayisi2238--rg-tarihi03061979--rg-sayisi16655--organ-ve-doku-alinmasi-saklanmasi-ve-nakli-hakkinda-kanun.html>

## Genetic Research

### Key Organizations

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

### Relevant Standards

- Regulation on Centers for Diagnosis and Genetic Diseases, No. 23368 (1998): <https://www.saglik.gov.tr/TR,10433/genetik-hastaliklar-tani-merkezleri-yonetmeligi.html>, <https://www.resmigazete.gov.tr/arsiv/23368.pdf>

## 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)



*International Compilation of Human Research Standards  
2021 Edition*

- Guideline on Clinical Research of Non-Embryonic Stem Cells (2006)
- Regulation on Assisted Reproductive Treatment Practices and Assisted Reproductive Treatment Centers: <https://www.saglik.gov.tr/TR,10515/uremeye-yardimci-tedavi-uygulamalari-ve-uremeye-yardimci-tedavi-merkezleri-hakkinda-yonetmelik.html>
- Regulation on Organ and Tissue Transplantation Services: <https://www.saglik.gov.tr/TR,10465/organ-ve-doku-nakli-hizmetleri-yonetmeligi.html>
- Guidelines for Clinical Research and Clinical Trials Using Tissues and Cells: <https://shgm.saglik.gov.tr/Eklenti/15612/0/kok-hucre-calismalari-genelgepdf.pdf>

**MIDDLE EAST/NORTH AFRICA – United Arab Emirates**

**General**

**Key Organization**

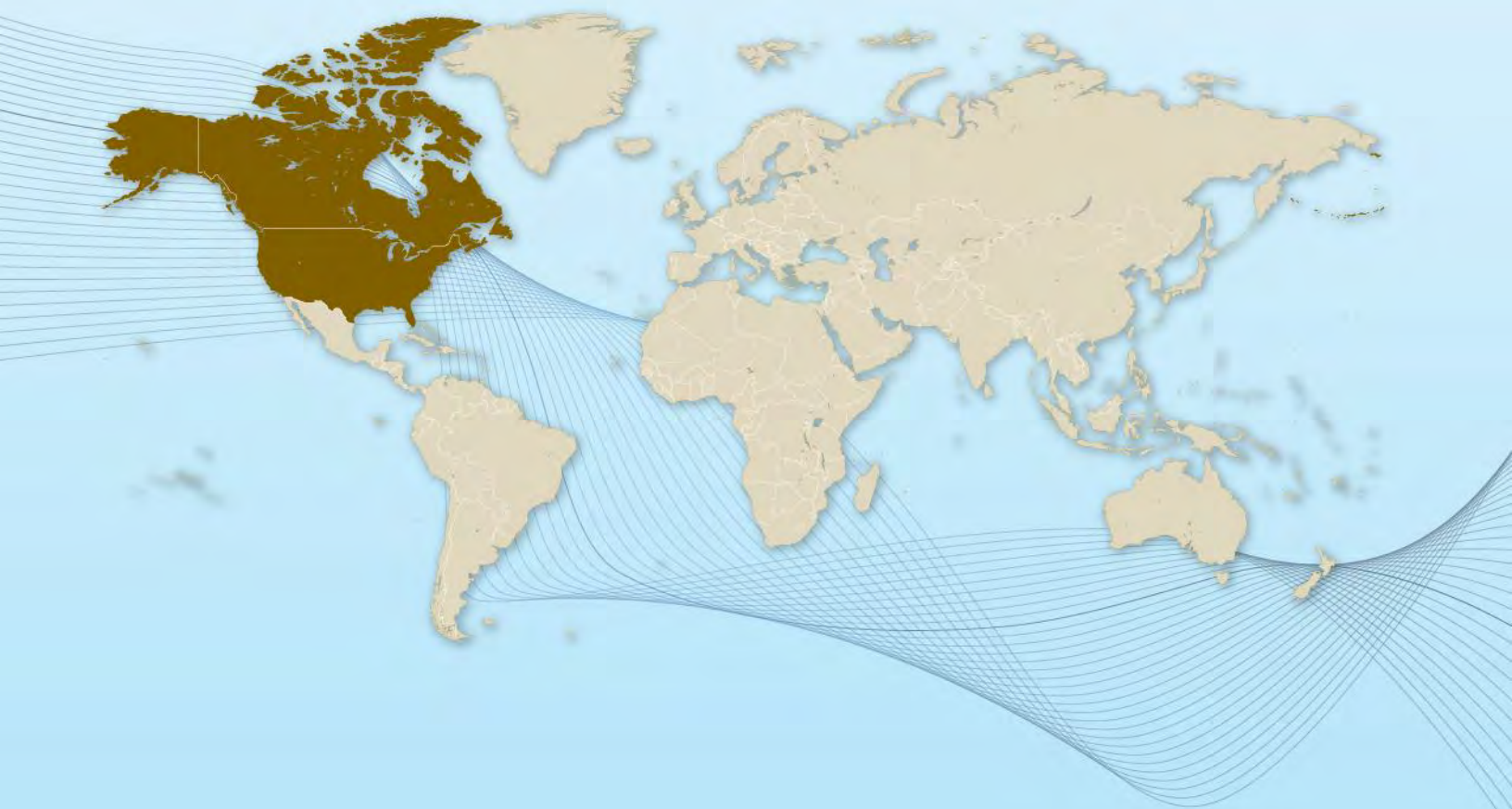
- Health Authority - Abu Dhabi: <http://www.haad.ae/haad/>

**Relevant Standards**

- Healthcare Guidelines, various: <https://www.doh.gov.ae/en/resources/guidelines>
- Standards, various: <https://www.doh.gov.ae/en/resources/standards>

International Compilation of Human  
Research Standards  
2021 Edition

# 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**

- Interagency Advisory Panel on Research Ethics (PRE): <https://ethics.gc.ca/eng/home.html>
- National Defence and the Canadian Armed Forces: <https://www.canada.ca/en/department-national-defence.html>
- Correctional Service of Canada: <http://www.csc-scc.gc.ca/index-eng.shtml>

#### **Relevant Standards**

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2<sup>nd</sup> Edition (2018): <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>
- National Defence and the Canadian Armed Forces, Research Involving Human Subjects (1998): <http://www.forces.gc.ca/en/about-policies-standards-defence-admin-orders-directives-5000/5061-0.page>
- Correctional Service of Canada: Commissioner's Directive - Research: DCOO9 (2017): <http://www.csc-scc.gc.ca/acts-and-regulations/009-cd-en.shtml>

### **Drugs, Biologics, and Devices**

#### **Drugs**

##### **Key Organizations**

- Health Canada, Therapeutic Products Directorate: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php>
- Interagency Advisory Panel on Research Ethics (PRE): <https://ethics.gc.ca/eng/home.html>

##### **Relevant Standards**

- Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials) (2001): [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/hpfb-dgpsa/pdf/compli-conform/1024-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/compli-conform/1024-eng.pdf)
- Health Canada, Good Clinical Practice, Various: <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices.html>
- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2<sup>nd</sup> Edition, Chapter 11: Clinical Trials (2018): <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>

#### **Devices**

##### **Key Organizations**

- Health Canada, Medical Devices: <http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php>

##### **Relevant Standards**

- Medical Devices Regulations (SOR/98-282) (1998): <http://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/FullText.html>

## Clinical Trial Registries

### Key Organizations

- Health Canada Clinical Trial Database: <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdonclin/index-eng.php>
- Interagency Advisory Panel on Research Ethics (PRE): <https://ethics.gc.ca/eng/home.html>

### Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 11.D. (2018): <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>

## Research Injury

### Key Organizations

- Interagency Advisory Panel on Research Ethics (PRE): <https://ethics.gc.ca/eng/home.html>

### Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 3, Article 3.2. (2018): <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>

## Social-Behavioral Research

### Key Organizations

- Interagency Advisory Panel on Research Ethics (PRE): <https://ethics.gc.ca/eng/home.html>

### Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 10. (2018): <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>

## Privacy/Data Protection

*NOTE: Each of the Canadian provinces and territories also has enacted privacy legislation.*

### Key Organizations

- Office of the Privacy Commissioner of Canada (OPC): <https://www.priv.gc.ca/en>
- Interagency Advisory Panel on Research Ethics (PRE): <https://ethics.gc.ca/eng/home.html>
- Canadian Institutes of Health Research (CIHR): <http://www.cihr-irsc.gc.ca/e/193.html>

### Relevant Standards

- Privacy Act, Sections 7-8 (1983): <http://laws-lois.justice.gc.ca/PDF/P-21.pdf>
- Personal Information Protection and Electronic Documents Act, Articles 5 and 7 (2001): <http://laws-lois.justice.gc.ca/PDF/P-8.6.pdf>
- OPC: SOR/2001-6, SOR/2001-7, and SOR/2001-8 (September 29, 2014)
- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2<sup>nd</sup> Edition, Chapter 5: Privacy and Confidentiality (2018): <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>

*International Compilation of Human Research Standards  
2021 Edition*

- CIHR Best Practices for Protecting Privacy in Health Research (2005): [http://www.cihr-irsc.gc.ca/e/documents/et\\_pbp\\_nov05\\_sept2005\\_e.pdf](http://www.cihr-irsc.gc.ca/e/documents/et_pbp_nov05_sept2005_e.pdf)

## Human Biological Materials

### Key Organizations

- Interagency Advisory Panel on Research Ethics (PRE): <https://ethics.gc.ca/eng/home.html>

### Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2<sup>nd</sup> Edition, Chapter 12: Human Biological Materials Including Materials Related to Human Reproduction (2018): <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>

## Genetic Research

### Key Organizations

- Interagency Advisory Panel on Research Ethics (PRE): <https://ethics.gc.ca/eng/home.html>
- Canadian Biotechnology Advisory Committee (CBAC): <http://www.hc-sc.gc.ca/sr-sr/biotech/role/strateg-eng.php>
- Health Canada, Biologics and Genetic Therapies Directorate: <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/bgtd-dpbtg/index-eng.php>

### Relevant Standards

- PRE, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2<sup>nd</sup> Edition, Chapter 13: Human Genetic Research (2018): <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>

## Embryos, Stem Cells, and Cloning

### Key Organizations

- Interagency Advisory Panel on Research Ethics (PRE): <https://ethics.gc.ca/eng/home.html>

### Relevant Standards

- Assisted Human Reproduction Act (2004): <http://laws-lois.justice.gc.ca/eng/acts/A-13.4/>
- Assisted Human Reproduction (Section 8 Consent) Regulations (2007): <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-137/index.html>
- PRE: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2<sup>nd</sup> Edition, Chapter 12, Sections E and F (2018): <http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf>

## NORTH AMERICA – United States

*For an overview of clinical research regulations in the United States, see the ClinRegs report:*  
<https://clinregs.niaid.nih.gov/country/united-states>

## General

### Key Organization and Relevant Standards

- Public Health Service Act (1993): <http://history.nih.gov/research/downloads/PL103-43.pdf>

*International Compilation of Human Research Standards  
2021 Edition*

- 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/](http://www.hhs.gov/ohrp/)
  - a. 45 CFR 46, Subparts A (the Common Rule), B, C, D, and E (2018):  
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>
  - b. OHRP, Human Research Protections Guidance, various:  
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html>
- 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:
  1. Agency for International Development: <https://www.usaid.gov/>
    - a. Protection of Human Subjects in Research Supported by USAID: A Mandatory Reference for ADS Chapter 200 (2015):  
<https://www.usaid.gov/sites/default/files/documents/1864/200mbe.pdf>
  2. Central Intelligence Agency: <https://www.cia.gov/index.html>:
    - a. Executive Order 12333, adopting 45 CFR 46 Subparts A, B, C, and D
  3. Department of Defense, Directorate of Human Research Protections (DOHRP):  
<https://rt.cto.mil/ddre-rt/dd-rtl/hsd/hrp/>
    - a. United States Code Title 10, Section 980: Limitation on Use of Humans as Experimental Subjects
    - b. DoDI 3216.02 (2011):  
<https://rcb.tamu.edu/humans/resources/DOD%20Directive%20321602p.pdf>
  4. Department of Education: <https://www.ed.gov/>
    - a. Protection of Pupil Rights Amendment (1974)
    - b. Family Educational Rights and Privacy Act (1974)
    - c. 34 CFR 98 (1984)
    - d. 34 CFR 99 (2000)
    - e. 34 CFR 350.4(c) (1991)
    - f. 34 CFR 356.3(c) (1991)
  5. Department of Energy: <http://science.energy.gov/ber/human-subjects/>
    - a. DOE Order 443.1B
    - b. DOE Order 481.1
  6. Department of Homeland Security: <https://www.dhs.gov/>
    - a. Public Law 108-458, Section 8306

*International Compilation of Human Research Standards  
2021 Edition*

- b. DHS Directive 026-04, Human Subjects Research (2007):  
<https://www.dhs.gov/xlibrary/assets/foia/mgmt-directive-026-04-protection-of-human-subjects.pdf>
- 7. Bureau of Prisons: <https://www.bop.gov>
  - a. 28 CFR 22 Privacy Regulation (1976): [http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr22\\_main\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr22_main_02.tpl)
  - b. 42 U.S.C. § 3789g Confidentiality of Information (1984):  
<http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap46-subchapVIII-sec3789g.htm>
  - c. 28 CFR 46 (1991), Subpart A: [http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr46\\_main\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr46_main_02.tpl)
- 8. Department of Veterans Affairs:
  - a. Office of Research Oversight (ORO): <http://www.va.gov/oro/>
  - b. Office of Research and Development: <http://www.research.va.gov>
  - c. 38 CFR 17.85 (1998)
  - d. VA, Policies, Human Research, various:  
[https://www.research.va.gov/resources/policies/human\\_research.cfm](https://www.research.va.gov/resources/policies/human_research.cfm)
- 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)
  - i. Subpart P: Review of Proposed and Completed Human Research (2013)
  - j. Subpart Q: Standards for Assessing Whether to Rely on the Results of Human Research in EPA Actions (2013)
  - k. Scientific and Ethical Approaches for Observational Exposure Studies (2008):  
<https://nepis.epa.gov/Exe/ZyPDF.cgi/P10012LY.PDF?Dockkey=P10012LY.PDF>

*International Compilation of Human Research Standards  
2021 Edition*

1. EPA Order 1000.17A: Policy and Procedures on Protection of Human Subjects in EPA Conducted or Supported Research (2016): <https://www.epa.gov/osa/epa-order-100017-policy-and-procedures-protection-human-research-subjects-epa-conducted-or>

**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**

- Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (2012): <https://uscode.house.gov/browse/prelim@title21&edition=prelim>
- Public Health Service Act, 42 USC Section 262 (1998): <https://uscode.house.gov/browse/prelim@title42&edition=prelim>
- 21<sup>st</sup> Century Cures Act, Section 3024 (2016): <https://www.govinfo.gov/content/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf>
- FDA, Regulations, Good Clinical Practice and Clinical Trials, various: <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials>
- FDA, Good Clinical Practice and Human Subject Protection in FDA-Regulated Clinical Trials: <https://www.fda.gov/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection>
- 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**

- Food, Drug, and Cosmetic Act, 21 USC Sections 355 and 371 (2012): <https://uscode.house.gov/browse/prelim@title21&edition=prelim>
- 21<sup>st</sup> Century Cures Act, Section 3024 (2016): <https://www.govinfo.gov/content/pkg/PLAW-114publ255/pdf/PLAW-114publ255.pdf>
- FDA, Regulations, Good Clinical Practice and Clinical Trials, various: <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials>
- FDA, Good Clinical Practice and Human Subject Protection in FDA-Regulated Clinical Trials: <https://www.fda.gov/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection>



*International Compilation of Human Research Standards  
2021 Edition*

- FDA, Devices, Guidance, Various: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>

## Clinical Trial Registries

### Key Organizations

- Food and Drug Administration: <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrials.gov-information>
- National Institutes of Health ClinicalTrials.gov: <https://www.clinicaltrials.gov/ct2/home>
- Office of Research Oversight (ORO): <http://www1.va.gov/oro/>

### Relevant Standards

- Food and Drug Administration Modernization Act, Section 113 (1997): <https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-modernization-act-fdama-1997>
- Food and Drug Administration Amendments Act, Section 801 (2007): <https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-amendments-act-fdaaa-2007>
- Clinical Trials Regulation and Results Information Submission, 42 CFR 11 (2016): <https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission>
- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (2016): <https://www.federalregister.gov/documents/2016/09/21/2016-22379/dissemination-of-nih-funded-clinical-trial-information>
- 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](http://www.research.va.gov/resources/ORD_Admin/clinical_trials/registration-faq.pdf)
- OHRP, Clinical Trial Informed Consent Form Posting (45 CFR 46.116(h)): <https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/index.html>

## 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, 38 CFR 17.85: Treatment of Research-Related Injuries to Human Subjects: <https://www.gpo.gov/fdsys/pkg/CFR-2013-title38-vol1/pdf/CFR-2013-title38-vol1-sec17-85.pdf>
- Department of Veterans Affairs, Handbook 1200.5, Appendix F, Paragraph 2a(11)

## Social-Behavioral Research

### Key Organizations

- Various

### Relevant Standards

- All Common Rule agencies, 45 CFR 46 and applicable subparts:  
<https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf>
- National Science Foundation, FAQs and Vignettes: <https://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp>

## Privacy/Data Protection

### Key Organizations

- Various

### Relevant Standards

- All Common Rule agencies, Common Rule at 45 CFR 46.111(a)(7) (2018):  
<https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf>
- Department of Justice, Privacy Act, 5 U.S.C. § 552a (1974):  
<http://www.justice.gov/opcl/privacyact1974.htm>
- Department of Health and Human Services (HHS), Office for Civil Rights (OCR), Health Insurance Portability and Accountability Act (HIPAA)(1996): <https://www.gpo.gov/fdsys/pkg/PLAW-104publ191/content-detail.html>
- HIPAA Privacy Rule, 45 CFR parts 160 and 164, Subparts A and C (2002):  
<http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html>
- HIPAA Security Rule, 45 CFR parts 160, 162, and 164 (2009):  
<http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/index.html>
- HIPAA Breach Notification Rule, 45 CFR §164.400-414:  
<http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/index.html>
- HHS, OCR, 21st Century Cures Act Research Guidance on Activities Preparatory to Research (2017): <https://www.hhs.gov/sites/default/files/remote-access-research-12-15-17.pdf>
- HHS, OCR, 21st Century Cures Act Research Guidance on Streamlining Authorization (2018):  
<https://www.hhs.gov/sites/default/files/hipaa-future-research-authorization-guidance-06122018%20v2.pdf>
- HHS, OCR, Various: <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>
- Confidential Information Protection and Statistical Efficiency Act (CIPSEA) (2002):  
<http://www.eia.gov/cipsea/cipsea.pdf>
- Health Information Technology for Economic and Clinical Health (HITECH) Act (2009):  
<https://www.gpo.gov/fdsys/pkg/PLAW-111publ5/pdf/PLAW-111publ5.pdf>
- NIH Policy on Certificates of Confidentiality (2017): <https://humansubjects.nih.gov/coc/index>

*International Compilation of Human Research Standards  
2021 Edition*

- NIH, HIPAA Resources, various: <http://privacyruleandresearch.nih.gov/>
- Agency for Healthcare Research and Quality (AHRQ), Confidentiality in AHRQ-Supported Research (2018): <https://grants.nih.gov/grants/guide/notice-files/NOT-HS-18-012.html>
- E-Government Act of 2002, Public Law 107-347: <https://www.gpo.gov/fdsys/pkg/PLAW-107publ347/pdf/PLAW-107publ347.pdf>

## Human Biological Materials

### Key Organizations

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

### Relevant Standards

- Guidance, various: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/biological-materials-and-data/index.html>

## Genetic Research

### Key Organizations

- FDA, Office of In Vitro Diagnostic Device Evaluation and Safety: <https://www.fda.gov/medical-devices/products-and-medical-procedures/vitro-diagnostics>
- 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/>
- HHS, Office for Civil Rights (OCR): <https://www.hhs.gov/hipaa/for-professionals/special-topics/genetic-information/index.html>

### Relevant Standards

- Genetic Information Nondiscrimination Act (GINA) (2008): <https://www.gpo.gov/fdsys/pkg/PLAW-110publ233/content-detail.html>
- All Common Rule agencies: Common Rule at 45 CFR 46: <https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf>
- FDA, Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable (2006): <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-informed-consent-vitro-diagnostic-device-studies-using-leftover-human-specimens-are-not>
- FDA, In Vitro Diagnostic (IVD) Device Studies, FAQs (2010): <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/vitro-diagnostic-ivd-device-studies-frequently-asked-questions>
- FDA, Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products. October 14, 1993. 58 FR 53248: <https://www.fda.gov/media/76647/download>

*International Compilation of Human Research Standards  
2021 Edition*

- FDA, CBER-Specific, Various: <https://www.fda.gov/vaccines-blood-biologics/other-recommendations-biologics-manufacturers/references-regulatory-process-office-tissues-and-advanced-therapies>
- OHRP, Research on Transplantation of Fetal Tissue, Public Law 103-43 (1993): <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/public-law-103-43/index.html>
- OHRP, Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (2009): <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-genetic-information-nondiscrimination-act/index.html>
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (2019): [https://osp.od.nih.gov/wp-content/uploads/NIH\\_Guidelines.pdf](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf)
- 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**

- Executive Order 13505, Removing Barriers to Responsible Scientific Research Involving Human Stem Cells, Executive Order 13505 (2009): <https://www.gpo.gov/fdsys/pkg/DCPD-200900136/pdf/DCPD-200900136.pdf>
- Research on Transplantation of Fetal Tissue. Public Law 103-43 (1993): <https://history.nih.gov/research/downloads/PL103-43.pdf>
- NAS, Guidelines for Human Embryonic Stem Cell Research (2005): [http://www.nap.edu/catalog.php?record\\_id=11278](http://www.nap.edu/catalog.php?record_id=11278)
- NAS, 2008 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research: [http://books.nap.edu/catalog.php?record\\_id=12260](http://books.nap.edu/catalog.php?record_id=12260)
- NAS, 2010 Final Report of the National Academies Human Embryonic Stem Cell Research Advisory Committee and 2010 Amendments to the National Academies Guidelines for Human Embryonic Stem Cell Research: [http://www.nap.edu/catalog.php?record\\_id=12923](http://www.nap.edu/catalog.php?record_id=12923)
- NIH, Guidelines on Human Stem Cell Research (2009): <https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research>
- NIH, Human Embryonic Stem Cell Registry (2016): [https://grants.nih.gov/stem\\_cells/registry/current.htm](https://grants.nih.gov/stem_cells/registry/current.htm)
- NIH, Various: <http://stemcells.nih.gov/>

## ACKNOWLEDGEMENTS

The HHS Office for Human Research Protections thanks the following individuals for providing updates or confirmations of accuracy for the 2021 edition of the International Compilation of Human Research Standards. We are particularly grateful for the assistance provided by **Dr. Carla Saenz** of the Pan American Health Organization, **Dr. Barbara Sina** of the Fogarty Division of International Training and Research, and **Dr. Jonathan Kagan** of the U.S. National Institute of Allergies and Infectious Diseases.

### *Multinational Organizations:*

Comac Medical Ltd.  
Pan American Health Organization  
The European Council

### *Africa:*

South Africa: Prof. Douglas R Wassenaar  
Zambia: Maureen Mupeta Kombe

### *Asia/Pacific:*

Australia: Jeremy Kenner  
India: Dr. Nandini K. Kumar  
Japan: Dr. Shimon Tashiro, Takashi Tsuchiya  
Malaysia: Dr. Nishakanthi Gopalan, Kuenyei Chin  
South Korea: Byung-in (B.I.) Choe, Kyoungtae  
Park, Yoon-Joung Chang, Sang-Min Park, Jinyoung  
Jeong, Seoyun Hong

### *Europe:*

Global Regulatory Affairs team at Comac Medical  
Ltd.  
Finland: Marko Ahteensuu

Germany: Claudia Leuker  
Macedonia: Marija Todorovska  
Serbia: Slobodan Zabunovic  
Switzerland: The International Society for  
Biological and Environmental Repositories  
(ISBER), Daniel Simeon-Dubach, Celeste Sandoval

### *Latin America and the Caribbean:*

Brazil: Pan American Health Organization (PAHO)  
- Brazil  
Chile: Dr. Juan Pablo Beca  
Grenada: Cheryl Cox Macpherson  
Mexico: M en C Ma. de los Dolores Delgado Ochoa  
Panama: Dr. Claude Vergès  
Peru: Dr. Carlos Zamudio Fuertes

### *Middle East/North Africa:*

Jordan: Dr. Amal Al Omari and the King Hussein  
Cancer Center, Amman  
Turkey: Dr. Hamdi Akan

OHRP would also like to thank other anonymous colleagues around the world for their invaluable contribution.